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Riga

Protim Solignum Ltd.

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On an authorisation of Celcure M65 through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Protim Solignum Ltd.** on 2nd February 2015 concerning an authorisation of **Celcure M65** through mutual recognition in parallel.

LEGMC has agreed with Product Assessment Report and Summary of Product Characteristics for **Celcure M65** developed by the reference Member State – United Kingdom.

Therefore, in accordance with Article 34 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 528/2012) LEGMC authorises the **Celcure M65** on the basis of mutual recognition process.

Celcure M65 is supplied as two liquid concentrates – Celcure M65A and Celcure 65B. The treating solution is obtained by automated mixing of the two concentrates at a ratio 4.35 : 1 for A and B respectively and then diluting with water to a concentration of 2.1% - 7.4 % product.

Celcure M65A contains the following active substance:

- Copper (II) Carbonate – Copper (II) Hydroxide (1:1) (CAS No 12069-69-1, EC No 235-113-6), concentration 17.27%,

Celcure 65B contains the following active substance:

- Didecyldimethylammonium Chloride (DDA Chloride) (CAS No 7173-51-5, EC No 230-525-2), concentration 20.65%,
- DDA Carbonate (CAS No 894406-76-9, EC No 451-900-9), concentration 4.345%.

LEGMC assigns the authorisation number for biocidal product Celcure M65 through mutual recognition:

I.V/2018/MR/019

The authorisation of Celcure M65 through mutual recognition is valid until 21st June 2028 based on reference Member State – United Kingdom decision.

The authorisation number of **Celcure M65** through mutual recognition shall be indicated on the label of the biocidal product.

The authorisation of **Celcure M65** through mutual recognition is granted on the following terms:

- Product type: 8 – Wood preservative (for softwood only);

- Fields of use: Use Class 1, Use Class 2, Use Class 3 and Use Class 4;
- Target organism – Wood rotting fungi and wood destroying insects including wood boring beetles and termites;
- Users: industrial use;
- Product description: Suspension Concentrate;
- Product stability: shelf life - 2 years;
- Packaging size: 600-1000 litre HDPE intermediate bulk container with screw cap.

The authorisation through mutual recognition applies only to the biocidal product **Celcure M65** in the composition, form and packing material for which the first authorisation is granted by reference Member State.

The information on the label (and if applicable an enclosed instruction of use) of the **Celcure M65** should be as it is indicated in the first authorisation of above mentioned biocidal 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 of *regulation 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.

Protim Solignum Ltd. as the authorisation holder 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 **Celcure M65** through mutual recognition may be re-opened for review before the 21st June 2028.

Additionally LEGMC would like to inform that **Protim Solignum Ltd.** is fully responsible of the content of the biocidal product **Celcure M65** as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask **Protim Solignum Ltd.** to notify the above mentioned information down to supply chain.

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