



Rīga

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BERKEM DEVELOPPEMENT

Marais Ouest
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France

On an authorisation of the biocidal product AXIL 2000 AB-B

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **BERKEM DEVELOPPEMENT** on 11 December 2019 concerning an authorisation of **AXIL 2000 AB-B** through mutual recognition in sequence.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **AXIL 2000 AB-B** developed by the reference Member States – Poland.

Therefore, in accordance with Article 33 of *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products* (Regulation (EU) No 528/2012), LEGMC authorises the **AXIL 2000 AB-B** on the basis of mutual recognition process.

The authorisation holder for **AXIL 2000 AB-B** in Latvia is:

BERKEM DEVELOPPEMENT

The biocidal product **AXIL 2000 AB-B** contains **50,0%** of *Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))* (CAS No 68424-85-1, EC No 270-325-2) as an active substance.

LEGMC assigns the authorisation number for biocidal product AXIL 2000 AB-B:

LV/2020/MR/002

The authorisation is valid until 5 December 2029.

The authorisation number shall be indicated on the label of the biocidal product.

The authorisation of **AXIL 2000 AB-B** through mutual recognition is granted on the following terms:

- Product type: 8 – Wood preservatives;
- Target organisms: mould fungi – spores and spore producing structures – *Aspergillus versicolor*; sapstain fungi – spores and spore producing structures – *Ceratocystis spp.*
- Users: industrial;
- Product description: emulsifiable concentrate;
- Product stability: shelf life 24 months;
- Use area: indoor areas;
- Pack sizes and packaging material: intermediate bulk container, PE, 1000 L.

The authorisation through mutual recognition applies only to the product **AXIL 2000 AB-B** in the composition, form and packing for which the authorisation is granted by reference Member State.

The information on the label (and if applicable an enclosed instruction of use) of the **AXIL 2000 AB-B** should be as it is indicated in the authorisation of above mentioned product, taking into account also the information which is stated in the Product Assessment Report and Summary of Product Characteristics issued by reference Member State.

The information on the label shall be in Latvian.

Notwithstanding content of the label specified above, requirements stated in:

- *Article 69 Regulation (EU) No 528/2012;*
- *Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of the substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;*
- all other relevant legislation shall be applied.

BERKEM DEVELOPPEMENT shall inform LEGMC about any changes in accordance with *Commission Implementing Regulation (EU) No 354/2013 of 18th April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.*

If the first authorisation issued by reference Member State is amended or revoked, the authorisation of **AXIL 2000 AB-B** through mutual recognition may be re-opened for review before 5 December 2029.

Application on renewal of an authorisation shall be submitted according to *Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition.*

Additionally LEGMC would like to inform that BERKEM DEVELOPPEMENT is fully responsible of the content of the biocidal product **AXIL 2000 AB-B** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask BERKEM DEVELOPPEMENT to notify the above mentioned information down to supply chain.

Head of Information Analysis Department



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