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

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

(submitted by the evaluating Competent Authority)



TRAVELSAFE MOSQUITO NET

Product type 18

Deltamethrin

Case Number in R4BP: BC-DL053121-56

Evaluating Competent Authority: FR

Date: October 2022

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# CONCLUSION

TRAVELSAFE MOSQUITO NET is a PT18 biocidal product containing 80 mg/m² deltamethrin, intended for indoor and outdoor use by non-professional against *Anopheles mosquitoes*. The product is an impregnated bed net intended to be used every day when sleeping or resting.

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

Physico-chemical studies were provided for TRAVELSAFE MOSQUITO NET. Based on these results, FR-CA considers that the stability of the product is demonstrated. An interim shelf life of 24 months can be granted based on accelerated storage stability study. Long term storage stability data must be generated in commercial packaging to support the ambient storage of the product for the claimed shelf life.

No specific concern is expected from physico chemical properties.

TRAVELSAFE MOSQUITO NET is not classified for any physico-chemical hazards.

Analytical method for the determination of deltamethrin is available and validated.

Analytical methods for determination of deltamethrin residues in different matrices are available and fully validated in the CAR of deltamethrin (May 2011). The applicant has a letter from Bayer SAS to access to the data supporting the approval of the active substance.

**Conclusion on efficacy**

The product TRAVELSAFE MOSQUITO NET has shown a sufficient efficacy as a long lasting insecticidal net against mosquitoes (*Anopheles spp.)* in tropical area.

**Conclusion on human risk assessment**

The risk is acceptable for person sleeping under treated net and washing the net.

**Conclusion on dietary risk assessment**

Dietary exposure is not relevant regarding the intended use of the product.

**Conclusion on environmental risk assessment**

The product TRAVELSAFE MOSQUITO NET is intended to be used by non-professionals, for an application indoor and outdoor as a bed net. No substance of concern has been identified.

It has been demonstrated that use of the product TRAVELSAFE MOSQUITO NET does pose a risk to environmental compartments without risk mitigation measures. Indeed, risks are identified *via* the STP for surface water and sediment compartments if the mosquito net is washed. A risk mitigation measure is proposed to prevent any release to the STP during the service life of the product:

* *This product MUST NOT be washed, due to risk to the environment.*
* *Use the mosquito net as indicated in the instructions for use. Do not use for other purposes.*

Outdoor, there is a risk for the soil compartment after 1.7 days of outdoor exposure to rain. A risk mitigation measure is proposed to prevent any release to soil during the outdoor use of the product:

* *Use outdoors only in locations protected from rain*.

**Substances of concern (SoCs)**

None of the co-formulant included in the product was identified as substance of concern.

**Post-authorisation conditions:**

The authorisation holder shall complete:

* Within two years, a long term storage study (24 months) on the product in commercial packaging at ambient temperature including the anlysis of the active substance content et the phys chem properties.
* Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance, and provide an assessment of this monitoring on national territory (overseas departments), and provide an assessment of this monitoring every five years.

**Overall conclusion**

According to the assessment performed for the biocidal product TRAVELSAFE MOSQUITO NET, the following uses are proposed for authorization, considering the appropriate risk mitigation measures indicated in the SPC below (§ 2):

|  |  |  |  |
| --- | --- | --- | --- |
| **Uses** | **Doses** | **Conditions of use** | **Conclusions** |
| Ready-to-use impregnated insecticidal net against *Anopheles* mosquitoes | NA | Only for use in the tropical areas Indoor or outdoors Non professional | **Acceptable** |

NA: not applicable

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| TRAVELSAFE MOSQUITO NETKid Box Style netBox style Mosquito net (Single)Box style Mosquito net (Double)Pyramid Mosquito netTropical Box Mosquito net (Single)Tropical Pop up Mosquito net (Double)Multi style Mosquito netTriangle Cocoon Mosquito netTropical Pop up Mosquito net (Single)Tropical Pop up Mosquito net (Double) |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Van Bergen Sports Int.b.v. |
| **Address** | Ondernemingsweg 10, 3641 RZ, Mijdrecht, Netherlands |
| **Authorisation number** | **FR-2022-0082** |
| **Date of the authorisation** | **18/10/2022** |
| **Expiry date of the authorisation** | **17/10/2032** |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | NRS Moon Netting |
| **Address of manufacturer** | Jebel Ali Free Zone PO Box 17364 Dubai United Arab Emirates |
| **Location of manufacturing sites 1** | 4 KM off Ferozepur Road, Kahna Kacha Road, 54000 Lahore Pakistan |
| **Location of manufacturing sites 2** | Xin Shi Ji Industrial Zone, Heshan village, 516123 Yuanzhou Town, Bolou CountyHuizhou, Guangdong China |

|  |  |
| --- | --- |
| **Name of manufacturer** | Landcent (China) Industrial Development Co, Ltd. |
| **Address of manufacturer** | 618 Dingyuan Road Shanghai 201616 Shanghai China |
| **Location of manufacturing sites** | Shengshan Village, Province. Balidian Town, Wuxing District, Huzhou City, ZhejiangChina |

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

|  |  |
| --- | --- |
| **Active substance** | Deltamethrin |
| **Name of manufacturer** | BAYER S.A.S - Environmental Science |
| **Address of manufacturer** | 16 rue Jean-Marie LeClair, CS 90106 F-69266 Lyon Cedex 09 France |
| **Location of manufacturing sites** | Bilag Industries Pvt Ltd 306/3, II Phase, GIDC, Vapi-396195 - India |

### Product composition and formulation

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

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

Yes [ ]

No [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | Deltamethrin |
| **IUPAC or EC name** | (*S*)-α-cyano-3-phenoxybenzyl(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate |
| **EC number** | 258-256-6 |
| **CAS number** | 52918-63-5 |
| **Index number in Annex VI of CLP** | 607-319-00-X |
| **Minimum purity / content** | 98.5% |
| **Structural formula** | C22H19Br2NO3Image illustrative de l’article Deltaméthrine |

#### Candidate(s) for substitution

Deltamethrin is not candidate for substitution or exclusion in accordance with Articles 10 and 5 respectively of the BPR (EU) Regulation 528/2012

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

| **Common Name** | **Chemical name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)[[2]](#footnote-3)** |
| --- | --- | --- | --- | --- | --- |
| Deltamethrin (technical, without the fiber of the mosquito net) | (S)-a-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2- dimethylcyclopropane carboxylate | Substance active | 52918-63-5 | 258-256-6 | 5.5% |

#### Information on technical equivalence

BAYER S.A.S - Environmental Science source is a reference source evaluated for the inclusion in the union list of approved substances.

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

None of the co-formulant included in the product was identified as substance of concern.

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

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

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

For further details, please refer to the Confidential Annex.

#### Type of formulation

|  |
| --- |
| Ready to use Long Lasting Insecticidal Net (LN) |

### Hazard and precautionary statements

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

*[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]*

| **Classification** |
| --- |
| Hazard category | Acute toxicity (oral), cat. 4Aquatic Acute 1Aquatic Chronic 1 |
| Hazard statement | H302: Harmful if swallowedH400: Very toxic to aquatic life.H410: Very toxic to aquatic life with long lasting effects.  |
|  |
| **Labelling** |
| Signal words | Warning |
| Hazard statements | H302: Harmful if swallowedH410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P264: Wash hands thoroughly after handling.P270: Do no eat, drink or smoke when using thisproduct.P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor/…/if you feel unwellP330: rinse mouthP273: Avoid release to the environment.P501: Dispose of contents/containers in accordance with local regulations. |
|  |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Insecticide net

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Mosquitoes *Anopheles sp.*-Adults |
| **Field of use** | IndoorOutdoor |
| **Application method(s)** | Ready-to-use impregnated net  |
| **Application rate(s) and frequency** | Ready-to use net.Use every day 1 net per bed |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Please refer to the relevant section (2.1.7). |

#### Use-specific instructions for use

|  |
| --- |
| *
 |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Comply with the instructions for use
* Replace the net if damaged (e.g. holes)
* The product is allowed to be used only in tropical areas against *Anopheles* spp, where there is a threat of vector-borne diseases spread by the claimed mosquito species (e.g malaria).

**General:*** Remove net from the bag and unfold. Ventilate up to 24 hours.
* Suspend the net over the bed. Carefully tuck the net under the mattress before going to sleep to provide barrier protection from mosquito bites. Each net come with auxiliary kit to facilitate hanging and or suspending of the net in a such a way that allows maximum cover as possible.
* When not in use the nets must be rolled up tightly and placed in the bag.
 |

#### Risk mitigation measures

|  |
| --- |
| * Inform the registration holder if the treatment is ineffective.
* This product MUST NOT be washed, due to risk to the environment.
* Use the mosquito net as indicated in the instructions for use. Do not use for other purposes.
* Use outdoors only in locations protected from rain.
* It is recommended to wash hands after setting up the net and taking the net down.
* Keep cats away from the product. Due to their particular sensitivity to deltamethrin, the product can cause severe adverse reactions in cats.
 |

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

|  |
| --- |
| * Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.
* IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
* IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
* IF ON SKIN: Wash skin with soap and water. If symptoms occur call a POISON CENTRE or a doctor.
* IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

If medical advice is needed, have product container or label at hand |

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

|  |
| --- |
| * Do not discharge unused product on the ground or into water courses.
* The product is not intended to be reused or recycled. Dispose of unused product, its packaging and all other waste, in accordance with local regulations
 |

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

|  |
| --- |
| - Store away from light.- Shelf life: 24 months.- Keep out of reach of children and pets |

### Other information

|  |
| --- |
| The technical content of the active substance including the fiber of the mosquito net is the following:* 0.20% (w/w) for the fiber of 100 and 150 Denier
* 0.27% (w/w) for the fiber of 75 Denier

Instructions and RMMs must be fixed to the net |

### 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)** |
| Bag | 260 g (1 kid) 160\*75\*135 | PE | - | Non-professional | Yes |
| 530 g (1 person) 220\*105\*200 |
| 750 g (2 persons)220\*200\*200 |
| 673 g (2 persons)ø1050\*240 |
| 520 g (1 person)220\*105\*200 |
| 750 g (2 persons)200\*200\*200 |
| 329 g (1 person)225\*120\*150 |
| 423 g (1 person)200\*100\*145 |
| 430 g (1-2 person)ø800\*240 |
| 604 g (2 person)ø1050\*240 |

L\*W\*H: Length, Width and Height in cm

ø\*H: Circumference and Height in cm

### Documentation

#### Data submitted in relation to product application

The product is not the representative formulation for the approval of deltamethrin.

New data with the product are submitted for the demonstration of the efficacy. Please refer to the list of references.

#### Access to documentation

The notifier Van Bergen Sports Int. BV provided a letter of access to data from the AS approval dossier.

## Assessment of the biocidal product

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

Table 2. Intended use # 1 – name of the use

|  |  |
| --- | --- |
| Product Type(s) | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| Where relevant, an exact description of the authorised use | Insecticidal Net |
| Target organism (including development stage) | Scientific name: Culicidae:Common name: Anopheles mosquitoesDevelopment stage: Adults  |
| Field of use | IndoorOutdoor |
| Application method(s) | Health protectionSuspend the net over the bed. Carefully tuck the net under the mattress or mat before going to sleep to provide barrier protection from mosquito bites. |
| Application rate(s) and frequency | Used everyday mostly at night when sleeping or resting - N/AN/A |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Kid Box Style net: 260gBox style Mosquito net (Single): 530gBox style Mosquito net (Double): 750gPyramid Mosquito net: 673gTropical Box Mosquito net (Single): 520gTropical Box Mosquito net (Double): 750gMulti style Mosquito net: 329gTriangle Cocoon Mosquito net: 423gTropical Pop up Mosquito net (Single): 430gTropical Pop up Mosquito net (Double): 604gPackaging material in contact with net: **Polyethylene** |

### Physical, chemical and technical properties

TRAVELSAFE MOSQUITO NET is a carrier based biocidal product of type B according to EU CA carrier guidance (CA-Nov16-Doc.4.3 – Final. Rev 1). The biocidal product is an insecticidal net (LN) impregnated with Deltamethrin (80.0 mg/m2). Regarding the physical-chemical properties, tests are carried out on the product as it is supplied to the user. Three nets were tested with 3 different deniers: 75 denier (TSARA SOFT LN (75 Denier)), 100 denier (TSARA SOFT LN (100 Denier)) and 150 denier (TSARA SOFT LN (150 Denier)). A denier is a unit of measure for the linear mass density of fibers. It is the mass in grams per 9000 meters of the fiber. Each net are sampling in 5 pieces of 25 x 25 cm before testing (See scheme below).



| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **GLP** | **FR-CA comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state and Colour at 20 °C and 101.3 kPa | Visual inspection | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | White solid fibre net | Rajasekharam, C. (2019)Report n°19094 | Y | Acceptable |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Blue solid fibre net | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | White solid fibre net | Rajasekharam, C. (2019)Report n°19087 |
| Odour at 20 °C and 101.3 kPa | Olfactory inspection | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | Synthetic material odour | Rajasekharam, C. (2019)Report n°19094 | Y | Acceptable |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Synthetic material odour | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Synthetic material odour | Rajasekharam, C. (2019)Report n°19087 |
| Acidity / alkalinity | - | - | Not relevant for LN formulation | - | - | - |
| Relative density / bulk density | - | - | Not relevant for LN formulation.The product are define by the textile density, which is 80.0 mg/m2 | - | - | - |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3. (54 °C ± 2 °C for 2 weeks)Validated analytical method n°19095 | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | TSARA SOFT LN (75 Denier) were sampling in 5 pieces of 25 x 25 cm and were stored during 14 days at 54 ± 2 °C in a capped glass bottle.

|  |  |  |
| --- | --- | --- |
|  | **Initial** | **After 14 days at 54 °C** |
| **Deltamethrin content** | 2.71 g/kg | 2.66 g/kg |
| **Deltamethrinvariation** | - | - 1.8% |
| **Deltamethrin content after 4th wash** | 2.54 g/kg | 2.54 g/kg |
| **Wash Resistance Index** | 98.4% | 98.8% |
| **Dimensional stability of netting to washing** | (Shrinkage) -1.0% (Warp) and -1.2% (Weft) | (Shrinkage) -1.3% (Warp) and -1.5% (Weft) |
| **Bursting Strength** | 345.0 kPa | 342.5 kPa |

Conclusion: There is no significant reduction in the active substance content and no significant change in the physical and chemical properties of test item. | Rajasekharam, C. (2019)Report n°19094 | Y | AcceptableNo significant reduc-tion in active ingre-dient content is observed. Moreover, no significant change in the physical-chemical properties tested were found in TSARA SOFT LN (75 Denier) stored at 54 °C for 14 days. |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | TSARA SOFT LN (100 Denier) were sampling in 5 pieces of 25 x 25 cm and were stored during 14 days at 54 ± 2 °C in a capped glass bottle.

|  |  |  |
| --- | --- | --- |
|  | **Initial** | **After 14 days at 54 °C** |
| **Deltamethrin content** | 2.27 g/kg | 2.20 g/kg |
| **Deltamethrinvariation** | - | - 3.1% |
| **Deltamethrin content after 4th wash** | 2.14 g/kg | 2.14 g/kg |
| **Wash Resistance Index** | 98.5% | 99.3% |
| **Dimensional stability of netting to washing** | (Shrinkage) -1.0% (Warp) and -1.0% (Weft) | (Shrinkage) -1.3% (Warp) and -1.5% (Weft) |
| **Bursting Strength** | 437.5 kPa | 438.3 kPa |

Conclusion: There is no significant reduction in the active substance content and no significant change in the physical and chemical properties of test item. | Rajasekharam, C. (2019)Report n°19093 | AcceptableNo significant reduc-tion in active ingre-dient content is observed. Moreover, no significant change in the physical-chemical properties tested were found in TSARA SOFT LN (100 Denier) stored at 54 °C for 14 days. |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | TSARA SOFT LN (150 Denier) were sampling in 5 pieces of 25 x 25 cm and were stored during 14 days at 54 ± 2 °C in a capped glass bottle.

|  |  |  |
| --- | --- | --- |
|  | **Initial** | **After 14 days at 54 °C** |
| **Deltamethrin content** | 1.83 g/kg | 1.79 g/kg |
| **Deltamethrinvariation** | - | - 3.1% |
| **Deltamethrin content after 4th wash** | 1.70 g/kg | 1.68 g/kg |
| **Wash Resistance Index** | 98.2% | 98.5% |
| **Dimensional stability of netting to washing** | (Shrinkage) -0.7% (Warp) and -0.8% (Weft) | (Shrinkage) -1.0% (Warp) and -1.2% (Weft) |
| **Bursting Strength** | 521.4 kPa | 515.8 kPa |

Conclusion: There is no significant reduction in the active substance content and no significant change in the physical and chemical properties of test item. | Rajasekharam, C. (2019)Report n°19087 | AcceptableNo significant reduc-tion in active ingre-dient content is observed. Moreover, no significant change in the physical-chemical properties tested were found in TSARA SOFT LN (150 Denier) stored at 54 °C for 14 days. |
| Storage stability test – **long term storage at ambient temperature** | - | - | No long term storage stability test were furnished by the applicant at the time of the submission. | - | - | DATAGAPLong term storage stability data must be generated in commercial packaging to support the ambient storage of the product for the claimed shelf life. No test has been planned for TRAVELSAFE MOSQUITO NET biocidal product. |
| Storage stability test – **low temperature stability test for liquids** | - | - | Not required for a solid formulation. | - | - | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | Effects of light are not examined. | - | - | Effects of light are not examined. Since commercial packaging (HDPE) is not considered as totally barrier to light and due to the photodegradation of Deltamethrin (DT50 = 4 days), the mitigation measure ”store away from light” is stated on the label. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See “Storage stability test – **accelerated storage”** | - | - | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See “Storage stability test – **long term storage at ambient temperature**” | - | - | - |
| Wettability | - | - | Not relevant for LN formulation | - | - | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant for LN formulation | - | - | - |
| Wet sieve analysis and dry sieve test | - | - | Not relevant for LN formulation | - | - | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant for LN formulation | - | - | - |
| Disintegration time | - | - | Not relevant for LN formulation | - | - | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not relevant for LN formulation | - | - | - |
| Persistent foaming | - | - | Not relevant for LN formulation | - | - | - |
| Flowability/Pourability/Dustability | - | - | Not relevant for LN formulation | - | - | - |
| Burning rate — smoke generators | - | - | Not relevant for LN formulation | - | - | - |
| Burning completeness — smoke generators | - | - | Not relevant for LN formulation | - | - | - |
| Composition of smoke — smoke generators | - | - | Not relevant for LN formulation | - | - | - |
| Spraying pattern — aerosols | - | - | Not relevant for LN formulation | - | - | - |
| Physical compatibility | - | - | Not relevant (solid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | - |
| Chemical compatibility | - | - | Not relevant (solid formulation not intended to be co-applied with other substances, mixtures or biocidal or non-biocidal products) | - | - | - |
| Degree of dissolution and dilution stability | - | - | Not relevant for LN formulation | - | - | - |
| Surface tension | - | - | Not relevant for LN formulation | - | - | - |
| Viscosity | - | - | Not relevant for LN formulation | - | - | - |
| Wash resistance index | CIPAC MT 195Validated analytical method n°19095 | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | Net samples (25 x 25 cm) were individually washed.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Before wash****Deltamethrin content (g/kg)** | **After 4th wash****Deltamethrin content (g/kg)** | **Wash Resistance Index (%)** |
| **Initial** | 2.71 | 2.54 | 98.4 |
| **After 14 days at 54 °C** | 2.66 | 2.54 | 98.8 |

 | Rajasekharam, C. (2019)Report n°19094 | Y | AcceptableAccording to WHO specification 333/LN/2 (World Health Organization, July 2017), wash resistance index of deltamethrin from the netting, when determined, shall be in the range 90% to 100%. |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Net samples (25 x 25 cm) were individually washed.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Before wash****Deltamethrin content (g/kg)** | **After 4th wash****Deltamethrin content (g/kg)** | **Wash Resistance Index (%)** |
| **Initial** | 2.27 | 2.14 | 98.5 |
| **After 14 days at 54 °C** | 2.20 | 2.14 | 99.3 |

 | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Net samples (25 x 25 cm) were individually washed.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Before wash****Deltamethrin content (g/kg)** | **After 4th wash****Deltamethrin content (g/kg)** | **Wash Resistance Index (%)** |
| **Initial** | 1.83 | 1.70 | 98.2 |
| **After 14 days at 54 °C** | 1.79 | 1.68 | 98.5 |

 | Rajasekharam, C. (2019)Report n°19087 |
| Fabric weight (mass per m²) | ISO 3801EN 12127 | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | The average gram per unit area was 31.91 g/m2. | Rajasekharam, C. (2019)Report n°19094 | Y | AcceptableAccording to WHO specification 333/LN/2 (World Health Organization, July 2017), mass per unit area shall be declared (30 g/m² for 75 denier yarn, 40 g/m² for 100 denier yarn and 42 g/m² for 150 denier yarn), and when determined, shall not differ from that declared by more than ± 10 %. |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | The average gram per unit area was 39.49 g/m2. | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | The average gram per unit area was 45.96 g/m2. | Rajasekharam, C. (2019)Report n°19087 |
| Netting mesh size | ISO 139(1973) | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | The average mesh size (holes/cm2) was 24 holes/cm2. | Rajasekharam, C. (2019)Report n°19094 | Y | AcceptableAccording to WHO specification 333/LN/2 (World Health Organization, July 2017), the average number of complete holes/cm² for 75 and 100 denier yarn shall be not less than 24 holes/cm² and the lowest value shall be not less than 23 holes/cm². For 150 denier yarn the average number of complete holes/cm² shall be not less than 14 holes/cm² and the lowest value shall be not less than 13 holes/cm². |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | The average mesh size (holes/cm2) was 24 holes/cm2. | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | The average mesh size (holes/cm2) was 14 holes/cm2. | Rajasekharam, C. (2019)Report n°19087 |
| Dimensional stability of netting to washing | ISO 3759(2007)ISO 6330(2001)ISO 5077(1984) | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | Dimensional stability of Deltamethrin before accelerated storage is (Shrinkage) -1.0% (Warp) and -1.2% (Weft).Dimensional stability of Deltamethrin after accelerated storage (14 days at 54 °C) is (Shrinkage) -1.3% (Warp) and -1.5% (Weft). | Rajasekharam, C. (2019)Report n°19094 | Y | AcceptableAccording to WHO specification 333/LN/2 (World Health Organization, July 2017), not more than 10% shrinkage and not more than 5% expansion in both directions. |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Dimensional stability of Deltamethrin before accelerated storage is (Shrinkage) -1.0% (Warp) and -1.0% (Weft).Dimensional stability of Deltamethrin after accelerated storage (14 days at 54 °C) is (Shrinkage) -1.3% (Warp) and -1.5% (Weft). | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Dimensional stability of Deltamethrin before accelerated storage is (Shrinkage) -0.7% (Warp) and -0.8% (Weft).Dimensional stability of Deltamethrin after accelerated storage (14 days at 54 °C) is (Shrinkage) -1.0% (Warp) and -1.2% (Weft). | Rajasekharam, C. (2019)Report n°19087 |
| Bursting Strength | ISO 13938-2:1999 | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | The average bursting strength determined for the Deltamethrin before accelerated storage is 345.0 kPa.The average bursting strength determined for the Deltamethrin after accelerated storage (14 days at 54 °C) is 342.5 kPa. | Rajasekharam, C. (2019)Report n°19094 | Y | AcceptableAccording to WHO specification 333/LN/2 (World Health Organization, July 2017), the minimum bursting strength of the fabric shall be declared as follows and, when determined, the average shall be not less than that declared: not less than 250, 350 or 420 kPa, respectively, for fabric made from 75, 100 or 150 denier yarn |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | The average bursting strength determined for the Deltamethrin before accelerated storage is 437.5 kPa.The average bursting strength determined for the Deltamethrin after accelerated storage (14 days at 54 °C) is 438.3 kPa. | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | The average bursting strength determined for the Deltamethrin before accelerated storage is 521.4 kPa.The average bursting strength determined for the Deltamethrin after accelerated storage (14 days at 54 °C) is 515.8 kPa. | Rajasekharam, C. (2019)Report n°19087 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| Product is ready to use insecticidal net (LN) impregnated with Deltamethrin (80.0 mg/m2). All studies have been performed in accordance with the current requirements and the results are considered to be acceptable. The appearance of the product is white or blue solid fibre net with synthetic material odour. The physico-chemical characteristics of the insecticidal net (LN) formulations have been correctly described.The accelerated stability study shows that insecticidal net (LN) formulation is stable during 14 days at 54 °C, as no significant reduction in deltamethrin content and no significant change in the physical-chemical properties tested are observed. An interim shelf life of 24 months can be granted based on accelerated storage stability study. Data on long term storage stability in commercial packaging will be required in post-authorisation within 2 years to confirm the 24month shelf-life. Effects of light are not examined. Since the commercial packaging (HDPE) is not considered as totally barrier to light and due to the photodegradation of deltamethrin, the mitigation measure ”store away from light” is stated on the label.Its technical characteristics are acceptable for a ready to use insecticidal net (LN) formulation.**Labelling mention:** Store away from light.**Shelf-life:** 24 months**Classification related to physical, chemical and technical properties of the product:** None**Post authorization data:** - Long term storage study (24 months) on the product in commercial packaging at ambient temperature is required in post-authorisation within two years. |

### Physical hazards and respective characteristics

Physical hazards characteristics were determined on the product as it is supplied to the user.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **GLP** | **Reference** | **Comments** |
| --- | --- | --- | --- | --- | --- | --- |
| Explosives | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.1 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to explosive or self-reactive properties. Therefore testing is not considered to be necessary. | - | - | AcceptableAccording to the composition, the product does not contain explosive compounds or chemical groups associated with explosive properties. As stated in CLP regulation, it can be assumed that the product is not explosive. |
| Flammable solids | EN 1102:2016 | TSARA SOFT LN (75 Denier)Batch n° 75D\_A80.0 mg/m2 or 2.7 g/kg in Deltamethrin | Test flame was not propagated on the specimens and did not ignite.  | Y | Rajasekharam, C. (2019)Report n°19094 | AcceptableAccording to CLP regulation, the product cannot be considered as flammable. |
| TSARA SOFT LN (100 Denier)Batch n° 100D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Test flame was not propagated on the specimens and did not ignite. | Y | Rajasekharam, C. (2019)Report n°19093 |
| TSARA SOFT LN (150 Denier)Batch n° 150D\_A80.0 mg/m2 or 2.0 g/kg in Deltamethrin | Test flame was not propagated on the specimens and did not ignite. | Y | Rajasekharam, C. (2019)Report n°19087 |
| Self-reactive substances and mixtures | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.1 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to self-reactive properties. Therefore testing is not considered to be necessary. | - | - | AcceptableAccording to the composition, the biocidal product does not contain self-reactive compounds according to European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) (Volume 1, Table A.6.1. and A.6.3.). As stated in CLP regulation, it can be assumed that the product is not self-reactive. |
| Pyrophoric solids | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.1 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to pyrophoric properties. Therefore testing is not considered to be necessary. | - | - | AcceptableAccording to the composition, the product does not contain pyrophoric compounds. As stated in CLP regulation, it can be assumed that the product is not pyrophoric. |
| Self-heating substances and mixtures | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.11 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to self-heating properties. Therefore testing is not considered to be necessary. | - | - | AcceptableAccording to the composition, the product does not contain self-heating compounds. As stated in CLP regulation, it can be assumed that the product is not self-heating. |
| Substances and mixtures which in contact with water emit flammable gases | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.13 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to this property. During the wash resistance index test (CIPAC MT 195), any emitting gases in contact with water was observed. | - | - | AcceptableAccording the wash resistance index test (CIPAC MT 195), any emitting gases in contact with water was observed. |
| Oxidising solids | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.13 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to oxidising properties. Therefore testing is not considered to be necessary. | - | - | AcceptableRegarding the composition, the product only contain substances where oxygen, fluorine or chlorine are chemically bonded only to carbon or hydrogen. Therefore, as stated in CLP regulation, it can be assumed that the product has no oxidising properties. |
| Organic peroxides | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.13 (ECHA)Statement | - | Not relevant to be conducted since none of the components present in the formulated biocidal product fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. | - | - | Acceptable |
| Corrosive to Metals | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.13 (ECHA)Statement | - | The biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components which are classified as Met. Corr. 1 (H290). Moreover, handling experience with the mixture indicated no corrosion of metals. | - | - | AcceptableAs it is supplied to the user, TRAVELSAFE MOSQUITO NET is a solid product. Therefore, it is not classified as corrosive to metal |
| Relative self-ignition temperature for solids | Guidance on the Application of the CLP Criteria Version 5.0 – July 2017 section 2.13 (ECHA)Statement | - | According to ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance, (R.7.1.12.1 Auto-ignition), “The study does not need to be conducted:- if the substance is explosive or ignites spontaneously with air at room temperature; or- for solids, if the substance has a melting point ≤ 160°C, or if preliminary results exclude self-heating of the substance up to 400°C.”Melting point of polyester fabric is 260 °C and the biocidal product (Mainly composed of a polyester fabric (Min 96.65%)) do not contain any components that are associated to explosive properties or ignites spontaneously with air at room temperature. | - | - | No test was providedHowever, no unacceptable risk is expected from the products with regards to the auto-ignition temperature.A test according to EC method A.15 on the product will be required in post authorisation. |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| TRAVELSAFE MOSQUITO NET is not classified as an explosive, oxidising, flammable and self-heating substance. |

### Methods for detection and identification

**Analytical Method for the determination of Deltamethrin in the product:**

The CIPAC method N 333/LN/M2/3 has been developed to determine deltamethrin content in deltamethrin long-lasting (coated onto polyester) insecticidal net. This method is appropriate for the determination of deltamethrin content in TRAVELSAFE MOSQUITO NET product. This method was validated through the inter-laboratory CIPAC process.

Complementary to this CIPAC method, an analytical method (study GLP n°19095) has been developed on TRAVELSAFE MOSQUITO NET. Only limited validation data (specificity and linearity) are presented as some criteria of this analytical method were validated during CIPAC method N 333/LN/M2/3 validation method.

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| **Analytical method for the analysis of**  **Deltamethrin in the product TRAVELSAFE MOSQUITO NET** |
| **Analytes (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Reference** |
| Acceptable range | Mean (test item fortified) | RSD (n=5)Test item not fortified |
| Active substance Deltamethrin | CIPAC method N 333/LN/M2/3 | N=5 in duplicate(from 50-150% 0.002041 mg/mL and 0.06138 mg/mL) | Linearity was studied by carrying out five concentrations between 0.002041 mg/mL and 0.06138 mg/mL.The response of the detector during the analysis of Deltamethrin (Y = 1E+08 X + 2088.3; r2 = 0.9998) was linear. | To demonstrate the specificity of the method, four solutions are analysed and chromatograms have been provided for: solvent blank, formulation blank, reference item and test item.No interference was found: no peak appears in the formulation blank and solvent blank at the retention time of Deltamethrin.The method is specific to Deltamethrin in TRAVELSAFE MOSQUITO NET. | Validated in CIPAC method N 333/LN/M2/3 | CIPAC method N 333/LN/M2/3Rajasekharam, C. (2019) Report n° 19095 |

**Analytical Methods for monitoring** **Deltamethrin residues:**

Analytical methods for determination of active ingredients residues have already been evaluated at EU level and are presented in the CAR of deltamethrin (May 2011). The notifier Van Bergen Sports Int. BV provided a letter of access to data from the AS approval dossier.

Analytical methods for monitoring deltamethrin residues in soil

The residues in soil are determined by LC-MS/MS using 1 transition, with a LOQ of 0.1 μg/kg.

Analytical methods for monitoring deltamethrin residues in air

The residues in air are quantified by means of GC-ECD with GC-MS for confirmation and a LOQ of 0.27 μg/m3, which is considered acceptable with respect to the systemic AEL of 0.0075 mg/kg bw/day (i.e. a LOQ of 2.25 μg/m3 is required).

Analytical methods for monitoring deltamethrin residues in water

Drinking water: Three acceptable methods are available for deltamethrin residues in drinking water with LOQs of 5.9 ng/L (LC-MS/MS with 1 transition), 0.05 μg/L (GC-ECD for quantification and confirmation) and 3 ng/L (GC-ECD and GC-MS/MS for quantification and confirmation respectively).

Surface water: An acceptable method is available deltamethrin residues in surface water with LOQ of 3 ng/L (GC-ECD and GC-MS/MS for quantification and confirmation respectively) which is lower than the relevant NOEC of 4.8 ng/L determined from a mesocosm study.

Analytical methods for monitoring deltamethrin residues in body fluids and tissues:

Deltamethrin residues in human and animal body fluids and tissues are determined either by GC-ECD (tissues) or GC-MS (whole blood; two methods) with LOQs of 0.02 mg/kg and 20 ng/L for the method for tissues and the most sensitive method for whole blood, respectively.

Analytical methods for monitoring Deltamethrin residues in food and feeding stuff of plant and animal origin:

It has been agreed (TM I 2010) that no monitoring method is required for deltamethrin residues in food and feeding stuffs as the intended use will not result in significant residues in those matrices when the label instruction is followed. However, two methods were provided (GC-ECD and LC-MS/MS) for various matrices which could be useful in case of suspected contamination. The LOQs of 0.02 mg/kg and 0.01 mg/kg for the GC-ECD method and LC-MS/MS-methods respectively are acceptable with respect to the available Maximum Residue Levels (MRLs) for Deltamethrin (as set by Regulation (EC) No 396/2005 of the European Parliament and of the Council).

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| **Conclusion on methods for detection and identification**  |
| The CIPAC method N 333/LN/M2/3 has been developed to determine deltamethrin content in deltamethrin long-lasting (coated onto polyester) insecticidal net. This method is appropriate for the determination of deltamethrin content in TRAVELSAFE MOSQUITO NET product. This method was validated through the inter-laboratory CIPAC process.Complementary to this CIPAC method, an analytical method (study GLP n°19095) has been developed on TRAVELSAFE MOSQUITO NET. Only limited validation data (specificity and linearity) are presented as some criteria of this analytical method were validated during CIPAC method N 333/LN/M2/3 validation method.Analytical methods for determination of deltamethrin residues in different matrices are available and fully validated in the CAR of deltamethrin (May 2011). The notifier Van Bergen Sports Int. BV provided a letter of access to data from the AS approval dossier. No other data is required.  |

### Efficacy against target organisms

#### Function and field of use

MG 03: Pest Control

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

TravelSafe Mosquito net is a ready-to-use impregnated net intended to kill mosquitoes *Anopheles sp*., potentially carrying vector-borne diseases (malaria).

Product is used indoor and outdoor by non-professional users, only for use in the tropical areas against mosquitoes *Anopheles sp*., potentially carrying vector-borne diseases (malaria).

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

Target organism to be controlled is mosquitoes (*Anopheles sp*.) potentially carrying vector-borne diseases (malaria) in order to ensure health protection.

Due to the specificity of the use (only in the tropical areas against mosquitoes *Anopheles sp*., potentially carrying vector-borne diseases (malaria)), other species such as *Culex sp*. and *Aedes sp*. have not been claimed and assessed in the efficacy assessment.

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

Deltamethrin is a pyrethroid insecticide which acts on harmful organisms by contact and ingestion. It expresses a strong knock-down effect, resulting in death.

#### Mode of action, including time delay

Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after pesticide absorption. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyper excitability.

#### Efficacy data

The applicant submitted several studies that contain both Phase I test (cone bioassay) and Phase II test (Small-scale field trials), and also Phase III tests (field studies), according to Guidelines for laboratory and field testing of long-lasting insecticidal mosquito nets WHO/CDS/WHOPES/GCDPP/2005.11. These studies were conducted with the product DAWA Plus 2nd generation or DawaPlus® 2.0 LN, both identical to the product TRAVELsafe Mosquito net.

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism****(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Impregnated net. | DAWA Plus 2nd generation 2.0 g/kg for 100 deniers (i.e 80 mg/m²) | *Anopheles gambiae*(susceptible strainKISUMU)10 batches of 5 mosquitoes : 50 mosquitoes/net | Laboratory testing (Phase I)cone bioassaysWHO 2005.11 | Cone bioassays carried out on several modalities (untreated polyester net, DawaPlus 2nd generation unwashed, DawaPlus 2nd Generation washed 20 times, WHO polyester LN unwashed and washed 3 times) at 3 stages: 1) After treatment, before any washing was done2) After all washings, just before the hut trial began3) After the hut trial.5 cones were placed in the 5 sections of the net (roof and 4 sides).3 min exposure time.The washes were done according to WHO standardised procedures.Exposure time was of 3 min and mortality was scored after 24h | Efficacy criteria: >80% mortality after 24H and >95% KD after 60 min.Results:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Before washing T0 | After washing | After field trial |
|  | %KD | %✞ | %KD | %✞ | %KD | % ✞ |
| Untreated | 0a | 0a | 0a | 1,8a | 0a | 0a |
| LN25 mg/m² unwashed | 100b | 100b | 100b | 100b | 100b | 100b |
| LN25 mg/m² washed 3x (WHO reference) | 100b | 100b | 95,1b | 82c | 96,9b | 89c |
| DawaPlus unwashed | 100b | 100b | 100b | 100b | 100b | 100b |
| Dawa Plus washed 20X | 100b | 100b | 100b | 100b | 100b | 100b |

 | Chabi J et al, 2009, Efficacy of a deltamethrin long-lasting insecticidal net (DAWA Plus 2nd generation-TANA netting) against wild susceptible population of *Anopheles gambiae* in experimental huts, Benin. |
| *Anopheles spp* (wild susceptible populations, free-flying). | Small-scale field trials (Phase II)WHO 2005.11 | 6 experimental huts in Benin, mosquito access is via 4 window slits with a 1 cm wide gap. Before testing in the experimental huts, the nets (including control) were deliberately holedaccording to WHOPES procedures (WHO 2005). Six holes were made in each net, 2 holes in each of the long side and 1 hole at each end. Each hole measures 4cm x 4cmIn each hut, 1 net is used per night and at the end of the week treatment rotated to another hut. The trial took place over 12 weeks.The washes were done according to WHO standardised procedures.3 modalities: Untreated net, DAWAPlus 2nd generation unwashed and washed 20x, WHO reference (LN25) unwashed and washed 3xOutcomes measured:-deterrency (reduction in hut entry)-Induced exophily (proportion of mosquitoes that exit early and are found in exit traps)-blood-feeding inhibition-immediate and delayed mortality) | Efficacy criteria: the product washed 20x should have an efficacy ≥ Polyester net conventionally treated washed (WHO 2005.11).Summary results (72 nights):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | ♀ caught | Exit rate | Blood feed  | mortality |
| Untreated net | 285a | 42.8%a | 37.5%a  | 4.2%a |
| LN25 mg/m² unwashed | 207a | 64.2%c | 5.8%bc | 69.5%bc |
| LN25 mg/m² washed 3x (WHO reference) | 297a | 56.9%bc | 10.4%c | 61.2%b |
| DawaPlus 2nd unwashed | 209a | 53.5%b | 6.7%bc | 74.1%c |
| DawaPlus 2nd 20x | 288a | 57.6%bc | 4.8%b | 61.1%b |

No significant difference in deterrency was noted between the treated and untreated nets.All treatments caused significantly higher mortality rates than the untreated control. As the results of DawaPlus 2nd was significantly higher or equal than results of polyester net treated and washed just before exhaustion (LN25 mg/m² washed 3x), it can be concluded that the product is effective (according to WHO 2005.11). |
| Impregnated net. | DawaPlus® 2.0 LN2.0 g/kg for 100 deniers (i.e 80 mg/m²) | *Anopheles gambiae (susceptible strain KISUMU)*10 batches of 5 mosquitoes:50 mosquitoes per net. | Laboratory testing (Phase I)Cone bioassaysWHO 2005.11 | Cone bioassays carried out on several modalities (untreated polyester net, DawaPlus 2.0 LN unwashed, DawaPlus 2.0 LN washed 20 times, WHO polyester LN unwashed and washed 3 times) at 3 stages: 1) After treatment, before any washing was done2) After all washings, just before the hut trial began3) After the hut trial.5 cones were placed in the 5 sections of the net (roof and 4 sides).The washes were done according to WHO standardised procedures.Exposure time was of 3 min and mortality was scored after 24h | Efficacy criteria: >80% mortality after 24H and >95% KD after 60 min. Results:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Before washing T0 | After washing | After field trial |
|  | %KD | %✞ | %KD | %✞ | %KD | % ✞ |
| Untreated | 0 | 0 | 0 | 0 | - | - |
| LN25 mg/m² unwashed | 100 | 100 | 92 | 100 | 98 | 98 |
| LN25 mg/m² washed 3x (WHO reference) | 100 | 100 | 76 | 84 | 66 | 66 |
| Dawa Plus unwashed | 100 | 100 | 90 | 98 | 100 | 100 |
| Dawa Plus washed 20 times | 100 | 100 | 86 | 96 | 82 | 82 |

  | Tungu P et al, June 2009Evaluation of DawaPLus 2.0 LN against Anopheles gambiae in experimental huts in Muheza, Tanzania |
| *Anopheles spp* (wild, free-flying, host-seeking). | Small-scale field trials (Phase II)WHO 2005.11 | 6 experimental huts in Tanzania with windows and veranda traps on each side, with rotation of openings to compensate for possible selective exit in one compass direction.Before testing in the experimental huts, the nets (including control) were deliberately holed with six holes (4cmx4cm) to simulate a torn net according to VVHOPES procedures (WHO 2005). In each hut, 1 net is used per night and at the end of the week, treatments rotated to another hut. The trial took place over 9 weeks.The washes were done according to WHO standardised procedures.3 modalities: Untreated net, DawaPlus® 2.0 LN unwashed and washed 20x, WHO reference (LN25) unwashed and washed 3xOutcomes measured:-deterrency (reduction in hut entry)-Induced exophily (proportion of mosquitoes that exit early and are found in exit traps)-blood-feeding inhibition-immediate and delayed mortality) | Efficacy criteria: the product washed 20x should have an efficacy ≥ Polyester net conventionally treated washed (WHO 2005.11).Summary results (54 nights):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | ♀ caught | Exit rate | Blood feed  | Mortality |
| Untreated net | 225a | 88.9%a | 21.3%a  | 0.9%a |
| LN25 mg/m² unwashed | 159a | 93.1%ac | 14,5%ab | 95.6%b |
| LN25 mg/m² 3x | 171a | 94.7%ac | 9.4%b | 57.3%cd |
| DawaPlus® 2.0 LN unwashed | 171a | 96.5%bc | 10.5%b | 91.2%b |
| DawaPlus® 2.0 LN 20x | 164a | 96.3%bc | 11%b | 67.7%c |

As the results of DawaPlus 2nd was significantly higher or equal than results of polyester net treated and washed just before exhaustion (LN25 3x), it can be concluded that the product is effective (according to WHO 2005.11). |
| Insecticide | Impregnated net. | DawaPlus® 2.0 LN | *Anopheles spp* (pyrethroid susceptible mosquito strains) | Field studies (Phase III)WHO 2005.11 | Burkina-Faso (2014-2017)Indonesia (2015-2018)Tanzania (2014-2017)The product was distributed free of cost to an equal number of households. Follow-up surveys were performed after distribution of nets, and at each survey (at 0/6/12/18/24/30/36 months) a randomized sample of several nets was collected for the purpose of bioefficacy and chemical content analysis. The standard WHO cone test was used to investigate mortality and KD | Cone test results

|  |  |  |
| --- | --- | --- |
| Field area | Dawa Plus | Positive controlPyrethroid based LN |
|  | Mean KD60 | Mortality 24H | Mean KD60 | Mortality 24H |
| Burkina Faso at 36 months | 99,92% | 100% | 99,96% | 100% |
| Indonesia at 36 months | 100% | 100% | / | / |
| Tanzania at 36 months | 96,6% | 92,3% | 97,8% | 89,1% |

Over a period of 3 years, the mean KD60 and mortality at 24H were above the target threshold (i.e ≥95% KD and ≥80% mortality) | Prequalification Unit – Vector Control Products Assessment (PQT/VCP)Decision documentTsara soft2018 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In the small scale field trials (in huts in Benin and Tanzania), the efficacy of the TRAVELSAFE MOSQUITO NET, washed 20 times, is higher or equal than the WHO reference net, against mosquitoes (*Anopheles sp*.). Indeed, in laboratory studies (cone bioassays), knockdown and mortality measured with the product TRAVELSAFE MOSQUITO NET (80 mg/m² deltamethrin) fulfil the WHO efficacy criteria (80% mortality after 24H and >95% KD after 60 min) unwashed and after 20 washes, against mosquitoes (*Anopheles sp.*).Moreover, following long-term field studies initiated in 2014/2015 for 3 years, in Burkina-Faso (*Anopheles aconitus*), Indonesia (*Anopheles gambiae*) and Tanzania (*Anopheles gambiae*), the product TRAVELSAFE MOSQUITO NET has obtained the status “prequalified” on the list of vector control products of WHO (October 2020), since over a period of 3 years, the mean KD60 and mortality at 24H were above the target threshold (i.e ≥95% KD and ≥80% mortality) for all the sitesThe product TRAVELSAFE MOSQUITO NET have shown a sufficient efficacy as a long lasting insecticidal net against mosquitoes (*Anopheles spp.),* washed up to 20 times, in tropical area. |

#### Occurrence of resistance and resistance management

Deltamethrin is a pyrethroid insecticide. Deltamethrin products are widely used for various applications: veterinary medicine, crop protection, indoors and outdoors biocide, and against numerous arthropods target organisms. Resistance to deltamethrin has already been reported in several insects, including mosquitoes.

Populations of *Anopheles gambiae[[3]](#footnote-4)[[4]](#footnote-5)[[5]](#footnote-6)* resistant to pyrethroids have been identified in West Africa, and in other parts of this continent.

More specifically concerning the mosquitoes *Anopheles sp*, deltamethrin resistant populations have been identified in different part of the world including Guinea[[6]](#footnote-7) (*Anopheles sp* mixed population). Moreover for *Anopheles gambiae[[7]](#footnote-8)[[8]](#footnote-9)*, deltamethrin resistant population have been identified on the African continent, in some countries like Benin[[9]](#footnote-10), and Tanzania[[10]](#footnote-11). Recent papers also show deltamethrin resistant populations of *Anopheles sp* against long-lasting insecticide-treated net[[11]](#footnote-12)[[12]](#footnote-13).

Therefore, the authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

It is requested to establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance on national territory (overseas departments), and provide an assessment of this monitoring every five years.

Moreover, to ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

Only use in the areas of mosquitoes *Anopheles sp*., potentially carrying vector-borne diseases (malaria).

#### Evaluation of the label claims

The product TRAVELSAFE MOSQUITO NET has shown a sufficient efficacy as a long lasting insecticidal net against mosquitoes (*Anopheles spp.),* washed up to 20 times, in tropical area.

#### 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

***Skin corrosion and irritation***

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | Not irritating to skin |
| Justification for the value/conclusion | The active substance and the co-formulants are not classified for this endpoint. Therefore, irritation of the skin is not expected.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

***Eye irritation***

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Not irritating for eye |
| Justification for the value/conclusion | The active substance and the co-formulants are not classified for this endpoint. Therefore, irritation of the eyes is not expected.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents. The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

***Respiratory tract irritation***

|  |
| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | The active substance and the co-formulants are not classified for this endpoint.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents.The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

***Skin sensitization***

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not sensitising |
| Justification for the value/conclusion | The active substance and the co-formulants are not classified for this endpoint. Therefore, sensitisation of the skin is not expected.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents.The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

***Respiratory sensitization (ADS)***

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not sensitising |
| Justification for the value/conclusion | The active substance and the co-formulants are not classified for this endpoint. Therefore, respiratory sensitisation is not expected.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents.The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

***Acute toxicity***

*Acute toxicity by oral route*

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | ATE between 300 and 2000 mg/kg |
| Justification for the selected value | The active substance is classified for this endpoint. The co-formulant are not classified for this endpoint. Therefore, considering the concentration of the active substance in the mixture, the ATE presented above is estimated. Net 100-150 denier: 1573 mg/kgNet 75 denier: 1570 mg/kg |
| Classification of the product according to CLP and DSD | A classification acute tox. 4 H302 is needed.  |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents.The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

*Acute toxicity by inhalation*

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | ATE > 5 mg/l (dust) and 20mg/l (vapour) |
| Justification for the selected value | The active substance is classified for this endpoint. The co-formulants are not classified for this endpoint. Therefore, considering the concentration of the active substance in the mixture, the ATE presented above is estimated.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents.The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

*Acute toxicity by dermal route*

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | ATE > 2000 mg/kg |
| Justification for the selected value | The active substance and the co-formulants are not classified for this endpoint. The ATE presented above is estimated.  |
| Classification of the product according to CLP and DSD | No classification is required |

|  |
| --- |
| **Data waiving** |
| Information requirement | No study is performed |
| Justification | According to the note for guidance “handling “carriers” in the authorisation of biocidal products, treated nets are considered as “functional Biocidal product” (case B). Therefore, the classification is based on the composition of the final product without carrier, after evaporation of the solvents.The classification of the mixture can be deduced from the respective properties of the active substance and the co-formulants, using the method by calculation described in the CLP regulation.  |

***Information on dermal absorption***

|  |
| --- |
| **Data waiving** |
| Information requirement | No dermal absorption study was provided by the applicant. |
| Justification | Deltamethrin will not be absorbed at more than 10% considering physico-chemical property of deltamethrin and available data. Indeed, after handling of the net, exposure to dry active substance will occur. The dermal absorption of this dry active substance will be inferior to the dermal absorption from the CAR obtained after handling of a solution containing a low concentration of active substance (0.1 g/l) and high level of solvent (90%), for which a dermal absorption of 2% is obtained. Moreover, WHO published in june 2021[[13]](#footnote-14) a generic risk assessment for human health of deltamethrin in treated nets. In this assessment a dermal absorption value of 1% is used. Therefore, as a conservative approach the value of 10% is used in the risk assessment. |

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Deltamethrin |
| Value(s)\* | 10% |
| Justification for the selected value(s) | Default value |

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

The assessment of substance of concern was performed according to the SoC guidance included in the BPR guidance (Part B+C, Vol III). Please see confidential PAR for more details.

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

Not relevant

***Other***

Not relevant

#### Exposure assessment and risk characterisation for human health

#### **Introductory remarks**

TRAVELSAFE MOSQUITO NET is an insecticidal net used by non-professional, containing 80 mg/m2 of deltamethrin.

Human exposure is determined according to the generic risk assessment model for insecticide-treated nets from WHO[[14]](#footnote-15). The body surfaces, weight and inhalation rates of adults, children, toddlers (1 to < 2 years) and infants (< 1 year) are issued from the recommendation 14 of the BPC ad hoc WG on human exposure[[15]](#footnote-16). For newborns (birth to 1 month), the values are issued from “Child-Specific Exposure Factors Handbook" (2008).

The potential scenario of exposure which are considered are:

* Person sleeping under treated nets (adult, children, toddler, infant and newborn).
* Exposure of newborns and infant via mother’s milk, who has slept under the net and washed it.
* Person washing a treated net.

As a worst case, it is assumed that the concentration of the insecticide in the net does not significantly change over the time.

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

Exposure during sleeping under treated net is considered as primary exposure.

Exposure via mother’s milk and washing of treated net is considered as secondary exposure.

Table 3.54 Summary table: main paths of human exposure

| **Summary table: main paths of human exposure** |
| --- |
| **Exposure path** | **Primary (direct) exposure**  | **Secondary (indirect) exposure**  |
| **Professional users** (including industrial users and trained professional users) | **Non-professional users** | **Professional users** (including industrial users and trained professional users) | **Non-professional bystanders/General public** | **Via food** |
| Oral | n/a | yes | n/a | Yes  |  |
| Dermal | n/a | yes | n/a | Yes  |  |
| Inhalation | n/a | yes | n/a | No  |  |

 *“n/a” (not applicable)*

#### **List of exposure scenarios**

Table 3.55 Summary table: exposure scenarios

| **Summary table: exposure scenarios** |
| --- |
| **Scenario and task number** | **Description of scenario and tasks** | **Exposed group** |
| **Primary exposure** |
| **[1]** | ***Person sleeping under treated net*** | Non-professional users(adults, children, young children, toddlers, infants and newborns) |
| **Combined primary exposure : not relevant** |
| **Secondary exposure** |
| **[2]** | ***Newborn and infant exposure via breast milk of mother sleeping in a treated net and washing them*** | General public(Infants and newborns) |
| **[3]** | ***Person washing the treated net*** | General public(adults) |
| **Combined secondary exposure: not relevant** |
| **Combined primary and secondary exposure** |
| **[1+2]** | ***Newborn and infant sleeping under treated net and exposed via breast milk of mother sleeping in a treated net and washing it*** |
| **[1+3]** | ***Adult and child sleeping under treated net and washing it*** |

#### **Reference values to be used in risk characterisation**

Table 3.56 Reference values to be used in risk characterisation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL) or NOAEC (LOAEC)** | **AF** | **Correction for absorption** | **Value** |
| AELshort-term | 13-week dog study | 1 mg/kg/d | 100 | 75% | 0.0075 mg/kg/d |
| AELmedium-term | 13-week and 1-year dog studies | 1 mg/kg/d | 100 | 75% | 0.0075 mg/kg/d |
| AELlong-term | 1 year dog study | 1 mg/kg/d | 100 | 75% | 0.0075 mg/kg/d |

#### **Specific reference value for groundwater**

Not relevant

#### **Professional users (including industrial users and trained professional users)**

*Not relevant*

#### **Non-professional users**

Scenario [1]: [Person sleeping under treated net]

Description and input parameters

Table 3.62 Description and input parameters

| **Description of Scenario [1]** |
| --- |
| Different categories of persons are considered:* adults,
* children,
* toddlers,
* Infants and
* newborns.

As mentioned above, exposure is determined according to the generic risk assessment model for insecticide-treated nets of WHO[[16]](#footnote-17).Potential routes of exposure are dermal (dislodgeable residues from the net being deposited on skin in contact with the net) and inhalation. Moreover, for infants and toddler, the contact via oral route (mouthed, chewed and sucked) is also considered. For inhalation route:According to the low vapor pressure of deltamethrin (1.24 \* 10^-8 at 25°C) and the experimental works reported in the WHO document, the exposure by inhalation is considered as negligible for deltametherin. For dermal route: For anyone sleeping under a treated net, contact between the net and the bare skin is expected. Exposure is determined according to the following formula: SysDtwa= systemic dose from dermal exposure (mg/kg/d)AbsD = dermal absorption (10% see above)Transl = translodgeable fraction (default 6%). This value is based on USEPA report 2012, in which studies on four pyrethroid are reported. ESA = exposed skin area (m2), assuming that the trunk, hands, arms, lower legs and feet are uncovered ant that one third of their total surface area could be in contact with the net (please see table below)SF = surface fraction of the insecticide = fraction available for skin contact (100-wash resistance index%) 🡪 100-98.2% = 1.8%TC = concentration of the a.i. in the net (mg/m2) -> 80 mg/m2.BW = body weight (please see table below)For oral route: Oral exposure may occur from hand to mouth transfer and from direct mouthing of the net in the case of infants and toddlers.Oral exposure via hand to mouth transfer can be calculated according to the following formula: SysDTWA = systemic dose from oral exposure from hand-to-mouth activity (mg/kg/d)AbsO = oral absorption 🡪 75% (AR of deltamethrin)Transl = translodgeability (default 6%). This value is based on USEPA report 2012, in which studies on four pyrethroid are reported. EHA = exposed hand area, assuming that one third of their surface is in contact with the net (please see table below)FHM = fraction of hand mouthed (default 16.4%). This value is based on USEPA report 2012.SE = salivary extraction fraction (default 57%). This value is based on USEPA report 2012.SF = surface fraction of the insecticide = fraction available for skin contact (100-wash resistance index%) 🡪 100-98.2% = 1.8%TC = concentration of the a.i. in the net (mg/m2) -> 80 mg/m2.BW = body weight (please see table below) |
| Oral exposure via mouthing of the net can be calculated according to the following formula. It is assumed that an area of 14 cm2 (0.0014 m2) of the net is in contact with the mouth overnight and that the fraction available on the net surface will be the target for salivary extraction: SysDTWA = systemic dose from oral exposure from direct net mouthing (mg/kg/d)AbsO = oral absorption 🡪 75% (AR of deltamethrin)SE = salivary extraction fraction (default 57%). This value is based on USEPA report 2012.NM = net mouthed, m2 (default 0.0014 m2)SF = surface fraction of the insecticide = fraction available for skin contact (100-wash resistance index%) 🡪 100-98.2% = 1.8%TC = concentration of the a.i. in the net (mg/m2) -> 80 mg/m2BW = body weight (please see table below) |

| **Input parameters for Scenario [1]** |
| --- |
| *Dermal route* |
|  | Parameters1 | Value | Reference and justification3 |
| ESA (m2) | adult | 0.41  | Generic risk assessment model for insecticide-treated nets of WHO and recommendation 14 of the ad hoc WG on human exposure.  |
| Child 6-12 years | 0.23 |
| Child 2-6 years | 0.17 |
| Toddler | 0.12 |
| Infant | 0.11 |
| Newborn | 0.08 | Generic risk assessment model for insecticide-treated nets of WHO and child-Specific Exposure Factors Handbook |
| Body weight (kg) | adult | 60 | Recommendation 14 of the ad hoc WG on human exposure |
| Child 6-12 years | 23.9 |
| Child 2-6 years | 15.6 |
| Toddler | 10 |
| Infant | 8 |
| Newborn | 4.2 | WHO |
| *Oral route* |
|  | Parameters1 | Value | Reference and justification3 |
| EHA (m2) | Toddler | 0.0077 | Generic risk assessment model for insecticide-treated nets of WHO and recommendation 14 of the ad hoc WG on human exposure.  |
| Infant | 0.0066 |
| Newborn | 0.005 | Generic risk assessment model for insecticide-treated nets of WHO and child-Specific Exposure Factors Handbook |

Outcome of systemic exposure and risk characterisation

Table 3.63 Summary table: estimated systemic exposure and risk characterisation for non-professional users

| **Summary table: estimated systemic exposure and risk characterisation for non-professional users** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated oral via hand to mouth contact****[mg/kg bw/day]** | **Estimated orall via mouthing, crewing and sucking** **[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = 0.0075mg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [1] | 1/no PPE |  |  |  |  |  |  |
| Adult | 5.90E-05 |   |   | 5.90E-05 | 1% | yes |
| Child 6-12 years | 8.46E-05 |   |   | 8.46E-05 | 1% | yes |
| Child 2-6 years | 9.65E-05 |   |   | 9.65E-05 | 1% | yes |
| Toddler | 1.07E-04 | 4.7E-06 | 8.62E-05 | 1.98E-04 | 3% | yes |
| Infant | 1.14E-04 | 5.0E-06 | 1.08E-04 | 2.27E-04 | 3% | yes |
| Newborn | 1.65E-04 | 7.2E-06 | 2.05E-04 | 3.77E-04 | 5% | yes |

Exposure is inferior to AEL for each sub population.

Combined scenarios

Not relevant

Outcome of (semi-)quantitative local exposure and risk characterisation

*Not relevant*

Outcome of qualitative local risk assessment

No local qualitative risk assessment is needed as the product is not classified for local effect.

Conclusion

The primary exposure is inferior to AEL for each subpopulation.

#### **Secondary exposure to professional bystanders and non-professional bystanders/general public**

Two scenarios are considered for secondary exposure:

* Exposure of newborn and infant via milk of mother sleeping in a treated net.
* Exposure of person washing the treated net.

Scenario [2]: [Exposure of newborn and infant via milk of mother sleeping in a treated net.]

Description and input parameters

Table 3.67 Description and input parameters

| **Description of Scenario [2]** |
| --- |
| Lactating women may sleep under the treated net. Therefore, newborns (0.1 month) and infants (< 1year) may be also exposed via breast milk. Exposure is determined according to the formula proposed in the WHO document: SolC = solubility constant; 0.361 for lipid soluble insecticidesDose Mbw = daily dose to the mother mg/kg bw (please see combined systemic dose (scenario 1+3)) T½ = first-order kinetics half time in the body of the insecticide, 1 day (worst case, CAR doc IIIA6.2 of deltamethrin). IR = ingestion rate of milk, kg/day; 75th percentile default for a newborn is 640 mL/day(USEPA, 2011), thus with a relative density of milk of 1.03, daily consumption wouldbe 0.66 kg/dayAbsO = fraction absorbed (75 %)BW = body weight (infant, 8 kg; newborn 4.2 kg; ) |

Outcome of systemic exposure and risk characterisation

Table 3.68 Summary table: estimated systemic exposure and risk characterisation for general public

| **Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** |
| --- |
| **Exposure scenario** | **Sub-****population** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = 0.0075mg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [2]  | Newborn | 9.04E-05 | nr | nr | 9.04E-05 | 1% | Yes |
| Infant  | 4.74E-05 | nr | nr | 4.74E-05 | 1% | Yes |

The exposure is inferior to AEL for newborns and infants.

Scenario [3]: [Exposure of person washing the treated net]

Description and input parameters

Table 3.67 Description and input parameters

| **Description of Scenario [3]** |
| --- |
| According to the WHO document, it is assumed that both adults and children (6-12 years) may carry out the manual washing of nets. The exposure is determined by the volume of the water used in washing, and the rate of release of the insecticide from the treated net. For a net of approximately 15m2, the volume of washing fluid is unlikely to be less than 4 litres. It is assumed that the 5 nets of a family are washed at a time. The volume of water used for washing is 4 litres. The contaminated skin is not rinsed immediately after washing of the net.Two routes of exposure are considered: * Dermal: during washing
* Oral via hand to mouth contact

For dermal route: Exposure is determined according to the following formula:SysDMAX = predicted maximal daily systemic dose from washing 5 nets (mg/kg/d)NoN = number of nets washed per day (default, 5)AbsD = dermal absorption (10% see above)VLS = volume of liquid on skin (adults 35.8 mL, children 6-12 years 17.7 mL, consisting of hands, forearms, ½ of lower legs and ½ of feet covered by a liquid film of 0.1 mm; see below)SF = surface fraction of the insecticide = fraction released in a wash = 1.8%TC = target concentration in the net (mg/m2) 🡪 80 mg/m2SN = size of the net m2VolW = volume of washing water (default, 4000 mL)BW = body weight (see below)For oral route: Exposure is determined according to the following formula:SysDMAX = predicted maximal daily systemic doseNoN = number of nets washed per day (default, 5)Abs O = oral absorption (default 75%)VLH = volume of liquid on hands covered by a liquid film of 0.1 mm (mL) (adult 8.2 mL, child 4.3 mL) (see below)SF = surface fraction released in a wash = fraction released in a wash= 1.8%TC = target concentration in the net (mg/m2) 🡪 80 mg/m2FHM = fraction of hand mouthed (default 16.4%). This value is based on USEPA report 2012.SN = size of the net (m2)VolW = volume of washing water (default 4 litres)BW = body weight (see below) |

| **Input parameters for Scenario [3]** |
| --- |
| *Dermal route* |
|  | Parameters1 | Value | Reference and justification3 |
| Exposed area surface: hands, forearms, ½ of lower legs and ½ of feet (cm2) | adult | 3580 | Recommendation 14 of the ad hoc WG on human exposure |
| child | 1772 |
| Body weight (kg) | adult | 60 |  |
| child | 23.9 |  |
| *Oral route* |
|  | Parameters1 | Value | Reference and justification3 |
| Exposed area surface: hands (cm2) | adult | 820 | Recommendation 14 of the ad hoc WG on human exposure |
| child | 428 |

Outcome of systemic exposure and risk characterisation

Table 3.68 Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public

| **Summary table: estimated systemic exposure and risk characterisation for professional bystanders and non-professional bystanders/general public** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = 0.0075mg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [3] (5 nets) | Adult | 4.54E-04 | 1.61E-03 | n/a | 2.06E-03 | 28% | Yes |
| Child  | 5.94E-04 | 2.00E-03 | n/a | 2.60E-03 | 35% | Yes |

Considering the washing of 5 nets, exposure is inferior to AEL for adult and child. .

Combined scenarios of secondary exposure

Not relevant

Outcome of (semi-)quantitative local exposure and risk characterisation

Not relevant

Outcome of qualitative local risk assessment

Not relevant

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

Two combined exposure scenario are considered:

* Scenario 1+2: newborn or infant sleeping in a treated net and who is exposed via the breast milk of its mother.
* Scenario 1+ 3: adult or child sleeping in a treated net and washing the same day the nets. This combined scenario will occur only several times in a year.

Table 3.64 Summary table: combined systemic exposure and risk characterisation for non-professional users

| **Summary table: combined systemic exposure and risk characterisation for non-professional users** |
| --- |
| **Scenarios combined** | **Sub-population** | **Estimated oral uptake****[mg/kg bw/day]** | **Estimated dermal uptake****[mg/kg bw/day]** | **Estimated inhalation uptake****[mg/kg bw/day]** | **Estimated total uptake****[mg/kg bw/day]** | **Estimated uptake/ AEL** **(%)**AEL = XXmg/kg bw/d | **Acceptable****(Yes/No)** |
| Scenario [1] + Scenario [2] | newborn | 3.03E-04 | 1.65E-04 | nr | 4.67E-04 | 6% | yes |
|  | infant | 1.60E-04 | 1.14E-04 | nr | 2.74E-04 | 4% | yes |
| Scenario [1] + Scenario [3 (5 nets)] | Adult | 4.54E-04 | 1.67E-03 | nr | 2.12E-03 | 28% | yes |
| Child  | 5.94E-04 | 2.09E-03 |  | 2.68E-03 | 36% | yes |

The combined exposures for scenario 1+2 are inferior to AEL for newborns and infants.

The combined exposures for scenario 1+3 are inferior to AEL for adults and children.

**Conclusion**

The exposures after sleeping in a treated net (scenario 1) are inferior to the AEL for all sub-populations.

For newborns and infants, if they are exposed also via breast milk (scenario 2), the combined exposures (scenario 1+2) are inferior to AEL.

The exposure after washing of 5 nets (scenario 3) is inferior to AEL for adult and child. The combined exposures (scenario 1 and 3) are also inferior to AEL for adult and child.

### Monitoring data

***Dietary exposure***

A scenario where food, drinking water or livestock exposure is foreseen is not relevant due to the intended use of the bednet.

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

| **Summary table of other (non-biocidal) uses** |
| --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection products | All plant and animals commodities | MRLs are set in Reg. (EU)2018/8323 |
| 2. | Veterinary use | Antiparasitic agent / Agent against ectoparasites | MRLs are set on ruminants (muscle. liver. kidney. fat and milk) and fin fish (muscle and skin natural proportions) in Reg. (EU) No 37/2010 |

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

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

3 It should be noted that the following reference values are set for deltamethrin: an ADI of 0.01 mg/kg bw/d and an ARfD of 0.01 mg/bw (Dir 03/05).

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

Not relevant

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

Not relevant.

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

Not relevant.

**Maximum residue limits or equivalent**

Not relevant.

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

See § “dietary exposure”.

### Risk assessment for animal health

Cats is considered to be a sensitive species to products.

Therefore, a risk mitigation measure for cats is added:

"Keep cats away from the product. Due to their particular sensitivity to deltamethrin, the product can cause severe adverse reactions in cats."

For the other species, the risk assessment is considered as covered by the risk assessment performed for newborns, infants and toddlers.

### Risk assessment for the environment

TRAVELSAFE MOSQUITO NET containing 80 mg/m² of Deltamethrin is a PT18 biocidal product intended for an indoor and outdoor use by non-professional against *Anopheles mosquitoes* every day when sleeping or resting.

#### Effects assessment on the environment

***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 biocidal product doesn’t contain any substances of concern. Therefore, the classification of the biocidal product is based only on the active substance, Deltamethrin.

In accordance with the guidance on application of the CLP criteria, the classification of Deltamethrin is Aquatic Acute 1 (M-factor 1 000 000) H400 and Aquatic Chronic 1 (M-factor 10 000) H410.

The environmental classification of this product according to CLP-Regulation (EC) No 1272/2008 is therefore: Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

It should be noted that with or without the carrier the classification of the product remains the same.

***Further Ecotoxicological studies***

|  |
| --- |
| **Data waiving** |
| Information requirement | No data are available. |
| Justification | The co-formulants contained in the product are not classified for the environment and are not considered as substances of concern. Available data on the active substance are therefore sufficient to assess the product. Therefore, no additional ecotoxicological study with the product is deemed necessary. |

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

No data is available.

***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 product TravelSafe Mosquito net is a ready-to-use repellent product containing 80 mg/m² of Deltamethrin. It is intended to be used by non-professionals indoor and outdoor against *Anopheles mosquitoes* (Culicidae). According to the intended uses, the bed net can be washed to a maximum of 20 times. So, STP is regarded as a point source of direct active ingredient emissions to environmental compartments following the washing of the bed net. Furthermore, there is a potential risk of direct emissions to soil when the bed net is used outdoor.

Refer to section 2.2.8.2 for further explanations.

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

|  |
| --- |
| **Data waiving** |
| Information requirement | Not relevant.  |
| Justification | The product contains a single active substance and does not contain any environmentally relevant substances of concern or co-formulants, which are likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance deltamethrin. The environmental fate and behaviour of the products may therefore be extrapolated from information available on the active substance. |

***Leaching behaviour (ADS)***

No new data is available.

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

No new data is available.

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

Not relevant.

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

Not relevant.

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

The biocidal product will not be sprayed.

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

The biocidal product will not be sprayed.

***Summary of PNECs***

The agreed PNECs for the sewage treatment plant (STP), surface water, sediment and soil under the EU review as detailed in the PT18 Deltamethrin active substance Assessment Report (2011) are summarised in the table below.

Deltamethrin:

|  |  |
| --- | --- |
| **PNEC** | **Justification** |
| PNECSTP | 30 µg/L | A NOEC of 300 µg/L from an activated sludge respiration test no inhibitory effect is reported in the CAR (2011). An assessment factor (AF) of 10 was applied to the NOEC to derive the PNEC. |
| PNECwater | 0.7 ng/L | The PNECwater presented in the CAR (2011) was derived from the NOEC of 0.0035 µg/L for fish and an AF of 5. |
| PNECsediment.EPM | 6.2 µg/kg ww | Equilibrium partitioning method  |
| PNECsoil | 75 µg/kg ww | The PNECsoil was based on inhibition of reproduction in springtail and with an assessment factor of 10 (CAR 2011). |
| a) PNECoral.birdb) PNECoral.mammals | a) 1.50E+01 mg/kgfoodb) 2.67E+00 mg/kgfood | a) The lowest NOEC exceeds 450 ppm.Taking into account a safety factor of 30, a PNECoral.bird of 15 mg/kg food is obtained (CAR 2011).b) The NOAEL was set at 80 ppm for parents and pups. Taking into account a safety factor of 30, a PNECoral,mammal of 2.67 mg/kg food is obtained (CAR 2011). |

BR2CA:

Considering the toxicity and the e-fate properties of the relevant metabolite BR2CA, it was considered that the assessment of the parent compound adequately covered the risk for this metabolite. No PNEC values are presented for BR2CA. And as the use of net is occasional outdoor, the assessment for groundwater is deemed as not relevant.

#### Exposure assessment

General information

|  |  |
| --- | --- |
| Assessed PT | PT 19 |
| Assessed scenarios | **Scenario 1**: Emissions during the service life of repellent factory-treated textiles (washing of the mosquito net)**Scenario 2**: Emission scenario for calculating the release of repellents leached out of tent textile (outdoor use of the mosquito net) |
| ESD(s) used | Emission Scenario Document for Product Type 19: Emission scenarios for repellents and attractants (ECHA. 2015) |
| Approach | **Scenario 1**: consumption-based approach**Scenario 2**: consumption-based approach |
| Distribution in the environment | Guidance on the BPR: Volume IV Environment. Assessment & Evaluation (Parts B+C)  |
| Groundwater simulation | Not relevant |
| Confidential Annexes | No |
| Life cycle steps assessed | **All scenarios**:Production: NoFormulation NoUse: NoService life: Yes |
| Remarks | - |

***Emission estimation***

The product TRAVELSAFE MOSQUITO NET is a ready-to-use repellent product containing 80 mg/m² of deltamethrin. It is intended to be used by non-professionals indoor and outdoor against *Anopheles mosquitoes* (Culicidae). Moreover, the bed net can be washed to a maximum of 20 times according to the intended use.

In this assessment, there are two emission scenarios covering the use of the bed net TravelSafe Mosquito:

- First, an indirect emission via the STP to surface water, sediment, soil and groundwater when the bed net is washed. The emission scenario during the service life of repellent factory-treated textiles from ESD PT19 was used to calculate the risk because this is the one that best fits to the use.

- Second, a direct emission when the bed net is applied outdoor. To calculate the risk, the ESD PT19 provides a scenario for tents and is the closest scenario that covers the use of the net outdoors.

**Scenario 1: Emissions during the service life of repellent factory-treated textiles (washing of mosquito net)**

According to the report of Rajasekharam, C. (2019), the worst case wash resistance index is 98.2% per washing event (section 2.2.2). By analogy, it was stated that a release of 1.8% per rain event could be considered as realistic and therefore the value of fraction released to wastewater is 0.018.

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **S/D/O/P** | **Remarks** |
| **Scenario 1:Emissions during the service life of repellent factory-treated textiles** |
| Number of inhabitants feeding one sewage treatment plant (Nlocal) | 10000 | [cap] | D | According to the ESD PT19 section 3.4.4.2 (2015). |
| Fraction released to wastewater (Fwater) | 0.018 | [-] | D | Details above. |
| Quantity of active ingredient in the fabric related to surface area (Qa.i..fabric) | 80 | [mg.m-2] | S | According to intended use. |
| Treated area of fabric washed per day (AREAfabric) | 12.5 | [m².d-1] | S/P | According to the ESD PT19 section 3.4.4.2 (2015). |
| Fraction of inhabitants using the product (Finh) | 0.01 | [-] | P | According to the ESD PT19 Table 3-5 (2015). |
| Market share of repellent (Fpenetr) | 0.5 | [-] | D | According to the ESD PT19 section 3.4.4.2 (2015). |

Calculations for Scenario [1]

*Emission to water*

$$Elocal\_{water}=N\_{local}×Q\_{a.i..fabric}×AREA\_{fabric}×F\_{inh}×F\_{water}×F\_{penetr}×10^{-6}$$

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Local emission (Elocalwater) [kg/d]** | **9.00E-04** | **-** |

The emission estimation rate to wastewater/STP expressed in kg.d-1 is next used for the calculation of PECs for the relevant environmental compartments.

**Scenario 2: Emission scenario for calculating the release of repellents leached out of tent textile (covering the outdoor use of the mosquito net)**

For this scenario, the default values from the ESD for the treated area (AREAfabric) and soil volume (Vsoil) have been kept to maintain the proportions. In fact, the mosquito net being smaller than a tent, the exposed soil will also be smaller.

According to the report of Rajasekharam, C. (2019), the worst case wash resistance index is 98.2% per washing event. By analogy, it was stated that a release of 1.8% per rain event could be considered as realistic. Therefore, the cumulative quantity of active ingredient leached out of 1 m² of treated net over the first camping season (Q\*leach) is:

Q\*leach = Qa.i.,fabric \* 0.018 \* TIMEexposure,outdoor = 80 \* 0.018 \* 120 = 1.73E+02 mg.m-²

|  |
| --- |
| **Input parameters for calculating the local emission** |
| **Input**  | **Value**  | **Unit** | **S/D/O/P** | **Remarks** |
| **Scenario 2:Emission scenario for calculating the release of repellents leached out of tent textile** |
| Quantity of active ingredient in the fabric related to surface area (Qa.i.,fabric) | 80 | [mg.m-2] | S | According to intended use |
| Treated area of fabric washed per day (AREAfabric) | 48 | [m²] | D | According to the ESD PT19 section 3.4.4.2 (2015). |
| Duration of net exposure outdoor (TIMEexposure,outdoor) | 120 | [d] | D | According to the ESD PT19 section 3.4.4.2 (2015). |
| Number of emission events (Nemission) | 120 | [d] | D | According to the ESD PT19 section 3.4.4.2 (2015). |
| Emission interval (Temission) | 1 | [d] | D | According to the ESD PT19 section 3.4.4.2 (2015). |
| Cumulative quantity of active ingredient leached out of 1 m² of treated net over the first camping season (Q\*leach) | 1.73E+02 | [mg.m-²] | O | Details above. |
| First order rate constant for removal from soil (kdegsoil) | 1.44E-02 | [d-1] | S | CAR 2011 |
| Soil volume (Vsoil) | 0.9 | [m3] | D | According to the ESD PT19 section 3.4.4.2 (2015). |
| Bulk density of wet soil (RHOsoil) | 1700 | [kgww.m-3] | D | According to the ESD PT19 section 3.4.4.2 (2015). |

Calculations for Scenario [2]

*Emission to soil*

$$E\_{soil,leach}=Q\*\_{leach}×AREA\_{fabric}/TIME\_{exposure,outdoors}$$

| **Resulting local emission to relevant environmental compartments** |
| --- |
| **Local emission (Esoil,leach) [mg/d]** | **6.91E+01** | **-** |

The emission estimation rate to soil, expressed in mg.d-1, is next used for the calculation of concentration in local soil after the first camping season.

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

| **Identification of relevant receiving compartments based on the exposure pathway** |
| --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes | Yes | No | No | Yes | No | Yes | Yes | No |
| Scenario 2 | No | No | No | No | No | No | Yes | Not relevant | No |

|  |
| --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** |
| **Input**  | **Value**  | **Unit** | **Remarks** |
| Molecular weight | 505.2 | g.mol-1 | AR 2011 |
| Vapour pressure (at 25°C) | 1.24E-08 | Pa | AR 2011 |
| Water solubility (at 20°C) | 5.00E-03 | mg/l | AR 2011 |
| Log Octanol/water partition coefficient | 4.6 | Log 10 | AR 2011 |
| Organic carbon/water partition coefficient (Koc) | 408 250 | l/kg | AR 2011 |
| Henry’s Law Constant (at 25°C) | 1.252E-03 | Pa/m3/mol | AR 2011 |
| Biodegradability | Not readily biodegradable  | - | AR 2011 |
| DT50 for degradation in soil | 48 | d (at 12ºC) | AR 2011 |

|  |
| --- |
| **Calculated fate and distribution in the STP** |
| **Compartment** | **Percentage [%]** | **Remarks** |
| **Scenario 1** |  |
| Air | 4.93E-05 |  |
| Water | 8.788 |  |
| Sludge | 91.22 |  |
| Degraded in STP | 0 |  |

***Calculated PEC values***

|  |
| --- |
| **Summary table on calculated PEC values** |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil / Clocalsoil** | **Clocalsoil,ref (considering degradation processes)** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1 (washing) | 3.95E-05 | 2.45E-06 | 2.18E-02 | 1.25E-03 | - | 7.59E-05 |
| Scenario 2(leaching by rain) | - | - | - | 5.42E+00 | 2.59E+00 | - |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning, i.e. the direct consumption of insecticide by birds or mammals and also honeybees is relevant only for outdoor uses. Moreover, according to the ESD for PT18, direct consumption of insecticide by birds or mammals may mainly occur when insecticides are applied as granular formulation. As the product is a net, it is not edible. Therefore, primary poisoning is not considered as relevant for the product TRAVELSAFE MOSQUITO NET.

Secondary poisoning

As deltamethrin has a log Kow > 3 (log Kow = 4.6) and a BCF > 100 (BCF in fish = 1400 L/kg. BMF =2 and BCF in earthworm = 483 L/kg), secondary poisoning may occur *via* the aquatic food chain and *via* the terrestrial food chain. The PEC values are calculated only for scenario 1 (in case of releases to the STP when the mosquito net is washed), as scenario 2 (outdoor use of the mosquito net) is relevant for restricted areas only.

|  |
| --- |
| **Summary table on calculated PECoral predator values – Scenario 1** |
| 3.43E-03 | [mg.kgwet fish-1] |
| 4.43E-05 | [mg.kgwet earthworms-1] |

#### Risk characterisation

***Atmosphere***

Conclusion:deltamethrin has a vapour pressure of 1.24 x 10-8 Pa at 25°C, indicating low volatility. The calculated Henry’s law constant is 1.252 x 10-3 Pa.m3.mol-1. Model calculation indicates that deltamethrin reacts with photochemically produced hydroxyl radicals in air, with a half-life of 16.4 hours. Hence, it is concluded that deltamethrin is unlikely to cause either any adverse effects via inhalation or biological effects away from the site of application. The substance will not pose a risk to the atmospheric environment.

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

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECSTP** |
| Scenario 1 (washing) | 1.32E-03 |
| Scenario 2 (leaching by rain) | - |

Conclusion: The calculated PEC/PNEC value for the sewage treatment plant (STP) is significantly < 1. Therefore, the proposed use of the product TRAVELSAFE MOSQUITO NET does not pose a risk to microorganisms in the STP.

***Aquatic compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 (washing) | **3.50E+00** | **3.51E+00**  |
| Scenario 2 (leaching by rain) | - | - |

Conclusion: The calculated PEC/PNEC value for surface water (covering sediment) is significantly > 1 for scenario 1. Therefore, the proposed use of the product TRAVELSAFE MOSQUITO NET does pose a risk to aquatic compartment if the treated net are washed.

It is worth noting that for sediment, considering the very Koc value, an additional factor of 10 should have been applied leading to a very high risk ratio.

A risk mitigation measure is proposed to prevent any release to the STP during the service life (cleaning of the mosquito net) of the product:

* ***This product MUST NOT be washed, due to risk to the environment.***
* ***Use the mosquito net as indicated in the instructions for use. Do not use for other purposes.***

***Terrestrial compartment***

|  |
| --- |
| **Summary table on calculated PEC/PNEC values** |
|  | **PEC/PNECsoil** | **PECsoil considering degradation processes/PNECsoil** |
| Scenario 1 (washing) | 1.66E-02 | - |
| Scenario 2(leaching by rain) | **7.23E+01** | **3.46E+01** |

Conclusion: The calculated PEC/PNEC value for soil is significantly < 1 for scenario 1, when the mosquito net is washed, but is > 1 for scenario 2 if the net is exposed to rain event for 120 days (default time for the first camping season).

However, the duration of 120 days can be excessive for a mosquito net. Therefore, the time (T) at which the use of the net outside in the rain leading to a risk for the environment (i.e. Clocalsoil = PNECsoil) was calculated according to the following equation:

T = (PNECsoil\* Vsoil \* RHOsoil) / Elocalsoil = 1.66E+00 days

This shows that after 1.7 days under the rain the mosquito net leads to environmental risks.

Therefore, it is considered the proposed use outdoor of the product TRAVELSAFE MOSQUITO NET does pose a risk to terrestrial compartment when used outdoor. A risk mitigation measure is proposed to prevent any release to soil during the outdoor use of the product:

***Apply only outdoors in locations protected from rain.***

***Groundwater***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Csludge (mg/kg)** | **PEClocalsoil (mg/kg)** | **PEClocalgroundwater (µg/l)** |
| Scenario 1 (washing) | 1.04E+00 | 1.25E-03 | 7.59E-05 |
| Scenario 2 (leaching by rain) | - | - | Restricted area – not relevant |

The calculated values for PEClocalgroundwater does not exceed the limit value in groundwater of 0.1 μg.L-1 for biocides (Directives 2006/118/EC and 98/83/EC).

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not considered as relevant for the product TRAVELSAFE MOSQUITO NET.

Secondary poisoning

|  |  |  |
| --- | --- | --- |
| **PECoral predator** | **RCRbirds**(PNECoral. bird = 1.50E+01 mg/kg food) | **RCRmammals**(PNECoral. mammals = 2.67E+00 mg/kg food) |
| 3.82E-02 [mg/kgwet fish] | 2.29E-04 | 1.29E-03 |
| 4.92E-04 [mg/kgwet earthworms] | 2.95E-06 | 1.66E-05 |

Conclusion: The PEC/PNEC ratios are below the trigger value of 1. Then, risk for birds and mammals following secondary poisoning is acceptable when using the product TRAVELSAFE MOSQUITO NET according to label recommendations.

***Mixture toxicity***

The product only contains one active substance and no environmentally relevant substances of concern. Therefore, a mixture assessment is not necessary.

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

An assessment of aggregated exposure is judged not relevant for the products of the TRAVELSAFE MOSQUITO NET based on the decision scheme developed by UBA (see Figure 1) as there is only one use for this product family.



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

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The product TRAVELSAFE MOSQUITO NET is intended to be used by non-professionals, for an application indoor and outdoor as a bed net. No substance of concern has been identified.It has been demonstrated that use of the product TRAVELSAFE MOSQUITO NET does pose a risk to environmental compartments without risk mitigation measures. Indeed, risks are identified *via* the STP for surface water and sediment compartments if the mosquito net is washed. A risk mitigation measure is proposed to prevent any release to the STP during the service life of the product: **This product MUST NOT be washed, due to risk to the environment. Use the mosquito net as indicated in the instructions for use. Do not use for other purposes.**Outdoor, there is a risk for the soil compartment after 1.7 days of outdoor exposure to rain. A risk mitigation measure is proposed to prevent any release to soil during the outdoor use of the product: ***Apply only outdoors in locations protected from rain***. |

# Annexes[[17]](#footnote-18)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title.Source (where different from company) Company. Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Chabi J et al | 2009 | Efficacy of a deltamethrin long-lasting insecticidal net (DAWA Plus 2nd generation-TANA netting) against wild susceptible population of *Anopheles gambiae* in experimental huts, Benin. | Yes | ORG |
| Tungu P.K et al | 2009 | Evaluation of DawaPLus 2.0 LN against Anopheles gambiae in experimental huts in Muheza, Tanzania  | Yes | ORG |
| WHO Decision document | 2018 | Prequalification Unit – Vector Control Products Assessment (PQT/VCP)Tsara soft | Yes | ORG |

## Output tables from exposure assessment tools



## New information on the active substance

## Residue behaviour

## Summaries of the efficacy studies (B.5.10.1-xx)[[18]](#footnote-19)

See Iuclid files

## Confidential annex

## Other

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. Following the guidance CA-Nov16-Doc.4.3 Final.Rev1 (Handling “carriers” in the authorisation of biocidal products), the content of the active substance for this product should be indicated excluding the fiber of the mosquito net. However, the content of the active substance to be reported in the SPC has been recently discussed at European level and the guidance document CA-Nov16-Doc.4.3 Final.Rev1 is currently under revision. Until a consensus is reached on the revision of this guidance, the content of the active substance is expressed both ways:

	* Excluding the fiber mosquito net : single concentration
	* Including the fiber of the mosquito net: range of concentration, corresponding to the variation of the active substance content, depending of the net Denier of the mosquito fiber (75, 100 or 150 Denier)Please refer to the section 6 of the SPC for the indication of the content of the active substance including the fiber of the mosquito net. [↑](#footnote-ref-3)
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13. Generic risk assessment – Human health. An active ingredient in insecticide-treated nets. WHO 16 june 2021 [↑](#footnote-ref-14)
14. Generic risk assessment model for insecticide-treated nets of WHO. 2nd edition - 2018 [↑](#footnote-ref-15)
15. Recommendation 14 of the BPC ad hoc WG on human exposure: Default human factor values for use in exposure assessments for biocidal products. [↑](#footnote-ref-16)
16. [↑](#footnote-ref-17)
17. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-18)
18. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-19)