COMMISSION IMPLEMENTING REGULATION (EU) 2022/2330

of 28 November 2022

granting a Union authorisation for the single biocidal product 'Christiansen LD Bednet' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (¹), and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 3 June 2016, Christiansen SARL submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a single biocidal product named 'Christiansen LD Bednet' of product-type 18, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Denmark had agreed to evaluate the application. The application was recorded under case number BC-GK024706-40 in the Register for Biocidal Products.
- (2) 'Christiansen LD Bednet' contains permethrin as the active substance included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 18.
- (3) On 7 December 2020, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 5 July 2021, the Agency submitted its opinion (²), the draft summary of the biocidal product characteristics ('SPC') of 'Christiansen LD Bednet' and the final assessment report on the single biocidal product, to the Commission in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'Christiansen LD Bednet' is a single biocidal product within the meaning of Article 3(1), point (r), of Regulation (EU) No 528/2012, that is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) of that Regulation.
- (6) On 22 July 2021, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Agency recommends authorising the product only for indoor use because of identified risks for the freshwater and sediment compartments, together with risk mitigation measures to protect the environment. Those measures ensure that the product would have no environmental impact.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 18 June 2021 on the Union authorisation of the biocidal product 'Christiansen LD Bednet' (ECHA/BPC/285/2021), https://echa.europa.eu/it/opinions-on-union-authorisation

- (8) On 12 October 2021, the Biocidal Products Committee amended the evaluating competent authority's report of the active substance permethrin to implement the conclusions of its environment working group regarding the persistency of that substance.
- (9) As permethrin has not yet formally been identified as a candidate for substitution in accordance with Article 10(5) of Regulation (EU) No 528/2012, no comparative assessment pursuant to Article 23 of that Regulation is required to be performed, and the authorisation of the product may be granted for a maximum period of 10 years. No additional risk mitigation measure were considered necessary to take into account that permethrin has been found to be persistent.
- (10) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Christiansen LD Bednet'.
- (11) The Commission also considers that, as the exposure assessment for human health and for the environment was conducted based on a maximum size of the biocidal product, the terms and conditions of the authorisation should include that no biocidal product of a greater size should be made available on the market.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0026815-0000 is granted to Christiansen SARL for the making available on the market and use of the single biocidal product 'Christiansen LD Bednet' subject to the terms and conditions set out in Annex I and in accordance with the summary of the biocidal product characteristics set out in Annex II.

The Union authorisation is valid from 19 December 2022 to 30 November 2032.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

TERMS AND CONDITIONS (EU-0026815-0000)

The authorisation of the treated net is granted for a maximum size of $21.2\ m^2$.

ANNEX II

Summary of product characteristics for a biocidal product

Christiansen LD bednet

Product type 18 - Insecticides, acaricides and products to control other arthropods (Pest control)

Authorisation number: EU-0026815-0000

R4BP asset number: EU-0026815-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Christiansen LD bednet Care Plus Mosquito Net Insect Ecran Moustiquaire Imprégnée Longue Durée Care & You Prév Kit Moustiquaires Pharmavoyage Moustiquaire Imprégnée Longue Durée
	Durée I Sleep Safer LD Impregnated Mosquito Bed Net

1.2. Authorisation holder

Name and address of the authorisation holder	Name CHRISTIANSEN SARL		
	Address	719 Chemin de Repentance, 13100 Aix en Provence France	
Authorisation number	EU-0026815-0000		
R4BP asset number	EU-0026815-0000		
Date of the authorisation	19 December 2022		
Expiry date of the authorisation	30 November 2032		

1.3. Manufacturer(s) of the product

Name of manufacturer	Hebei Light Industrial Products Imp./Exp. Corporation Ltd
Address of manufacturer	26, Zhongjiu Road, Youyi Street N., 050071 Shijiazhuang China
Location of manufacturing sites	Ningjin Shuangli Knitting Co., Ltd., Dalu Villages, Ningjin County, 055551 Hebei China

Name of manufacturer	SHIJIAZHUANG ORIENTAL HORIZON IMPORT AND EXPORT CO.,LTD
Address of manufacturer	NO.448 HEPING WEST ROAD, 050072 SHIJIAZHUANG China
Location of manufacturing sites	SHENZHOU YUTONG KNITTING CO., LTD, Xiduzhuang Village, Shenzhou Town, Shenzhou City, Hengshui City, 055551 Hebei China

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, 600 008 Chennai India	
Location of manufacturing sites	A-4/1 & 2, SIPCOT Industrial Complex, Pachayankuppam, Cuddalore, 607 005 Tamil Nadu India	

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Permethrin		Active Substance	52645-53-1	258-067-9	0,9

2.2. Type of formulation

LN - Long-lasting insecticidal net

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Very toxic to aquatic life with long lasting effects. Contains permethrin. May produce an allergic reaction.	
Precautionary statements	Avoid release to the environment. Dispose of container to in accordance with national legislation.	

4. AUTHORISED USE(S)

4.1. Use description

Table 1

Use # 1 – Non-professional

Product type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)		
Where relevant, an exact description of	Non-washable Insecticide treated bednet for use in tropical areas only.		
the authorised use	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(s) (including development stage)	Scientific name: Anopheles Common name: Anopheles mosquitoes Development stage: Adults		
	Scientific name: Aedes Common name: Aedes mosquitoes Development stage: Adults		
Field(s) 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	Sachet, Plastic: PET, D9ø x H22 cm Sachet, Plastic: PET, L22 x 14 x 8 cm Sachet, Plastic: PET, D10 x H25 cm Sachet, Plastic: PET, D10 x H34 cm Sachet, Plastic: PET, D14ø x H34 cm Sachet, Plastic: PET, 25 x 25 x 9 cm Sachet, Plastic: PET, D11ø x H27 cm Sachet, Plastic: PET, D11ø x H27 cm Sachet, Plastic: PET, D10ø x 25 cm Sachet, Plastic: PET, D12ø x H37 cm Sachet, Plastic: PET, D13ø x 28 cm Sachet, Plastic: PET, D15ø x H39 cm Sachet, Plastic: PET, L26 x W20 cm Sachet, Plastic: PET, 17 x 20 x 6 cm in a cardboard box Sachet, Plastic: PET, L39 x W32 x 8 cm Sachet, Plastic: PET, D10ø x 59L cm Sachet, Plastic: PET, D10ø x H16 cm Sachet, Plastic: PET, D7ø x H18 cm		

4.1.1. Use-specific instructions for use

See General instructions for use.

4.1.2. Use-specific risk mitigation measures

See General instructions for use.

4.1.3. 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.

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

See General instructions for use.

4.1.5. 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.

5. **GENERAL DIRECTIONS FOR USE** (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 mosquitoes to enter.

Apply first 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.

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.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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.

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.

5.4. Instructions for safe disposal of the product and its packaging

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

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

Empty containers should be disposed of in accordance with local regulations.

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

6. **OTHER INFORMATION**

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