

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product:

Insecticide Textile Contact

ECHA/BPC/263/2020

Adopted

17 June 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product Insecticide Textile Contact

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: Insecticide Textile Contact

Authorisation holder: DAKEM

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 24 April 2016, recorded in R4BP3 under case number BC-JR023293-31, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation to ECHA on 9 December 2019. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-35 Process Flow) and its Working Groups (WG-I in March/April 2020). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product/biocidal product family was reached on 17 June 2020.

The BPC opinion was adopted by consensus. The opinion is 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 does not meet the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may not be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

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

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product/biocidal product family.

General

The biocidal product ***Insecticide Textile Contact*** contains 0.8 % permethrin and is an oil in water emulsion. It is a ready-for-use insecticide and acaricide trigger spray for treatment of textiles (bed nets, clothes & household fabrics). The product is intended to be applied indoors by non-professional users. Apart from the active substance, the biocidal product does not contain co-formulants identified as a substance of concern.

Physico-chemical properties

Physico-chemical studies were provided that cover the product ***Insecticide Textile Contact***. The product is stable after accelerated storage at +40°C for 8 weeks and after 36 months at ambient temperature in the commercial packaging. A shelf life of 36 months can be granted.

Physico chemical dangers have been assessed, the product is not explosive, does not possess oxidizing properties and is not flammable nor auto-flammable.

The analytical method for the determination of the active substance in the biocidal product is validated according to SANCO/3030/99 rev.4. However, a validated method determining the cis/trans isomers ratio is lacking.

A letter of access to the active substance permethrin has been provided, therefore the validated methods of analysis for soil, air and water in the permethrin Competent Authority Report (CAR) can be used.

Efficacy

Based on the efficacy tests submitted/validated and according to the requirements of the TNsG PT 18/19 guidance (from 2012), the product Insecticide Textile Contact as a RTU biocidal insecticide/acaricide product containing 0.8 % w/w permethrin and intended to be applied by spraying with an application rate of 50 ml of product/m² (\approx 0.4 g a.i./m²) efficacy is demonstrated for:

- 1) On cotton-made **MOSQUITO NETS** to kill mosquitoes and to prevent mosquitoes bites up to 6 months.
- 2) On cotton-made **WORN CLOTHES** (outer side) to kill mosquitoes and fleas and to prevent mosquitoes bites up to 6 months.
- 3) On cotton-made **HOUSEHOLD FABRICS** (unwashed) to kill house flies, mosquitoes, cockroaches, fleas and ticks up to 6 months.

The efficacy of the product is not demonstrated after washing (whatever the washing procedure i.e. with water, dry washed or steam cleaned).

Human Health

When the product is used as intended (a ready-for-use insecticide and acaricide trigger spray for treatment of textiles, clothes and bed nets used by non-professional users), **the risk for non-professional user is considered unacceptable**. On one hand, there is an identified risk for non-professional applying the product, e.g. an adult applying the trigger spray. And on the other hand, there is an identified risk for general public secondarily exposed to the treated materials.

These unacceptable risks cannot be mitigated for the following reasons:

- the use foreseen is a non-professional use only: therefore no restriction of user category is possible as no use of PPE is foreseen as decrease of the number of risk management measure (RMM) possible,
- most of the unsafe uses result from secondary exposure to the clothing that has been treated. The only reasonable RMM that could thus be put in place would be to forbid from using or wearing the treated textile. However, as the aim of the product is for people, including children, to wear clothing (or sleep in bedsheets) that have been treated in order to be protected from insect such as mosquitoes, this would remove the goals that the product aim to achieve and make it senseless,
- the assessment had to be performed with default values due to the lack of supporting data to determine proper values for some coefficient, such as dermal absorption coefficient and transfert coefficient. This lead naturally to higher exposure value with any exposure scenario used.

Dietary exposure is not relevant regarding the intended use of the product. However, the following RMM should be implemented on the label in order to avoid any misuses of the product:

- *Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.*

In addition, due to the presence of permethrin in the product, the following additional RMM are highly advised:

Measures to protect humans:

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

Measures to protect animals: cats are known to be sensible to pyrethroids:

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

- *Against fleas and ticks, treat the textile materials after keeping your domestic animals away. Let them get back in the room when the product is completely dry. Do not treat directly your animals or their baskets/blanket.*

Environment

Two scenarios for environmental exposure were used:

- Scenario 1 considered the treatment of textiles by spraying. Environmental exposure is possible through spray drift on the floor and on the applicator, followed by wet-cleaning the floor or washing the applicator's clothes and subsequent emission to the sewers. A Tier I assessment was performed considering a daily treatment frequency as is the norm according to the ESD. Due to calculated risks for the STP, surface water, sediment, soil and groundwater compartments, a Tier II calculation was considered in which the treatment frequency was lowered to a maximum of 2 treatments per year based on the product label.
- Scenario 2 considered the washing of the treated textiles and subsequent emission to the sewers. In a Tier I assessment, only ESD standards were considered, leading to environmental risks for the STP, surface water, sediment, soil and groundwater compartments. In a subsequent Tier II calculation, the standard wash-off fraction from the ESD was lowered based on a provided washing study, and the washing frequency was lowered to once per month instead of once per day.

Some of the Tier II-refinements (treated textile surface, frequency of treatment and frequency of washing) were considered as not realistic and therefore not considered acceptable. Nevertheless, these Tier II calculations showed unacceptable risks for the environment (surface water and sediment for permethrin and groundwater for its metabolites DCVA and PBA), even when considering the 2 scenarios separately.

When the product is used as intended, **the risk for the environment is considered unacceptable. Both the application of the product to textiles, and the washing of treated textiles, will lead to unacceptable risks to surface water and sediment.**

A series of RMM were proposed by the applicant to possibly reduce the risks to an acceptable level:

- *Place a disposable plastic sheet (supplied with the product) under the textile while spraying it with the product.*
- *After the treatment, the sheet should be disposed and potential other spillage should be dry cleaned and disposed with solid waste.*
- *Do not treat textiles, clothes and bed nets more than once a year.*
- *Do not wash treated bed nets.*
- *Do not treat bed sheets, wash them at 60°C minimum.*
- *Do not wash treated textiles with water, treated textiles should be dry washed or steam cleaned.*
- *Do not treat textiles close to drains or waterways.*

However, these RMMs were not considered acceptable or sufficient to show a safe use.

The use of a plastic sheet to mitigate the risks of the treatment scenario was not considered as a feasible RMM for public users. Furthermore, even in cases where such a sheet would be used, it would be insufficient to reduce the risks of the textile treatment to acceptable levels. Emissions via spray drift on the applicator's clothes alone would already cause unacceptable risks.

Only dry-cleaning treated clothes is not considered as feasible either, as the product is intended for outdoor and sport clothing.

Overall Conclusion

When the product is used as intended, the product will be efficacious. But the product will present an unacceptable risk for non-professional users due to an identified risk for non-professional applying the product and due to an identified risk for secondary exposure to the treated materials. Furthermore, there is no use leading to acceptable risk for the environment, due to identified risks for surface water and sediment. Therefore, an authorisation for the product ***Insecticide Textile Contact*** cannot be granted due to unacceptable risks for non-professional users and for the environment.

b) Presentation of the biocidal product, including classification and labelling

Not relevant, since the eCA is of the opinion that the biocidal product ***Insecticide Textile Contact*** should not be authorised.

c) Description of uses proposed to be authorised

Not relevant, since the eCA is of the opinion that the biocidal product ***Insecticide Textile Contact*** should not be authorised.

d) 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.

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

Not relevant, since the eCA is of the opinion that the biocidal product ***Insecticide Textile Contact*** should not be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product/biocidal product family

As the conditions of Article 19(1) are not met it is proposed that the biocidal product ***Insecticide Textile Contact*** shall not be authorised due to unacceptable risks for non-professional users (for adults applying the product and for general public exposed to the treated articles) and for the environment (for surface water and sediment).