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# COMMISSION IMPLEMENTING DECISION

## of 15 May 2024

## concerning the extension of the action taken by the Malta Competition and Consumer Affairs Authority permitting the making available on the market and use of the biocidal product Wofasteril® SC super in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(C/2024/3111)

**(Only the English and Maltese text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 [1], and in particular Article 55(1), third subparagraph, thereof,

Whereas:

(1) On 21 June 2023, the Malta Competition and Consumer Affairs Authority ('the Maltese competent authority') adopted, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012, a decision to permit until 18 December 2023 the making available on the market and use, in the High Degree Isolation Unit (HDIU) at Mater Dei Hospital in Msida, of the biocidal product Wofasteril® SC super ('the action'). The Maltese competent authority informed the Commission and the competent authorities of the other Member States of the action and the justification for it in accordance with Article 55(1), second subparagraph, of that Regulation.

(2) According to the information provided by the Maltese competent authority, the action was necessary in order to protect public health. The biocidal product Wofasteril® SC super is used for the disinfection of personal protective equipment (PPE) of healthcare professionals in the HDIU, before the PPE is removed by the healthcare professionals after coming out of the patients' rooms. As the HDIU accommodates patients suspected or confirmed to be suffering from diseases caused by highly infectious agents, such as viruses causing viral haemorrhagic fever, decontamination measures are crucial for the safety of healthcare personnel.

(3) As indicated by the Maltese competent authority, the safe management of patients in the HDIU requires stringent donning and doffing of PPE to ensure maximum staff safety. As part of the doffing procedure, PPE is to be disinfected before its removal. The decontamination system installed in Mater Dei Hospital specifically uses Wofasteril® SC super, which, according to the manufacturer of the system, is the only biocidal product that has proven to be efficacious with that decontamination system. Wofasteril® SC super is therefore essential and indispensable for the HDIU to function appropriately and to ensure the safety of its staff.

(4) Wofasteril® SC super is a biocidal product of product-type 2 ('disinfectants and algaecides not intended for direct application to humans or animals'), as defined in Annex V to Regulation (EU) No 528/2012. Wofasteril® SC super contains peracetic acid as an active substance. Peracetic acid is approved for use in products of product-type 2 and an application for Union authorisation of Wofasteril® SC super is currently under evaluation.

[1] OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

(5) On 24 November 2023, the Commission received a reasoned request from the Maltese competent authority to allow the extension of the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request included the same information provided when the action was taken and was based on concerns that the discontinued use of Wofasteril® SC super, in the absence of alternatives to be used in the decontamination system at the HDIU at Mater Dei Hospital, would not allow the proper decontamination of PPE of healthcare professionals and would constitute a threat to public health, given the highly infectious nature of the diseases treated in the HDIU. The Commission analysed the information included in the reasoned request, as outlined above.

(6) The lack of proper decontamination of PPE of healthcare professionals in the HDIU at Mater Dei Hospital might endanger public health and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the Maltese competent authority to extend the action.

(7) Since the action expired on 18 December 2023, this Decision should apply retroactively.

(8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

*Article 1*

The Malta Competition and Consumer Affairs Authority may extend until 21 June 2025 the action to permit the making available on the market and use of the biocidal product Wofasteril® SC super for the decontamination of Personal Protective Equipment of healthcare professionals in the High Degree Isolation Unit at Mater Dei Hospital in Msida, provided that it ensures that the product is only used under its supervision.

*Article 2*

This Decision is addressed to the Malta Competition and Consumer Affairs Authority.

It shall apply from 19 December 2023.

Done at Brussels, 15 May 2024.

*For the Commission*
Stella KYRIAKIDES
*Member of the Commission*