Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)

**ADDENDUM: NA-MRS**



Aquawood TIG

Product type 8

3-Iodo-2-propynyl butylcarbamat (IPBC) and Tebuconazole as included in the Union list of approved active substances

Case Number in R4BP: MRS-BC-PN062898-04

Evaluating Competent Authority: AT

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# Background and CONCLUSION

## Background Information

The authorisation holder ADLER-Werk Lackfabrik Johann Berghofer GmbH & Co KG has applied for a mutual recognition in sequence (cMS: ES) of the authorised product family Aquawood TIG. in accordance with Regulation (EU) No 528/2012.

In the commenting phase, the PAR was changed in some aspects. Please cf. to the following chapters for details. Only the chapters that are changed are presented.

As the agreed changes stem from a NA-MRS procedure, a CG referral was issued by the cMS. The CG outcome dated 8 November 2021 was considered in this PAR addendum.

## Conclusion

Article 19 of Regulation (EU) No 528/2012 is still fulfilled.

# ASSESSMENT Report (Amendments)

## Summary of the product assessment

### Administrative information

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#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | 3-iodo-2-propynylbutylcarbamate (IPBC) |
| **Name of manufacturer** | Troy Chemical Company BV |
| **Address of manufacturer** | Uiverlaan 12E, 3145XN Maassluis, Netherland |
| **Location of manufacturing sites** | 8 Vreeland Road, 1111 Florham Park, NJ United States |

### Product family composition and formulation

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#### Qualitative and quantitative information on the composition of the biocidal product family

***FIRST INFORMATION LEVEL***

***Composition of Biocidal product family "Aquawood TIG"***

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| IPBC | 3-iodo-2-propynylbutylcarbamate | Active substance | 55406-53-6 | 259-627-5 | 0.80 | 0.80 |
| Tebuconazole | 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol | Active substance | 107534-96-3 | 403-640-2 | 0.40 | 0.40 |
| **Substances of concern** |
| Co-formulant containing MIT | MIT: 2-methyl-2H-isothiazol-3-one | Preservative | MIT: 2682-20-4 | MIT: 220-239-6 | 0.00 | 0.30 |

***SECOND INFORMATION LEVEL – meta SPCs***

The biocidal product family comprises only one meta SPC, therefore the range of the meta SPC is the same as in the family.

***Third information level: individual products in the meta SPCs***

***Composition of individual products in meta SPC 1***

| **Common name** | **Product name / Trade name** |
| --- | --- |
| **BPF** | **Aquawood TIG mid brown** | **Aquawood TIG E Kastanie** | **Aquawood TIG HighRes Castagno /** Aquawood Primo A5 | **Aquawood Ligno+** | **Aquawood TIM NG** | **Aquawood Primo A1** | **Aquawood Primo A4** | **Aquawood Primo A6** | **Aquawood Primo TIM** | **Aquawood TIG E1** | **Aquawood TIG E3** | **Aquawood TIG E4** | **Aquawood TIG E5** | **Aquawood Ligno+ Base** | **Aquawood Primo A3 /** Aquawood Ligno+Base Eiche Natur | **Aquawood Primo A2** |
| **Content (% w/w)** |
| **Min** | **Max** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 3-Iodo-2-propynyl butylcarbamat (IPBC) | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 | 0.8 |
| Tebuconazole | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| **Substances of concern** |
| Acticide MBS containing the SoC MIT | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |

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#### Information on the substance(s) of concern

Based on the harmonised classification of Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation, 13th ATP) 2-methylisothiazol-3(2H)-one (MIT, CAS No. 2682-20-4) was identified as substances of concern (SoC) in relation to human health.

MIT triggers the classification of the products within the biocidal product family (BPF) with Skin Sens. 1, H317 based on its content that is above the SCL of 0.0015%.

According to ECHA (2017[[1]](#footnote-2)) “Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products”, the SoC MIT trigger the assignment to band B.

Therefor only, a qualitative risk assessment would be performed under the consideration of potential for exposure to the SoC, the concentration of the substance in the product and the use pattern of the product.

If exposure is regarded to be significant, in addition to the P-statements normally associated with the concerned H-statements, further risk mitigation measures, as appropriate, should be considered. However, primary exposure is limited o professional use only and the mandatory PPE (coated coverall, gloves and boots) are protective against local effects as well. Secondary exposure scenarios relevant to Aquawood TIG are limited to inhalation of volatilised residues indoors which represent a low level of exposure. Therefore the assigned P-Phrases are considered appropriate to mitigate the local effects of the SoC MIT.

### Hazard and precautionary statements

**Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008**

| **Classification** | Skin. Sens. 1, H317 |
| --- | --- |
| Aquatic Chronic 2, H411 |
| **Labelling** |
| Pictograms | GHS 07 | GHS 09 |
| GHS07 | GHS09 |
| Signal word | Warning |
| Hazard statements | H317 May cause an allergic skin reaction |
| H411 Toxic to aquatic life with long lasting effects |
| Precautionary statements | P261 Avoid breathing dust/fume/gas/mist/vapours/spray. |
| P272 Contaminated work clothing should not be allowed out of the workplace. |
| P273 Avoid release to the environment |
| P302+P352 IF ON SKIN: Wash with plenty of water. |
| P333+P313 If skin irritation or rash occurs: Get medical advice. |
| P391 Collect spillage |
| P501 Dispose of contents in accordance with local/regional/national/internationalregulations. |
| Note | **--** |

### Authorised use(s)

#### Use description

|  |  |
| --- | --- |
| **Product Type** | 8 |
| **Where relevant, an exact description of the authorised use** | --- |
| **Target organism (including development stage)** | Scientific name: no dataCommon name: wood rotting fungiDevelopment stage: no dataScientific name: no dataCommon name: wood discolouring fungi (blue stain)Development stage: no data |
| **Field of use** | IndoorAuthorisation is restricted to use on windows (frames), doors and conservatories only (use class 2 and 3, timbers not in ground contact, either continually exposed to the weather or protected from the weather but subject to frequent wetting). The product must not be applied outside of dedicated treatment facilities. |
| **Application method(s)** | No changes |
| **Application rate(s) and frequency** |
| **Category(ies) of users** |
| **Pack sizes and packaging material** |

### General directions for use

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#### Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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| --- |
| **First aid instructions:**IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.3-IODO-2-PROPYNYL-N-BUTYL CARBAMATE is a carbamate compound which has weak anticholinesterase activity. DO NOT USE if under medical advice not to work with anticholinesterase compounds.**Emergency measures to protect the environment:** If the product contaminates lakes, rivers, sewers or soil, inform the appropriate authorities in accordance with local regulations.Contain and collect spillage with an inert absorbent (e.g. sand, earth etc.). For large amounts: Pump off the product. |

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#### Conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
| Store in a cool place, protected from frost in tightly closed original packaging.Do not store at temperature above 40 ºC.Shelf-life: 12 months |

### Other information

No changes.

### Packaging of the biocidal product

No changes.

### Documentation

No changes.

## Assessment of the biocidal product (family)

### Intended use(s) as applied for by the applicant

No changes.

### Physical, chemical and technical properties

No changes.

### Physical hazards and respective characteristics

No changes.

### Methods for detection and identification

No changes.

### Efficacy against target organisms

No changes.

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin sensitization***

No skin sensitisation test is avialalbe for the BPF Aquawood TIG. Therefore the classification and labelling of the components were considered for this endpoint.

**Summary table of human data on skin sensitisation**

No human data on skin sensitisation available.

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | The products of the BPF Aquawood TIG are sensitizing to skin. |
| Justification for the value/conclusion | The SoC MIT is contained in the products above the SCL of 0.0015%. |
| Classification of the product according to CLP  | A classification with Skin Sens. 1, H317 May cause an allergic skin reaction is required according to the CLP Regualtion (EC) No 1272/2008.  |

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#### Risk characterisation for human health

##### Risk characterisation for local effects

Based on the authorised use and application methods primary exposure is limited to professionals and the mandatory PPE (coated coverall, gloves and boots) are protective against local effects (Skin Sens. 1, H317) as well.

Secondary exposure scenarios relevant to Aquawood TIG are limited to inhalation of volatilised residues indoors which represent a low level of exposure. Therefore the assigned P-Phrases are considered appropriate to mitigate the local effects of the SoC MIT and no additional risk mitigation measures are proposed. Risk from local effects are considered to be accaptable.

### Risk assessment for animal health

No changes.

### Risk assessment for the environment

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

The classification of the biocidal product Aquawood TIG is determined based on the harmonised classification of the active substances IPBC and tebuconazole. IPBC is classified under Regulation (EG) Nr. 1272/2008 (CLP) as aquatic acute 1 (M=10) and aquatic chronic 1 (M=1) (ATP06). Tebuconazole is classified as aquatic acute 1 (M=1) and aquatic chronic 1 (M=10) (ATP07). With regard to the concentrations of both active substances (c(Tebuconazole)=0.4% and c(IPBC)=0.8%), the biocidal product has to be classified as aquatic chronic 2, H411: Toxic to aquatic life with long lasting effects. This classification includes the GHS-pictogram GHS09 and the precautionary statements P273, P391 and P501.

### Measures to protect man, animals and the environment

No changes.

### Assessment of a combination of biocidal products

No changes.

### Comparative assessment

No changes.

# Annexes

No changes.

1. ECHA (2017) Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 4.0 December 2017 [↑](#footnote-ref-2)