EUROPEAN
COMMISSION

Brussels, 10.11.2023
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COMMISSION IMPLEMENTING DECISION

of 10.11.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Boehringer Ingelheim RCV GmbH & Co KG for a use of 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

(Only the English text is authentic)

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated ('4-tert-OPnEO'), is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 19 November 2021, Boehringer Ingelheim RCV GmbH & Co KG ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of 4-tert-OPnEO[2]. The use for which the authorisation was sought is industrial use of 4-tert-OPnEO as a detergent in the purification of lipidated OspA protein subsequently used for manufacturing of Lyme disease vaccine candidate.

(3) The European Chemicals Agency sent the opinions on the application, adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the Agency[3], to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 5 December 2022, the Commission received the opinions.

(4) RAC concluded in its opinion that it is not possible to determine a predicted no-effect concentration for the endocrine disrupting properties of 4-tert-OPnEO for the environment in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that, therefore, 4-tert-OPnEO is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation.

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1 OJ L 396, 30.12.2006, p. 1.

2 Different names and abbreviations are used to refer to the substance in the chemical safety report, including 'OPnEO'.

3 https://echa.europa.eu/documents/10162/30d7885e-3b03-2f73-e88f-50ef68600d86

As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to 4-tert-OPnEO and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) RAC noted that risk to the environment cannot be excluded for non-threshold substances, such as 4-tert-OPnEO, even at low exposure levels. Consequently, RAC takes the emissions of the substance as a proxy for the risk.

(6) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to the environment. RAC noted that all solid waste and the liquid waste contaminated with the highest concentrations of 4-tert-OPnEO will be collected for incineration so that releases to the environmental compartments have been minimized as far as technically and practically possible. The applicant has provided justification to the RAC that the collection of the remaining wastewater was not practically feasible since it implies a significant increase in collected wastewater volume. However, in order to confirm the representativeness of the estimated releases as well as the effectiveness of the risk management measures and operational conditions in place, RAC recommended to carry out a monitoring programme. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendation.

(7) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the risks to the environment arising from the use of that substance. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the use outweigh the risk to the environment arising from that use.

(8) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, an authorisation may be granted if the applicant for authorisation submits a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible.

(9) In its opinion, SEAC concluded that there are no suitable alternative substances or technologies available by the date of the adoption of the opinion, for the applicant and in the Union. The Commission, having evaluated SEAC's assessment and all relevant information available, concludes that further research and development and testing are necessary to assess whether the identified alternatives allow preserving the structure of the proteins and whether they reach a sufficient selectivity and rate of protein solubilisation and isolation for the manufacturing of a Lyme disease vaccine candidate as required by the applicable regulatory framework. Thus, the Commission considers that it cannot be deemed that the identified alternatives allow the functionality needed for the use for which authorisation is sought. Therefore, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

(10) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of 4-tert-OPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.

(11) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional emission information.

(12) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at twelve years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the emissions to the environment, the socio-economic benefits of the use of the substance, the lack of suitable alternatives within a shorter timeframe and the research and development efforts undertaken by the applicant, as well as the regulatory approval process for vaccines.

(13) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official languages of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(14) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision neither affects the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible, nor does it affect the obligation of the employer to eliminate or reduce to a minimum risks to the health and safety of workers at work involving hazardous chemical agents in accordance with Article 5(2) of Council Directive 98/24/EC[4]. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7] and 98/24/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

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4 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).

5 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

6 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

7 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

(15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[8] or Directive 2010/75/EU[9] of the European Parliament and of the Council, nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(16) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO):

Authorisation number	Authorised use
REACH/23/31/0	Industrial use as a detergent in the purification of lipidated OspA protein subsequently used for manufacturing of Lyme disease vaccine candidate

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12].

Article 2

1. The review period shall expire on 19 November 2033.

2. The authorisation shall cease to be valid on 19 November 2033 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 19 May 2031.

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8 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

9 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

10 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

11 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

12 https://ec.europa.eu/docsroom/documents/52536

Article 3

1. The monitoring arrangements set out in paragraphs 2, 3 and 4 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring the releases of 4-tert-OPnEO and its principal degradation products into the wastewater prior to its release to the off-site sewage treatment plant once the full-scale production starts. The monitoring programme shall:

   (a) be carried out at least four times per year and during the time of operation. The frequency of the measurements shall be sufficient to capture the variability in concentrations of the substance and its principal degradation products in the wastewater due to changes or operational fluctuations in the process;

   (b) be based on an analytical method capable of adequately characterising the substance and its principal degradation products in wastewater, at an appropriately low limit of quantification;

   (c) be recorded as to include details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

3. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 2 and related contextual information to regularly review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce emissions of 4-tert-OPnEO to a level as low as technically and practically possible.

4. The authorisation holder shall document and keep the information obtained from the monitoring programme referred to in paragraph 2, as well as the outcome and conclusions of the review and of any action taken in accordance with paragraph 3. The authorisation holder shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 4

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 5

Where the authorisation holder submits a review report, it shall include the information referred to in Article 3(4).

Article 6

This Decision is addressed to Boehringer Ingelheim RCV GmbH & Co KG, Dr.-Boehringer-Gasse 5-11, 1121, Wien, Austria

Done at Brussels, 10.11.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION