EUROPEAN
COMMISSION

Brussels, 4.10.2022
C(2022) 6922 final

COMMISSION IMPLEMENTING DECISION

of 4.10.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to bioMérieux SA for certain uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

(Only the English text is authentic)

COMMISSION IMPLEMENTING DECISION

of 4.10.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to bioMérieux SA for certain uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)

(Only the English text is authentic)

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 20 February 2019, bioMérieux SA ('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. The uses for which authorisation was sought are industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of reagents for molecular in vitro preparative and testing applications ('use 1'), industrial use of 4-tert-OPnEO for its non-ionic detergent properties in view of controlling the amount of non-specific reactions in the formulation of in vitro reagents for clinical and industrial in-vitro testing immunoassays ('use 2'); industrial use of 4-tert-OPnEO for its non-ionic detergent properties, used for the extraction of biological material which is further formulated and coated on articles intended for clinical and industrial in vitro testing applications ('use 3').

(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[2] and sent to it pursuant to Article 64(5), third 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 for the environment of 4-tert-

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

[2] https://echa.europa.eu/documents/10162/dd467d08-d023-46db-aeab-278ffdc4bc94
https://echa.europa.eu/documents/10162/217193e2-ebf7-4bd8-09bc-701b18455054
https://echa.europa.eu/documents/10162/d6de8193-908d-5f5f-939e-df8293a5c42a

OPnEO 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. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and authorisations 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, 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 all liquid and solid waste is disposed of for incineration, and that the applicant thereby has demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. However, in order to address shortcomings regarding the release estimates and taking into account that residual releases of 4-tert-OPnEO originating from the washing of glassware are discharged into wastewater, RAC recommended to carry out a monitoring programme. Such monitoring programme would also aim to ensure the effectiveness of the risk management measures and operational conditions in place. Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(7) In its opinions on uses 2 and 3, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective to limit the risk to the environment. RAC noted that releases occur during different production steps and acknowledged that there are no technical restraints for their collection, thus recommended as condition to ensure that all releases during those steps are collected for adequate treatment. In addition, RAC noted that residual releases of 4-tert-OPnEO into the wastewater also originate from laundry and glassware washing, after treatment in the on-site wastewater treatment plant, thus recommended to carry out a monitoring programme of that wastewater. However, the Commission acknowledged that the applicant implemented changes to the production steps as to ensure that all releases, including from washing steps, are collected and disposed of for incineration by December 2021 at the latest. The applicant implemented those changes after the adoption of RAC’s opinions and informed the Commission through the submission of an updated chemical safety report. Having evaluated RAC’s assessment, the Commission agrees with the recommendation to set out monitoring programmes.

(8) In its opinion on all uses, SEAC concluded that it has no substantial reservations on the quantitative and the qualitative elements of the applicant’s assessment of the socio-economic benefits and the risk to the environment associated with the continued uses of the substance. Taking into account SEAC’s assessment, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with the uses of the substance, the estimated combined emissions from two sites of a few kilograms of the substance per year, the estimated combined benefits due to avoided profit losses and job losses in the order between tens of millions of euro and one hundred million euro per year, the estimated combined costs of avoiding the remaining releases of the substance in the order of hundreds of millions of euro per kilogram, the qualitatively assessed additional socio-economic benefits of the continued uses of the substance due to the availability of in-vitro applications used in

clinical and industrial applications, and any relevant distributional impacts, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of the substance outweigh the risk to human health and 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 applied for should be considered to be technically feasible.

(10) In its opinions on all uses, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that further research is required to establish whether any of the identified alternatives allows achieving the detergency in mild conditions, protein stabilisation and solubilisation, wettability, virus inactivation and lysis performance, required in reagent formulation, control of non-specific reactions, and preparation of biological material for in-vitro testing applications. Thus, the Commission considers that it cannot be deemed that the identified alternatives allow the functionality needed for the use applied for. 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.

(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) The Commission has based its assessment on the relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on the existence of 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 additional emission information be generated.

(13) 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 socio-economic benefits, the emissions, the lack of suitable alternatives within a shorter timeline, the long investment cycles, as well as the high performance requirements and regulatory approvals necessary for medical devices.

(14) In its opinion on use 3, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 4 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the socio-economic benefits, the emissions and the ongoing research and development activities.

(15) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language 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 does not affect 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 or 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[3]. 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[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC or any national binding occupational limit values which may be stricter than the applicable Union limit values.

(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[7] or Directive 2010/75/EU of the European Parliament and of the Council[8], 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[9] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[10]. 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.

---

3 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).

4 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).

5 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).

6 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).

7 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).

8 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).

9 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).

10 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).

(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,

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/22/28/0	Industrial use for its non-ionic detergent properties in the formulation of reagents for molecular in vitro preparative and testing applications
REACH/22/28/1	Industrial use for its non-ionic detergent properties in view of controlling the amount of non-specific reactions in the formulation of in vitro reagents for clinical and industrial in-vitro testing immunoassays
REACH/22/28/2	Industrial use for its non-ionic detergent properties, used for the extraction of biological material which is further formulated and coated on articles intended for clinical and industrial in vitro testing applications

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety reports[11], and to the conditions set out in Article 2 this Decision.

Article 2

1. As regards the authorisation bearing numbers REACH/22/28/1 and REACH/22/28/2, the conditions set out in paragraphs 2 to 4 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring 4-tert-OPnEO and its principal degradation products prior to release of wastewater to the local sewage treatment plant. The monitoring programme shall:

   (a) be carried out at least four times per year while the plant is in operation. The frequency of the measurements shall be such as to capture variability in the concentrations of 4-tert-OPnEO 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 4-tert-OPnEO and its principal degradation products in wastewater at appropriately low limit of quantification;

[11] https://ec.europa.eu/docsroom/documents/44385
https://ec.europa.eu/docsroom/documents/49454

(c) be recorded so 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 in the measurements referred to in 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 paragraphs 2 and 3 and submit it, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. As regards the authorisation bearing numbers REACH/22/28/0 and REACH/22/28/1, the review period shall expire on 4 January 2033.

The authorisations bearing numbers REACH/22/28/0 and REACH/22/28/1 shall cease to be valid on 4 January 2033 with regard to an authorised use if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

2. As regards the authorisation bearing number REACH/22/28/2, the review period shall expire on 4 January 2025.

The authorisation bearing number REACH/22/28/2 shall cease to be valid on 4 January 2025 if the review report for that use has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2023.

Article 4

1. As regards the authorisation bearing number REACH/22/28/0, the monitoring arrangements set out in paragraphs 2 to 5 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring 4-tert-OPnEO and its principal degradation products prior to release of wastewater to the local sewage treatment plant. The monitoring programme shall:

(a) be carried out at least four times per year while the plant is in operation. The frequency of the measurements shall be such as to capture variability in the concentrations of 4-tert-OPnEO 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 4-tert-OPnEO and its principal degradation products in wastewater at appropriately low limit of quantification;

(c) be recorded so 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 in the analysis and measurements referred to in 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 carry out for the first time by 4 October 2023, and afterwards when new information becomes available, a study on the feasibility of implementing collection and treatment of the remaining releases originating from washing the glassware, and subsequently act on the outcome of that study.

5. The authorisation holder shall document and keep the information obtained in accordance with paragraphs 2 to 4 and submit it, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

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

(a) as regards the authorisation bearing numbers REACH/22/28/1 and REACH/22/28/2, the information referred to in Article 2(4);

(b) as regards the authorisation bearing number REACH/22/28/0, the information referred to in Article 4(5).

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 use takes place in an official language of that Member State.

Article 7

This Decision is addressed to BioMérieux SA, Chemin de l'Orme, 69280, Marcy-l'Etoile, France.

Done at Brussels, 4.10.2022

For the Commission
Thierry BRETON
Member of the Commission