Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product:

Pesguard® Gel

ECHA/BPC/269/2020

Adopted

8 October 2020

Opinion of the Biocidal Products Committee

on the Union authorisation of biocidal product

Pesguard® Gel

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:	**Pesguard® Gel**
Authorisation holder:	**Sumitomo Chemical Agro Europe SAS**
Active substances common name:	**pyriproxyfen, clothianidin**
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 21 September 2016, recorded in R4BP3 under case number BC-HS027052-37, the evaluating Competent Authority (The Netherlands) submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 31 March 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-36) and its Working Groups (WG II 2020). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product Pesguard® Gel was reached on 8 October 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 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 Pesguard® Gel 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

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

General

The biocidal product Pesguard® Gel is a ready to use bait for professional use against cockroaches which contains the active substances pyriproxyfen (0.515%) and clothianidin (0.526%).

Acetic acid and potassium sorbate are considered substances of concern (SoC) for human health and environment. In line with BPR guidance (Volume III Human Health - Assessment & Evaluation (Parts B+C)), acetic acid is identified as a SoC for human health as SCOEL values for this substance are available. Additionally, potassium sorbate is included in the Union List of approved active substances for PT 8 and as it is present >0.1 %, the substance complies with the triggers for substance of concern, and is therefore considered a SoC from a human health and environmental point of view.

Based on the risk assessment no adverse health effects or adverse effects for the environment are expected after exposure to these SoCs by using the product in accordance to the SPC.

The following use has been assessed:

- Professional Use – RTU Bait

Physico-chemical properties

The information on composition, physical and chemical properties and analytical methods is acceptable. The product contains 0.526% technical clothianidin and 0.515% technical pyriproxyfen. It has a shelf-life of 2 years in polypropylene syringes. Pesguard Gel is not sensitive to elevated temperatures or humidity. The product should however be protected from frost and stored away from direct sunlight.

With regard to physical and chemical hazards, Pesguard® Gel is not classified.

The content of the active substances can be monitored using a validated HPLC-UV method.

Efficacy

The efficacy package provided demonstrates that Pesguard® Gel is effective against German cockroaches (*Blattella germanica*), Brown banded cockroaches (*Supella longipalpa*), Oriental cockroaches (*Blatta orientalis*) and American Cockroaches (*Periplaneta americana*) both as nymphs and adults. The gel should be applied as a number of spots of approximately 4 mm diameter (each spot comprising approximately 0.032g of bait). Inject the bait in cracks and crevices, or in concealed locations inaccessible to man or domestic animals. Behind refrigerators cupboards and shelves, under kitchen appliances, in electrical control boxes, voids and ducting and under bathroom fixtures etc.

In cases of severe infestation, where larger cockroach species are present (e.g. *B. orientalis* or *P. americana*), in areas that are particularly dirty or cluttered or where alternative sources of food cannot be entirely eliminated the higher application rate should be used.

Infestation level	**Recommended application rate (number of 4mm diameter spots (approximately 0.032g of bait) per m^2)**
Light	1 – 2
Medium	3 – 6
Heavy	6 - 10

Resistance management

As part of the resistance management associated with IGRs (such as pyriproxyfen), IRAC (the Insecticide Resistance Action Committee) has recommended that for non-crop protection uses (such as the PT18 uses) IGRs should be used in mixture or co-formulation with insecticides with other modes of action. This is especially important, as populations of cockroaches are already resistant to other insecticide modes of action. *Pesguard*® Gel bait combines two of the most effective non-pyrethroid modes of action, so it can be considered that this product fits well with the recommendations of IRAC. As part of the biocide authorisation of pyriproxyfen, one of the recommendations was: 'To prevent resistance the label should recommend alternation of the product with products containing an active substance with a different mode of action'. *Pesguard*® Gel bait achieves this within a co-formulated product with clothianidin.

Sumitomo Chemical has a resistance monitoring scheme in place for their biocidal products, monitoring feedback from customers and literature publications, for their biocidal products and the monitoring of resistance to *Pesguard*® Gel bait will be conducted, once product authorisation is granted.

Human health

Pesguard® *Gel* is applied by injecting the bait into cracks and crevices, void spaces and other locations where insects may live, feed and breed.

The risk associated with direct use of the product Pesguard® Gel is considered to be very low or even negligible. Given the dermal sensitisation hazard of Pesguard® Gel professional users are required to wear suitable protective gloves when handling the product.

However, as a precautionary approach using a reverse reference scenario and considering an operator wearing gloves, it was demonstrated that a bead of 3000 mm of clothianidin or

1500 mm pyriproxyfen spread on the gloves could lead to predicted exposure at the AEL, which although applicator guns can be messy tools, is unlikely for a trained professional operator following good hygiene practice.

If it is considered that the penetration of clothianidin and pyriproxyfen through protective gloves is 10%, the operator would need to get about 12 g - 24 g (pyriproxyfen and clothianidin, respectively) of product on the outside of the gloves. This would mean a bead of 1500 mm (150 cm) and 3000 mm (300 cm) would be required spread for pyriproxyfen and clothianidin, respectively, on the outer surface of the gloves to reach the AEL and this would need to remain on the surface until the actives had migrated through the paste and penetrated the glove.

Pesguard® Gel is applied by injecting the bait into cracks and crevices, void spaces and other locations where insects may live, feed and breed. Additionally, the product should only be applied to areas inaccessible to children and pets. However, a reverse reference scenario is included for accidental exposure. In a very worst case exposure scenario for hand-to-mouth exposure, as an infant (6 monts-1 year old) picks up a bead of product, and the full amount of the product is orally absorbed (i.e. 100% oral absorption). Considering the lower dermal absorption values (i.e. 50% for clothianidin 40% for pyriproxyfen), dermal exposure by dermal contact or via hand-to-mouth behaviour, which consists of 90% dermal exposure and 10% of the dermal exposure considered for oral exposure, is therefore covered by this scenario for all age groups.

Based on the human health risk assessment, no adverse health effects are expected for the protected (gloves) professional user and for the general public (including indirect exposure via food) after use of Pesguard® Gel in accordance with the intended use.

Environment

The product *Pesguard® Gel* (containing 0.5% w/w clothianidin and 0.5% w/w pyriproxyfen) is a ready to use gel product in a container for use in a bait applicator gun for the control of cockroaches. Spots of gel bait are injected into cracks and crevices where the insects may live. Each spot consists of approximately 0.032 g bait and 1-2 spots per m^2 are applied for maintenance treatments up to a maximum of 6-10 spots per m^2 for heavy infestations.

Both clothianidin and pyriproxyfen have been assessed under the EU Review programme. The assessment also considers an OECD 314B study on biodegradation in activated sludge of the active substance pyriproxyfen which also includes the metabolites 4'-OH-Pyr, DPH-Pyr and PYPAC.

For both the active substances and the metabolites, no unacceptable risk was identified upon exposure to STP, aquatic, and terrestrial compartments. No unacceptable towards bees and soil organisms. Also no risk of primary and secondary poisoning of birds and mammals is seen.

It can be concluded that the use of Pesguard® Gel as proposed presents an acceptable risk to the environment.

b) 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.

c) 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.

d) Comparative assessment

The active substance pyriproxyfen 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.

The active substance clothianidin contained in the biocidal product meets the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product was performed in accordance with Article 23(1) of Regulation (EU) No 528/2012 and following the Technical Guidance Note on comparative assessment of biocidal products (CA-May15-Doc.4.3.a – Final)[1]. The first step in comparative assessment is to perform an assessment of the existing chemical diversity in authorised biocidal products to minimise the occurrence of resistance. As a general rule (CA-May15-Doc.4.3.a-Final) three different and independent active substance/mode of action combinations are needed to consider that diversity is adequate.

As it was concluded that there is not an adequate chemical diversity and in line with Article 23(3)(b) and the Technical Guidance Note, and since clothianidin does not meet the exclusion criteria as outlined in Article 5(1), the comparative assessment for Pesguard® Gel could be finalised at the screening stage and it is concluded that the application can be taken forward to product authorisation in accordance with Article 23(6) of the BPR.

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

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product have been evaluated.

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

The physico-chemical properties of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised uses, 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;

[1] The document is available at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3.

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 uses 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(s) described under section 2.1 of this opinion, subject to compliance with the proposed SPC.

Two co-formulants are identified as potentially having endocrine-disrupting properties. There is however no need to trigger a process under REACH by the eCA (The Netherlands) in line with paragraph 31(b) of the note CA-March18-Doc.7.3.b-final[2], as one of them is an active substance undergoing currently an assessment on endocrine-disrupting properties and for the other a process under REACH has already been triggered.

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[2] The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation (Note agreed by Member States' Competent Authorities for Biocidal Products).