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COMMISSION IMPLEMENTING DECISION (EU) 2025/2309

of 13 November 2025

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product ERO MP in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2025) 7594)

(Text with EEA relevance)

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 36(3) thereof,

Whereas:

(1) On 26 April 2018, the company European Registration Office B.V. ('the applicant') submitted to the competent authorities of Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, Poland and Spain an application for an authorisation granted by mutual recognition in accordance with Article 34 of Regulation (EU) No 528/2012 of the biocidal product ERO MP ('the product'). The product is a product for veterinary hygiene of product-type 3 in accordance with Annex V to Regulation (EU) No 528/2012, contains 24 % w/w of the active substance chlorocresol and is a disinfectant for professional use to be applied by low-pressure spraying of a diluted concentrate in non-porous surfaces and materials (use 1) and in floors and walls of animal housing (use 2). The product and its dilutions are classified as skin corrosive (H314) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([2]). The Netherlands is the reference Member State responsible for the evaluation in accordance with Article 34(1) of Regulation (EU) No 528/2012.

(2) On 4 July 2023, France referred objections to the coordination group pursuant to Article 35(2) of Regulation (EU) No 528/2012, indicating that the product does not meet the condition for authorisation laid down in Article 19(1), point (b)(iii), of that Regulation. According to France, a systemic exposure and risk assessment considering the acceptable exposure levels for chlorocresol should be performed. France considered that the use of the product by spraying does not meet the criteria for concluding qualitatively on the acceptability for professional exposure listed in Table 27 of Section 4.3.2.5.iv of the Guidance on the Biocidal Products Regulation Volume III Human Health – Assessment & Evaluation (Parts B+C), version 2.0; October 2015) ([3]) as the proposed risk mitigation measures and personal protective equipment are not sufficient to achieve a negligible exposure. France also considered that a combined systemic risk assessment should be carried out in accordance with Section 4.4.1 of that Guidance on the Biocidal Products Regulation as the product contains one active substance (chlorocresol) and the substance of concern propan-2-ol.

(3) As no agreement was reached in the coordination group on whether the biocidal product complies with the conditions for authorisation, on 15 July 2024 the Netherlands referred the unresolved objection to the Commission and provided the Commission with a detailed statement of the matter on which Member States were unable to reach an agreement and the reasons for their disagreement in accordance with Article 36(1) of Regulation (EU) No 528/2012. That statement was forwarded to the Member States concerned and to the applicant.

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

([2]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: https://data.europa.eu/eli/reg/2008/1272/oj).

([3]) https://echa.europa.eu/documents/10162/2672387/biocides_guidance_vol_iii_part_b_v20_superseded_en.pdf/7ad2c0c7-fb56-041d-9382-bb31eeb97da2?t=1507708448620.

(4) On 21 January 2025, the Commission asked the European Chemicals Agency (the 'Agency') for an opinion in relation to the disagreement in accordance with Article 36(2) of Regulation (EU) No 528/2012. The Agency was asked to conclude on whether a systemic exposure and risk assessment is necessary and if so, the outcome of that risk assessment. The Agency was also asked to conclude on whether the local risk from the use of the product is acceptable considering appropriate risk mitigation measures and wearing of personal protective equipment. Furthermore, the Agency was asked if it is necessary to conduct a combined exposure and risk assessment for chlorocresol and the substance of concern, propan-2-ol, and if so, the outcome of that risk assessment. Finally, the Agency was asked to clarify, based on the answers to the first questions, if the condition in Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012 is met for the product.

(5) On 16 May 2025, the Biocidal Products Committee of the Agency adopted its opinion ([4]). According to the Agency, a systemic exposure and risk assessment for the active substance chlorocresol and a combined risk assessment for the active substance and substance of concern should be performed. The Agency concluded that the systemic exposure and risk assessment, the local risk assessment and the combined risk assessment result in no unacceptable risks from the use of the product when applying certain risk mitigation measures. The Agency concluded that the product meets the conditions of Article 19(1), point (b)(iii), of Regulation (EU) No 528/2012.

(6) 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

1. The biocidal product ERO MP identified by the case number BC-HH039197-39 in the Register for Biocidal Products meets the condition for authorisation laid down in Article 19(1) point (b)(iii), of Regulation (EU) No 528/2012, subject to the following risk mitigation measures:

(a) wearing of the following personal protective equipment for the use of the product:

  (i) butyl rubber, LLDPE, neoprene, viton or butyl or latex chemical resistant gloves of at least Type B in accordance with EN ISO 374-1:2016 ([5]) or equivalent;

  (ii) impermeable coveralls of at least class 4 in accordance with the EN ISO 6529:2013 ([6])or equivalent;

  (iii) boots of at least class 2 in accordance with EN ISO 20345:2022 ([7]) or equivalent,

  (iv) chemical resistant tape to seal gap between sleeves and gloves and between boots and trousers of type A – EN 374-1:2016 ([8]) or ASTM F 739 ([9]) or equivalent;

  (v) face shield in accordance with EN 166 or equivalent ([10]);

  (vi) for use 1, respiratory protective equipment of protection factor 4 in accordance with EN 149:2001 ([11]), and for use 2, respiratory protective equipment of protection factor 10 in accordance with EN 149:2001;

(b) for re-entry in the treated areas, until the surfaces are dried, use of the same set of personal protective equipment as described in point (a) for use 2;

(c) applying by pressure sprayer at pressure lower than 3 bar;

(d) semi-automated or automated mixing and loading of the product;

([4]) https://echa.europa.eu/bg/bpc-opinions-on-article-38.
([5]) EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks (ISO 374-1:2016).
([6]) EN ISO 6529:2013. Protective clothing – Protection against chemicals – Determination of resistance of protective clothing materials to permeation by liquids and gases.
([7]) EN ISO 20345:2022. Personal protective equipment – Safety footwear (ISO 20345:2021).
([8]) EN ISO 374-1:2016. Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks (ISO 374-1:2016).
([9]) ASTM (American Society for Testing and Materials) Method F739-96.
([10]) EN 166:2002 Personal eye protection.
([11]) EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking.

(e) using spraying lance of at least 1 meter for the application of the product;

(f) applying the product backwards and only to floors (downward spraying only);

(g) ensuring that the stables are ventilated at maximum capacity during disinfection with the product and that there is no access of uninvolved persons during and after the use of the product until the treated surfaces are dry;

(h) limiting the use only to areas that are inaccessible to children;

(i) keeping the product out of reach of children and non-target animals;

(j) removing all food, feed and drinks prior to usage;

(k) using only in empty animal housing;

(l) training of the users to ensure appropriate handling of the product and the personal protective equipment prior to use.

2. Paragraph 1 shall be without prejudice to the application by employers of Council Directive 98/24/EC ([12]) and other Union legislation in the area of health and safety at work.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 November 2025.

For the Commission
Olivér VÁRHELYI
Member of the Commission

([12]) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).