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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE NATIONAL AUTHORISATION APPLICATION**



**V33 IMPREGNAT DO DREWNA BUDOWLANEGO**

Product type 8 Wood preservatives

Cypermethrin, Propiconazole and Tebuconazole as included in the Union list of approved active substances

NA-MIC Case Number in R4BP: BC-GQ062470-33

Evaluating Competent Authority: Poland

Date: 04.08.2022

**1. CONCLUSION**

The biocidal product V33 IMPREGNAT DO DREWNA BUDOWLANEGO (authorisation number: PL/2017/0297/MR/SBP, asset number: PL-0014151-0000, source case number:   
BC-MA019359-48) is authorised in Poland as the same biocidal product authorised (NA-BBS) V33 IMPREGNAT DO DREWNA KONSTRUKCYJNEGO (authorisation number:   
PL/2017/0288/MR, asset number: PL-0012861-0000, source case number:   
BC-TF017341-50) that is authorised in Poland by NA-MRS procedure from the reference product V33 TRAITEMENT BOIS MULTI USAGES authorised in France (authorisation number: FR-2017-0027, asset number: FR-0012421-0000, source case number: [BC-TF017337-39](https://r4bp-main.echa.europa.eu/r4bp-web-authority/case/na-app.xhtml?id=BC-TF017337-39)).

In 26.10.2020 the case owner submitted an application for national authorisation minor change on request (NA-MIC) (case number: BC-GQ062470-33). Proposed change concerned minor change of composition of the product and change in pack size range. France was designated as reference Member State for this application as it was also reference Member State for the same minor change applications submitted for product V33 TRAITEMENT BOIS MULTI USAGES (NA-MIC case number: BC-WD034339-35, NA-MIC Case Number: BC-WD034339-35).

The consolidated Product Assessment Report for product V33 TRAITEMENT BOIS MULTI USAGES (amended in March 2018 and updated August 2021) is considered applicable for an amendment by NA-MIC of the product V33 IMPREGNAT DO DREWNA BUDOWLANEGO.

Examining the change concerning addition of packaging’s sizes (0.75L, 2.5L, 20L, 60L and 215L) the FR-CA concluded that claimed change could have an impact on the human health risk assessment for brush application (including brush and injection) for professional users. It led to a revised risk assessment confirming the acceptable risk for worst-case scenario (professional user, application by brush and injection, without PPE). It was also concluded that claimed change do not modify the assessment of the product’s physico-chemical properties and analytical methods neither efficacy assessment and risk assessment for environment. Those conclusions are applicable to product V33 IMPREGNAT DO DREWNA BUDOWLANEGO.

Examining the change concerning substitution of a corrosion inhibitor (PAR Confidential Annex) by water, on the basis of submitted data the FR-CA concluded that the claimed change does not modify the assessment of the product’s physico-chemical properties, hazards and analytical methods nor classification, efficacy assessment and risk assessment for the product. So the overall conclusions for product remains unchanged. Those conclusions are applicable to product V33 IMPREGNAT DO DREWNA BUDOWLANEGO.

**Conditions for the amending authorisation of the biocidal product   
V33 IMPREGNAT DO DREWNA BUDOWLANEGO in Poland:**

The conclusions concerning fulfilment of the conditions for granting authorisation according to Article 19(1) of Regulation (EU) No 528/2012 remains valid.

Description of the conditions for the authorisation of this biocidal product is presented   
in the summary of product characteristics (SPC).