

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product:

Christiansen LD Bednet

ECHA/BPC/285/2021

Adopted

18 June 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product Christiansen LD Bednet

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product: Christiansen LD Bednet

Authorisation holder: CHRISTIANSEN SARL

Active substance common name: Permethrin

Product type: 18

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 3 June 2016, recorded in R4BP3 under case number BC-GK024706-40, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 7 December 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-39) and its Working Groups (WG I 2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the Union authorisation of the biocidal product was reached on 18 June 2021.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion and the minority position including their grounds are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012.

The biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of Christiansen LD Bednet referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

Christiansen LD Bednet is a carrier-based biocidal product where the polyester bednet is treated with the insecticide permethrin with the purpose of protecting humans staying under it against nuisance mosquito bites. Christiansen LD Bednet contains 0.9 % permethrin (CAS number 52645-53-1) and is to be used indoors by the general public (non-professional users) by fixing the net over a bed to prevent mosquitos from entering. Christiansen LD bednet is marketed in different sizes; the largest being 21.2 m².

Physico-chemical properties

The biocidal product Christiansen LD Bednet is a carrier-based product of type B, where the product is a bednet made of polyester impregnated with 0.9% (w/w) permethrin. According to the document "Handling "carriers" in the authorisation of biocidal products" (CA-Nov16-Doc.4.3-Final), tests for carrier-based products may be performed using the impregnation liquid except the storage stability tests.

The storage stability studies were performed on the bednet, and the permethrin content on the net was determined. The studies showed that both the product and the packaging material were stable during storage. The remaining APCP properties were tested with the impregnation solution.

The accelerated storage test of the bednet impregnated with the impregnation solution showed an acceptable degree of degradation of 0.7% at 54 °C after 2 weeks. The long-term storage test at ambient temperature showed an acceptable degree of degradation of 4.71 % after 36 months at 20 °C, with a cis:trans isomeric ratio of 29:71.

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

Applying the agreements as laid down in the document "Handling "carriers" in the authorisation of biocidal products" would require that the test on 'surface tension' should

have been provided. As this test was not provided there is a data gap with regards to this endpoint. However, this endpoint is not not relevant as the biocidal product is a solid and consequently surface tension does not contribute to the performance properties of the impregnated bednet. The test for corrosivity to metals was not available but could be waived. As a conclusion the product is not classified with respect to physical hazards.

The shelf-life for the carrier-based product Christiansen LD Bednet has been granted for 3 years.

Analytical methods for the determination of the active substance in the biocidal product are available and validated.

Efficacy

Christiansen LD bednet is sufficiently effective against *Anopheles* spp. and *Aedes* spp. In accordance with Guidance on the BPR Vol. II Efficacy – Assessment and Evaluation (Parts B+C) only use in tropical areas can be authorised as sufficient testing against *Culex* spp. have not been performed. Resistance to permethrin has been reported for the use of permethrin as a general insecticide against a wide range of insects. Resistance should be monitored on a continuous basis.

The following instructions for use have to be applied to ensure the efficacy of the product and to minimise the risk of resistance:

- Apply first non-chemical methods such as regular window screen insect nets if possible. Use of the insecticide treated mosquito net 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;
- The product is to be used only in tropical areas;
- In case of continuous infestation: to minimise the risk of resistance, alternate products containing different active substances;
- 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).

Human health

Christiansen LD Bednet is not classified regarding human health (HH), however it should be labelled with EUH 208 "Contains permethrin. May produce an allergic reaction". The classification of the product is based on the active substance permethrin alone as no other substance is classified.

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).

According to the risk characterisation, the biocidal product Christiansen LD Bednet does not pose an unacceptable health risk for the the non-professional users and the general public (including combined scenarios) for the authorised uses.

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 are required:

- Avoid contact with skin and eyes;
- It is recommended to wash hands after setting up the net and after taking the net down.

A risk mitigation measure for cats to avoid contact with the product is added due to their specific sensitivity to permethrin: "Keep cats away from the product due to their high sensitivity to permethrin toxicity

Based on the intended use and the proposed measures, the acute and chronic exposure to residues resulting from the intended use is unlikely to cause a dietary risk to consumers. However, the product should not be applied in the vicinity of food or feed. Therefore, the following sentence has been added: "Keep away from food, drinks and animal feeding stuffs."

Environment

Christiansen LD Bednet is classified as "very toxic to aquatic life with long lasting effects" (H400 and H410). The environmental classification of the product is based on the active substance permethrin alone as no other substance in the product has an environmental classification.

One substance of concern was identified for the environment due to the co-formulant being an active substance from another product type. However, as this co-formulant is only present in the impregnation fluid and not in the final product supplied to the user, it was not considered in the environmental risk assessment and not reflected in the SPC of the product as a substance of concern.

For the environmental risk assessment, the emission from washing the net during servicelife of the product was assessed.

The environmental risk assessment of the biocidal product showed risk in the freshwater and sediment compartment, hence the risk mitigation measure "This product MUST NOT be washed, due to risk to the environment" is required. In addition, the risk mitigation measure to "Use the mosquito net as indicated in the instructions for use. Do not use for other purposes" has been added and the exact description of the authorised use has been amended to "*Non washable* Insecticide treated bednet", to further ensure that the risk mitigation measure to not wash the product is adhered to.

Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

b) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

c) Comparative assessment

The active substance permethrin contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

d) Overall conclusion of the evaluation of the uses proposed to be authorised

The physical, chemical and technical properties, physical hazards and respective characteristics, the safety for human and animal health and for the environment and the efficacy of the intended use of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product are met.

The physical, chemical and technical properties, physical hazards and respective characteristics of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use, according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the biocidal product shall be authorised, for the use described under section 2.1 of this opinion, subject to compliance with the proposed SPC and the following condition.

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