EUROPEAN
COMMISSION

Brussels, 15.6.2023
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COMMISSION IMPLEMENTING DECISION

of 15.6.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Merck Millipore Limited for certain uses 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 14 June 2019, Merck Millipore Limited ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of 4-tert-OPnEO[2]. The uses for which the authorisation was sought are industrial use of 4-tert-OPnEO as a surface-active ingredient for the production of two types of mixed cellulose ester membranes (lateral flow and microfiltration membranes) ('use 1') and downstream use of 4-tert-OPnEO as component of mixed cellulose ester membranes ('use 2').

(3) On 17 December 2020, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[3] and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinions 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

[1] OJ L 396, 30.12.2006, p. 1.

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

[3] https://echa.europa.eu/documents/10162/6259f814-5aea-e15b-baaa-13ed74dabdcf
https://echa.europa.eu/documents/10162/55e6f68a-3f15-aade-858c-6d73269e0c9a

to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. 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 on use 1, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective to limit the risk to the environment. RAC noted that the applicant has demonstrated that emissions have been prevented or minimised as far as technically and practically possible. However, in order to confirm the effectiveness of the risk management measures and operational conditions, RAC recommended to carry out a monitoring programme. Having evaluated the RAC's assessment, the Commission agrees with its conclusion and recommendation.

(7) In its opinion on use 2, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective to limit the risk to the environment as regards exposure scenario 1, whereas they are not appropriate and effective as regards exposure scenario 2. As regards exposure scenario 1, RAC noted that used products are treated as hazardous waste and that emissions into the environmental compartment are therefore expected to be zero. As regards exposure scenario 2, although there is no direct discharge of 4-tert-OPnEO to wastewater, releases of the substance may occur from the potential landfilling of used products from consumer uses. Therefore, RAC recommended certain conditions for authorisation involving changes to the product design and the system for the collection and further treatment of the products as regards exposure scenario 2. Having evaluated the RAC's assessment, the Commission agrees with its conclusion and recommendation.

(8) In its opinions on uses 1 and 2, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the socio-economic benefits and of the risk to the environment associated with the continued use of 4-tert-OPnEO. Taking into account SEAC's conclusion, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with both uses of 4-tert-OPnEO, the estimated remaining combined emissions in the order of hundreds of grams of the substance per year, the estimated economic benefits due to avoided profit losses and avoided social cost of job losses at minimum in the order of between ten million euro and hundred million euro over the entire review period for both uses, the estimated combined costs of avoiding the remaining releases of the substance in the order of millions of euro and tens of millions of euro per kilogram, the qualitatively assessed additional socio-economic benefits of the continued uses due to the avoided loss of supply and avoided increase in the price of mixed cellulose ester (MCE) membranes used in multiple industrial and life science sectors, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of 4-tert-OPnEO outweigh the risk to human health or the environment arising from those uses.

(9) 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 an authorisation is sought should be considered to be technically feasible.

(10) In its opinions on uses 1 and 2, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the sunset date. The Commission, having evaluated the SEAC's assessment and all relevant information available, notes that the identified alternatives would still need to undergo extensive testing to verify whether they provide, among others, the required membrane wettability, biocompatibility and product stability in MCE membranes, as well as to obtain regulatory approvals. Thus, the Commission considers that it cannot be deemed that the identified alternatives allow the functionality needed for the uses applied for. Therefore, the Commission agrees with the 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.

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

(12) However, for the sake of clarity, the Commission considers it appropriate to align the description of use 2 with the information provided in the application and assessed in the opinions, by including the reference to the two types of membranes covered by that use. Therefore, use 2 should read as 'Downstream use as component of two types of mixed cellulose ester membranes (lateral flow and microfiltration membranes)'.

(13) 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.

(14) In its opinions, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 12 years for uses 1 and 2. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and, in particular, the low emissions, the socio-economic benefits, the lack of suitable alternatives within a shorter timeline, as well as the high performance requirements and regulatory approvals needed for medicinal products.

(15) 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.

(16) 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.

(17) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], 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.

(18) 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,

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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).

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).

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 uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO):

Authorisation number	Authorised use
REACH/23/20/0	Industrial use as a surface-active ingredient for the production of two types of mixed cellulose ester membranes (lateral flow and microfiltration membranes)
REACH/23/20/1	Downstream use as component of two types of mixed cellulose ester membranes (lateral flow and microfiltration membranes)

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], and to the conditions set out in Article 2.

Article 2

1. The authorisation bearing number REACH/23/20/1 shall be subject to the conditions set out in paragraphs 2 to 6, as regards exposure scenario 2.

2. The authorisation holder shall carry out, at the latest by 15 June 2024, a study on:

   (a) the possibilities to implement changes to the product design as to minimise release to environmental compartments;

   (b) the feasibility to implement a system for the collection and adequate treatment of used products following consumer use. The treatment shall minimise releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Disposal as domestic waste or landfilling does not constitute adequate treatment.

3. The authorisation holder shall act without delay upon the outcome of the study referred to in paragraph 2, document such actions and make that information available, upon request, to the competent authority of the Member State where the use takes place.

4. Following the implementation of changes in accordance with paragraph 3, the authorisation holder shall provide consumers with specific instructions on appropriate disposal of used products as waste with the aim to minimise release to environmental compartments. As regards products containing mixed cellulose ester membranes made with 4-tert-OPnEO that can be disposed as domestic waste or discharged into wastewater, the authorisation holder shall ensure that those instructions specify that disposal as domestic waste or into wastewater is not allowed.

[12] https://ec.europa.eu/docsroom/documents/44404

5. If the feasibility study referred to in paragraph 2 shows that changes are not feasible, the authorisation holder shall at minimum provide consumers and professional users with instructions on appropriate disposal of used products as waste with the aim to minimise release to environmental compartments.

6. If a system for the collection and further treatment of used products in accordance with paragraph 2(b) is implemented, the authorisation holder shall keep track of the return rate of the products.

Article 3

The review period shall expire on 4 January 2033.

The authorisation shall cease to be valid on 4 January 2033 if the review report for those uses has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

Article 4

1. As regards the authorisation bearing number REACH/23/20/0, the monitoring arrangements set out in paragraph 2 to 4 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring the concentration of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site wastewater treatment plant. Those measurements shall be:

   (a) carried out at least four times per year and during the time of operation and be sufficiently frequent to capture the variability in concentrations of 4-tert-OPnEO and its principal degradation products in the wastewater due to changes or operational fluctuations in the process;

   (b) based on an analytical method capable of adequately characterising 4-tert-OPnEO and its principal degradation products in wastewater at appropriately low limit of quantification;

   (c) recorded with 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 in accordance with paragraph 2 and related contextual information to 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 in accordance with paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any measure taken in accordance with paragraph 3. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 5

Where the authorisation holder submits a review report, it shall include:

1. as regards the authorisation bearing number REACH/23/20/0, the information referred to in Article 4(4);

2. as regards the authorisation bearing number REACH/23/20/1, the information referred to in Article 2(3) and (6).

Article 6

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 uses take place in an official language of that Member State.

Article 7

This Decision is addressed to Merck Millipore Limited, 37, Tullagreen, Carrigtwohill, Cork, Ireland.

Done at Brussels, 15.6.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION