

## **Biocidal Products Committee (BPC)**

Opinion on the minor change to the Union authorisation of the biocidal product:

**TWP 094**

**ECHA/BPC/420/2024**

Adopted

07/05/2024

**BPC**  
BIOCIDAL PRODUCTS  
COMMITTEE



## Opinion of the Biocidal Products Committee

### on the minor change to a Union authorisation

In accordance with Article 12(4) of Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the minor change<sup>1</sup> to the Union authorisation of:

<b>Name of the biocidal product</b>	<b>TWP 094</b>
<b>Asset number</b>	<b>EU-0028968-0000</b>
<b>Authorisation holder</b>	<b>TROY CHEMICAL COMPANY BV</b>

This document presents the opinion adopted by the BPC, having regard to the conclusions of the ECHA secretariat.

### Procedural history

Following the submission of an application on 15 December 2023, recorded in R4BP 3 under case number BC-XB090959-16, the ECHA secretariat presented its conclusions to the Member State Competent Authorities (MSCA). In order to review the draft revised product assessment report (PAR), the draft revised summary of product characteristics (SPC) and the conclusions of the ECHA secretariat, the Agency organised a consultation of the MSCAs. Revisions agreed upon were presented and the draft revised PAR and the draft revised SPC were updated accordingly.

### Adoption of the BPC opinion

The BPC opinion on the minor change to the Union authorisation of the biocidal product was adopted on 7 May 2024.

The BPC opinion was adopted by consensus.

The opinion is published on the ECHA website.

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<sup>1</sup> This minor change application is grouped change and includes also administrative changes - Article 4(d) of Commission Implementing Regulation (EU) No 354/2013

## Detailed BPC opinion and background

### 1. Overall conclusion

The overall conclusion of the BPC is that the authorisation of TWP 094 can be amended with the proposed minor change.

After the introduction of the changes, the biocidal product meets the conditions laid down in Article 19(1) of the BPR and therefore the authorisation of TWP 094 may be amended with the proposed changes as specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

In addition, the submitted data fulfils the post-authorisation requirements set in Commission Implementing Regulation (EU) 2023/1041.

The BPC agreed on the draft revised SPC of TWP 094 submitted with the minor change application, as referred to in Article 22(2) of the BPR.

### 2. BPC Opinion

#### 2.1 BPC conclusions of the evaluation

##### a) Procedural aspects

In Annex I of the Commission Implementing Regulation (EU) 2023/1041, granting an authorisation of the biocidal product TWP 094, the Commission included the post-authorisation requirement to provide a long-term storage test at ambient temperature to confirm the shelf life of the biocidal product of 12 months. It is further noted that the study must include a test of degree of dissolution and dilution stability after storage for 12 months at ambient temperature. In addition, the authorisation holder shall provide a test of persistent foaming and a test on degree of dissolution and dilution stability to confirm the soluble concentrate formulation type of the product TWP 094. The deadline included in the Implementing regulation for the authorisation holder to provide the data to the Agency is 19 June 2024. The data requested as post-authorisation requirement were provided by the authorisation holder on 11 September 2023 (with some parts already delivered on 8 June 2022).

In parallel the authorisation holder submitted the same data in support of an application for a minor change to a Union authorisation, with the intention to extend the shelf life from 12 to 24 months.

The authorisation holder submitted the same data to ECHA (in the context of the minor change application) and to the evaluating Competent authority (to fulfil the post-authorisation requirements). Therefore the ECHA Secretariat evaluated the submitted data in a close cooperation with the evaluating Competent authority Denmark (eCA DK). The conclusion of the evaluations conducted by the ECHA Secretariat and the eCA DK are presented in this opinion.

##### b) Description of the changes as proposed by the authorisation holder

The following changes to the authorised product were proposed by the authorisation holder:

Proposed change No 1:

- Replacement of concrete package sizes by ranges;
- Extension of the packaging range – extending the smallest packaging size for use #3 and #4 to 30 L from 120 L.
- Extension of packaging volume range for non-professional use in use #1 from maximally 5L to maximally 25L.
- Addition of packaging materials – inclusion of poly(ethylene terephthalate) (PET) lined cans for use #1 and #2.
- Addition of packaging material and extension of packaging material for bottles/drums and intermediate bulk container (IBC) from high-density polyethylene (HDPE) to other polyolefins (PE, PP)
- Addition of packaging types bottle and drum for all uses.

**Table 1**

<b>Use</b>	<b>Approved packaging information</b>	<b>New packaging information as included in this change application</b>		
1	Can HDPE: 0.375 L, 0.75 L, 1.0 L, 2.5 L, 5.0 L  For professional use only:  Can HDPE: 10 L, 20 L, 25 L	Can	PET lined metal	From 0.375 L to 25 L
		Drum	PET lined metal	From 0.375 L to 25 L
		Can	Polyolefin (HDPE, PE or PP)	From 0.375 L to 25 L
		Bottle	Polyolefin (HDPE, PE or PP)	From 0.375 L to 25 L
		Drum	Polyolefin (HDPE, PE or PP)	From 20 L to 25 L
2	Can HDPE: 0.375 L, 0.75 L, 1.0 L, 2.5 L, 5.0 L, 10 L, 20 L, 25 L	Can	PET lined metal	From 0.375 L to 25 L
		Drum	PET lined metal	From 0.375 L to 25 L
		Can	Polyolefin (HDPE, PE or PP)	From 0.375 L to 25 L
		Bottle	Polyolefin (HDPE, PE or PP)	From 0.375 L to 25 L
		Drum	Polyolefin (HDPE, PE or PP)	From 20 L to 25 L
3	Can/IBC (intermediate bulk container)  HDPE: 120 L, 220 L, 1000 L	Can	Polyolefin (HDPE, PE or PP)	From 30 L to 60 L
		Bottle	Polyolefin (HDPE, PE or PP)	From 30 L to 60 L
		Drum	Polyolefin (HDPE, PE or PP)	From 30 L to 450 L
		IBC	Polyolefin (HDPE, PE or PP)	From 200 L to 1000 L

Use	Approved packaging information	New packaging information as included in this change application		
4	Can/IBC HDPE: 120 L, 220 L, 1000 L	Can	Polyolefin (HDPE, PE or PP)	From 30 L to 60 L
		Bottle	Polyolefin (HDPE, PE or PP)	From 30 L to 60 L
		Drum	Polyolefin (HDPE, PE or PP)	From 30 L to 450 L
		IBC	Polyolefin (HDPE, PE or PP)	From 200 L to 1000 L

Proposed change No 2:

Extension of the shelf life from 12 to 24 months.

Proposed change No 3:

Addition of trade names for the product:

- 9011AA5
- Boracol\_Combo
- CUPRINOL GRUNDOLJA PT8
- Cuprinol Wood Preserver Clear BPR
- Consolan Bläueschutz Aqua RBP
- Diaxyl Stopper
- Diaxyl Fix
- HNS3AA5
- Koralan GL 530
- LUXOL IMPREGNACE WB 2.0
- NATURAQUA PROTECTIVE PRIMER
- Nordsjö Tinova Wood Base Oil PT8
- Pinotex Superbase PT8
- Pinotex Wood Base Aqua
- Sadolin Superbase Pro
- Sikkens CETOL AKTIVA UNIVERSAL RBP
- Sikkens CETOL BL AKTIVA RBP
- StoPrim Protect Wood

- Tenco Houtconserveer WB
- VIDARON IMPREGNAT GRUNTUJĄCY DO DREWNA
- VIDARON IMPREGNAT OCHRONNY DO DREWNA PRO
- VIDARON GRUNT IMPREGNUJĄCY DO DREWNA ULTRA
- W2300CC000
- Xyladecor Tuinhoutbeschermer Prevent – Protection Bois de Jardin Prevent
- Xyladecor Xylamon IMPRAEGNIERGRUND RBP
- XWC1AA5

Proposed change No 4:

1. Addition of the formulators of the biocidal product.

<b>Name of manufacturer</b>	Kurt Obermeier GmbH
<b>Address of manufacturer</b>	Berghäuser Str. 70, 57319 Bad Berleburg, Germany
<b>Location of manufacturing sites</b>	Berghäuser Str. 70, 57319 Bad Berleburg, Germany

<b>Name of manufacturer</b>	Fabryka Farb i Lakierów Śnieżka SA
<b>Address of manufacturer</b>	ul. Dębicka 44, 39-207 Brzeźnica, Poland
<b>Location of manufacturing sites</b>	ul. Dębicka 44, 39-207 Brzeźnica, Poland

<b>Name of manufacturer</b>	Osmo Holz und Color GmbH & Co. KG
<b>Address of manufacturer</b>	Affhüppen Esch 12, 48231 Warendorf, Germany
<b>Location of manufacturing sites</b>	Lütkenbecker Weg 12, 48155 Münster, Germany

**c) Summary of the evaluation and conclusions**

The effects of the proposed change on the physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the already authorised biocidal product have been evaluated.

Proposed changes No 1 and 2:

**i) Physico-chemical properties**

The proposed change regarding addition of a new packaging material (PET lined metal can) is supported by new long-term storage stability testing. The initial observations regarding this packaging material after 6 months of testing (small areas of discolouration) have been

explained and shown not to be due to product interaction. There is enough evidence to conclude that the new packaging has no effect on the previous conclusions regarding the product.

The proposed change regarding addition of a new packaging material (PE and PP) is supported by read-across argumentation to already existing packaging, which have been found to be acceptable in the initial Union authorisation application. The new packaging material is considered to be acceptable by extrapolation without further data for water based formulations according to the "Guidance on the BPR: Volume I Parts A+B+C". There is no concern that the new packaging has an effect on the conclusions regarding the product.

The proposed change regarding replacing concrete packaging sizes by a range is supported by read-across argumentation to already existing packaging which have been found to be acceptable in the initial authorisation. Typically the smallest and/or largest packaging have to be considered possible worst case, the intermediate volumes can be accepted by read-across. There is no concern that the new packaging size range has an effect on the conclusions regarding the product.

The proposed change regarding the packaging type (addition of bottles and drums in all uses) is supported by the storage stability experiments which were performed on HDPE bottles. Bottles can be considered the worst case packaging type considering the more complex form and the higher surface to volume ratio compared to cans and drums. There is no concern that the new packaging type has an effect on the conclusions regarding the product.

**Table 2**

<b>Use</b>	<b>Packaging information accepted (type; material; volume)</b>
1	Can; PET lined metal; from 0.375 L to 25 L Drum; PET lined metal; from 0.375 L to 25 L Can; HDPE, PE or PP; from 0.375 L to 25 L Bottle; HDPE, PE or PP; from 0.375 L to 25 L Drum; HDPE, PE or PP; from 20 L to 25 L
2	Can; PET lined metal; from 0.375 L to 25 L Drum; PET lined metal; From 0.375 L to 25 L Can; HDPE, PE or PP; from 0.375 L to 25 L Bottle; HDPE, PE or PP; from 0.375 L to 25 L Drum; HDPE, PE or PP; from 20 L to 25 L
3	Can; HDPE, PE or PP; from 30 L to 60 L Bottle; HDPE, PE or PP; from 30 L to 60 L Drum; HDPE, PE or PP; from 30 L to 450 L IBC; HDPE, PE or PP; from 200 L to 1000 L
4	Can; HDPE, PE or PP; from 30 L to 60 L Bottle; HDPE, PE or PP; from 30 L to 60 L Drum; HDPE, PE or PP; from 30 L to 450 L IBC; HDPE, PE or PP; from 200 L to 1000 L



The proposed change in shelf-life (Change No 2) is supported by new endpoint studies regarding storage stability, dilution stability and persistent foaming.

The new data delivered supports the claim that the biocidal product is stable for 24 months at ambient temperature and that the product does not show persistent foaming nor any sedimentation in the dilution stability tests.

The proposed change does not affect the physico-chemical hazards of the product.

## ii) Efficacy

The proposed changes do not affect the efficacy of the biocidal product TWP 094. It is therefore not necessary to perform a supplementary evaluation.

## iii) Human health

The proposed changes do not affect the conclusions reached for human and animal health associated with the use of the biocidal product TWP 094. It is therefore not necessary to perform a supplementary evaluation.

## iv) Environment

The proposed changes do not affect the conclusions made regarding the negligible emissions from the production and formulation steps. Similarly, the emission from the application step remain the same as they are not influenced by the material/size/volume of the packaging. Therefore, the proposed changes in packaging do not impact on the present environmental risk assessment and the conclusions remain valid for all the considered uses and user categories. It is therefore not necessary to perform a supplementary evaluation.

Proposed changes No 3 and 4:

The evaluation of the changes proposed by the authorisation holder is presented below:

#	Evaluation	Evaluation outcome
3.	The requested change matches the description for <b>Change No 2 of section 1</b> of Title 1 of the Annex to the Changes Regulation.	Acceptable* with the exception to the trade name "NATURAQUA PROTECTIVE PRIMER".  It is considered that in accordance with Article 69(2) of the BPR the trade name "NATURAQUA PROTECTIVE PRIMER" contains the misleading term and thus, the trade name as proposed by the applicant is not acceptable. <sup>2</sup>
4.	The requested change matches the description for <b>Change No 4 of section 2</b> of Title 1 of the Annex to the Changes Regulation.	Acceptable

\*Change requiring prior notification

## v) Overall conclusion of the evaluation

The outcome of the evaluation, as reflected in the PAR, is that the proposed change does not affect the conclusions with regard to the fulfilment of the conditions of Article 19(1) of the BPR.

<sup>2</sup> [CA-June23-Doc.4.9-Final.rev1 - Misleading terms in trade names.docx](#)

In addition, the submitted data fulfils the post-authorisation requirements set in Commission Implementing Regulation (EU) 2023/1041.

## **2.2 BPC opinion on the changes to the Union authorisation**

As the conditions of Article 19(1) of the BPR are met it is proposed that the authorisation of product TWP 094 shall be amended with the proposed changes.

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**Annex**

**Draft Revised Summary of Product Characteristics**