Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

TWP 094

ECHA/BPC/348/2022

Adopted

16 June 2022

Opinion of the Biocidal Products Committee

on the Union authorisation of single biocidal product TWP 094

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:	**TWP 094**
Authorisation holder:	**TROY CHEMICAL COMPANY BV**
Active substances common name:	**3-Iodo-2-propynyl butylcarbamate (IPBC) (CAS number 55406-53-6)**
Product types:	**PT 8**

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 12 November 2018, recorded in R4BP3 under case number BC-QN044827-14, 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 07 January 2022. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-43) and its Working Groups (WG I 2022). 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 TWP 094 was reached on 16 June 2022.

The BPC opinion was adopted by consensus. The opinionis published on the ECHA website at: https://echa.europa.eu/opinions-on-union-authorisation/bpc.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(1)(r).

The single 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 TWP 094 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

TWP 094 is an 'AL - Any other liquid and SL - Soluble concentrate' single biocidal product containing 0.75% (w/w) 3-Iodo-2-propynyl butylcarbamate (IPBC) (CAS number 55406-53-6) as the active substance. The product does not contain any non-active substances (co-formulants) considered as substances of concern (SoC). TWP 094 is a wood preservative (PT 8) for the control of blue stain fungi and wood rotting fungi in Use class 2 and 3. It may be used by industrial-, professional- and non-professional users. Application is by automated dipping, automated spraying, flow coating/deluging, and vacuum pressure impregnation (industrial users), manual dipping (professionals), and by brushing and rolling (professional- and non-professional users).

TWP 094 is ready-to use (RTU) (formulation type AL) for all applications except vacuum pressure impregnation, for which it is applied to wood as a dilution (formulation type SL). When used for vacuum pressure impregnation, the RTU product is loaded into the application equipment via a fully automated pumping/transfer system. Dilution of the product with water to yield a ~ 10% in-use solution occurs within the application equipment prior to treatment of wood. Use of a ~ 10% dilution of TWP 094 for vacuum pressure impregnation and use of the undiluted (RTU) product for all other application methods is supported by the effectivity data presented for TWP 094. The exposure and risk assessments for human health considers exposure to RTU TWP 094 for all applications except vacuum pressure impregnation, and to the diluted product in the specific case of vacuum pressure impregnation. The risk assessment for the environment considers emission scenarios based on wood treated with RTU TWP 094 or with the diluted product.

Physico-chemical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. TWP 094 is an off-white water-based product with no discernible odour.

Based on the accelerated storage stability test and the submitted interim results of a long-term storage stability test at ambient temperature, a shelf life of one year in the packaging material HDPE can be granted. The results of this long-term storage are to be provided via a post-authorisation requirement no later than 1 July 2022 in order to confirm the shelf life of the biocidal product. In addition, if the degradation would exceed 10%, efficacy data and information on the degradation products and their impact on risk assessment is required in agreement with the ECHA Guidance on the Biocidal Products Regulation (Vol. I, Parts A+B+C, version 2.0, 2018 - further APCP Guidance) and have to be included in information requested for post-authorisation. The packaging material PET lined metal cannot be authorised as the submitted storage stability tests did not demonstrate that this packaging material would be stable for storage of the biocidal product.

Based on the results during the storage stability studies, the following storage conditions are required: store below 35°C, protect from frost, protect from light.

During the opinion forming process the applicant clarified the use of the product for double vacuum/vacuum processes, i.e. the product is diluted with water before being applied to wood. Consequently, the formulation type 'AL - Any other liquid' could not be applied for this specific use and the eCA proposed to apply an additional formulation type 'SL - Soluble concentrate'. Consequently, additional data need to be submitted to address technical properties of the product for formulation type SL and have to be included in information requested for post-authorisation: persistent foaming (section 3.6.5.7 of the APCP Guidance) and degree of dissolution and dilution stability (section 3.6.7 of the APCP Guidance).

The physical hazards of the biocidal product were examined. No physical hazards were identified.

Two validated analytical methods for the determination of the concentration of active substance in the biocidal product are available. No analytical methods for residues, relevant impurities or substances of concern were required. Validated analytical methods for monitoring of relevant components of the biocidal product and residues thereof in soil, air, water, animal, and human body fluids and tissues are available in the IPBC PT8 CAR[1] (CA DK, 2008). Analytical method for monitoring in/on food and feeding stuff were waived as the biocidal product is not intended to come into contact with food and feeding stuff when applied according to the instructions.

Efficacy

TWP 094 has been shown to be efficacious against blue stain fungi (*Sydowia polyspora*, *Aureobasidium pullulans spp.*) for all intended uses with the exception of vacuum pressure impregnation, and against wood rotting fungi (*Gloeophyllum trabeum*, *Poria placenta*, *Coniophora puteana*) for all intended uses. As a consequence, only a claim against wood rotting fungi will be authorised for penetrative processes. The risk of development of resistance to carbamates used in wood preservation is considered low, as the number of treatments is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure.

[1] Competent Authority Report.

Human health

TWP 094 does not require classification for human health end-points, though requires labelling with the EUH208 statement: “Contains 3-Iodo-2-propynyl butylcarbamate (IPBC). May produce an allergic reaction.” No substances of concern (SoC) were identified.

Human health risk assessment (HHRA) was carried out for all intended uses of TWP 094 as applied for by the Applicant. The HHRA was carried out according to ECHA’s *Guidance on the BPR, Volume III Humana Health – Assessment & Evaluation (Parts B+C)*, Version 4.0, December 2017, with consideration of other applicable guidance documents. The conclusion of the exposure and risk assessment is that the intended uses of TWP 094 are not expected to have unacceptable acute or chronic risks for human health if the directions for use, as specified in the product’s SPC, are followed. The following risk mitigation measures (RMMs) are considered relevant for the use of TWP 094:

Industrial use

When TWP 094 is applied by automated dipping, automated spraying or flow coating/deluging the following RMMs should be implemented:

- TWP 094 may only be loaded into industrial application equipment via a fully automated pumping/transfer system.

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).

- Wear a protective coverall (type 6, EN 13034).

- TW0 094 must only be used in fully automated dipping processes where all steps in the treatment and drying process are mechanised and no manual handling takes place, including when the treated articles are transported through the dip tank to draining/drying and storage (if not already surface dry before moving to storage). Where appropriate, the wooden articles to be treated must be fully secured (e.g. via tension belts or clamping devices) prior to treatment and during the dipping process, and must not be manually handled until after the treated articles are surface dry.

When TWP 094 is applied by vacuum pressure impregnation the following RMMs should be implemented:

- TWP 094 may only be loaded into industrial application equipment via a fully automated pumping/transfer system.

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).

- Wear a protective coverall (type 6, EN 13034).

Professional use

When TWP 094 is applied by manual dipping the following RMMs should be implemented:

- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within product information).

- Wear a protective coverall (type 6, EN 13034).

- Application by manual dipping can be performed for a maximum of 30 minutes per day.

No unacceptable risks were identified for professional users without the use of PPE when applying TWP 094 by brushing and rolling.

Non-professional use

No unacceptable risk was identified for non-professional users applying the product by brushing and rolling.

General public

No unacceptable risk for the general public (all age-groups) was identified in connection with the industrial, professional, and non-professional uses of TWP 094. However, to protect human health (and animal health) – the following RMMs are considered appropriate:

For industrial, professional, and non-professional use:

- Do not use on wood which may come in direct contact with food, feed and livestock.

For professional and non-professional use:

- 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/pets.

Exposure of animals (pets and livestock) directly, or via their food or drinking water, to TWP 094 can be excluded when the product is applied according to the intended uses. However, it cannot be excluded that such exposure might occur. Risk assessment for animal health has not been carried out, though the safe use on human exposure (including the most relevant age groups) is considered to cover incidental exposure of animals to the product during application and their exposure (unintended) to treated wood once dry.

Environment

TWP 094 is classified as aquatic chronic category 3 (H412 - Harmful to aquatic life with long lasting effects). Only the active substance, IPBC, contributes to the classification.

No substance of concern has been identified. The environmental risk assessment (ERA) was therefore based on the active substance, IPBC, only. The ERA was carried out according to the Emission Scenario Document for PT8 (OECD, 2013), the Technical Agreements for Biocides (ENV) (ECHA, July 2021) and the Guidance on the BPR, Vol. IV, part B+C (ECHA, 2017).

The conclusion of the ERA is that it is unlikely that the intended uses have unacceptable risk for the environment if the directions for use, as specified in the SPC, are followed. The following RMMs are considered relevant for the use of TWP 094:

For brushing and rolling by non-professionals and professionals:

- Do not apply near bodies of surface water.

- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

For manual dipping by professionals:

- During product application (to timbers) and whilst surfaces are drying, do not contaminate the environment. All losses of the product have to be contained by covering the ground (e.g. by tarpaulin) and disposed of in a safe way.

- Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water.

- Any losses of the product shall be collected for reuse or disposal.

For industrial uses:

- Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water.

- Any losses of the product shall be collected for reuse or disposal.

Overall conclusion:

The overall conclusion of the assessment is that the uses #1 (brushing and rolling by non-professionals and professionals), #2 (manual dipping by professionals), #3 (automated dipping, automated spraying and flow coating/deluging by industrial users), and #4 (double vacuum/low pressure process by industrial users) may be authorised with the RMMs suggested above. The product may be authorised for use against wood-rotting fungi and blue stain fungi for all superficial applications (use #1, 2 and 3), but only against wood-rotting fungi for penetrative applications (use #4).

Use number	Use description	Target organisms	Application method	Application rate (min-max)	Conclusion
1	Brushing and rolling by non-professionals and professionals	Blue stain fungi and wood rotting fungi (brown rot)	Brushing and rolling	100 mL/m^2 (blue stain fungi) 150 - 160 mL/m^2 (wood rotting fungi)	Acceptable with RMMs*
2	Manual dipping by professionals		Manual dipping		
3	Automated dipping, automated spraying, flow coating/deluging by industrial users		Automated dipping, automated spraying, flow coating/deluging		
4	Double vacuum/low pressure process by industrial users	Wood rotting fungi (brown rot)	Double vacuum/ low pressure process	74.6 - 79.5 kg/m^3	

* Please refer to the general and specific directions of use in the PAR and SPC for more details.

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 3-Iodo-2-propynyl butylcarbamate (IPBC) 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 was not needed.

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 substance 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 use(s), 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 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 single biocidal product shall be authorised, for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC and the following conditions:

The authorisation holder shall complete, within the stated timeframe, the actions set out in the table below:

Description	Due date
Long term storage test at ambient temperature: Results obtained after storage for 12 months. The study must include a test of degree of dissolution and dilution stability after storage for 12 months at ambient temperature. In addition, if the degradation exceeds 10%, efficacy data and information on the degradation products and their impact on risk assessment is required and have to be included.	1 November 2022
For the formulation type SL (soluble concentrate) test of persistent foaming and degree of dissolution and dilution stability.	1 November 2022

It is noted that for the biocidal product TWP 094 the fact that data is to be provided after the authorisation is granted does not affect the conclusion on the fulfilment of the conditions under Article 19(1) on the basis of the existing data.

One of the co-formulants of the product contains substances that are PBT/vPvB. The applicant has demonstrated adequate efforts to substitute these substances. Since the sum of these substances in the product is below 0.1% (w/w), they are not regarded as substances of concern.

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