

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 UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Christiansen LD Bednet

Product type 18

Permethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-GK024706-40

Evaluating Competent Authority: DK CA

Date: [XX/xxxxxx/20XX]

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1 CONCLUSION

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier ¹	Country (if relevant)
Christiansen LD	•
Trade names:	•
Christiansen LD bednet	• European Union
Care Plus® Mosquito Net	• Norway
Care Plus® Mosquito Net	• Netherlands
Care Plus® Mosquito Net	• Italy
Care Plus® Mosquito Net	• Germany
Care Plus® Mosquito Net	• France
Insect Ecran Moustiquaire Imprégnée Longue Durée	• France
Care & You Prév Kit Moustiquaires	• France
Pharmavoyage Moustiquaire Imprégnée Longue Durée	• France
I Sleep Safer LD Impregnated Mosquito Bed Net	• France
Care Plus® Mosquito Net	• Belgium
Care Plus® Mosquito Net	• Sweden

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	Name	CHRISTIANSEN SARL
	Address	719 Chemin de Repentance, 13100 Aix en Provence, France
Pre-submission phase started on		
Pre-submission phase concluded on		
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Hebei Light Industrial Products Imp./Exp. Group Co. Ltd
Address of manufacturer	26, ZhongJiu Road, Youyi Street N. Shijiazhuang, 050071, CHINA

¹ Please fill in here the identifying product name from R4BP 3.

Location of manufacturing sites	Ningjin Shuangli Knitting Co., Ltd., Dalu Villages, Ningjin County, 055551 Hebei, CHINA
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Name of manufacturer	SHIJIAZHUANG ORIENTAL HORIZON IMPORT AND EXPORT CO.,LTD
Address of manufacturer	No. 448 Heping West Road, Shijiazhuang 050072, CHINA
Location of manufacturing sites	SHENZHOU YUTONG KNITTING CO., LTD Xiduzhuang Village, Shenzhou Town, Shenzhou City, Hengshui City, Hebei Province, CHINA

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

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Ltd.
Address of manufacturer	Jhaver Centre, Rajah Annamalai Building, IV Floor, 72 Marshalls Road, Egmore, Chennai 600 008, INDIA
Location of manufacturing sites	A-4/1 & 2, SIPCOT Industrial Complex, Pachayankuppam, Cuddalore - 607 005, Tamil Nadu, INDIA

2.1.2 Product composition and formulation

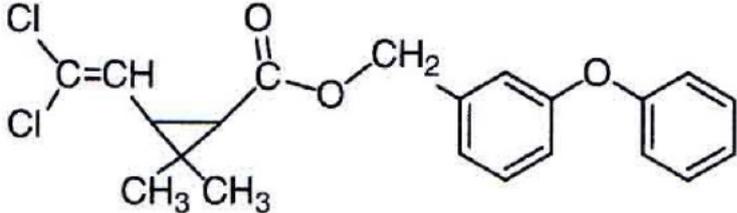
The full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

2.1.2.1 Identity of the active substance

According to the Competent Authority Meeting document 4.3 from November 2016 insect nets may be regarded as a carrier-based product of type B. The carrier component (the net) should therefore not be considered as a part of the composition of the biocidal product. The classification is based on the biocidal mixture/substance used in the product only excluding the carrier component, and the content of the active substance indicated in the SPC should be the same which is considered for classification purposes.

Main constituent(s)	
ISO name	Permethrin (EN-ISO), Permethrine (F-ISO)
IUPAC or EC name	3-phenoxybenzyl (1R,3R;1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	930 g/kg The minimum purity of the Tagros source is 93% w/w sum of all permethrin isomers. Total cis range: 25 – 28% ratio Total trans range: 75 - 72% ratio 1Rcis range: 7.9 – 8.3% w/w. 1Scis range: 15.8 – 16.7% w/w. 1Rtrans range: 45.4 – 46.1% w/w. 1Strans range: 22.5 – 23.0% w/w.
Structural formula	 <p>Two pairs of diastereomers (each consisting of a racemic pair of enantiomers; see below) are present in a ratio of approximately 25:75</p>

SI No	Name of isomer	Structure	Proportions
1	1R, <i>cis</i>	<p>(2) (1R, <i>cis</i>)</p>	sum ≈ 25%
2	1S, <i>cis</i>	<p>(4) (1S, <i>cis</i>)</p>	
3	1R, <i>trans</i>	<p>(1) (1R, <i>trans</i>)</p>	sum ≈ 75%
4	1S, <i>trans</i>	<p>(3) (1S, <i>trans</i>)</p>	

2.1.2.2 Candidate(s) for substitution

At the moment, permethrin is not a candidate for substitution in accordance with Article 10 of BPR. Depending on the outcome of the ECHA PBT working group there may be a requirement for the substance to be considered as a candidate for substitution as identified in the provisions of Article 10 of Regulation (EU) No 528/2012 according to the Assessment Report for permethrin.

According to the WG-III-2019, permethrin fulfils the criterion for vP and T. Moreover, bioaccumulation issues have been brought up for discussion at the ECHA PBT WG, and are currently under further evaluation by eCA. If found bioaccumulative, it will fulfil the three PBT criteria and should then be considered as a candidate for substitution or exclusion as identified in the provisions of Article 10 and 5 of Regulation (EU) No 528/2012.

At time of evaluation for this product this information is not considered final, as the information have not been discussed at BPC level. Permethrin has therefore not been considered as a candidate for substitution in the evaluation of Christiansen LD bednet.

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

Information on the qualitative and quantitative information on the composition of the active substance in Christiansen LD bednet is provided in the tables below. The full composition of the product is provided in the confidential annex.

2.1.2.4 Composition of the impregnation fluid

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.99 tech. 0.9207 pure

Composition of the Net

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.9
Polyester (PET)	poly(ethylene terephthalate)	Net (Carrier component)	25038-59-9		

2.1.2.5 Information on the substance(s) of concern

Christiansen LD bednet does not contain any substances of concern for the environment or human health according to Article 3(f) of Regulation (EU) No. 528/2012, for further information see the confidential annex 3.7.2.

A co-formulant is considered a SoC if it has known or possible endocrine disrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information. Thus, Christiansen LD bednet is not considered to having endocrine-disrupting properties (see confidential annex section 3.7.3 for full evaluation).

2.1.2.6 Type of formulation

The product is an insect net impregnated with permethrin with long-lasting effect. According to CA-Nov16-Doc.4.3 it is a carrier-based biocidal product of type B.

LN - Long-lasting insecticidal net.

2.1.3 Hazard and precautionary statements

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

According to the Competent Authority Meeting document 4.3 from November 2016 insect nets may be regarded as a carrier based product of type B. The carrier component (the net) should therefore not be considered as a part of the composition of the biocidal product. The classification is based on the biocidal mixture/substance used in the product only excluding the carrier component. The following classification is based on the harmonised classification of permethrin (H302 Acute Tox. 4 , H317 Skin Sens. 1, H332 Acute Tox. 4, H400 Aquatic Acute 1 (m-factor = 1000) and H410 (m-factor = 10000)) and the assessment report for permethrin (IE, 2014).

Classification	
Hazard category	Aquatic Acute 1 Aquatic chronic 1
Hazard statement	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning (GHS09 pictogram)
Hazard statements	H410 Very toxic to aquatic life with long-lasting effects.
Precautionary statements	P273 Avoid release to the environment. P501 Dispose the content/container accordingly to local rules.
Note	EUH 208 Contains permethrin. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 2.1. Use # 1 – Non-professional

Product Type	18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Non-washable Insecticide treated bednet for use in tropical areas only. Christiansen LD bednet is a contact insecticide that prevents biting of mosquitoes. Only use in tropical areas against <i>Anopheles</i> spp. and <i>Aedes</i> spp. is authorised.
Target organism (including development stage)	Scientific name: <i>Anopheles</i> Common name: Anopheles mosquitoes Development stage: Adults Scientific name: <i>Aedes</i> Common name: Aedes mosquitoes Development stage: Adults
Field of use	Indoor
Application method(s)	Method: Personal protection Detailed description: Fix over the bed to prevent mosquitos to enter.

Application rate(s) and frequency	Application Rate: This is a textile product used over a bed; no application rate. Dilution (%): - Number and timing of application: This is a textile bed net to be used over the bed during the night and dawn.
Category(ies) of users	General public (Non-professional)
Pack sizes and packaging material	Please see the relevant section (2.1.7).

2.1.4.2 Use-specific instructions for use

See General instructions for use.

2.1.4.3 Use-specific risk mitigation measures

See General instructions for use.

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

See General instructions for use.

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

See General instructions for use.

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

See General instructions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Read attached instructions before use.

Comply with the instructions for use.

The product is authorised to be used only in tropical areas where there is a threat of vector-borne diseases spread by the claimed mosquito species.

Keep out of the reach of children and pets when not in use.

Fix the top of the bednet over the bed, and the lower rim is carefully wrapped under the mattress, so that no space is left for mosquitos to enter.

Apply non-chemical methods such as regular window screen insect nets if possible in order to minimise the use of biocides. Use of the insecticide treated bednet is recommended when other methods of mosquito control are not sufficient, not feasible (e.g. when travelling) or in areas with high risk of vector-borne diseases.

In the case of continuous infestation, to minimise the risk of resistance, alternative products containing active substances with different mode of action should be used

Inform the authorisation holder if the treatment is ineffective.

Do not treat the bednet with an insecticide or repellent.

Replace the bednet if damaged (e.g. holes).

Domestic animals such as a cat should not sleep in proximity to the bednet.

The bednet can only be used indoors.

DO NOT WASH OR DRY CLEAN PRODUCT.

Do not iron the product.

2.1.5.2 Risk mitigation measures

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

Avoid contact with skin and eyes.

Wash hands with soap and water after setting up the net and taking the net down.

This product **MUST NOT** be washed, due to risk to the environment.

Use the bednet as indicated in the instructions for use. Do not use for other purposes.

Keep away from food, drinks and animal feeding stuffs.

2.1.5.3 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.

Environmental precautions: Release to the environment, water, groundwater, soil is forbidden. Dispose of contents at a hazardous waste facility.

If the product enters drains or sewers, the local water authority should be contacted immediately; in the case of contamination of streams, rivers or lakes, contact national authorities.

This product contains permethrin which is dangerous for bees.

2.1.5.4 Instructions for safe disposal of the product and its packaging

May not be disposed of in sewers, including rainwater canals.

The product is not intended to be reused or recycled. Dispose unused products, contaminated packaging and used bednets as hazardous waste.

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

Storage: Conditions for safe storage, including any incompatibilities:

- Keep out of the reach of children and pets (particularly cats).
- Keep packaging tightly closed.
- Observe the label precautions.
- Store in original package as specified herein.
- Keep out of direct sunlight.
- Store away from direct sunlight or other heat sources.
- Store separately from oxidizing agents and strongly alkaline and strongly acidic materials.

Packaging / tank material: Plastic packaging is recommended.

Specific end use(s):

Store at ambient temperature.

Shelf life: 36 months.

2.1.6 Other information

The bednet manufactured by CHRISTIANSEN is a net made of polyester.

2.1.7 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)
Sachet	D9ø x H22 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	L22 x 14 x 8 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D10 x H25 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	22 x 22 x 8 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D14ø x H34 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	25 x 25 x 9 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet + box	24 x 26 x 9 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D11ø x H27	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D10ø x 25 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D12ø x H37 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D13ø x 28 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D15ø x H39 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	L26 x W20 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet + box	17 x 20 x 6 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	L39 x W32 x 8 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D10ø x 59L cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D6ø x H16 cm	Plastic: PET	Adhesive tape	Non-professional	Yes
Sachet	D7ø x H18 cm	Plastic: PET	Adhesive tape	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself has been submitted in function of this product application.

All new information relates to the biocidal product described within this application. See Annex 3.3 for complete reference list.

2.1.8.2 Access to documentation

A letter of access has been granted to the complete Tagros dossier for the active substance Permethrin.

2.1.8.3 Similar conditions of use

Products may be applied for Union authorisation if they have similar conditions of use across the Union and do not contain substances that fall under Article 5. Permethrin does not fall under article 5 of Regulation No 528/2012.

The applicant states that Christiansen LD bednet is a polyester bednet treated with the insecticide permethrin on the purpose of protecting humans staying under it against insect bites nuisance from mosquitos, that may carry vector-borne diseases. The product applies to Union citizens travelling to areas where they can be exposed to mosquitos carrying the vector. The eCA DK therefore considers that the product has similar conditions of use across the Union and is eligible for Union Authorisation.

2.2 Assessment of the biocidal product

2.2.1 Physical, chemical and technical properties

The biocidal product Christiansen LD is a carrier-based product of type B, where the product is a bed net made of polyester impregnated with 0.9% permethrin. Regarding the physical-chemical properties, the stability tests are carried out on the product as it is supplied to the user and all other physical-chemical properties were tested on the impregnation solution according to Competent Authority Meeting document 4.3 from November 2016.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	Impregnation liquid, 0.9% Permethrin	Impregnation solution: Whitish homogenous liquid Carrier component: Textile net, solid with a thickness of 75 deniers, made of polyester. Fabric weight: 30 g/m ² . Mesh size: 25 holes/cm ² or 156 holes/inch ² Models for 1-3 persons: Triangular, circular, rectangular, sheets, self standing domes.	Impregnation solution: [REDACTED], 2019 IUCLID: 3.1 Carrier component: [REDACTED], 2010 [REDACTED], 2016 [REDACTED], 2017 b IUCLID: 3.1
Colour at 20 °C and 101.3 kPa	Dyed textile net, by visual inspection	Impregnated textile net, 0.9% Permethrin	White, blue, green, red, yellow, army green.	[REDACTED], 2017 b
Odour at 20 °C and 101.3 kPa		Impregnation liquid, 0.9% Permethrin	Characteristic odour of aromatic compounds	FDS DS moustiquaires eng, [REDACTED] (2016) IUCLID Section 3.1
Acidity / alkalinity	Aqueous solution for Christiansen LD Bednet, Permethrin (0.977 % w/w). pH: CIPAC Handbook J MT 75.3	Impregnation liquid, 0.977% Permethrin Batch.: 010818	pH 6.27	[REDACTED], (2019). IUCLID Section 3.2

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Relative density/ bulk density	OECD Test Guideline 109 (Density of Liquids and Solids), updated in October 2012. Density at 20 degrees Celsius relative to water at 4 degrees Celsius.	Aqueous solution for Christiansen LD Bednet, (0.977 % w/w) Batch.: 010818	Relative density of the impregnation solution liquid 1.011 g/cm ³ Density of net 1.3 – 1.4 g/cm ³	██████████, (2019). IUCLID Section 3.3 ██████████, (2010) IUCLID Section 3.2
Storage stability test – accelerated storage 2016 Supporting study only.	CIPAC MT 46.3.4 (CIPAC/4956/m) - Temp.: 54°C ± 2°C - Time: 14 days and 4 weeks - Storage in a closed glass bottle - Storage of 5 combined pieces of 25 cm x 25 cm taken from each side/roof of the net according to the FAO/WHO specifications Manual	Concentration of permethrin in impregnation fluid 2.139 % w/w – pure. Concentration of permethrin in net 0.9%. Mo 390	Content of permethrin prior to storage: 7,33 g/kg (18.6% less than declared content of 9 g/kg) Following storage (2 weeks): 7.3 g/kg Variation: -0.7% Following storage (4 weeks): 7.2 g/kg Variation: -1.6% Cis:trans isomer ratio 29:71	██████████, (2016) IUCLID Section 3.4.1
Storage stability test – accelerated storage 2020	CIPAC MT 46.4 -Temp.: 54°C ±2°C -Time: 14 days -Storage of net pieces of 25 cm x 25 cm in a closed glass bottle	Concentration of permethrin in impregnation fluid 0.9207 % w/w – pure. Concentration of permethrin in the net 0.9% 06/10/19	Content of permethrin prior to storage: 9,2 g/kg (2.2% more than declared content of 9 g/kg) Following storage (2 weeks): 9.3 g/kg Variation: 1.09% Permethrin cis:trans isomer ratio 26:74	██████████, (2020)
Storage stability test – long term storage at ambient temperature	CRA-W. Standard: CropLife technical monograph n° 17, 2 nd Edition -Temp.: 20°C ±2°C -Time: 36 months	Concentration of permethrin in impregnation fluid 2.139 % w/w – pure. Concentration of permethrin in net 0.9%. Mo 390	Content of permethrin prior to storage: 7.33 g/kg (18.6% less than declared content of 9 g/kg). cis:trans isomer ratio 27:73.	██████████, Final test report 24292, ██████████, (2019) IUCLID Sect. 3.4.1 A.I. Supplier Certificate of Analysis.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	<p>-Storage of the entire net in its commercial type package.</p> <p>Permethrin content and isomer ratio on Christiansen LD Bed net according to:</p> <p>CRA-W PA-U10-RESSM010</p> <p>based on CIPAC 331/LN/M/3(GC FID), CIPAC Handbook M, p 159</p>		<p>Content of permethrin after 36 months storage at 20°C: 7.0 g/kg, cis:trans isomer ratio 29:71.</p> <p>This shows a decrease in the content of permethrin of 4.5% after 36 months.</p> <p>The content of 7.33 g/kg (18.6% less than declared content of 9 g/kg) is within tolerance limits for a heterogenic formulation which is 25% for formulation with an active substance content of < 25g/kg.</p> <p>The read across from the old formulation of the impregnation liquid to the new is justified, and the content of permethrin in the net is identical in the two impregnated nets.</p> <p>The replicate analysis (n = 2, RSD = 0.0%) of a quality control sample performed concurrently with the analysis of net samples showed results within the limits of the quality control chart. The accuracy (trueness and precision) of the analytical method is therefore confirmed.</p>	<p>██████████ ██████████ (2018).</p>
Storage stability test – low tem-	Not required for solids	-	-	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
perature stability test for liquids				
Effects on content of the active substance and technical characteristics of the biocidal product - light	Store away from light. The technical active ingredient permethrin is unchanged according to LOA and identity test Cf doc. Pigeon O, 2016, CRA-W ref. RE-15-U10-24150.	N / A	N / A	N / A IUCLID 3.4.2.1.
Effects on content of the active substance and technical characteristics of the biocidal product - temperature and humidity	This is a textile product impregnated with permethrin. The technical active ingredient permethrin is unchanged according to LOA and identity test.			██████████ (2016) IUCLID Section 3.4.2.2 (Cf 3.4.2.1.)
Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material	The product is a textile. N / A	This is a textile. N / A	The package material has not been affected by storage and there are no effects on the physical or chemical properties. The flexible packs with half-covering carton cannot be stacked, so stacking is not applied. The product packages are stored standing vertically in carton boxes. Where the packaging is a non-flexible carton box, it is placed on shelves. Flexible packs with half-covering carton are hanging in a loop at hooks. This is commercial practice for the products.	1342-18 Assessment report, Permethrin, Product-Type 18. Rapporteur: Ireland (2014). IUCLID Section 3.4.2.3 (Cf 3.4.1)
Wettability	Neither the impregnation solu-	N / A	N / A	██████████ (2016).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	tion nor the textile impregnated with permethrin are intended to be dispersed in water. N / A			
Suspensibility, spontaneity and dispersion stability	This is a textile impregnated with permethrin not intended to be dispersed in water. The impregnation solution is a homogeneous liquid. N / A.	N / A	The liquid is applied in a controlled environment in the production only, therefore the test is not relevant. N / A	N / A
Wet sieve analysis and dry sieve test	Not applicable as the impregnation liquid is not a water dispersible products. N/A	N / A	N / A	N / A
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable as the impregnation liquid is not an emulsion. N/A	N / A	N / A	N / A
Disintegration time	Neither the impregnation solution nor the textile impregnated with permethrin is a tablet. N/A	N / A	N / A	N / A
Particle size distribution, content of dust/fines, attrition, friability	Neither the impregnation solution nor the textile impregnated with permethrin is a powder or granule formulation.	N / A	N / A	N / A
Persistent foaming	N / A. This is a textile impregnated with permethrin not intended to be dispersed in water.	N / A	N / A	N / A
Flowability/Pourability/Dustability	Not relevant for the impregnation solution or the textile impregnated with permethrin, because neither has to be poured or are granules.	N / A	N / A	N / A

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Burning rate — smoke generators	Not relevant for the impregnation solution or the textile impregnated with permethrin, because neither are smoke generators.	N / A	N / A	N / A
Burning completeness — smoke generators	Not relevant for the impregnation solution or the textile impregnated with permethrin, because neither are smoke generators.	N / A	N / A	N / A
Composition of smoke — smoke generators	Not relevant for the impregnation solution or the textile impregnated with permethrin, because neither are smoke generators.	N / A	N / A	N / A
Spraying pattern — aerosols	Not relevant for the impregnation solution or the textile impregnated with permethrin, because neither has to be sprayed.	N / A	N / A	N / A
Physical compatibility	The packaging is plastic and the product shall be stored separately from oxidizing agents and strongly alkaline and strongly acidic materials. For storage recommendations of the product packages, see endpoint Reactivity towards container material	N / A	N / A	N / A

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Chemical compatibility	The packaging is plastic and the product shall be stored separately from oxidizing agents and strongly alkaline and strongly acidic materials.	N / A	N / A	N / A
Degree of dissolution and dilution stability	Not relevant as neither the impregnation solution nor the textile impregnated with permethrin are used in water soluble bags or as tablets.	N/A	N/A	N/A
Surface tension	The document CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers" does not consider the specific situation for this application. Applying the current rules would result in that the test on surface tension should have been provided. Therefore the application has a data gap with regards to the surface tension. However, in the opinion of the eCA, the end point is considered not relevant since the end user does not come in contact with the impregnation liquid.			
Viscosity	OECD Test guideline 114 (Viscosity of liquids).	Impregnation fluid 0.9% Permethrin. Batch.: 010818	20°C at a shear range from 1000 to 2000 [s ⁻¹] with the viscosity average (25 points) at 2.2	██████████ (2019). IUCLID Section 3.9,

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	Test item is aqueous liquid for Christiansen LD Bednet (Permethrin 0.977 % w/w).		mPa*s and an RSD % of 1.82. 40°C at a shear range from 1220 to 2000 [s ⁻¹] with the viscosity average (18 points) at 1.5 mPa*s and an RSD % of 4.11. The behaviour is characterized as Newtonian like fluids.	
Burstingstrength - Netfabric - Seams	ISO 13938-2:1999		For the seams: Mean value before accelerated storage: 393 kPa, mean value after accelerated storage: 405 kPa For the net fabric: An unchanged value of 374 kPa. The height at burst: Before accelerated storage: Mean value of 8.4 mm for the net fabric and 9.9 mm for the seams. After accelerated storage: Mean value of 8.7 mm for the net fabric and 11 mm for the seams.	2020 IUCLID section 3.4.1

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

The biocidal product Christiansen LD is a carrier-based product of type B, where the product is a bed net made of polyester impregnated with 0.9% permethrin.

Regarding the physical-chemical properties, some properties were tested on the impregnation solution.

The storage stability studies were performed on the bed net, and the permethrin content of the net was determined.

The formulation of the impregnation solution has been changed in relation to the concentration of permethrin in 2019.

The accelerated stability study of the bed net impregnated with the original impregnation solution (2016) showed an acceptable degradation of the active substance at 54 °C for 2 and 4 weeks. The content of permethrin was 7 g/kg and this is 18% below the declared content of 9 g/kg. This is still within the tolerance limit for heterogenic formulation. This study is a supporting study for the read across between the old (2016) formulation and the new formulation.

The accelerated stability study of the bed net impregnated with the impregnation solution (2019, final formulation of the biocidal product) showed an acceptable degradation of 0.7% at 54 °C for 2 weeks.

The long-term stability study showed an acceptable degradation of 4.71 % after 36 months at 20 °C, with a cis:trans isomer ration of 29:71. This storage stability study was performed on the bednet with the old (2016) impregnation formulation.

As the content of permethrin on the bednet does not change, and the degradation of permethrin is acceptable, the read across between the old (2016) and the new (2019) formulation is acceptable. The accelerated stability study on the bednet with the new (2019) impregnation solution supports this result, and is acceptable.

Bursting strength and height at burst were measured before and after accelerated storage of the finished bed net.

The physical-chemical properties of Christiansen LD are considered acceptable. The pH of the impregnation fluid is 6.27. The dynamic viscosity of the impregnation solution is 1.82 mPa*s at 20 °C and 2.2 mPa*s at 40 °C and shows a Newtonian behaviour.

2.2.2 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosives		Impregnation fluid 0.9% Permethrin.	An exothermic decomposition was not observed during the boiling point measurement by DSC (EC method A.2). In addition, a rough estimate indicates that the oxygen balance is less than -200. As no exothermic decomposition energy	1342-18 Assessment report ██████████ ██████████ (2019 b)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			above 500 J/g is observed, the product is not explosive.	
Flammable gases	N / A	N / A	N / A	N / A
Flammable aerosols	N / A	N / A	N / A	N / A
Oxidising gases	N / A	N / A	N / A	N / A
Gases under pressure	N / A	N / A	N / A	N / A
Flammable liquids	The aqueous liquid for Christiansen LD bednet was tested according to EC Method A.9, Flash point, test method ISO 3679:2015, and according to EC Method A.2, Boiling point.	Impregnation fluid 0.9% Permethrin.	Flash point: Test item does not ignite and turns off the test flame at 87°C. Boiling point The heat flow record shows an endothermic effect between 66°C and 126°C, with peak at 107°C and onset at 99°C. The boiling point of the sample is 99°C.	██████████ ██████████ (2019 b) IUCILID Section 4.6 (Cf 4.2) – Recorded under 4.2. Flammability. Chemical physical characteristics on the sample labelled as Christiansen LD bednet.
Flammable solids	The test is not required as the physical hazards are evaluated based on the impregnation liquid.	N / A	N / A	N / A
Self-reactive substances and mixtures		Impregnation fluid 0.9% Permethrin.	During the boiling point measurement using DSC, only an endothermic signal was observed, by heating the mixture. (Approx. -1400 J/g). Therefore, it can be concluded that the heat of decomposition is less	██████████ ██████████ (2019 b)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			than 300 J/g. Hence, it is concluded that the liquid is not self-reactive.	
Pyrophoric liquids		Impregnation fluid 0.9% Permethrin.	Experience in use and handling do not indicate pyrophoric properties of the impregnation liquid	N / A
Pyrophoric solids		N / A	Not relevant as the formulation is liquid. According to CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers", tests for carrier based products must be performed using the impregnation liquid. As the endpoint is only applicable to solids, testing of this property is not relevant.	N / A
Self-heating substances and mixtures		N / A	Not relevant, formulation is a liquid. According to CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers", tests for carrier based products must be performed using the impregnation liquid. As	N / A

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			the endpoint is only applicable to solids, testing of this property is not relevant. During the production process the product is heated, and there is no experience of self-heating properties.	
Substances and mixtures which in contact with water emit flammable gases		N / A	Experience in use and handling demonstrate that no flammable gases are emitted when the liquid comes in contact with water.	N / A
Oxidising liquids		N / A	The substance contains Oxygen and Chlorine, but these are only chemically bound to Carbon or Hydrogen.	N / A
Oxidising solids		N / A	Not relevant, formulation is a liquid. According to CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers", tests for carrier based products must be performed using the impregnation liquid. As the endpoint is only applicable	N / A

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			to solids, testing of this property is not relevant.	
Organic peroxides		N / A	The liquid does not contain ingredients which have the functional group of organic peroxide. The liquid does not contain hydrogen peroxide, hence the formation of organic peroxides can be excluded.	N / A
Corrosive to metals			Not relevant, as the classification must be applicable for the product as distributed, a classification as corrosive to metals is not appropriate for the Christiansen LD bednet, as the product is not a liquid.	
Auto-ignition temperatures of products (liquids and gases)			The liquid is not flammable. The study does not need to be conducted for liquids non-flammable in air, e.g. no flash point up to 200°C. As the product has no flash point below the boiling point no auto-ignition test is required.	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Relative self-ignition temperature for solids			Not relevant, formulation is a liquid. According to CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers", tests for carrier based products must be performed using the impregnation liquid. As the endpoint is only applicable to solids, testing of this property is not relevant.	
Dust explosion hazard			Not relevant, formulation is a liquid. According to CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers", tests for carrier based products must be performed using the impregnation liquid. As the endpoint is only applicable to solids, testing of this property is not relevant, only solids.	

Conclusion on the physical hazards and respective characteristics of the product

Christiansen LD is a carrier-based product of type B.

According to the CA-Nov16-Doc.4.3. According to CA-Nov16-Doc.4.3-Final clarifies the handling of "carriers", tests for carrier based products may be performed using the impregnation liquid.

The end product is a bed net made of polyester impregnated with 0.9% permethrin. The impregnation solution that is tested on is not flammable, not oxidizing, not self-heating nor explosive and should not be classified for physical hazards.

2.2.3 Methods for detection and identification

Extraction of permethrin from the bednet:

See confidential Annex

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range (*)	Mean (*)	RSD (*)		
<i>Content and identification of permethrin</i>	ECHA 18-G-03-EN and SANCO 3030/99 rev. 4, validated GLP method, GC-FID	3 levels, two preparations for each level. n=6. 50% - 100% - 150% of the analyte additions.	0.45% - 1.35% w/w of the analyte in the test sample. 5 levels, two preparations for each level. = 1.0000 R ² = 1.0000 Slope: 5.5604 Intercept: -0.0031 Confidence interval at 95% for the intercept = [-0.0039; 0.0039]	Specific method. (Blank and placebo do not interfere with the analyte peak) There is provided chromatograms with blank, placebo and sample. There is no interference with the analyt peak.	50%: 100.52 100%:100.13 150%:100.09	100.25	0.28 % RSD% < 2.69% and is acceptable	Limit of repeatability: 0.15 LOQ 0.5 g/kg	Eurofins ref. 1016432A01_1, [REDACTED] (2019).

<i>Content and identification of permethrin</i>	ECHA 18-G-03-EN and SANCO 3030/99 rev. 4, validated GLP method, GC-FID	N=6 No outlier found (Grubbs, Dixon)	SQ = 0.000 Confidence interval 0.93 % +/- 0.01%	Specific method. (Blank and placebo do not interfere)	0.93 w/w - 0.94w/w	0.933	0.54%	Limit of repeatability: 0.02 %	Eurofins ref. 1143404A01, [REDACTED] (2020).
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The storage stability studies were performed on the bed net, and the permethrin content of the net was determined. The analytical method is for the liquid and for the permethrin liquid extracted from the net.

*) Each result is the mean of two chromatographic injections (duplicate injections).

The mosquito net is used indoor and cannot be washed. Exposure to soil or aquatic compartments as well as to food and feed is expected to be negligible and data is not required for monitoring purposes.

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
<i>No data required. Molecule does not classify as toxic or highly toxic.</i>									1342-18 Assessment report, IE 2014

Conclusion on the methods for detection and identification of the product
Christiansen LD is a carrier-based product of type B, where the product is a bed net made of polyester impregnated with 0.9% permethrin. The analytical method provided in support of this application for permethrin (active substance) is considered validated according to requirements in the ECHA guidance on information requirements.

Analytical methods for determination of permethrin in soil, air and water are not required considering the intended use of the biocidal product (the insect net).

Acceptable methods for permethrin are available for food and feeding stuffs and in tissue in the active substance dossier and does not need to be submitted for the product.

Method validation for the quantification of the active ingredient Permethrin in the test item Christiansen LD Bed net (VERNIER A, BELUSSI C (2019) as well as verification of the precision of the validated method for quantification of active ingredient in Aqueous liquid for Christiansen LD Bed net were performed Feb-March 2019 by Eurofins Biolab S.r.l., Italy (BONETTI A, (2019)).

With reference to Eurofins Biolab Report No 1016432A01_1, Physico-chemical tests according to GLP, VERNIER A, BELUSSI C, (2019), quantification and identification tests were performed for Christiansen LD Bed net and for the aqueous liquid for Christiansen LD Bed net. The test method was GC-FID, and the parameters under investigation were specificity, linearity, accuracy and precision. Shapiro test was carried out to evaluate the normal distribution of data. Huber, Grubbs and Dixon tests were applied to precision data in order to evaluate outliers.

The method described and identified as STULV19AA0218-1 GLP-MdP proved to be specific, linear, precise and accurate and was successfully validated for permethrin quantification in the test item "Christiansen LD Bed net".

2.2.4 Efficacy against target organisms

2.2.4.1 Function and field of use

Textile mosquito net to be used over the bed during the night and dawn for the protection of humans against mosquitoes.

Christiansen LD bednet offers protection against mosquitos. To be effective the mesh of a mosquito net must be fine enough to exclude such insects.

Christiansen LD bednet is impregnated with an insecticide to impair the movement of host-seeking mosquitoes through a damaged net and to kill mosquitoes after contact with the net. Additionally, the efficacy of the insecticide treated mosquito net will generally lower the pressure from mosquitoes. Further treatment by the user is not relevant.

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

Protection of humans against mosquitoes; Anopheles spp. and Aedes spp., in tropical areas only.

2.2.4.3 Effects on target organisms, including unacceptable suffering

Permethrin is an acute toxin with fast knock-down and kill effect.

2.2.4.4 Mode of action, including time delay

Permethrin is a synthetic pyrethroid belonging to IRAC Mode of action Group 3. It is a sodium channel modulator that keeps sodium channels open, causing hyperexcitation and, in some cases, nerve block. Sodium channels are involved in the propagation of action potentials along nerve axons.

Permethrin is a fast-acting substance.

2.2.4.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organisms	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
<i>Insecticide</i>	Indoor	Permethrin (0.9%)	Adult females. <i>Anopheles gambiae</i> , <i>Aedes aegypti</i> , <i>Aedes albopictus</i> , <i>Culex pipiens</i>	Laboratory test. The efficacy of the bednet to kill mosquitoes in a WHO tunnel test is assessed. The method measures the mortality and blood-feeding success of mosquitoes in an experimental chamber. This method tests the possible passage of mosquitoes through a damaged net after 0 to 25 washes.	The assay is carried out by releasing non-blood-fed female mosquitoes into a tunnel, where suitable bait e.g. a mouse is placed behind the test object (400 cm ² bednet). Nine 1 cm holes are made in the net. 100 female mosquitoes were introduced to the cage. They had to pass the bednet to reach the bait. After an exposure of 12 hours the mosquitoes were removed from each section and mortality and blood-feeding were recorded. Net samples were washed 0, 5, 10, 15, 20 and 25 times. An untreated net served as control. Four replicates were conducted at each time point for washed/unwashed treated and untreated nets.	In the experiments with untreated and unwashed bednet samples 87-90% of the female mosquitoes of all four species pass through the net. 75-93% of the females were blood-fed. Mortalities were recorded after 12 and 24 hours. Control mortalities ranged from 2-4%. The mortality was 100% in all other cases irrespective of mosquito species and the number of washes. The product showed to give full protection against <i>An. gambiae</i> , <i>Ae. aegypti</i> , <i>Ae. albopictus</i> , and <i>C. pipiens</i> in this laboratory experiment investigating the efficacy of damaged insecticide-treated bednets.	██████████ (2015). Assessment of the insecticide efficacy of an anti-mosquito impregnated bednet.LLIN bednet Christiansen (permethrin). TEC Laboratory, Anglet, France. Report 2003/1015R .
<i>Insecticide</i>	Indoor	Permethrin (0.9%)	Adult females. <i>Aedes aegypti</i>	Laboratory test. Direct contact test.	Bednets were stored for two years and were washed 20 times.	The control showed no knock-down and 2% mortality.	██████████ (2016). Assessment of

				Ten replicates were conducted on four samples of bednet.	In the direct contact test 5 insecticide-susceptible, non-blood fed <i>Aedes aegypti</i> are exposed to the test product for 3 minutes, after which they are held for 24 hours. Knock down was measured after 1 hour and mortality after 24 hours. Untreated bednet was used as control with similar number of controls.	The two years old washed bednet showed 100% knock down and 100% mortality	the insecticide efficacy of an anti-mosquito impregnated bednet. Bednet Christiansen. Trial after 2 years of storage. TEC Laboratory, Anglet, France. Report Study 1716-2Y/0114R.
<i>Insecticide</i>	Indoor	Permethrin (0.9%)	Adult females. <i>Aedes aegypti</i> , <i>Culex quinquefasciatus</i> , <i>Anopheles gambiae</i>	Laboratory test. Direct contact test. Ten replicates were conducted on four samples of bednet for each mosquito species.	Bednets were stored for three years and were washed 20 times. In the direct contact test 5 insecticide-susceptible, non-blood fed <i>Aedes aegypti</i> / <i>Culex quinquefasciatus</i> / <i>Anopheles gambiae</i> are exposed to the test product for 3 minutes, after which they are held for 24 hours. Knock down was measured after 1 hour and mortality after 24 hours. Untreated bednet was used as control with similar number of controls.	The control showed no knock-down and 2 % mortality. The three years old washed bednet showed 100% knock down and 100% mortality	██████████ (2017). Assessment of the insecticide efficacy of an anti-mosquito impregnated bednet. Bednet Christiansen. Trial after 3 years of storage. TEC Laboratory, Anglet, France. Report Study 1716-3Y/0114.

Insecticide	Indoor	Permethrin (0.9%)	Adult females. <i>Anopheles gambiae</i> and <i>Aedes aegypti</i>	<p>Simulated use ambient chamber test.</p> <p>The study was a partially randomized, double blind placebo controlled study, where the insecticide status of the test objects was unknown.</p>	<p>All nets were holed to WHO standard, with one 4x4 cm on each of the shorter sides and two 4x4 cm on the longer sides.</p> <p>Laboratory reared insecticide-susceptible mosquitoes were used for the tests. The susceptibility status of the strains used, were verified by bioassay.</p> <p>The mosquitoes are released inside of compartments made from durable netting meaning that experiments are conducted under ambient conditions similar to use of the product. Each experimental compartment contains a steel bed frame with a foam mattress on which a volunteer sleeps during each test and over which one of the bed nets was draped. A human volunteer slept beneath the bed net from 18:00 to 06:30. For each test 10 <i>An. gambiae</i> and 10 <i>Ae. aegypti</i> were introduced to the compartments. At 06:30 the following day the mosquitos were collected by aspirator. At 09:00 they were scored for blood-feeding success and at 09:00 the following day mortality was assessed.</p>	<p>Under untreated control nets, an average of 44% of the total <i>Ae. aegypti</i> and 43% of the total <i>An. gambiae</i> released obtained a blood-meal each night.</p> <p>Under LD bednet with holes, 12% and 13% of the released <i>Ae. aegypti</i> and <i>An. gambiae</i>, respectively, obtained a blood-meal.</p> <p>The calculated personal protection was 90% and 91% for <i>Ae. aegypti</i> and <i>An. gambiae</i>, respectively.</p> <p>The control corrected mortality was 93% and 71% for <i>Ae. aegypti</i> and <i>An. gambiae</i>, respectively.</p> <p>The impregnated bed nets subjected to damage to simulate the WHO criteria of a damaged net significantly reduced feeding success and increased mortality for <i>Ae. aegypti</i> and <i>An. gambiae</i>. The bed nets gave satisfactorily protection, 90% and 91%, against <i>Ae. aegypti</i> and <i>An. gambiae</i>, respectively.</p>	<p>██████████ ██████████ (2017). Ifakara ambient chamber test evaluation of a permethrin long-lasting insecticidal net against insectary reared populations of <i>Anopheles gambiae</i> s.s. and <i>Aedes aegypti</i> in Tanzania. Ifakara Health Institute, Bagamoyo, Tanzania. BIT019 Technical Report V04.</p>
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					The experiments run with 10 bed nets (6 treated and 4 untreated) for 10 nights, with the 10 volunteers rotating.		
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Conclusion on the efficacy of the product

The applicant provided efficacy data showing that Christiansen LD bednet impregnated with 0.9% permethrin is effective against *Anopheles* spp. and *Aedes* spp. The product is only authorized to be used in tropical areas. The bednet will be effective after 3 years storage. Washing does not affect the efficacy of Christiansen LD bednet, but due to the environmental risk, washing of the net is strictly prohibited.

2.2.4.6 Occurrence of resistance and resistance management

Resistance to permethrin has been reported for a number of pests both in agriculture and public health (German cockroach (Atkinson et al., 1991)², house fly (Meyer et al., 1987)³, stable fly (Pitzer et al., 2010)⁴, *Culex* mosquitoes (Wan-Norafilack et al., 2013)⁵, *Aedes* mosquitoes (Saavedra-Rodriguez et al., 2008)⁶, *Anopheles* mosquitoes (Corbel et al., 2004)⁷ when permethrin has been used as a general insecticide (PT18 use). In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms (see Assessment Report permethrin, PT08, April 2014).

In a study performed in Thailand, some populations of *Aedes aegypti* and *Culex quinquefasciatus* have been found to be resistant against permethrin. Permethrin had been introduced to the relevant region ten years before the study was conducted. Permethrin is among the main insecticides used in controlling vector-borne diseases throughout Thailand. If certain populations of mosquitoes are resistant to DDT, they might become resistant to permethrin as well, as cross-resistance has been observed (Somboon et al., 2003)⁸.

Culex quinquefasciatus is a model organism for studying resistance due to its inherent ability to resist insecticides. Permethrin induces both killing and avoidance responses in *Culex* mosquitoes. Studies on the resistance of *C. quinquefasciatus* have been conducted for example the US, India, Malaysia and Thailand. All these studies showed various levels of resistance against permethrin in these populations (Wan-Norafikah et al., 2013).

Additionally, the reason for developing resistance against permethrin is species-dependent. In general it can be said that resistance develops due to uncontrolled use of the insecticide. It has been documented that resistance is occurring due to reduced neural sensitivity due to a specific mutation, enhanced metabolic detoxification of permethrin, and reduced penetration ratio. Other mechanisms are likely to exist but have not been described so far. Additionally, permethrin has been described to be less effective at higher temperatures, especially above 30 °C (Somboon et al., 2003; Wan-Norafikah et al., 2013).

² Atkinson et al. (1991) Pyrethroid resistance and synergism in a field strain of the German cockroach (Diptera: *Blattellidae*)

³ Meyer et al. (1987) House fly (Diptera: *Muscidae*) resistance to permethrin on southern California dairies.

⁴ Pitzer et al. (2010) Assessing permethrin resistance in the stable fly (Diptera: *Muscidae*) in Florida by using laboratory selections and field evaluations.

⁵ Wan-Norafilack et al. (2013) Development of permethrin resistance in *Culex quinquefasciatus* Say in Kuala Lumpur, Malaysia

⁶ Saavedra-Rodriguez et al. (2008) Quantitative trait loci mapping of genome regions controlling permethrin resistance in the mosquito *Aedes aegypti*

⁷ Corbel et al. (2004) Dosage-dependent effects of permethrin-treated nets on the behaviour of *Anopheles gambiae* and the selection of pyrethroid resistance

⁸ Somboon et al. (2003) Insecticide susceptibility tests of *Anopheles minimus* s.l., *Aedes aegypti*, *Aedes albopictus*, and *Culex quinquefasciatus* in northern Thailand.

Resistance should be monitored on a continuous basis. Should the authorisation holder become aware of reports of resistance this should be reported to the competent authorities and/or ECHA.

2.2.4.7 Known limitations

2.2.4.8 Replace the bednet if damaged (e.g. holes), protection against mosquitoes is not sufficient if the bednet is damaged. Evaluation of the label claims

The accepted label claim is: "Insecticide treated Christiansen LD bednet for human protection against *Anopheles* spp. and *Aedes* spp." Protection against diseases must not be included in the label claim.

The target organisms indicated are *Anopheles gambiae*, *Aedes aegypti*, *Aedes albopictus*, *Culex pipiens*. Only use in tropical areas against *Anopheles* spp. and *Aedes* spp. can be accepted. Indications of the vector capacity of these mosquito species for various diseases must not be a part of the label claim.

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

None

2.2.5 Risk assessment for human health

The toxicology of Christiansen LD bednet was examined according to standard requirements. The product is not identical to the representative product in the EU – review program for inclusion of permethrin in Annex I of regulation No. 528/2012. The toxicological properties of the active substance are summarised in the CA report: Permethrin – RMS IE 2014. A washing study (██████ 2016) was submitted for the product and used in calculations for dermal exposure (see section 2.2.5.2 Exposure assessment).

Acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation have not been performed on the product Christiansen LD bednet. The criteria for classification of mixtures according to Regulation 1272/2008 (CLP) were followed.

2.2.5.1 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	A skin irritation study with Christiansen LD bednet has not been conducted. Testing of the pure active substances permethrin revealed no skin-irritating potential. No further co-formulant is classified for skin irritation. It is therefore concluded that the biocidal product has no skin-irritating potential.
Classification of the product according to CLP and DSD	According to the CLP regulation, no classification for skin irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The toxicity of the active substances and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP). Testing of the pure active substance permethrin revealed no skin-irritating potential. Therefore, no classification for skin irritation is necessary.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eyes

Justification for the value/conclusion	An eye irritation study with Christiansen LD bednet has not been conducted. Testing of the pure active substance permethrin revealed no eye-irritating potential. It is therefore concluded that the biocidal product has no eye-irritating potential.
Classification of the product according to CLP and DSD	According to CLP, no classification for eye irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	<p>The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP).</p> <p>Testing of the pure active substance permethrin revealed no eye irritating potential. No further co-formulant is classified for eye irritation. Therefore, the biocidal product does not need to be classified for eye irritation.</p>

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract
Justification for the value/conclusion	A respiratory tract irritation study with Christiansen LD bednet has not been conducted. Testing of the pure active substance permethrin revealed no respiratory tract irritation potential. It is therefore concluded that the biocidal product has no respiratory tract irritation potential.
Classification of the product according to CLP	According to CLP, no classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of

	<p>the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP).</p> <p>Testing of the pure active substance permethrin revealed no eye irritating potential. No further co-formulant is classified for eye irritation. Therefore, the biocidal product does not need to be classified for eye irritation.</p>
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Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	A skin sensitisation test with Christiansen LD bednet has not been conducted. According to the current harmonised classification according to Regulation (EC) No 1272/2008 (CLP Regulation) permethrin is classified for skin-sensitising potential. The concentration of permethrin in Christiansen LD bednet is below 1%. It is therefore concluded that the biocidal product. has no skin-sensitising potential.
Classification of the product according to CLP and DSD	According to Regulation 1272/2008 (CLP), the biocidal product does not need to be classified with Skin Sens. 1, H317, but needs to be labelled with EUH 208 "Contains permethrin. May produce an allergic reaction".

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	A respiratory sensitisation test with Christiansen LD bednet has not been conducted. Testing of the pure active substances permethrin revealed no respiratory sensitisation potential. It is therefore concluded that the biocidal product has no potential for respiratory sensitising.
Classification of the product according to CLP and DSD	According to CLP no classification for respiratory sensitisation is necessary.

Data waiving	
Information requirement	Respiratory sensitization.

Justification	<p>Toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP).</p> <p>Testing of the pure active substance permethrin revealed no respiratory sensitising potential. No further ingredient is classified for sensitising to the respiratory tract. Therefore, the biocidal product does not need to be classified for respiratory tract sensitisation.</p>
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Acute toxicityAcute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with Christiansen LD bednet have not been conducted. Testing of the pure active substance revealed oral toxicity potential with LD ₅₀ values ranging from 480-554 mg/kg bw/day resulting in classification as harmful if swallowed (H302). However, using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP), the biocidal product does not need to be classified for acute oral toxicity.
Classification of the product according to CLP and DSD	According to CLP, no classification for acute oral toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	<p>The toxicity of the active substance and the co-formulant is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).</p> <p>The active substance permethrin is classified as Acute Tox. 4, H302 according to CLP.</p> <p>Specific concentration limits are not specified for permethrin in Annex VI of Regulation 1272/2008, so that the generic concentration limit of the CLP Regulation applies.</p>

	According to CLP, the concentration of permethrin is below the concentration limit of 1%. Thus the ingredients do not need to be taken into consideration for the purpose of classification.
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Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with Christiansen LD bednet have not been conducted. Testing of the pure active substance permethrin revealed acute inhalation toxicity potential, thus permethrin is classified as Acute Tox. 4, H332. The Acute Toxicity Estimate (ATE) of a mixture was estimated. Using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP), the biocidal product does not need to be classified for acute inhalation toxicity.
Classification of the product according to CLP	According to CLP, no classification for acute inhalation toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	<p>The toxicity of the active substance and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).</p> <p>Testing of the pure active substance permethrin revealed acute inhalation toxicity potential, thus permethrin is classified as Acute Tox. 4, H332. Specific concentration limits are not specified for permethrin in Annex VI of Regulation 1272/2008, so that the generic concentration limit of the CLP applies.</p> <p>According to CLP, the concentration of permethrin is below the concentration limit of 1%. Thus the ingredients do not need to be taken into consideration for the purpose of classification.</p>

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with Christiansen LD bednet have not been conducted. Testing of the pure active substance permethrin revealed no acute dermal toxicity. It is therefore concluded that the biocidal product does not need to be classified for acute dermal toxicity.
Classification of the product according to CLP and DSD	According to CLP, no classification for acute dermal toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	<p>The toxicity of the active substances and the co-formulants is known and no synergistic effects are expected. Thus, toxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation 1272/2008 (CLP).</p> <p>Testing of the pure active substance permethrin revealed no acute dermal toxicity. Therefore, the biocidal product does not need to be classified for acute dermal toxicity.</p>

Information on dermal absorption

The document CA-July13-Doc6.2.b presents the approach for assessment of dermal absorption in biocidal products to be authorised. If no dermal absorption studies exist with the specific formulation of the biocidal product, next step is to either apply a default value from the *EFSA (2017) Guidance on dermal absorption*⁹ for a first worst-case exposure estimate or perform read across with data from the CAR of the active substance or other product formulations similar to the biocidal product to be authorised. The last option can be used if both of the following two conditions are met:

1. It is justified that the formulations presented in dermal absorption studies submitted for the active substance approval (or the other product formulation) have a similar composition as compared to the biocidal product to be authorised when using the criteria laid down in the before mentioned *EFSA (2017) Guidance on dermal absorption*, and

⁹ EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp

2. The applicant holds a Letter of access from the data owner of the dermal absorption study which is relevant for the biocidal product to be authorised.

If no safe use can be demonstrated, further refinements should be applied in the external exposure calculation. If the unacceptable risk remains, dermal absorption test studies for the specific formulation should be performed before the introduction of risk mitigation measures.

There are no dermal absorption study available with the specific formulation of Christiansen LD bednet. The rMS has conducted a read across to the representative product formulation in the CAR of permethrin in PT 18 (2014, IE). This read across is placed in the confidential annex – using EFSA (2017) "Guidance on dermal absorption" the dermal absorption value of 3 % from the CAR has been selected.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Permethrin
Value(s)	3 %
Justification for the selected value(s)	The value of 3 % is from the CAR of permethrin in PT 18. For further justification please refer to the confidential annex (section 3.7).

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

The biocidal product Christiansen LD bednet does not contain any substances of concern. For the full assessment of components considered a potential substance of concern, please refer to section 3.7 Confidential annex.

Available toxicological data relating to a mixture

The biocidal product contains no non-active substances that are classified in Annex VI of Regulation 1272/2008, respectively at concentrations leading to a classification of the biocidal product.

2.2.5.2 Exposure assessment

The biocidal product Christiansen LD bednet is a mosquito net treated with permethrin for use by non-professional users. Human exposure evaluation relates to the use phases of the product and cover primary and secondary exposure. Christiansen LD Bednet is impregnated with the active substance permethrin at the concentration of 9 g/kg (0.9 % w/w) in the net, corresponding to 270 mg/m²¹⁰ of mosquito net.

The calculated exposure assessment and risk characterization are assessed and performed with the biggest mosquito net "Christiansen LD bednet" - Impregnated Bednet Permethrin (21.2 m²) as a worst-case scenario.

¹⁰ R4BP case number BC-GK024706-40: "Specs_techniques_CHRISTIANSEN_bednet_DK_amended" - reply 20171109

The potential routes of exposure which have been taken into account in the risk assessment for those sleeping under treated nets are inhalation, dislodgeable residues from the net being deposited on skin in contact with the net and, in case of newborns (0-1 month), infants (6 to < 12 months) and toddlers (1 to < 2 years), the additionally possibility that the net may be mouthed and chewed or sucked. Furthermore pregnant and lactating women may sleep under Christiansen LD bednet. Newborns and infants may therefore also be exposed through breast milk.

The risk assessment has been performed according to the revised edition (2nd edition) of the World Health Organisation (WHO) guidance "A generic risk assessment model for insecticide-treated nets" (2018). In addition to WHO's guidance, Recommendation 14 "Default human factor values for use in exposure assessments for biocidal products" (2017) has been used to estimate bodyweight and surface area for adults, children (6 to < 11 years), young children (2 to < 6 years), toddlers and infants. Values on newborns (e.g. bodyweight, surface area and breathing volume) are from "Child-Specific Exposure Factors Handbook" (2008).

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

The exposure assessment and risk characterisation for human health is divided into two scenarios: scenario 1 for people sleeping under the net and scenario 2 for infants and newborns breastfeeding from a woman who has been sleeping under the net. According to Volume III Human health, Part B+C "primary exposure" is defined as: "Primary exposure to biocidal products occurs to the individual who actively uses the biocidal products, i.e. the user.". Since the intended use of the bednet is to sleep under the net, it is assumed, that the primary exposure is covered by scenario 1 for people sleeping under the net (including inhalation, dermal and oral exposure as described in the text above).

"Secondary exposure" is according to Volume III Human health, Part B+C defined as: "Secondary exposure is exposure that may occur during or after the actual use or application of the biocidal product." and as "unintentional exposure". Infants and newborns who are breastfeeding from a woman who has been sleeping under the net (scenario 2) is assumed to be secondary exposed, since this exposure is beyond the use of the bednet (sleeping under the bednet). Therefore infants and newborns (general public) are secondarily exposed to the bednet.

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

List of scenarios

Summary table: Scenarios			
Scenario number	Scenario	Primary or secondary exposure Description of scenario	Exposed group
1.	Sleeping under treated net	Primary exposure Indoor use. Sleeping under treated net	Non-professional users (adults, children, young children, toddlers, infants and newborns)
2.	Exposure via breast milk	Secondary exposure Indoor use. Exposure of infants through breast milk	General public (Infants and newborns)

Industrial exposure

Not relevant since no industrial exposure is foreseen.

Professional exposure

Not relevant since no professional exposure is foreseen. If the product is used by a person while he or she is doing their job, the exposure is not foreseen to be different from the exposure that non-professional users may experience.

Non-professional exposure

The potential routes of exposure that need to be taken into account in risk assessment for adult, child (6 to < 11 years), young child (2 to < 6 years), toddler (1 to < 2 years), infant (6 to < 12 months) and newborns (0-1 month) sleeping under treated nets are inhalation, dislodgeable residues from the net being deposited on skin in contact with the net (dermal exposure). In the case of newborn, infant and toddler, the additional possibility that the net may be mouthed, chewed or sucked is evaluated, hence exposure *via* the hand-to-mouth transfer and the direct oral contact with the treated net.

Values for bodyweight and surface area are from Recommendation 14 (for adult, child, young child, toddler and infant) and Child-Specific Exposure Factors Handbook (2008) (for newborn).

As an estimate, it is assumed that the net is used every night the year around. It is also assumed that the concentration of insecticide in the net is not significantly changed over the time it is used, hence the exposure resulting from sleeping under the net is the same as that from an unused net.

Description of Scenario 1: Sleeping under permethrin impregnated bednet (primary exposure)

According to the WHO 2nd edition (2018) ⁴ the following assumptions are considered:

Inhalation: As a worst case approach the following is assumed for the predicted daily systemic dose from inhalation exposure ($SysD_{inh}$) while sleeping under treated net:

$$SysD_{inh} = \frac{Abs_{inh} \cdot C_{air} \cdot BV \cdot H}{BW}, \quad \text{where } C_{air}[\mu g/m^3] = 1.01 \cdot 10^{-3} \cdot SC[mg/m^2] \cdot VP[\mu Pa]$$

The value for breathing volume (BV) for adults, children, young children, toddlers and infants are from Recommendation 14 for long term exposure, since the exposure for long term values does include rest and sleep periods. For newborns the breathing volume is estimated from Child-specific Exposure Factors Handbook (2008) for newborns in age 0-1 month ($3.63 \text{ m}^3/\text{day}^9 = 0.15 \text{ m}^3/\text{h}$). The average time spent under the net each day (H) for adults, children, young children, toddlers and infants are from WHO's guidance (2008), and for newborns the value is estimated from Child-Specific Exposure Factors Handbook (2008) where the hours of sleep per day for newborns in age 0-1 month is 13 h ⁹.

Skin contact: For an individual sleeping under a treated bed-net it is assumed that

- A fraction of the active ingredient permethrin can be released from the surface of the net. Hence, the fraction available for skin contact can be estimated from the wash-resistance index (WRI) as $100 - WRI\%$ (WHO 2nd Edition (2018)). The release of permethrin is estimated from the stability test report (RE/15/U10/24150 ⁵) on Christiansen LD bednet, when comparing wash number 1 (active substance retention (% of wash 0) = 88.4 %) with wash number 0 (active substance retention (% of wash 0) = 100 %) resulting in a permethrin retention of $(100-88.4)\% = 11.6\%$ rounded up to 12 % (SF).
- Out of the surface fraction (SF) 6 % ⁴ of the amount of permethrin is estimated to be translocable to the skin in contact with the net each night (transl). The value of 6 % has been chosen based on the following description in WHO 2nd Edition (2018) regarding the default value in the guidance: "For chemicals that do not have chemical-specific data, USEPA (2012) recommends a screening level point estimate of 0.06 for use in post-application dermal exposure assessments based on studies on 3 pyrethroids, chlorpyrifos and piperonylbutoxide. **This, taken to be the default value for the transfer of the insecticide from the net to the sleeper during a night, would be a worst-case estimate since it assumes that 6% of the surface fraction (SF) is dislodged, and that 1/3 of the total surface area could be in contact with the net.**"
- the trunk, hands, arms, lower legs and feet are uncovered ⁴
- for newborns the exposed skin area (ESA) includes the whole leg in contrast to the lower leg for adults, children, young children, toddlers and infants, since Child-Specific Exposure Factors Handbook (2008) does not contain a value for lower leg only
- 1/3 (33.3 %) ⁴ of their total body surface area could be in contact with the net
- the dermal absorption from the net surface (Abs_D) is 3 % (see section "Information on dermal absorption")
- The predicted daily systemic dose from dermal exposure ($SysD_D$) while sleeping under treated net:

$$SysD_D = \frac{Abs_D \cdot Transl \cdot ESA \cdot SF \cdot TC}{BW}$$

Oral exposure (for toddlers, infants, newborns only): For hand-to-mouth transfer a transfer coefficient (SE) of 57 %⁷ is assumed. As with skin contact (EHA) it is assumed, that 1/3 (33.3 %) ⁴ of their hand could be in contact with the net. The value for surface area for the hands of a newborn is from Child-specific Exposure Factors Handbook (2008) and is the surface area for newborns in age 0-1 month (0.015 m²), hence 1/3 (33.3 %) ⁴ of this value gives the EHA-value 0.005 m². For the definition of SF see the description regarding "Skin contact". The predicted daily systemic dose from hand-to-mouth transfer (SysD_{HM}) is:

$$SysD_{HM} = \frac{Abs_o \cdot SE \cdot Transl \cdot EHA \cdot FHM \cdot SF \cdot TC}{BW}$$

For mouthing it is assumed that a default salivary extraction fraction of 57% out of the surface fraction is transferred to the mouth and swallowed. As a worst case, it is assumed that an area of 0.0014 m² ⁴ of the net is in contact with the mouth overnight (NM). The predicted daily systemic dose from mouthing transfer (SysD_M) is:

$$SysD_M = \frac{Abs_o \cdot SE \cdot NM \cdot SF \cdot TC}{BW}$$

	Parameters		Value	
	Tier 1	Inhalation exposure		
Abs _{inh} - Absorption from the respiratory tract (%) ¹		100 (fraction = 1)		
SC - Surface concentration of insecticide in the net (mg/m ²) ²		270		
VP - vapour pressure at 20°C (µPa) ¹		2.155		
C _{air} - Concentration of insecticide in breathing zone (µg/m ³) ⁴		$1.01 \cdot 10^{-3} \cdot 270 \cdot 2.155 = 5.88 \cdot 10^{-1}$		
BV - Breathing volume, long term exposure (m ³ /h)		Adult ³ :	16 m ³ /24 h	= 0.67
		Child ³ :	12 m ³ /24 h	= 0.50
		Young child ³ :	10.1 m ³ /24 h	= 0.42
		Toddler ³ :	8 m ³ /24 h	= 0.33
		Infant ³ :	5.4 m ³ /24 h	= 0.23
		Newborn ⁹ :	3.63/24 h	= 0.15
H - Average time spent under net each day (h)		Adult ⁴ :	9	
		Child ⁴ :	10	
		Young child ⁴ :	10	
		Toddler ⁴ :	12	
	Infant ⁴ :	13		
	Newborn ⁹ :	13		
BW - Body weight (kg)	Adult ³ :	60		
	Child ³ :	23.9		
	Young child ³ :	15.6		
	Toddler ³ :	10		
	Infant ³ :	8		
	Newborn ⁹ :	4.8		
Dermal exposure				
Abs _D - Dermal absorption from net surface (%) ⁸	3 (fraction = 0.03)			
Transl - Fraction of the insecticide translocageable from the net to skin during a night's sleep (%) ^{4, 6}	6 (fraction = 0.06)			
ESA - Skin surface area in contact with the net (m ²)	Adult ³ :	0.41		
	Child ³ :	0.23		
	Young child ³ :	0.17		
	Toddler ³ :	0.12		
	Infant ³ :	0.11		
	Newborn ⁹ :	0.08		
TC - Target concentration of insecticide in the net (mg/m ²) ²	270			
SF - Surface fraction of the insecticide (100 - wash resistance index) (%) ⁵	12 (fraction = 0.12)			

BW - Body weight (kg)	Adult ³ : Child ³ : Young child ³ : Toddler ³ : Infant ³ : Newborn ⁹ :	60 23.9 15.6 10 8 4.8
Oral exposure (hand-to-mouth)		
Abs _o - Oral absorption (%) ¹	100 (fraction = 1)	
Transl - fraction of the insecticide translocable from the net to skin during a night's sleep (%) ^{4, 6}	6 (fraction = 0.06)	
EHA - Surface area of the hand (m ²)	Toddler ^{3, 4} : Infant ^{3, 4} : Newborn ⁹ :	0.008 0.007 1/3·0.015 m ² = 0.005
FHM - transfer from hands to mouth (%) ⁴	16.4 (fraction = 0.164)	
SE - Salivary extraction fraction ^{4, 7}	0.57	
SF - Surface fraction of the insecticide (100-wash resistance index) (%) ⁵	12 (fraction = 0.12)	
TC - target concentration of insecticide on the net (mg/m ²) ²	270	
BW - Body weight (kg)	Toddler ³ : Infant ³ : Newborn ⁹ :	10 8 4.8
Oral exposure (mouthing)		
Abs _o - Oral absorption (%) ¹	100 (fraction = 1)	
SE - Salivary extraction fraction ⁷	0.57	
NM - Area of net mouthed (75 th percentile) (m ²) ⁴	0.0014	
SF - Surface fraction of the insecticide (100-wash resistance index) (%) ⁵	12 (fraction = 0.12)	
TC - target concentration of insecticide on the net (mg/m ²) ²	270	
BW - Body weight (kg)	Toddler ³ : Infant ³ : Newborn ⁹ :	10 8 4.8

¹ Assessment report permethrin, IE 2014² R4BP case number BC-GK024706-40: "Specs_techniques_Christiansen_bednet_DK_amended" - reply 2017.11.09³ Recommendation 14 "Default human factor values for use in exposure assessments for biocidal products"⁴ WHO 2nd Edition (2018): "A generic risk assessment model for insecticide-treated nets"⁵ Stability test report, RE/15/U10/24150⁶ 75th percentile from carpets. USEPA (2012): Standard operating procedures for residential pesticide exposure assessment. Washington (DC). United States Environmental Protection Agency, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention.⁷ USEPA (2012): Standard operating procedures for residential pesticide exposure assessment. Washington (DC). United States Environmental Protection Agency, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention

⁸ See section "Information on dermal absorption" and confidential annex

⁹ USEPA (2008): "Child-specific exposure factors handbook (final report)"

Calculations for Scenario 1

The predicted daily systemic dose from the inhalation, dermal exposure and oral exposure (including hand-to-mouth transfer and mouthing) of people sleeping under Christiansen LD bednet is presented in Table 2.2, Table 2.3, Table 2.4 and Table 2.5, respectively.

Inhalation exposure							
Group	Abs _{Inh} (%)	C _{air} (µg/m ³)	BV (m ³ /h)	H (h)	BW (kg)	SysD _{Inh} (µg/kg bw/day)	SysD _{Inh} (mg/kg bw/day)
Adult	100	5.88·10 ⁻¹	0.67	9	60	5.9·10 ⁻²	5.9·10 ⁻⁵
Child			0.50	10	23.9	1.2·10 ⁻¹	1.2·10 ⁻⁴
Young child			0.42	10	15.6	1.6·10 ⁻¹	1.6·10 ⁻⁴
Toddler			0.33	12	10	2.3·10 ⁻¹	2.3·10 ⁻⁴
Infant			0.23	13	8	2.2·10 ⁻¹	2.2·10 ⁻⁴
Newborn			0.15	13	4.8	2.4·10 ⁻¹	2.4·10 ⁻⁴

Table 2.2 Inhalation exposure to permethrin (SysD_{Inh})

Dermal exposure							
Group	AbsD (%)	Transl (%)	ESA (m ²)	SF (%)	TC (mg/m ²)	BW (kg)	SysD _D (mg/kg bw/day)
Adult	3	6	0.41	12	270	60	4.0·10 ⁻⁴
Child			0.23			23.9	5.6·10 ⁻⁴
Young child			0.17			15.6	6.4·10 ⁻⁴
Toddler			0.12			10	7.0·10 ⁻⁴
Infant			0.11			8	8.0·10 ⁻⁴
Newborn			0.08			4.8	9.7·10 ⁻⁴

Table 2.3 Dermal exposure to permethrin (SysD_D)

Oral exposure - hand-to-mouth transfer								
Group	AbsO (%)	Transl (%)	EHA (m ²)	SE	SF (%)	TC (mg/m ²)	BW (kg)	SysD _{HM} (mg/kg bw/day)
Toddler	100	6	0.008	0.57	12	270	10	1.5·10 ⁻⁴
Infant			0.007				8	1.6·10 ⁻⁴
Newborn			0.005				4.8	1.9·10 ⁻⁴

Table 2.4 Oral exposure from "hand-to-mouth transfer" to permethrin (SysD_{HM})

Oral exposure – mouthing transfer							
Group	AbsO (%)	SE (%)	NM (m ²)	SF (%)	TC (mg/m ²)	BW (kg)	SysD _M (mg/kg bw/day)
Toddler	100	57	0.0014	12	270	10	2.6·10 ⁻³
Infant						8	3.2·10 ⁻³
Newborn						4.8	5.4·10 ⁻³

Table 2.5 Oral exposure from "mouthing" to permethrin (SysD_M)

Summary table: Systemic exposure from non-professional uses						
Exposure scenario, Tier	Group	Estimated inhalation uptake, SysD _{Inh} (mg/kg bw/day)	Estimated dermal uptake, SysD _D (mg/kg bw/day)	Estimated oral uptake for hand-to-mouth, SysD _{HM} (mg/kg bw/day)	Estimated oral uptake for mouth-ing, SysD _M (mg/kg bw/day)	Estimated total uptake (mg/kg bw/day)
Scenario 1, Tier 1	Adult	5.9·10 ⁻⁵	4.0·10 ⁻⁴	NA	NA	4.6·10 ⁻⁴
	Child	1.2·10 ⁻⁴	5.6·10 ⁻⁴	NA	NA	6.8·10 ⁻⁴
	Young child	1.6·10 ⁻⁴	6.4·10 ⁻⁴	NA	NA	7.9·10 ⁻⁴
	Toddler	2.3·10 ⁻⁴	7.0·10 ⁻⁴	1.5·10 ⁻⁴	2.6·10 ⁻³	3.7·10 ⁻³
	Infant	2.2·10 ⁻⁴	8.0·10 ⁻⁴	1.6·10 ⁻⁴	3.2·10 ⁻³	4.4·10 ⁻³
	Newborn	2.4·10 ⁻⁴	9.7·10 ⁻⁴	1.9·10 ⁻⁴	5.4·10 ⁻³	6.8·10 ⁻³

Table 2.6: Summary table for systemic exposure for non-professional users for adults, children, young children, toddlers, infants and newborns.

Combined scenarios

Please see the combined scenarios (Table 2.9) under the section "Exposure of the general public".

Exposure of the general public

Pregnant and lactating women may sleep under Christiansen LD bednet. Infants (6-12 months) and newborns (0-1 month) may therefore also be exposed through breast milk. Models from World Health Organisation (WHO) (2018), 2nd edition are used in the risk assessment in these calculations. Values for bodyweight are from Recommendation 14 (for infant) and Child-Specific Exposure Factors Handbook (2008) (for newborn).

Description of Scenario 2: Exposure through breast milk (secondary exposure)

The following is assumed:

- The body burden of the insecticide is at steady state, where the

$$\text{body burden} = \frac{\text{Daily dose} \left[\frac{\text{mg}}{\text{kg bw}} \right] \cdot T^{1/2} [\text{days}]}{\ln(2)}$$

- For lipid-soluble insecticides ($pKow \geq 2$), the insecticide is concentrated in the adipose tissue, and the concentration in adipose tissue is (assuming body fat content of 20 %) 5·body burden [mg/kg]. The average fat content of breast milk is 50 g/L, thus the insecticide concentration in breast milk is:
- $C_{Milk} = 5 \cdot DoseM \cdot \frac{0.05}{\ln(2)} = 0.361 \cdot DoseM$, where *DoseM* is the daily dose to the mother
- The factor 0.361 in the above equation is the solubility constant (SolC) for lipid soluble insecticides.
- The time-weighted average (TWA) daily dose of the mother (DoseM TWA) corresponds the total exposure of an adult sleeping under the net, hence dermal and inhalation exposure from sleeping under the net (scenario 1). Hand-to-mouth transfer and mouthing is not a part of the daily dose of the mother since it is assumed that only infants and toddlers are doing so.

Predicted daily systemic dose from mother's milk (SysD_{MM}) is:

$$SysD_{MM} = \frac{SolC \cdot DoseM \cdot T^{1/2} \cdot IR \cdot Abs_o}{BW}$$

It is considered worst-case scenario that a new born with a body weight of 4.8 kg (according to Child-Specific Exposure Factors Handbook (2008)) is breastfeeding comparing to an infant with a body weight of 8 kg (Recommendation 14 "Default human factor values for use in exposure assessments for biocidal products").

	Parameters	Value
Tier 1	SolC – Solubility constant; 0.361 for lipid soluble insecticides ⁴	0.361
	DoseM = Estimated total systematic exposure for women sleeping under the net (Table 2.6) (mg/kg bw/day) ¹	4.6·10 ⁻⁴
	T ^{1/2} = First-order kinetics half-time in the body of the insecticide, permethrin (days) ²	12.4 h/24 h/day =5.2·10 ⁻¹
	Abs _o = gastrointestinal absorption (%) ²	100 (fraction = 1)

	IR = Ingestion rate of milk (kg/day) ^{3, 4}	0.66
	BW = bodyweight (kg)	Infant ⁴ : 8 Newborn ⁵ : 4.8

¹ From scenario 2: Total exposure on an adult sleeping under the net (inhalation and dermal exposure)

² Assessment report permethrin, IE 2014, DOC IIIA 6.2(1)

³ Default 75th percentile newborn, 640 mL/day USEPA, 2011, assuming a relative density of 1.03, daily consumption equals 0.66 kg/day

⁴ WHO 2nd Edition, 2018 "A generic risk assessment model for insecticide-treated nets"

⁵ USEPA (2008): "Child-specific exposure factors handbook (final report)"

Calculations for Scenario 2

Pregnant and lactating women may sleep under the permethrin impregnated bed-net. Infants and newborns may therefore also be exposed through breast milk. Estimation of the exposure of infants and newborns through breast milk is presented in Table 2.7: Exposure via breast milk (SysD_{MM}).

Exposure through breast milk							
Group	SolC	DoseM (mg/kg bw/day)	T ^{1/2} (days)	IR (kg/day)	Abs _o (%)	BW (kg)	SysD _{MM} (mg/kg bw/day)
Infant	0.361	4.6·10 ⁻⁴	5.2·10 ⁻¹	0.66	100	8	7.0·10 ⁻⁶
New born						4.8	1.2·10 ⁻⁵

Table 2.7: Exposure via breast milk (SysD_{MM})

Summary table: Permethrin exposure through breast milk (SysD _{MM})		
Exposure scenario, Tier	Group	Systemic (mg/kg bw/day)
Scenario 2, Tier 1	Infant	7.0·10 ⁻⁶
	New born	1.2·10 ⁻⁵

Table 2.8: Summary table for systemic exposure for general public for infants and newborns.

Combined scenarios

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined, Tier	Group	Estimated total uptake from sleeping under the net, scenario 1 (Table 2.6)	Estimated uptake through breast-milk, scenario 2 (Table 2.8)	Estimated total uptake
Scenario 1 and 2 Tier 1	Infant	$4.4 \cdot 10^{-3}$	$7.0 \cdot 10^{-6}$	$4.4 \cdot 10^{-3}$
	Newborn	$6.8 \cdot 10^{-3}$	$1.2 \cdot 10^{-5}$	$6.8 \cdot 10^{-3}$

Table 2.9: Combined scenarios for scenario 1 and scenario 2 for infants and newborns.

Monitoring data

No data available.

Dietary exposure

A scenario where food, drinking water or livestock exposure is foreseen is not relevant due to the intended use of the bednet. The use is indoors and it is recommended to keep the bednet separated from foodstuffs. The expected time of use is at night.

Information of non-biocidal use of the active substance

No other (non-biocidal) use of the active substance is foreseen.

Even if permethrin is not approved in the EU as a plant protection product, there are applicable MRLs under the Reg. (EU) 2017/623.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Food, drinking water or livestock exposure by permethrin can be excluded when applied according to the recommended uses.

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

This is a polyester bednet coated with permethrin and intended for the use of the non-professional users. The professional and/or industrial application is not relevant. Food, drinking water or livestock exposure by permethrin can be excluded when applied according to the recommended uses.

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

This is a polyester bednet coated with permethrin. The intended non-professional users is foreseen to take place at night. Any transfer into foods is considered to be not relevant.

Food, drinking water or livestock exposure by permethrin can be excluded when applied according to the recommended uses.

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

Exposure during the production of the biocidal product should be addressed under other EU legislation (e.g. REACH) and not repeated under Regulation (EU) 528/2012. The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for permethrin which are existing biocidal active substances within the EU.

Aggregated exposure

The aggregated exposure and assessment is addressed in the risk characterisation for mixtures.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group	Tier	Estimated total uptake (mg/kg bw/day)
1 (Table 2.6)	Non-professionals	1	Adult: $4.6 \cdot 10^{-4}$ Child: $6.8 \cdot 10^{-4}$ Young child: $7.9 \cdot 10^{-4}$ Toddler: $3.7 \cdot 10^{-3}$ Infant: $4.4 \cdot 10^{-3}$ Newborn: $6.8 \cdot 10^{-3}$
2 (Table 2.8)	General public	1	Infant: $7.0 \cdot 10^{-6}$ Newborn: $1.2 \cdot 10^{-5}$
Combined scenarios 1 and 2 (Table 2.9)	General public	1	Infant: $4.4 \cdot 10^{-3}$ Newborn: $6.8 \cdot 10^{-3}$

2.2.5.3 Risk characterisation for human health

In the present risk assessments the systemic exposure estimates are compared to the corresponding AEL's (exposure/AEL-ratio = %AEL) for each use. For all scenarios repeated exposure for a non-professional user and general public has been assessed using the long term and medium term AEL (0.05 mg/kg bw/day) values which are based on the NOAEL (5 mg/kg bw/day) obtained in the 1-year dog study after taking an oral absorption value of 100 % and a safety factor of 100 into account. The rationale for setting the AEL's of the active substance permethrin can be found in the respective CA report. The reference doses and the relevant NOAEL-values from which they are derived are summarised in the following tables.

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) (mg/kg bw/day)	AF ¹	Correction for oral absorption	Value (mg/kg bw/day)
AEL short-term	2-year oral study in rats	59.43	100	-	0.5
AEL medium-term	12 month study in dog	5	100	-	0.05
AEL long-term	12 month study in dog	5	100	-	0.05

¹ Compensating for inter/intra species variation

Maximum residue limits or equivalent

The proposal is for non-crop use. Therefore, analytical methods for residues in food of plant and animal origin are not required. An acceptable validated method for residues of permethrin in soil was presented. Acceptable validated methods were provided for residues of permethrin in water and in air.

Risk for industrial users

This is an impregnated polyester bednet for non-professional users. No use is foreseen for industrial users.

Risk for professional users

This is an impregnated polyester bednet for non-professional users. No use is foreseen for professional users.

Risk for non-professional users

Systemic effects

Scenario	Tier	Systemic NOAEL (mg/kg bw/day)	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake/AEL (%)	Acceptable (Yes/No)
Scenario 1: Sleeping under permethrin im- pregnated bed-net	1	5	0.05	Adult: $4.6 \cdot 10^{-4}$	0.9	Yes
				Child: $6.8 \cdot 10^{-4}$	1.4	
				Young child: $7.9 \cdot 10^{-4}$	1.6	
				Toddler: $3.7 \cdot 10^{-3}$	7.3	
				Infant: $4.4 \cdot 10^{-3}$	8.8	
				Newborn $6.8 \cdot 10^{-3}$	13.6	

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL (mg/kg bw/day)	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1 and 2	1	5	0.05	Infant: $4.4 \cdot 10^{-3}$	8.8	Yes
				Newborn: $6.8 \cdot 10^{-3}$	13.6	

Local effects

The biocidal product is not classified for local effects. Therefore, risk characterisation for local effects is not required.

Conclusion

Insecticides have been extensively used for treatment of nets to protect against malaria and other vector-borne diseases. The biocidal product Christiansen LD bednet is a textile product coated with 0.9 % permethrin. According to the risk characterisation presented above, the biocidal product Christiansen LD bednet does not pose an unacceptable health risk for the non-professionals (primary exposure of adults, children, young children, toddlers, infants and newborns) and general public (secondary exposure of infants and newborns) for the authorised uses: sleeping under Christiansen LD bednet and, in the case of infants and newborns, the combined scenarios (scenario 1 and scenario 2) for sleeping under the Christiansen LD bednet and exposure through breast milk from an exposed women. Thus, the risk characterizations provided, resulted in acceptable risk compared to the relevant AELs for permethrin.

However, considering the potential environmental risk to the aqueous compartment, it is recommended not to wash the insecticide-treated bednet. A risk assessment for human health concerning washing the net is therefore not relevant and omitted.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL (mg/kg bw/day)	AEL (mg/kg bw/day)	Estimated uptake (mg/kg bw/day)	Estimated uptake/AEL (%)	Acceptable (Yes/No)
Scenario 2: Exposure via breast milk	1	5	0.05	Infant: $7.0 \cdot 10^{-6}$	0.01	Yes
				Newborn: $1.2 \cdot 10^{-5}$	0.02	

Combined scenarios

Please see the combined scenarios (Table 2.9) under the section "Exposure of the general public".

Local effects

The biocidal product is not classified for local effects. Therefore, risk characterisation for local effects is not required.

The biocidal product Christiansen LD bednet contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation) after dermal exposure, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons:

"Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice."

Conclusion

Insecticides have been extensively used for treatment of nets to protect against malaria and other vector-borne diseases. The biocidal product Christiansen LD bednet is a textile product coated with 0.9 % permethrin. According to the risk characterisation presented above, the biocidal product Christiansen LD bednet does not pose an unacceptable health risk for the general public (secondary exposure of infants and children) for the authorised uses: exposure of (6-12 months) and newborns (0-1 month) through breast milk from an exposed women. Thus, the risk characterizations provided, resulted in acceptable risk compared to the relevant AELs for permethrin.

However, considering the potential environmental risk to the aqueous compartment, it is recommended not to wash the insecticide-treated bednet. A risk assessment for human health concerning washing the net is therefore not relevant and omitted.

The biocidal product Christiansen LD bednet contains the pyrethroid permethrin. Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation) after dermal exposure, which are normally transient and do not persist. Hence, an appropriate labelling on the packaging is required to inform susceptible persons:

"Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice."

As the Christiansen LD bednet is labelled as EUH 208 and as permethrin may cause paresthesia, two risk mitigation measures has been added in the PAR:

- "Avoid contact with skin and eyes."
- "Wash hands after setting up the net and taking the net down."

Risk for consumers via residues in food

Based on the intended use and the proposed restriction, the acute and chronic exposure to residues resulting from the intended use is unlikely to cause a dietary risk to consumers. The product should not be applied in the vicinity of food or feed. Regarding consumer health protection, there are no objections against the intended uses.

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

Not relevant for Christiansen LD bednet. The formulation contains only one active substance and no substance of concern is present in the formulation.

2.2.6 Risk assessment for animal health

Food, drinking water or livestock exposure of permethrin can be excluded when applied according to the recommended uses. Therefore no unacceptable risk to animal health is to be expected.

Cats is considered to be a sensitive species to products with high concentrations of permethrin, possibly due to insufficient glucuronide conjugation capability¹¹ (they have a less efficient detoxification process than dogs). Besides, the relatively high surface area to weight ratio of cats means that smaller individuals tend to receive higher doses on a mg/kg basis. Therefore an risk mitigation measure for cats is added:

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

2.2.7 Risk assessment for the environment

Christiansen LD bednet is a bednet impregnated with 0.9% permethrin for use indoor. The net is not to be washed.

No new data on environment and exposure for the active substance was submitted. A washing study (██████ 2016) was submitted for the product (see 2.2.7.2 Exposure assessment – Biocidal product specific data)

As the net is only to be used indoor and not to be washed, no exposure of the environmental compartments is expected to occur and therefore no risk assessment for the environment is deemed necessary.

However, a risk assessment for the environment has been performed to highlight the potential risk if the product is misused. The risk assessment for the environment has been based on the guidelines in the Emission Scenario Document (ESD) for PT 19, since the scenarios described in the ESD for PT 18 do not include nets, and ESD for PT 19, Repellents and attractants, does. The risk assessment is elaborated on the basis of the emission scenario for factory-treated textiles as described in ESD for PT 19.

The emission scenario for calculating the release during the industrial application of insect-repellents to textiles/fibres from the ESD for PT19 have not been performed, as the manufacturing site of the product is located outside the EU borders. If the manufacturing site of the product is relocated to within the borders of the EU, the assessment should be performed.

2.2.7.1 Effects assessment on the environment

In the environmental exposure assessment, two scenarios are assessed. Both scenarios account for service life.

- 1) Emissions due to washing / cleaning of factory-treated bednets. The largest and smallest bednet is applied for the calculation.
- 2) No emissions from washing / cleaning (on the assumption that the suggested recommendation saying "must not be washed" is followed).

For both scenarios, the average consumption-based approach is applied.

The assessment is based on the active substance, including relevant metabolites, as there has not been submitted any effect studies regarding the product, and as there is no substance of environmental concern in the product.

¹¹ Richardson, J.A. (2000) Permethrin Spot On Toxicoses in Cats, The journal of Veterinary Emergency and critical care.

Summary table on calculated PNEC values from the Assessment Report of permethrin			
<i>Compartment</i>	<i>Permethrin</i>	<i>DCVA</i>	<i>PBA</i>
STP	0.00495 mg/L	Not relevant, permethrin is not degraded in the STP.	Not relevant, permethrin is not degraded in the STP.
Surface water	0.00047 µg/L	0.015 mg/L	0.010 mg/L
Sediment	0.000217 mg/kg wwt	0.055 mg/kg dwt (0.012 mg/kg wwt)	0.042 mg/kg dwt (0.009 mg/kg wwt)
Soil	0.198 mg/kg dwt* (0.175 mg/kg wwt)*	4.6 mg/kg wwt	1.44 mg/kg wwt
Oral bird	16.7 mg/kg food		
Small mammal	120 mg/kg food		

*As decided on the 22nd Coordination Group meeting

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

Permethrin is the only substance in the biocidal product that has an environmental classification. Permethrin has a harmonised classification as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with m-factors equal to 100 and 10000 respectively according to the assessment report for permethrin (IE, 2014). The harmonised classification of permethrin is H400 and H410 both with m-factors of 1000, hence a worstcase of Aquatic Acute 1 (H400) m-factor = 1000 and Aquatic Chronic (H410) m-factor = 10000 was used for the classification of this product. The impregnation fluid contains 0.99 % permethrin and a classification of H400 and H410 is therefore triggered by permethrin alone.

Christiansen LD bednet does not contain any substances of concern for the environment according to Article 3(f) of Regulation (EU) No. 528/2012, for further information see the confidential annex 3.7.2.

A co-formulant is considered a SoC if it has known or possible endocrine-disrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information. Thus Christiansen LD Bednet is not considered to having endocrine-disrupting properties (see confidential annex section 3.7.3 for full evaluation).

Further ecotoxicological studies

No specific eco-toxicological studies have been made with Christiansen LD bednet and therefore no new data are available. The data below apply to the active ingredient permethrin.

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

Christiansen LD bednet is only to be used indoor and not to be washed. Accordingly the use may only result in negligible emission to soil, sewage treatment plants, surface water,

groundwater, and sediment. Due to the low vapour pressure of permethrin volatilization of permethrin is considered to be negligible and therefore the air compartment is not considered further.

However if the instructions of "Do not wash" are not followed, an emission to sewage treatment plants may occur. Therefore the emission is estimated for this scenario below.

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 intended indoor use of the product gives no reason to believe that risk should occur for bees.

2.2.7.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Emissions due to washing/cleaning of factory-treated bednets - For the largest bednet - For the smallest bednet Scenario 2 (Non washing): Emissions due to non-washing of factory-treated bednets (including risk mitigation measure)
ESD(s) used	A suitable scenario was not identified in the available emission scenario document for Product Type 18. This provides only tonnage-based approach. A scenario was identified in the emission scenario document for Product Type 19: Emission scenarios for repellents and attractants (ECHA, 2015).
Approach	Scenario 1: Average consumption-based approach. Scenario 2 (Non washing): Average consumption-based approach.
Distribution in the environment	Calculated based on Vol IV ENV Part B+C (2017)
Groundwater simulation	Simulation for leaching to groundwater using the FOCUS models was performed.
Confidential Annexes	No
Life cycle steps assessed	Scenario No 1 and 2: Production: No Formulation: No Use: No Service life: Yes
Remarks	No

Biocidal product specific data

A washing study was performed on net pieces representative of the mosquito nets put on the market. In all cases, the retention of active substance was higher than 88%. On average 3.08 % of the active substance leached out at each washing of the net (RE-15-U10-24150).

For the environmental risk assessment, a worst-case assumption of 12 % emission from each wash was assumed – Fwater = 0.12.

The biocidal product is marketed in different shapes and sizes. All types of the biocidal product contains 0.027 mg AS / cm², because all are impregnated with 9 g/kg AS and 1 m² of net weigh 30 g for all types of nets.

Example:

$$1 \text{ m}^2 \text{ net} * 30 \text{ g/m}^2 = 30 \text{ g}$$

$$30 * 9 \text{ g/kg AS} / 1000 = 0.27 \text{ g AS} / \text{net}$$

$$0.27 \text{ g AS} / \text{net} / 1 \text{ m}^2 = 0.27 \text{ g AS} / \text{m}^2$$

Calculations have been made for the individual designs of bednet. The treated area of bednet washed per day (AREAbednet) is calculated from the largest (212,000 cm²/d) and smallest (24,000 cm²/d) size of bednet applied for.

Fate and distribution in exposed environmental compartments

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

(Yes): indicates indirect exposure

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	391.29	g/mol	
Melting point	33-35	°C	(Tagros)
Boiling point	305	°C	(Tagros)
Vapour pressure (at 20°C)	2.155e-06	Pa	(Tagros)
Water solubility (at 20°C)	1.8E-01	mg/l (20 °C)	(Tagros)
Log Octanol/water partition coefficient	4.67	---	(Tagros)
Organic carbon/water partition coefficient (Koc)	26930	l/kg	
Henry's Law Constant (at X C)[if measured data available]	4.6E-03	Pa/m ³ /mol	(Tagros)
Biodegradability	Not readily biodegradable		
DT ₅₀ for hydrolysis in surface water	Hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively.	d (at 25°C /pH: 9.6)	(Bayer/Sumitomo – Worstcase compared to Tagros data)

	At pH 9.6 and 25°C : 35 and 42 days (cis and trans respectively)		
DT ₅₀ for photolysis in surface water	6.42E+05	d	(Tagros)
DT ₅₀ for degradation in soil	106	d (at 12°C)	(Bayer/Sumitomo – Worstcase compared to Tagros data)
DT ₅₀ for degradation in air	0.701	d	Based respectively on a 12-hour day with hydroxyl radical concentration of 1.5e6 radicals/cm ³ and on a 24-hour day with hydroxyl radical concentration of 5e5 radicals/cm ³
BCF fish	500 - 570	L/kg	
BCF earthworms	15108	L/kg _{wwt}	

Emission estimation**Scenario 1****The largest bednet.**

Values which are provided in the emission scenario are identified as "Default value".
Values which are provided by the Applicant dataset are identified by "Set value".

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: Emissions due to washing / cleaning of factory-treated bednets			
Number of inhabitants feeding one sewage treatment plant (Nlocal)	10,000	cap	Default value
Fraction released to wastewater (Fwater)	0.12	dimensionless	Set value
Quantity of active ingredient in the garment related to surface area (Qas)	0.027	mg/cm ²	Set value
Treated area of bednets washed per day (AREAbednet)	212,000	cm ² /d	Set value
Fraction of inhabitants using the product (Finh)	0.01	dimensionless	Default value
Market share (Fpenetr)	0.5	dimensionless	Default value

Calculations for Scenario 1:

$$E_{\text{localwater}} = N_{\text{local}} * F_{\text{water}} * Q_{\text{as}} * A_{\text{REAbednet}} * F_{\text{inh}} * F_{\text{penetr}} * 10^{-6}$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (Elocal_{compartment}) [kg/d]	Remarks
STP	3.4E-02	

Smallest bednet

Values which are provided in the emission scenario are identified as "Default value".
Values which are provided by the Applicant dataset are identified by "Set value".

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: Emissions due to washing / cleaning of factory-treated bednets			
Number of inhabitants feeding one sewage treatment plant (Nlocal)	10,000	cap	Default value
Fraction released to wastewater (Fwater)	0.12	dimensionless	Default value Set value
Quantity of active ingredient in the garment related to surface area (Qas)	0.027	mg/cm ²	Set value

Treated area of bednets washed per day (AREAbednet)	24,000	cm ² /d	Set value
Fraction of inhabitants using the product (Finh)	0.01	dimensionless	Default value
Market share (Fpenetr)	0.5	dimensionless	Default value

Calculations for Scenario 1:

$$E_{\text{localwater}} = N_{\text{local}} * F_{\text{water}} * Q_{\text{as}} * \text{AREAbednet} * F_{\text{inh}} * F_{\text{penetr}} * 10^{-6}$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (E _{localcompartment}) [kg/d]	Remarks
STP	3.89E-03	

Scenario No 2 (Non washing)

Values which are provided in the emission scenario are identified as "Default value".
Values which are provided by the Applicant dataset are identified by "Set value".

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario: Emissions due to no washing of factory-treated bednets			
Number of inhabitants feeding one sewage treatment plant (N _{local})	10,000	cap	Default value
Fraction released to wastewater (F _{water})	0	dimensionless	Set value
Quantity of active ingredient in the garment related to surface area (Q _{as})	0.027	mg/cm ²	Set value
Treated area of bednets washed per day (AREAbednet)	212,000	cm ² /d	Set value
Fraction of inhabitants using the product (F _{inh})	0.01	dimensionless	Default value
Market share (F _{penetr})	0.5	dimensionless	Default value

Calculations for Scenario:

$$E_{\text{localwater}} = N_{\text{local}} * F_{\text{water}} * Q_{\text{as}} * \text{AREAbednet} * F_{\text{inh}} * F_{\text{penetr}} * 10^{-6}$$

Resulting local emission to relevant environmental compartments		
Compartment	Local emission (E _{localcompartment}) [kg/d]	Remarks
STP	0	

In order to mitigate the risk of emission to the environment of the active ingredient, it is recommend that the bednet is not washed.

Calculated fate and distribution in the STP	
Compartment	Percentage [%]
Air	0.0014
Water	26.19
Sludge	73.81
Degraded in STP	0

Fate and distribution in STP were estimated with EUSES 2.2.0, which uses Simpletreat 4.0.

Calculated PEC values

Predicted environmental soil, water, sediment and groundwater concentrations were calculated with EUSES 2.2.0.

Summary table on calculated PEC values								
	PEC _{STP}	PEC _{water}	PEC _{sed}	PEC _{seawater}	PEC _{seased}	PEC _{soil}	PEC _{GW}	PEC _{air}
	[mg/L]	[mg/L]	[mg/kg _{wwt}]	[mg/L]	[mg/kg _{wwt}]	[mg/kg _{wwt}]	[µg/L]	[mg/m ³]
Scenario 1								
Largest Bednet	4.49E-03	4.32E-04	2.53E-01	Not assessed	Not assessed	Agri (Eco) (30)=4.57E-02 Agri (180) =2.96E-02 Grass (180) = 1.18E-02	6.23E-02	Not assessed
Smallest Bednet	5.09E-04	4.89E-05	2.87E-02	Not assessed	Not assessed	Agri (Eco) (30)=5.18E-03 Agri (180) = 3.35E-03 Grass (180) =1.34E-03	7.05E-03	Not assessed
Scenario 2	0	0	0	Not assessed	Not assessed	0	0	Not assessed

Predicted environmental concentrations for the metabolites of permethrin

Parameters for calculation of PEC metabolites

	DCVA	PBA
Molecular weight [g/mol]	209.07	214.22
Molecular correction factor	0.534	0.548
K _{soil-water} (m ³ /m ³)	1.17	3.75
Max. occurrence in soil degradation studies	11.3 %	15.0 %
Max. occurrence in water compartment	62.6 %	28.8 %

Max. occurrence in sediment compartment	21.7 %	16.4 %
DT50 soil	175 d (12 °C)	2.5 d (12 °C)
Koc	37.55 l/kg	188.53 l/kg

Predicted environmental water and sediment metabolite concentrations can be calculated by multiplying the PEC of the parent by a correction factor for the molecular weight and considering the highest percentage of metabolite occurrence (from water and sediment degradation studies).

The PEC soil and PEC groundwater for metabolites were calculated according to the "Exposure assessment of metabolites in the terrestrial compartment" document (TAB ENV 10, version 2.1, December 2019)

Summary table on calculated PEC values for metabolites								
	PEC _{STP}	PEC _{water}	PEC _{sed}	PEC _{seawater}	PEC _{seas}	PEC _{soil}	PEC _{GW}	PEC _{air}
	[mg/L]	[mg/l]	[mg/kg _{wwt}]	[mg/l]	[mg/kg _{wwt}]	[mg/kg _{wwt}]	[µg/l]	[mg/m ³]
Scenario 1								
DCVA (Largest Bednet)	Permethrin is not degraded in STP	1.44E-04	2.93E-02	Not assessed	Not assessed	Agri (eco) (30) = 6.81E-03 Agri (180) = 5.17E-03 Grass (180) = 1.03E-03	7.51E+00	Not assessed
DCVA (smallest Bednet)	Permethrin is not degraded in STP	1.63E-05	3.40E-03	Not assessed	Not assessed	Agri (eco) (30) = 7.71E-04 Agri (180) = 5.85E-04 Grass (180) = 3.27E-04	8.50E-01	Not assessed
PBA (Largest Bednet)	Permethrin is not degraded in STP	6.82E-05	2.27E-02	Not assessed	Not assessed	Agri (eco) (30) = 9.03E-04 Agri (180) = 1.51E-04 Grass (180) = 3.01E-05	6.83E-02	Not assessed
PBA (smallest Bednet)	Permethrin is not degraded in STP	7.72E-06	2.58E-03	Not assessed	Not assessed	Agri (eco) (180) = 1.02E-04 Agri (180) = 1.70E-05 Grass (180) = 3.41E-06	7.73E-03	Not assessed
Scenario 2 (Non washing)	0	0	0	Not assessed	Not assessed	0	0	Not assessed

FOCUS pearl refinements

The PEC groundwater for DCVA for the largest and smallest size bednet exceeded the maximum permissible concentration in groundwater of 0.1 µg/l. A refinement of the PEC's that exceeded the threshold was performed using FOCUS PEARL.

PEC_{GW} - FOCUS PEARL refined

	Permethrin [µg/l]	DCVA [µg/l]
Largest bednet	< 1.00E-06*	< 1.00E-06
Smallest bednet	< 1.00E-06*	< 1.00E-06

*The FOCUS PEARL refinement was also performed for permethrin as more accurate result are achieved when modelling the parent and metabolite in the same simulation.

Primary and secondary poisoning

Primary poisoning

Due to the exclusive indoor use of Christiansen LD Bednet, the environment is not directly exposed to the biocidal product. Therefore primary poisoning is not relevant for the biocidal product Christiansen LD Bednet, and has not been assessed.

Secondary poisoning

Secondary poisoning of birds and small mammals are only considered for the parent compound permethrin as neither DCVA nor PBA has potential for bioaccumulation in the food chain. They are less lipophilic substances with a logKow's of ≈ 1.8 and 2.7 respectively and are less toxic. The half-lives for degradation in water/soil are 94.4 days/175 days for DCVA and 63.3/2.5 for PBA.

Input parameters for Permethrin		
	Value	Unit
BCF fish	570	l/kg
BMF	1	-
BCF earthworm	15108	l/kg wwt earthworm

In the Guidance on BPR Vol IV Part B+C (2017), a scenario where 50% of the diet comes from a local area and 50% of the diet comes from a regional area is the most appropriate for the assessment.

Calculated PEC values		
	PEC_{oral, predator} (mg/kg wet fish)	PEC_{oral, predator} (mg/kg wet earthworm)
Scenario 1		
Largest bednet	0.123	0.424
Smallest bednet	0.014	0.048
Scenario 2 (Non washing)	0	0

2.2.7.3 Risk characterisation

Atmosphere

Conclusion: Due to the properties of the active substance permethrin, air is not considered a relevant compartment for the risk assessment of Christiansen LD Bednet.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC _{STP}
Scenario 1	
Largest bednet	0.91
Smallest bednet	0.103
Scenario 2 (Non washing)	0

Conclusion: In a situation where wet washing of mosquito nets is assumed (see scenario 1), the risk for the STP is acceptable since the PEC/PNEC ratios are below 1.

Aquatic compartment

Calculated PEC/PNEC values		
	PEC/PNEC _{water}	PEC/PNEC _{sed}
Scenario 1		
Largest bednet	919.15	1165.90
Smallest bednet	104.1	132.2
Scenario 2 (Non washing)	0	0

Conclusion: In the situation where wet washing of mosquito nets is assumed (see scenario 1), the risk for the environment is not acceptable since the PEC/PNEC ratios are above 1. For controlling the risk at an acceptable level (PEC/PNEC below 1), the nets must not be washed is required on product labels (see scenario 2).

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC _{soil}
Scenario 1	
Largest bednet	0.26
Smallest bednet	0.03
Scenario 2 (Non washing)	0

Conclusion: In a situation where wet washing of mosquito nets is assumed (see scenario 1), the risk for the soil compartment is acceptable since the PEC/PNEC ratios are below 1.

Groundwater

Calculated PEC values	
	PEC _{GW} (µg/L)
Scenario 1	
Largest bednet	6.23E-02
Smallest bednet	7.05E-03
Scenario 2 (Non washing)	

The maximum permissible concentration in groundwater laid down by Directive 98/83/EC is 0.1 µg/l.

No unacceptable risk was found for permethrin in any scenario, as the calculated concentration did not exceed the maximum permissible concentration, however a risk was found for the metabolite DCVA, hence a FOCUS PEARL refinement was performed.

Conclusion: After refinement with FOCUS PEARL no risk is found in the groundwater compartment for any substance (parent or metabolite).

Primary and secondary poisoning

Primary poisoning

Due to the exclusive indoor use of Christiansen LD Bednet, the environment is not directly exposed to the biocidal product. Therefore, primary poisoning is not relevant for the biocidal product Christiansen LD Bednet and has not been assessed.

Secondary poisoning

Secondary poisoning of birds and small mammals were only considered for the parent compound permethrin as neither DCVA nor PBA has potential for bioaccumulation in the food chain.

Calculated PEC/PNEC values				
	PEC _{oral, predator} (mg/kg wet fish)		PEC _{oral, predator} (mg/kg wet earthworm)	
Scenario 1				
	Fish	Small Mammal	Fish	Small Mammal
Largest bednet	0.007	0.001	0.025	0.004
Smallest bednet	<0.001	<0.001	0.003	<0.001
Scenario 2 (Non washing)	0	0	0	0

Conclusion: The risk of secondary poisoning is acceptable for permethrin for all scenarios.

Metabolites – PEC/PNEC

Summary table on calculated PEC/PNEC values – Metabolite DCVA

	PEC/PNEC _{water}	PEC/PNEC _{sed}	PEC/PNEC _{STP}	PEC/PNEC _{soil}	PEC _{GW}
Scenario 1					
Largest bednet	0.010	2.443	Not assessed	0.001	<0.001*
Smallest bednet	0.001	0.283	Not assessed	<0.001	<0.001*
Scenario 2 (Non washing)	0	0	Not assessed	0	0

*PEC value is refined with FOCUS PEARL.

Summary table on calculated PEC/PNEC values – Metabolite PBA					
	PEC/PNEC _{water}	PEC/PNEC _{sed}	PEC/PNEC _{STP}	PEC/PNEC _{soil}	PEC _{GW}
Scenario 1					
Largest bednet	0.007	2.526	Not assessed	<0.001	0.068
Smallest bednet	0.001	0.287	Not assessed	<0.001	<0.008
Scenario 2 (Non washing)	0	0	Not assessed	0	0

Conclusion: In a situation where wet washing of mosquito net is assumed (see scenario 1) the risk for the environment is not acceptable for both metabolites for the largest size mosquito net, as the risk quotient for sediment is > 1.

For the metabolite DCVA there was also an unacceptable risk in groundwater, however the refinement of PEC groundwater with FOCUS PEARL shows no risk for DCVA in groundwater.

For controlling the risk in the sediment compartment, the nets must not be washed (see scenario 2).

Mixture toxicity

The product contains only one active substance (permethrin). Therefore an assessment of mixture toxicity is not relevant.

Aggregated exposure (combined for relevant emission sources)

There is no aggregated exposure foreseen, as the product are only to be used indoor and is not to be washed. Therefore, an assessment of aggregated exposure is not relevant.

Overall conclusion on the risk assessment for the environment of the product

On the basis of the calculations made with the environmental risk assessment, the risk is acceptable for the STP and terrestrial compartment since the PEC/PNEC ratio is below 1 for both Permethrin and its metabolites. For the groundwater compartment no unacceptable risk was found for any substance after refinement with FOCUS PEARL on the metabolite DCVA.

For the aquatic compartment and sediment it was stated that: In the situation where wet washing of mosquito nets is assumed (see scenario 1), the risk for the environment is not acceptable since the PEC/PNEC ratios are above 1. So, for controlling the

risk at an acceptable level (PEC/PNEC below 1), the nets must not be washed (see scenario 2).

For controlling the risk at an acceptable level, the nets must not be washed (see scenario 2)

2.2.8 Measures to protect man, animals and the environment

2.2.8.1 Recommended methods and precautions concerning handling, use, storage, disposal, transport or fire

Handling

- Aeration of the mosquito net before use is recommended.
- Keep out of the reach of children and pets when not in use.
- Keep cats away from the product. Due to their particular sensitivity to permethrin, the product can cause severe adverse reactions in cats.
- Wash hands after setting up the net and taking the net down.
- DO NOT WASH OR DRY CLEAN PRODUCT.
- Do not pollute water with product or packaging.
- Keep away from food, drinks and animal stuffs.

Use

- Observe the label precautions.
- Avoid contact with skin and eyes.
- Domestic animals such as a cat should not sleep in the presence of the impregnated mosquito net.
- Keep cats away from the product due to high sensitivity to permethrin toxicity.
- Keep container closed when not in use.
- Use only indoors

Storage

- Observe the label precautions.
- Keep out of reach of children and pets (particularly cats).
- Keep container tightly closed.
- Storage condition(s): Store in original container.
- Keep in the dark.
- Store away from direct sunlight or other heat sources.
- Product is stable for 3 years from production date, at room temperature.
- Store separately from oxidizing agents and strongly alkaline and strongly acidic materials.
- Packaging / tank material: Plastic packaging is recommended.

Disposal

- May not be disposed of in sewers, including rainwater canals.
- Dispose of contents to hazardous waste.

Transport

- Transport followed: ADR, IMDG, IATA.
- Comply with special provision 335 of ADR and the IMDG:
- Contains: < 10g of an environmentally hazardous liquid

Fire

- Extinguishing media: dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂), water spray, sand, earth.
 - Special hazards arising from the substance or mixture: Fire will produce dense black smoke.
 - In case of fire, corrosive and harmful gases come free.
- Advice for firefighters: Use a self-contained breathing apparatus and also a protective suit.
- Specific method(s): If an area is heavily exposed to fire and if conditions permit, let fire burn itself out because water may increase the area contaminated.
 - Extinguishing media which must NOT be used for safety reasons:
 - Do not use a solid water stream as it may scatter and spread fire.
 - Do not allow run-off from firefighting to enter drains or water courses.
 - Hazardous decomposition products:
Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide.

First aid measures

- 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.

Emergency measures to protect the environment

Release to the environment, water, groundwater, soil is forbidden. Dispose of contents to hazardous waste. If the product enters drains or sewers, the local water company should be contacted immediately; in the case of contamination of streams, rivers or lakes, contact national authorities.

This product MUST NOT be washed, due to risks to the environment.

Methods and material for containment and cleaning up:

Shovel into suitable and closed container for disposal.

Dispose as hazardous waste.

2.2.9 Assessment of a combination of biocidal products

The product is not intended to be authorised for the use with other biocidal products.

2.2.10 Comparative assessment

Since the active substance included in this formulation is not considered to be a substance for substitution or exclusion, no comparative assessment has to be performed. See section 2.1.2.2 for more information.

3 Annexes

3.1 Output tables from exposure assessment tools

Human health

3.1.1.1 Dermal exposure – surface area

The figures for potential surface area in contact with the net shown below have been estimated using data on skin surface areas of parts of the body adapted from Recommendation 14 and "Child-specific exposure factors handbook (final report)" (2008), assuming that the trunk, hands, arms, lower legs (except for newborns, where the value for surface area is for the whole leg, since no value for lower leg is available for newborns) and feet are uncovered, and that 1/3 (33.3 %) (WHO 2nd edition (2018)) of their total surface area could be in contact with the net.

	Unit	Newborn ²	Infant ¹	Toddler ¹	Young child ¹	Child ¹	Adult ¹
% bodysurface contact with net		33.3 % ³					
Hands	cm ²	150	198,8	230.4	330.9	427.8	820
Arms		400	582,2	681.6	945.2	1269.6	2270
Trunk		1040	1689,2	1977.6	2774.4	3624.8	5940
Lower legs (except for newborns where it is the whole leg)		Whole leg = 600	459,2	537.6	748	1090.2	2132
Feet		190	246	288	428.4	604.9	1130
Total			793.33	1058.47	1238.40	1742.30	2339.10
Total	m ²	0.08	0.11	0.12	0.17	0.23	0.41

¹ Recommendation 14 "Default human factor values for use in exposure assessments for biocidal products"

² Child-specific exposure factors handbook (final report)

³ WHO 2nd Edition, 2018 "A generic risk assessment model for insecticide-treated nets"

3.1.1.2 Examples of calculations for the exposure assessment

Scenario 1 – inhalation – adult

$$SysD_{inh} = \frac{Abs_{inh} \cdot C_{air} \cdot BV \cdot H}{BW} = \frac{1 \cdot (1.01 \cdot 10^{-3} \cdot 270 \cdot 2.155) \left[\frac{\mu g}{m^3} \right] \cdot 0.67 \frac{m^3}{h} \cdot 9h}{60kg} = \frac{1 \cdot 5.88 \cdot 10^{-1} \frac{\mu g}{m^3} \cdot 0.67 \frac{m^3}{h} \cdot 9h}{60kg} = 5.9 \cdot 10^{-2} \frac{\mu g}{kg} = 5.9 \cdot 10^{-5} \frac{mg}{kg}$$

Scenario 1 – dermal absorption – adult

$$SysD = \frac{Abs_D \cdot Transl \cdot ESA \cdot SF \cdot TC}{BW} = \frac{0.03 \cdot 0.06 \cdot 0.41m^2 \cdot 0.12 \cdot 270 \frac{mg}{m^2}}{60 kg} = 4.0 \cdot 10^{-4} \frac{mg}{kg}$$

Scenario 1 – hand-to-mouth transfer – toddler

$$SysD_{HM} = \frac{Abs_O \cdot SE \cdot Transl \cdot EHA \cdot FHM \cdot SF \cdot TC}{BW} = \frac{1 \cdot 0.57 \cdot 0.06 \cdot 0.008m^2 \cdot 0.164 \cdot 0.12 \cdot 270 \frac{mg}{m^2}}{10kg} = 1.5 \cdot 10^{-4} \frac{mg}{kg}$$

Scenario 1 – mouthing – toddler

$$SysD_M = \frac{Abs_O \cdot SE \cdot NM \cdot SF \cdot TC}{BW} = \frac{1 \cdot 0.57 \cdot 0.0014m^2 \cdot 0.12 \cdot 270 \frac{mg}{m^2}}{10kg} = 2.6 \cdot 10^{-3} \frac{mg}{kg}$$

Scenario 1 – total exposure

Exposure	Unit	Adults	Child	Young child	Toddler	Infant	Newborn
Systemic inhalation exposure	mg/kg	5.9E-05	1.2E-04	1.6E-04	2.3E-04	2.2E-04	2.4E-04
Systemic dermal exposure	mg/kg	3.7E-03	5.2E-03	5.9E-03	6.5E-03	7.5E-03	9.1E-03
Systemic hand-to-mouth transfer	mg/kg	0.0E+00	0.0E+00	0.0E+00	1.5E-04	1.6E-04	1.9E-04
Systemic mouthing	mg/kg	0.0E+00	0.0E+00	0.0E+00	2.6E-03	3.2E-03	5.4E-03
Combined exposure	mg/kg	3.8E-03	5.4E-03	6.1E-03	9.5E-03	1.1E-02	1.5E-02

Scenario 2 – exposure through breast milk – infant

$$SysD_{MM} = \frac{SolC \cdot DoseM \cdot T^{1/2} \cdot IR \cdot Abs_O}{BW} = \frac{0.361 \cdot 4.6 \cdot 10^{-4} \frac{mg}{kg} \cdot 5.2 \cdot 10^{-1} \cdot 0.66 kg \cdot 1}{8kg} = 7.0 \cdot 10^{-6} \frac{mg}{kg}$$

3.1.1.3 Calculations for the risk characterisation

Scenario 1

Exposure	Unit	Adults	Child	Young child	Toddler	Infant	Newborn
Combined exposure	mg/kg	4,6E-04	6,8E-04	7,9E-04	3,7E-03	4,4E-03	6,8E-03
AEL_{medium term}	mg/kg	0.05	0.05	0.05	0.05	0.05	0.05
%AEL	%	0,9	1,4	1,6	7,3	8,8	13,6
Acceptabel	Yes/No	Yes	Yes	Yes	Yes	Yes	Yes

Scenario 2

Exposure½	Unit	Infant	New born
Combined exposure	mg/kg	7.0E-06	1.2E-06
AEL_{medium term}	mg/kg	0.05	0.05
%AEL	%	0.01	0.02
Acceptable	Yes/No	Yes	Yes

3.2 Environment: FOCUS PEARL modelling

FOCUS PEARL modelling:

The transformation scheme for permethrin in soil considered 11.3 % transformation to DCVA in accordance with the Technical Agreements for Biocides (TAB) Environment (ENV) entry number 10 (Version 2.1, December 2019).

The Simulation model FOCUS PEARL 4.4.4 is used for the refinement of the environmental exposure assessment of metabolite DCVA in the groundwater compartment for scenario 1.

Input parameters for modelling with FOCUS PEARL			
Input			Remarks
Application rate of a.s. permethrin	155.55 (Arable)) g/ha/year	31.11 (Grassland) g/ha/year	Scenario 1 – Largest Bednet
Number of applications	1 (20 days before emergence – Incorporation into soil)	1 (1 st . of March – Incorporation into soil)	
Crop	Arable (Maize and Winter Cereals)	Grassland (alfalfa)	
FOCUS PEARL Parameters	Permethrin	DCVA	
Molecular weight [g/mol]	391.29	209.07	
Water solubility [mg/L]	0.18 (20°C)	127.6 (25°C)	
Vapour pressure [Pa]	2.16E-06 (20°C)	0.26 (°25)	
<u>Transformation</u>			
half life DT ₅₀ [d]	106 (12°C)	175 (12°C)	
Formulation fraction (f _{ij})		0.113	TAB ENV 10 (2.1, December 2019)
plant uptake factor	0	0	
Interception by plants	No	No	
Koc [l/kg]	26930	37.55	
Kom=Koc/1.724	15620.7	21.78	
Freundlich exponent	1.09	0.65	
Molar activation energy	65.4	65.4	TAB ENV 23 (2.1, December 2019)

For the calculation of PEC groundwater, the following application scheme is used: Sewage Sludge Application on soil. In case of running sewage sludge application scenarios in FOCUS groundwater models it was agreed at WG-II-2014 that both grassland (alfalfa) and agricultural land (maize) should be used. In case of grassland application, the scenario considers one sewage sludge application per year on 1st of March (absolute application) and 10 cm incorporation depth. In case of agricultural land application, the scenario considers one sewage sludge application per year to maize and winter cereals 20 days before crop event "emergence" (relative application) and 20 cm incorporation depth.

LOCATION	Permethrin [$\mu\text{g/L}$]		
	Arable land		Grassland
	Winter cereals	Maize	Alfalfa
CHATEAUDUN	0.000000	0.000000	0.000000
HAMBURG	0.000000	0.000000	0.000000
JOKIOINEN	0.000000	-	0.000000
KREMSMUNSTER	0.000000	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000	0.000000
PIACENZA	0.000000	0.000000	0.000000
PORTO	0.000000	0.000000	0.000000
SEVILLA	0.000000	0.000000	0.000000
THIVA	0.000000	0.000000	0.000000

LOCATION	DCVA [$\mu\text{g/L}$]		
	Arable land		Grassland
	Winter cereals	Maize	Alfalfa
CHATEAUDUN	0.000000	0.000000	0.000000
HAMBURG	0.000000	0.000000	0.000000
JOKIOINEN	0.000000	0.000000	0.000000
KREMSMUNSTER	0.000000	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000	0.000000
PIACENZA	0.000000	0.000000	0.000000
PORTO	0.000000	0.000000	0.000000
SEVILLA	0.000000	0.000000	0.000000
THIVA	0.000000	0.000000	0.000000

The FOCUS PEARL simulations were performed on the small bednet as well, because the DCVA metabolite exceeded the concentration limit of 0.1 $\mu\text{g/L}$ in this scenario as well. The application for permethrin on grassland and arable land in this scenario is 3.52 and 17.61 g/ha/year respectively.

The results for the small size bednet is as follows:

LOCATION	Permethrin [$\mu\text{g/L}$]		
	Arable land		Grassland
	Winter cereals	Maize	Alfalfa
CHATEAUDUN	0.000000	0.000000	0.000000
HAMBURG	0.000000	0.000000	0.000000
JOKIOINEN	0.000000	-	0.000000
KREMSMUNSTER	0.000000	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000	0.000000
PIACENZA	0.000000	0.000000	0.000000
PORTO	0.000000	0.000000	0.000000
SEVILLA	0.000000	0.000000	0.000000
THIVA	0.000000	0.000000	0.000000

LOCATION	DCVA [$\mu\text{g/L}$]		
	Arable land		Grassland
	Winter cereals	Maize	Alfalfa
CHATEAUDUN	0.000000	0.000000	0.000000
HAMBURG	0.000000	0.000000	0.000000
JOKIOINEN	0.000000	0.000000	0.000000
KREMSMUNSTER	0.000000	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000	0.000000
PIACENZA	0.000000	0.000000	0.000000
PORTO	0.000000	0.000000	0.000000
SEVILLA	0.000000	0.000000	0.000000
THIVA	0.000000	0.000000	0.000000

3.3 List of studies for the biocidal product

Christiansen LD bednet Data Sources:

Legal entity owner for all references listed below is Christiansen SARL							
Author	Year	Title	Bibliographic source	Testing laboratory	Report no.	Endpoint names	Endpoint UUID's
██████████ ██████████ ██████████ ██████████	2015	Assessment of the insecticide efficacy of an anti-mosquito impregnated bednet, Tunnel test		T.E.C. LABORATORY, 1 rue Jules Védrines - ZAC Maignon, F-64600 Anglet	Study no 2003/101 5R	n/a	
██████████	2016	Test report, Final report (Identity test, content and isomer cis:trans ratio, accelerated storage test, Wash resistance index)		Walloon Agricultural Research Centre, (CRA-W), Agriculture And Natural Environment Department (D3), Plant Protection Products And Biocides Physico-Chemistry And Residues Unit (U10), Carson Building, Rue du Bordia, 11, B-5030 Gembloux, Belgium	Report No RE/15/U10/24150	3.4.1. 5 6.1 6.7 10.1	IUC5-d1738b37-bf90-493b-b85a-35fcb22b4a6f IUC5-3fa6f767-538d-45e7-a776-4669f4a74391 IUC5-78f2ea4c-a6b9-4b7a-395-58b709d0015b IUC5-623e60e3-33de-488f-86e2-553dad18eeb2 IUC5-045714a5-9edb-db9-9eb6-7f050f17ddeb
██████████	2016	Mosquito Bednets incorporating Permethrin – Environmental Risk Assessment		Consultancy for Environmental & Human Toxicology & Risk Assessment, CEHTRA SAS, (Bordeaux Agency), 43 Rue Laroque,	Report No CFR-16.023	9 9.2	IUC5-70e5eebe-522a-43c6-a78b-a6dd1443d81e IUC5-7f13c898-f136-4062-90e1-66fcc6afe3db IUC5-1286ef21-b5be-4069-9f32-08333aba572f

				33560 Sainte-Eulalie FRANCE		9.2.2.1 10.1	IUC5-045714a5-9edb-4db9-9eb6-7f050f17ddeb
██████████ ██████████ ██████████	2016	ASSESSMENT OF THE INSECTICIDE EFFICACY OF AN ANTI-MOSQUITO IMPREGNATED FABRIC – TRIAL AFTER TWO YEARS OF STORAGE		T.E.C. LABORATORY, 1 rue Jules Védrines - ZAC Maignon, F-64600 Anglet	Report No 1716-2Y/0114	3.4.1. 6.7	IUC5-d1738b37-bf90-493b-b85a-35fcb22b4a6f IUC5-623e60e3-33de-488f-86e2-553dad18eeb2
██████████ ██████████	2017	ASSESSMENT OF THE INSECTICIDE EFFICACY OF AN ANTI-MOSQUITO IMPREGNATED BEDNET – BEDNET CHRISTIANSEN – AFTER THREE YEARS OF STORAGE		T.E.C. LABORATORY, 1 rue Jules Védrines - ZAC Maignon, F-64600 Anglet	Report No 1716-3Y/0114	6.7	IUC5-623e60e3-33de-488f-86e2-553dad18eeb2
██████████ ██████████	2017	Ifakara Ambient Chamber Test evaluation of a permethrin long-lasting insecticidal net against insectary reared populations of <i>Anopheles gambiae s.s.</i> and <i>Aedes aegypti</i> in Tanzania		IHI, Ifakara Health Institute, Bagamoyo Branch, Tanzania	BIT019 Technical Report V04	6.7 6.9	IUC5-623e60e3-33de-488f-86e2-553dad18eeb2 UUID: See above For Sec. 6.7
██████████	2017	Interim test report with the same material as test report 24150. Ambient storage test for 1 year plus accelerated storage test for 2 weeks		Walloon Agricultural Research Centre, (CRA-W), Agriculture and Natural Environment Department (D3), Plant Protection Products and Biocides Physico-chemistry and Residues Unit (U10), Carson Building,	Report No RE-16-U10-24292	3.4.1. 6.7	IUC5-d1738b37-bf90493b-b85a-35fcb22b4a6f IUC5-623e60e3-33de-488f-86e2-553dad18eeb2

				Rue du Bordia, 11, B-5030 Gembloux, BELGIUM			
██████████	2016	Material Safety Data Sheet (EN) + (FR) + (GER), MOUSTI-QUAIRES CHRISTIAN-SEN LN		n/a	EC/830/2015	3.1 6.1 6.5	IUC5-a9c79d12-d638-431d-963d-ee51e016fd82 IUC5-78f2ea4c-a6b9-4b7a-b395-58b709d0015b See 6.1.
██████████ █	2017	Christiansen LD – Sizes, Packaging, Brand name (Products with packaging dimensions)		CHRISTIANSEN SARL, 719, Chemin de Repentance, 13100 Aix en Provence, FRANCE	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978
██████████ █	2017 b	Christiansen Technical Specifications Bednet (amended)		CHRISTIANSEN SARL, 719, Chemin de Repentance, 13100 Aix en Provence, FRANCE	n/a	3.1	IUC5-a9c79d12-d638-431d-963d-ee51e016fd82
██████████ ██████████	2018	Test report, 2 nd Interim report (Identity test, content and isomer cis:trans ratio, Ambient storage test, 24 months at 20 degrees C)		Walloon Agricultural Research Centre, (CRA-W), Agriculture And Natural Environment Department (D3), Plant Protection Products And Bio-cides Physico-Chemistry And Residues Unit (U10), Carson Building, Rue du Bordia, 11, B-5030 Gembloux, Belgium	RE/16/U10/24292 second interim report	3.4.1 6.7	IUC5-d1738b37-bf90-493b-b85a-35fcb22b4a6f IUC5-623e60e3-33de-488f-86e2-553dad18eeb2

██████████	2019	Chemical Physical Properties Determination on the test item "Aqueous liquid for Christiansen LD Bed net"		EUROFINS BIOLAB S.R.L. Via B. Buozzi, 2, 20090 Vimodrone (MI), Italy	STULV19 AA0984-1 GLP	3.1 3.2 3.3 3.9	IUC5-a9c79d12-d638-431d-963d-ee51e016fd82 IUC5-729a13b1-7395-451e-8758-3680d74fc8f7 IUC5-b4be5cc5-dd46-4df8-9db9-5fc90da39028 IUC5-b1828f9c-e1bf-4ccd-9259-0b7d85661a66
██████████ ██████████	2019	Verification of the precision of the validated method for the quantification of permethrin in the test item "Aqueous liquid for Christiansen LD Bed Net"		EUROFINS BIOLAB S.R.L. Via B. Buozzi, 2, 20090 Vimodrone (MI), Italy	STULV19 AA0248-1 GLP	5	IUC5-3fa6f767-538d-45e7-776-4669f4a74391
██████████ ██████████	2019	Physico-chemical tests according to GLP		EUROFINS BIOLAB S.R.L. Via B. Buozzi, 2, 20090 Vimodrone (MI), Italy	1016432A 01_1	5	IUC5-3fa6f767-538d-45e7-a776-4669f4a74391
██████████ ██████████	2019 a	Physico-Chemical tests according to GLP		Innovhub - Stazioni Sperimentali Industria S.r.l., Via Galileo Galilei, 1, 20097 San Donato Milanese (MI), Italy	1016431A 01	4.2	IUC5-9c255fb0-7674-4f9a-948c-25063a00aabc
██████████ ██████████	2019 b	Determination of Boiling point and Flash point on the sample Aqueous liquid for Christiansen LD bed net		Innovhub - Stazioni Sperimentali Industria S.r.l., Via Galileo Galilei, 1, 20097 San Donato Milanese (MI), Italy	1901332 GLP Study no. 505	4.2	IUC5-9c255fb0-7674-4f9a-948c-25063a00aabc

██████████ ██████████	2019	Test report (Permethrin content and <i>cis:trans</i> ratio after storage at 20 °C for 36 months)		Walloon Agricultural Research Centre (CRA-W), Carson Building, Rue du Bordia, 11, B-5030 GEMBLoux, Belgium	RE/16/U10/24292 Final_v2	3.4.1 6.7	IUC5-d1738b37-bf90-493b-b85a-35fcb22b4a6f IUC5-623e60e3-33de-488f-86e2-553dad18eeb2
██████████	2020	Verification of specificity of the validated method for the quantification of permethrin in the test item "Aqueous liquid for Christiansen LD Bed Net"		EUROFINS BIOLAB S.R.L. Via B. Buozzi, 2, 20090 Vimodrone (MI), Italy	STULV19 AA5461-1 GLP Cover no 1143404A 01	5	IUC5-3fa6f767-538d-45e7-a776-4669f4a74391
██████████ ██████████	2020	Test report (Permethrin content and <i>cis:trans</i> isomer test and bursting strength test before and after accelerated storage.)		Walloon Agricultural Research Centre (CRA-W), Carson Building, Rue du Bordia, 11, B-5030 GEMBLoux, Belgium	RE/19/U10/25030	3.4.1 6.7	IUC5-d1738b37-bf90-493b-b85a-35fcb22b4a6f IUC5-623e60e3-33de-488f-86e2-553dad18eeb2
██████████	2019	Human Risk Assessment – Christiansen LD – May 2019 version 2		EURION Consulting, Centre for European Regulatory Affairs (CERA) S.A.S.	n/a	8.3.1 8.3.2 8.5.2 8.5.3 8.6 8.7.1	IUC5-b79b888c-637d-4258-9aa7-8ca8ebbbb28e IUC5-9a983521-c8fa-4f36-863c-f35b3046b821 IUC5-23f64aad-365d-4361-8d9e-bdf0fbf9f21d IUC5-f49ea24f-c7c1-457c-b449-4000c7915874 IUC5-fca65059-1f4b-49fc-b3a9-39417ae0978c

							IUC5-10941882-3d72-4a4d-bc77-a53046897a08
██████████	2018	Testing report (quantification)		SGS-CSTC Standards Technical Services (Tianjin) Co. Ltd., No 41, Fifth Avenue, TEDA, Tianjin, China	MNS1800 65TJ	5	IUC5-3fa6f767-538d-45e7-a776-4669f4a74391

Other data sources incl. Letter of Access provided by:

Active ingredient manufacturer and its representative in the Union, Polyester net manufacturer, distribution channel

Author	Year	Title	Bibliographic source	Testing laboratory	Report number	Endpoint names	Endpoint UUIDs
██████████ ██████████	2015	Certificate Of Analysis, Permethrin Technical (25:75)		Tagros General Laboratory, Cuddalore, Tamilnadu, INDIA	FOR / QC / 049	n/a	
██████████	2016	LETTER OF ACCESS TO DATA CONCERNING PERMETHRIN TECHNICAL – PRODUCT TYPE 18		LIMARU N.V., Ziepstraat 5, B 3680 Neeroeteren, BELGIUM, on behalf of Tagros Chemicals India Ltd. Chennai	n/a	5 8.1.1 8.1.2 8.3.1 8.3.2	IUC5-3fa6f767-538d-45e7-a776-4669f4a74391 IUC5-14f333d2-ebe7-4efb-9fb6-2d2ac14e8b1e IUC5-5701b62a-3cd4-49b1-8701-27d244703697 IUC5-b79b888c-637d-4258-9aa7-8ca8ebbbb28e IUC5-9a983521-c8fa-4f36-863c-f35b3046b821 IUC5-328c5ab1-fbf3-

						8.5.1	45b7-b2d4-79975146a574
						8.5.3	IUC5-f49ea24f-c7c1-457c-b449-4000c7915874
						8.6	IUC5-fca65059-1f4b-49fc-b3a9-39417ae0978c
						9.2.1.6	IUC5-b03b303d-7a85-4487-9944-46474efeacf9
						9.2.2.1	IUC5-1286ef21-b5be-4069-9f32-08333aba572f
						9.2.2.2	IUC5-d9dec303-24f0-40bf-839b-8bea883084fb
						9.2.4	IUC5-78ca76d4-2b32-4eb0-b5e7-0c3d90ec26b0
						9.2.6	IUC5-50524adf-b977-4a75-a869-5a3a41afcf8
						9.2.8	IUC5-c6c10547-d0e0-49b9-be23-4811986745f6
Rapporteur: Ireland	2014	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, Evaluation of active substances, Assessment Report, Permethrin, Product-Type 18, (Insecticides, acaricides and products to control other arthropods)		Rapporteur: Ireland (Owner: ECHA)	1342-18	9.2	IUC5-7f13c898-f136-4062-90e1-66fcc6afe3db
						9.2.4	IUC5-78ca76d4-2b32-4eb0-b5e7-0c3d90ec26b0
						9.2.5	IUC5-dee0696b-9ffc-4878-bb34-a9b37b09c938
						9.2.8	IUC5-c6c10547-d0e0-49b9-be23-4811986745f6

Insecticide Resistance Action Committee (IRAC)	2010	Insecticide Mode of Action classification: A key to effective insecticide resistance management in mosquitoes		Insecticide Resistance Action Committee (IRAC) (Owner)	n/a	6.1	IUC5-78f2ea4c-a6b9-4b7a-b395-58b709d0015b
World Health Organisation (WHO)	2015	Conditions for use of long-lasting nets treated with insecticidal nets treated with a pyrethroid and Piperonyl Butoxide		Global Malaria Programme, Evidence Review Group (ERG), World Health Organisation (WHO)	n/a	6.1 6.7	IUC5-78f2ea4c-a6b9-4b7a-b395-58b709d0015b IUC5-623e60e3-33de-488f-86e2-553dad18eeb2
██████████	2010	Polyester PET MSDS		IANGSU HENGLI CHEMICAL FIBRE CO., LTD., No 1 Hengli Road Economic Development Zone of Nanma Shengze Town, Wujiang Suzhou city, Jiangsu province, China, tel 86 512 63837633. (Owner)	n/a	3.1	IUC5-a9c79d12-d638-431d-963d-ee51e016fd82
World Health Organisation (WHO)	2011	WHO Specifications and Evaluations for Public Health Pesticides, Permethrin 25:75 (cis:trans isomer ratio)		FAO/WHO EVALUATION REPORT 331/2010	n/a	3.3. 8.5.2 8.5.3	IUC5-b4be5cc5-dd46-4df8-9db9-5fc90da39028 IUC5-23f64aad-365d-4361-8d9e-bdf0fbf9f21d IUC5-f49ea24f-c7c1-457c-b449-4000c7915874
██████████	2015	Polyester Packing Bag MSDS		Hebei Light Industrial Products Import & Export Group Co., Ltd., 26 Zhongjiu Road,	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978

				Youyi Street N., Shijiazhuang 050071 CHINA, tel. 86 - 311 - 87759850			
██████	2016	Polyethylene Plastic Bag MSDS		Hebei Light Industrial Products Import & Export Group Co., Ltd., 26 Zhongjiu Road, Youyi Street N., Shijiazhuang 050071 CHINA, tel. 86 - 311 - 87759850	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978
██████ (b)	2015	Export Carton MSDS		Hebei Light Industrial Products Import & Export Group Co., Ltd., 26 Zhongjiu Road, Youyi Street N., Shijiazhuang 050071 CHINA, tel. 86 - 311 - 87759850	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978
██████ (c)	2015	Packing inner box MSDS (client marketing box)		Hebei Light Industrial Products Import & Export Group Co., Ltd., 26 Zhongjiu Road, Youyi Street N., Shijiazhuang 050071 CHINA, tel. 86 - 311 - 87759850	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978

██████████	2015	Banderole BANGLA Serie 2 HD		Katadyn France, 5 Rue Gallice, 38100 Grenoble, FRANCE, +33 (0)4.76.96.42.46, www.pharmavoyage.fr, info@katadyn.fr	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978
██████████	2013	Enjoy the tropics without bites (leaflet in packaging)		Katadyn France, 5 Rue Gallice, 38100 Grenoble, FRANCE, +33 (0)4.76.96.42.46, www.pharmavoyage.fr, info@katadyn.fr	n/a	12.3	IUC5-893c2082-e61a-44ca-98fe-8f785b8cb978
██████████ ██████████	2018	Certificate Of Analysis, Permethrin Technical (25:75) (COA)		Tagros General Laboratory, Cuddalore, Tamilnadu, INDIA Owner: LIMARU NV on behalf of Tagros Chemicals India Ltd. Chennai	FOR / QC / 049	n/a	

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)¹²

3.6 Confidential annex

Please see separate confidential annex

3.7 Other

¹² If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.