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

**ADDENDUM**

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



AXIL PAL

Product type 8

IPBC, propiconazole and tebuconazole

Case Number in R4BP: BC-PD038654-40

Evaluating Competent Authority: France

Date: September 2018

Table of Contents

[Table of Contents 2](#_Toc525127026)

[*1* CONCLUSION 4](#_Toc525127027)

[*2* ASSESSMENT REPORT 5](#_Toc525127028)

[2.1 Summary of the product assessment 5](#_Toc525127029)

[2.1.1 Administrative information 5](#_Toc525127030)

[**2.1.1.1** Identifier of the product / product family 5](#_Toc525127031)

[**2.1.1.2** Authorisation holder 5](#_Toc525127032)

[**2.1.1.3** Manufacturer(s) of the products of the family 5](#_Toc525127033)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 5](#_Toc525127034)

[2.1.2 Product (family) composition and formulation 6](#_Toc525127035)

[**2.1.2.1** Identity of the active substance 6](#_Toc525127036)

[**2.1.2.2** Candidate(s) for substitution 7](#_Toc525127037)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 8](#_Toc525127038)

[**2.1.2.4** Information on technical equivalence 8](#_Toc525127039)

[**2.1.2.5** Information on the substance(s) of concern 8](#_Toc525127040)

[**2.1.2.6** Type of formulation 8](#_Toc525127041)

[2.1.3 Hazard and precautionary statements 8](#_Toc525127042)

[2.1.4 Authorised use(s) 9](#_Toc525127043)

[**2.1.4.1** Use description 9](#_Toc525127044)

[**2.1.4.2** Use description 10](#_Toc525127045)

[2.1.5 General directions for use 11](#_Toc525127046)

[**2.1.5.1** Instructions for use 11](#_Toc525127047)

[**2.1.5.2** Risk mitigation measures 12](#_Toc525127048)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc525127049)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 12](#_Toc525127050)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 13](#_Toc525127051)

[2.1.6 Other information 13](#_Toc525127052)

[2.1.7 Packaging of the biocidal product 13](#_Toc525127053)

[2.2 Assessment of the biocidal product (family) 13](#_Toc525127054)

[2.2.1 Intended use(s) as applied for by the applicant 13](#_Toc525127055)

[2.2.2 Physical, chemical and technical properties 14](#_Toc525127056)

[2.2.6 Risk assessment for human health 15](#_Toc525127057)

**Note to the reader:**

This addendum to the PAR for the minor change application of the product authorisation is based on the PAR of the first authorisation evaluated by BE.

Only sections subject to minor changes are presented in this document.

1. **History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *BE* | *BC-MX019838-96* | 08.2016 | Initial assessment : AXIL 2000 |
| NA-MRS | *FR* | *BC-CY027770-18* | 07.08.2017 | Mutual recognition in sequence |
| NA-BBS | *FR* | *BC-FJ034126-51* | 27.12.2017 | Same product : AXIL PAL |
| NA-MAC | *FR* | *BC-MS038233-25* | 14/09/2018 | Major change application: addition of the treatment of wood intended to inter into indirect contact with food and/or feeding stuff. |
| NA-MIC | *FR* | BC- PD038654-40 | xx.xx.xxxx | Minor change application: addition of packaging sizes |

# CONCLUSION

Following AXIL PAL latest authorisation, change claimed in the frame of the minor change application consists in the addition of packing sizes (ranging from 20 to 500L).

* *Physico-chemical properties*

New sizes for packaging are claimed of this minor change. The material of the packaging remains the same (HDPE). Compatibility of the product with HDPE material has already been demonstrated at the product authorisation stage. New sizes are acceptable without any additional physico chemical test.

* *Risk assessment for human health*

The initial evaluation of the exposure having been carried out with a packaging of 1000L, the minor change request consisting in the addition of packaging ranging from 20 to 500L has no impact on the risk characterisation.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| AXIL PAL |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BERKEM SAS |
| **Address** | MARAIS OUEST  24680 GARDONNE  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | SARPAP & CECIL INDUSTRIES SAS – BERKEM GROUP |
| **Address of manufacturer** | MARAIS OUEST F  24680 GARDONNE  France |
| **Location of manufacturing sites** | MARAIS OUEST F  24680 GARDONNE  France |

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

|  |  |
| --- | --- |
| **Active substance** | Tebuconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  50569 Köln  Germany |
| **Location of manufacturing sites** | Bayer CropScience Corp.  Hawthorn Road, P.O. Box 4913 MO 6  4120-001 Kansas City  United-States |

|  |  |
| --- | --- |
| **Active substance** | Propiconazole |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  50569 Köln  Germany |
| **Location of manufacturing sites** | Syngenta Crop Protection AG.  1870 Monthey  Switzerland |

|  |  |
| --- | --- |
| **Active substance** | IPBC |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1  50569 Köln  Germany |
| **Location of manufacturing sites** | Shanghai Hui Long Chemicals Co Ltd.  Dengta Jiazhu Rd.  201815 District Shanghai  China |

|  |  |
| --- | --- |
| **Active substance** | IPBC |
| **Name of manufacturer** | TROY Corporation |
| **Address of manufacturer** | Uiverlaan 12e  3140 AC Maasluis  Netherlands |
| **Location of manufacturing sites** | One Avenue L  NJ 07105 Newark  United-States |

### Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | IPBC |
| **IUPAC or EC name** | Butylcarbamate de  3-iodo-2-propynyle |
| **EC number** | 259-627-5 |
| **CAS number** | 55406-53-6 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 980 g/kg |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Tebuconazole |
| **IUPAC or EC name** | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol |
| **EC number** | 403-640-2 |
| **CAS number** | 107534-96-3 |
| **Index number in Annex VI of CLP** | 603-197-00-7 |
| **Minimum purity / content** | 95.0% |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Propiconazole |
| **IUPAC or EC name** | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole |
| **EC number** | 262-104-4 |
| **CAS number** | 60207-90-1 |
| **Index number in Annex VI of CLP** | 613-205-00-0 |
| **Minimum purity / content** | 94.0% |
| **Structural formula** |  |

#### Candidate(s) for substitution

*Not relevant*

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (technical %)** |
| --- | --- | --- | --- | --- | --- |
| IPBC | 3-iodo-2-propynylbutylcarbamate | Active substance | 55406-53-6 | 259-627-5 | 0,76 % w/w |
| Propiconazole | 1-[[2-(2,4- dichlorophenyl)-4-propyl- 1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0,80 % w/w |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol | Active substance | 107534-96-3 | 403-640-2 | 0,80 % w/w |

#### Information on technical equivalence

*Not relevant*

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

*Not relevant*

#### Type of formulation

|  |
| --- |
| ME - Microemulsion |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin Sens 1  Aquatic chronic 2 |
| Hazard statement | H317: May cause an allergic reaction  H411: Toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H317: May cause an allergic reaction  H411: Toxic to aquatic life with long lasting effects |
| Precautionary statements | P261 : Avoid breathing vapours  P272 : Contaminated work clothing should not be allowed out of the workplace.  P273 : Avoid release to the environment  P280 : Wear protective gloves / protective clothing/ eye protection/face protection  P302 + P352 : IF ON SKIN : Wash with plenty of water  P333 + P313 : If skin irritation or rash occurs:Get medical advice  P321 : Specific treatment (see on this label)  P362 + P364 : Take off contaminated clothing and wash it before reuse  P501 : Dispose of contents to be in accordance with all local, regional, national and international regulations. |
|  | |
| Note | **-** |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Preventive wood treatment for use class 3

|  |  |
| --- | --- |
| **Product Type** | PT 8 – wood preservative |
| **Where relevant, an exact description of the authorised use** | Preventive wood preservation for use class 3 |
| **Target organism (including development stage)** | Brown rot fungi |
| **Field of use** | Outdoor |
| **Application method(s)** | Automated spraying and flow-coating  Superficial application for wood use class 3 by automated spraying and flow-coating |
| **Application rate(s) and frequency** | 120 g of the product diluted 10 % w/w /m² of wood |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Drum (HDPE) : 20 L, 60 L and 220 L  IBC (HDPE) : 500 L and 1000 L |

##### 

##### Use-specific instructions for use[[1]](#footnote-1)

|  |
| --- |
| - |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply to wood that may be in contact with food and drink (human food and / or feed of livestock). * Treated wood should not be used for case of food contact (human food and / or feed) or in contact with livestock. |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

#### Use description

Table 2. Use # 2 – Preservation of wood by temporary treatment of sawn timber

|  |  |
| --- | --- |
| **Product Type** | PT 8 – wood preservative |
| **Where relevant, an exact description of the authorised use** | Preservation of wood by temporary treatment of sawn timber |
| **Target organism (including development stage)** | Mould fungi  Sapstain fungi |
| **Field of use** | Outdoor |
| **Application method(s)** | Dipping application  Short dipping application of fresh sawn timber : the wood to be treated is immersed in a dipping tank |
| **Application rate(s) and frequency** | Product diluted 5% w/w during 20s |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Drum (HDPE) : 20 L, 60 L and 220 L  IBC (HDPE) : 500 L and 1000 L |

##### Use-specific instructions for use[[2]](#footnote-2)

|  |
| --- |
| - |

##### Use-specific risk mitigation measures

|  |
| --- |
| * Treated wood must not be used as wood in contact with livestock (fences, barriers, stables ...) * An intermediate protecting paper or cardboard layer (approved for direct alimentary contact) must always be put between the treated wood and the food (package or not). |

##### Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

##### Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

##### Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Respect the application rates of the product and the authorized classes of use. * Notify the person responsible for placing on the market in case of non-effectiveness of the treatment. * The treatment is carried out by surface application (automated spraying, flow-coating and short dipping). The ready-to-use product is prepared by stirring gently in water. The product is miscible in water, regardless of the proportion, and is easy to homogenize. The concentration of the ready-to-use preparation can be controlled by means of a refractometer. * The frozen wood can not be treated. * A preliminary test must be carried out for the treatment of exotic wood or rich in tannin. * Other cuts and cuts must be treated. * For exterior use Class 3 treated wood must be finished with a top coat. * After use, rinse the equipment with water. * Fixation: 4 hours after draining, under cover, in a sealed environment. * Drying time: 24 to 48 hours, in a ventilated atmosphere, under normal conditions. |

#### Risk mitigation measures

|  |
| --- |
| * The application phases of the product must be carried out using automated systems limiting the handling / handling of wood treated by professionals. * Wear chemically resistant gloves (glove material to be specified by the authorization holder in the product information) and a combination of type 4 during handling of wet treated wood. * A protective layer is necessary after treatment with the product. * Avoid any discharge to the environment during the application phase of the product and during the storage and transport phases of the wood after treatment. * Industrial application should only be carried out in impervious enclosed areas, allowing the recovery of all discharges. * Storage of freshly treated wood in an industrial environment is permitted only in a covered area, on an impermeable and solvent resistant surface, connected to holding tanks, or any other means for the collection of leachates, in order to prevent leaching of the product from the weather to the ground, sewers, bodies of water or streams. * Until use, store the wood away from the weather. * All releases resulting from the application of the product and the storage of treated wood must be considered hazardous waste and be treated as such. |

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

|  |
| --- |
| * In case of skin contact: Take off contaminated clothing and shoes and wash the contaminated area thoroughly with water. If signs of irritation / burns occur, contact Poison Control Center. * In case of eye contact: Rinse eyes thoroughly with lukewarm water holding eyelids apart and continue flushing with lukewarm water for 10 minutes. In case of lens wear: rinse immediately with warm water and remove the lenses if there is no contraindication and continue rinsing under a thin stream of warm water for 10 minutes. If signs of irritation or visual disturbances persist, consult a doctor. * In case of inhalation: take the subject out in the open air and put him in a half-sitting position; in case of symptoms and / or inhalation of high concentrations contact Poison Control Center or call 15/112. * In case of contact with the mouth: rinse thoroughly with water and contact the poison control center or call 15/112. * In case of disturbances of consciousness, place the subject in lateral safety position (lying on the side); call 15/112. Do not drink or induce vomiting. * Keep the packaging and / or instructions available. |

#### Instructions for safe disposal of the product and its packaging

|  |
| --- |
| * Do not dispose of the biocidal product in the pipes (sinks, toilets ...), gutters, streams, in the open field or in any other outdoor environment. * Dispose of unused product, its packaging and any other waste in an appropriate collection circuit. |

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

|  |
| --- |
| * Product shelf-life under normal storage conditions: 2 years * Keep the original container duly closed in a dry place, protected from light and moisture, under normal temperature conditions (frost-free). * Ensure adequate ventilation of the storage area. |

### Other information

|  |
| --- |
| The petitioner must inform users of the product of the MRLs established in the phytosanitary regulations for tebuconazole and propiconazole. They may be held liable for exceeding these MRLs when carrying out checks on products stored on AXIL PAL treated wood. |

### Packaging of the biocidal product

Previous packaging accepted for the first authorisation are HDPE IBC of 1000L

New packagings claimed for this minor change and are summarized in the following table.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Can | 20L | HDPE | - | Industrial | Yes |
| Drum | 60L | HDPE | - | Industrial | Yes |
| Drum | 220L | HDPE | - | Industrial | Yes |
| IBC | 500L | HDPE | - | Industrial | Yes |

Compatibility of the product with HDPE packaging has already been demonstrated at the product authorisation stage. Consequently, new sizes are acceptable without any additional test.

## Assessment of the biocidal product (family)

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

Table 3. Intended use # 3 – Wood preservation for use class 3

|  |  |
| --- | --- |
| Product Type(s) | PT 8 – wood preservative |
| Where relevant, an exact description of the authorised use | Preventive wood preservation for use class 3 |
| Target organism (including development stage) | Brown rot fungi |
| Field of use | Outdoor |
| Application method(s) | Automated spraying and flow-coating  Superficial application for wood use class 3 by automated spraying and flow-coating |
| Application rate(s) and frequency | 120 g of the product diluted 10 % w/w /m² of wood |
| Category(ies) of user(s) | Professionals |
| Pack sizes and packaging material | Can / drum, Plastic: high density polyethylene (HDPE) - 20L  Drum, Plastic: High Density Polyethylene (HDPE) - 60L  Drum, Plastic: High Density Polyethylene (HDPE) - 220L  IBC (intermediate bulk container), Plastic: high density polyethylene (HDPE) - 500L  IBC (intermediate bulk container) - Plastic: high density polyethylene (HDPE) - 1000 L |

Table 4. Intended use # 4 – Temporary preventive treatment of freshly sawn timber

|  |  |
| --- | --- |
| Product Type(s) | PT 8 – wood preservative |
| Where relevant, an exact description of the authorised use | Preservation of wood by temporary treatment of sawn timber |
| Target organism (including development stage) | Mould fungi  Sapstain fungi |
| Field of use | Outdoor |
| Application method(s) | Dipping application  Short dipping application of fresh sawn timber : the wood to be treated is immersed in a dipping tank |
| Application rate(s) and frequency | Product diluted 5% w/w during 20s |
| Category(ies) of user(s) | Professionals |
| Pack sizes and packaging material | Can / drum, Plastic: high density polyethylene (HDPE) - 20L  Drum, Plastic: High Density Polyethylene (HDPE) - 60L  Drum, Plastic: High Density Polyethylene (HDPE) - 220L  IBC (intermediate bulk container), Plastic: high density polyethylene (HDPE) - 500L  IBC (intermediate bulk container) - Plastic: high density polyethylene (HDPE) - 1000 L |

### Physical, chemical and technical properties

No new data have been submitted for this minor change. Compatibility of the product with HDPE packaging has already been demonstrated for the product authorisation. Consequently, new sizes are acceptable without any additional test.

*Please refer to the product assessment report related to AXIL PAL product authorisation under Regulation UE n° 528/2012.*

### Risk assessment for human health

The initial evaluation of the exposure having been carried out with a packaging of 1000L, the minor change request consisting in the addition of packaging ranging from 20 to 500L has no impact on hazard assessment, exposure assessment and on the risk characterisation.

1. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-1)
2. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-2)