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On an authorisation of the biocidal product family Sea 1 through mutual recognition in Latvia

Latvian Environment, Geology and Meteorology Centre (LEGMC) has evaluated an application submitted by **Jotun A/S** on 20th December 2017 concerning an authorisation of biocidal product family **Sea 1** through mutual recognition in parallel.

According to assessment made by reference Member States (rMS) – Norway for *Sea 1* conditions according to Article 19 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) are fulfilled. However, for use by non-professional users, there is an unacceptable effect on human health and, hence, Article 19(1)(iii) of the BPR is not fulfilled. Therefore, rMS authorised *Sea 1* for professional users according to Article 19(1) and for non-professional users according to Article 19(5) of Regulation (EU) No. 528/2012, respectively.

LEGMC agrees with the assessment performed by rMS. LEGMC agrees to authorise *Sea 1* for professional users according to Article 19(1) of Regulation (EU) No. 528/2012.

LEGMC considers that not authorising *Sea 1* for non-professional uses would result in disproportioned negative impact on society, therefore, use by non-professionals is authorised in Latvia in line with Article 19(5) of Regulation (EU) No. 528/2012. As a requirement, appropriate risk mitigation measures are set to ensure that the exposure to humans is minimized: the authorisation holder must make sure that personal protective equipment is available at the point of sale and that information about the use of protective equipment and application of the respective risks mitigations measures has to be highlighted on the labels and instruction of use.

LEGMC authorises the biocidal product family *Sea 1* on the basis of mutual recognition process in accordance with Article 34 of Regulation (EU) No 528/2012.

The authorisation holder for *Sea 1* in Latvia is:

Jotun A/S.

The biocidal product family *Sea 1* contains ***Dicopper oxide*** (CAS No. 1317-39-1, EC No. 215-270-7), concentration **7,01-50% w/w** as the active substance**.**

LEGMC assigns the authorisation number **LV/2024/MR/005** for biocidal product family Sea 1.

The authorisation is valid until 21 September 2033.

In accordance with Article 22(2)(d) of the Regulation (EU) 528/2012 authorisation numbers with the following suffix for biocidal products within family are indicated in the following table:

Trade name	Authorisation number
NonStop VK Red	LV/2024/MR/005/01/001
NonStop VK Black	LV/2024/MR/005/01/002
Mare Nostrum SP Red	LV/2024/MR/005/01/003
NonStop VK Blue	LV/2024/MR/005/02/001
NonStop VK Dark Blue	LV/2024/MR/005/02/002
Racing VK Red	LV/2024/MR/005/03/001
Racing VK Black	LV/2024/MR/005/03/002
Mare Nostrum SP Black	LV/2024/MR/005/04/001
NonStop EC Red	LV/2024/MR/005/05/001
NonStop EC Black	LV/2024/MR/005/05/002
NonStop EC Blue	LV/2024/MR/005/06/001
NonStop EC Dark Blue	LV/2024/MR/005/06/002
NonStop EC Grey	LV/2024/MR/005/06/003
NonStop EC White	LV/2024/MR/005/06/004
Racing VK Blue	LV/2024/MR/005/07/001
Racing VK Dark Blue	LV/2024/MR/005/07/002
NonStop II Blue	LV/2024/MR/005/08/001
NonStop II Dark Blue	LV/2024/MR/005/08/002
Princess S1M5	LV/2024/MR/005/08/003
Racing VK S1M7	LV/2024/MR/005/09/001
NonStop EC S1M6	LV/2024/MR/005/10/001
NonStop II S1M9	LV/2024/MR/005/11/001
Mare Nostrum SP Dark Blue	LV/2024/MR/005/12/001
Imperial S1M10	LV/2024/MR/005/13/001
SeaQuantum EU	LV/2024/MR/005/14/001
SeaForce EU	LV/2024/MR/005/15/001
NonStop II Red	LV/2024/MR/005/16/001
NonStop II Black	LV/2024/MR/005/16/002
Racing Red	LV/2024/MR/005/17/001
Racing Black	LV/2024/MR/005/17/002
Racing Blue	LV/2024/MR/005/18/001
Racing Dark Blue	LV/2024/MR/005/18/002
Racing S1M8	LV/2024/MR/005/19/001
Mare Nostrum Red	LV/2024/MR/005/20/001
Mare Nostrum Dark Blue	LV/2024/MR/005/20/002
Mare Nostrum Black	LV/2024/MR/005/20/003

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

The authorisation of biocidal product family *Sea 1* through mutual recognition is granted on the following terms:

- Product type: 21 – Anti fouling products;

- Target organisms: Slime, Weed (macro algae) and Animals (All development stages);
- Users: general public and professional;
- Product description: anti fouling paint;
- Product stability: as described in Summary of Product Characteristics;
- Use area: indoor and outdoor areas;
- Pack sizes and packaging material: as indicated in Summary of Product Characteristics.

The authorisation through mutual recognition applies only to the biocidal product family *Sea 1* in the composition, form and packing for which the first authorisation is granted by rMS.

The information on the label (and if applicable an enclosed instruction of use) of the biocidal product family *Sea 1* should be as it is indicated in the first authorisation of above-mentioned biocidal product family, taking into account also the information which is stated in the Product Assessment Report and Summary of Product Characteristics issued by rMS.

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.

Jotun A/S 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 rMS is amended or revoked, the authorisation of biocidal product family *Sea 1* through mutual recognition may be re-opened for review before 21 September 2033.

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 Jotun A/S is fully responsible of the contents of the biocidal product family *Sea 1* as well as its classification, labelling, instruction of use and safety data sheet.

LEGMC would like to ask Jotun A/S to notify the above-mentioned information down to supply chain.

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