EUROPEAN
COMMISSION

Brussels, 23.5.2025
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COMMISSION IMPLEMENTING DECISION

of 23.5.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to BioMérieux SA for a use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) in the context of a review and amending Implementing Decision C(2022) 6922

(Only the English text is authentic)

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(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 4 October 2022, by Commission Implementing Decision C(2022) 6922[2], an authorisation was granted to BioMérieux SA for certain uses of 4-tert-OPnEO, including the 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. BioMérieux SA was assigned, for this use, authorisation number REACH/22/28/2. The expiry of the review period referred to in Article 60(9), point (e) of Regulation (EC) No 1907/2006 for that authorised use of 4-tert-OPnEO was set at 4 January 2025.

(3) On 21 June 2023, BioMérieux SA submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation for the use of 4-tert-OPnEO[3]. The use for which authorisation was sought is the 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.

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1 OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj .

2 Commission Implementing Decision C(2022) 6922 of 4 October 2022 granting an authorisation for certain uses of 4-(1,1,3,3- tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (BioMérieux SA).

3 Different names and abbreviations are currently used to refer to the substance, including ‘OPE’ in the chemical safety report.

(4) The European Chemicals Agency sent the opinions[4] on the review report adopted by its Committee for Risk Assessment ('RAC') and its Committee for Socio-economic Analysis ('SEAC') to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 16 August 2024, the Commission received the opinions.

(5) In its opinion, RAC concluded that it is not possible to determine a predicted no-effect concentration for the endocrine disrupting properties for the environment of 4-tert-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 4-tert-OPnEO and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(6) RAC noted that despite the absence of a dose-response relation, a risk to the environment cannot be excluded for 4-tert-OPnEO, even at low exposure levels. Consequently, RAC takes the emissions of the substance as a proxy for the risk.

(7) In its opinion, RAC concluded that the risk management measures and operational conditions described in the review report are expected to be appropriate and effective in limiting the risk to the environment posed by the use of 4-tert-OPnEO described in the review report. In particular, RAC notes that all solid waste and possibly contaminated rinsing water originating from the washing of some non-disposable equipment used during the mixtures formulation and antigen purification steps are collected and disposed of for incineration so that the use for which an authorisation is sought may result in no releases of the substance to the environment. Hence, BioMérieux SA has demonstrated that emissions have been prevented or reduced to a level as low as technically and practically possible. However, RAC recommended imposing additional monitoring arrangements for environmental release of 4-tert-OPnEO with the aim to address some shortcomings in emissions estimates and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions in place.

(8) Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations. Nevertheless, the Commission notes that certain measures set out in Implementing Decision C(2022) 6922 have not been not implemented by BioMérieux SA, as indicated by RAC. Therefore, the Commission considers appropriate to set out additional measures, as a condition for authorisation, among others to ensure that the provisions are duly implemented.

(9) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the risk to the environment arising from the use of 4-tert-OPnEO. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that BioMérieux SA has demonstrated that the benefits of the use outweigh the risk to the environment arising from that use.

(10) For an alternative to be suitable it needs to 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, the

[4] https://echa.europa.eu/documents/10162/22779b12-e5bf-6b6c-cade-3581f315e37b

applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

(11) 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.

(12) In its opinion, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant but that there were technically and economically feasible alternatives in the Union at the time of adoption of the opinions. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that there is a technically and economically feasible alternative technology which is commercially available in the Union, providing the overall functionality of the substance for the use for which an authorisation is sought. However, the Commission considers that additional research is needed for BioMérieux SA to improve and adapt that technology in order to eliminate the technical limitations in terms of detergent properties with protein solubilisation, virus inactivation and analytical and clinical performance, and that BioMérieux SA would require, among others, to redesign a new antigen selection based on recombinant protein technology. The Commission therefore agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.

(13) In its opinion, SEAC concluded that the substitution plan is credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the use for which an authorisation is sought and the substitution plan submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(14) 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 review report, provided that the risk management measures described in the chemical safety report are applied and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

(15) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holder to generate and include additional information about emissions in the review report.

(16) In its opinion, SEAC recommended the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 7 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are expected to be appropriate and effective to limit the risk, SEAC's conclusion on the risk to the environment and on the socio-economic benefits of the use of the substance.

(17) 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.

(18) This Decision does not affect the obligation of the authorisation holder to ensure that the 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[5]. 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[6], 92/85/EEC[7], 94/33/EC[8] and 98/24/EC or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(19) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive 2010/75/EU[10] 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[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament

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5 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).

6 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, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

7 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, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

8 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, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

9 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, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

10 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, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

11 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, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(20) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. Implementing Decision C(2022) 6922 should be amended regarding the authorisation bearing number REACH/22/28/2.

(21) 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 to the following person for the following use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated ('4-tert-OPnEO'):

Authorisation number	Authorisation holder	Authorised use
REACH/25/28/0/R1	BioMérieux SA	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 report[13], and to the conditions set out in Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 7.

2. By 23 May 2026, and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing the following measures:

   (a) switch to disposable intermediate containers, allowing to avoid as much as possible rinsing operations;

   (b) optimisation of the process to reduce the liquid waste and the cleaning operations burden;

   (c) additional technical improvements to minimise 4-tert-OPnEO release to the local sewage treatment plant.

[12] 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, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

[13] https://ec.europa.eu/docsroom/documents/61776

The authorisation holder shall act in accordance with the outcome of that study.

3. The authorisation holder shall implement a monitoring programme measuring the concentration of 4-tert-OPnEO and its principal degradation products in the rinsing effluents generated during the cleaning operations of the non-disposable equipment before sending to the glassware laundry. The programme shall include measurements which shall:

   (a) be carried out at the latest by 23 August 2025, during the time of operation and performed on each rinsing water phase and on the effluent produced after the final cleaning step with specific cleaning solution;

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

   (c) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

   (d) be recorded so as to include contextual information associated with each set of measurements;

4. 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 on-site sewage treatment plant. The programme shall include measurements which shall:

   (a) be carried out at the latest by 23 August 2025, for 24 hours and at least four times per year afterwards 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 representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

   (d) be recorded so as to include contextual information associated with each set of measurements. The record should at least contain details on the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values.

5. The authorisation holder shall carry out a mass balance analysis. The analysis shall be based on the outcome of the monitoring programmes referred to in paragraphs 3 and 4 and shall:

   (a) be carried out for the first time by 23 November 2025 and annually thereafter;

   (b) include details of the calculations carried out;

   (c) include the assumptions made, if any;

   (d) include the corresponding release values;

   (e) include discharges generated during cleaning operations.

6. The authorisation holder shall use the information gathered by way of the measurements and calculations referred to in paragraphs 3 to 5 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, introduce measures to further reduce emissions of 4-tert-OPnEO to a level as low as technically and practically possible.

7. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 3 and 4, including the contextual information associated with each set of measurements, as well as the information on the outcome and conclusions of the reviews and on any measure taken in accordance with paragraphs 2, 5 and 6 and shall make that information available, upon request, to the competent authority of the Member State where the authorised use take place.

Article 3

The review period shall expire on 4 January 2032.

The authorisation shall cease to be valid on 4 January 2032 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2030.

Article 4

The following monitoring arrangements shall apply: the authorisation holder shall document the steps taken to substitute 4-tert-OPnEO in accordance with the substitution plan, including information concerning any deviations from the initial substitution plan and any contingency measures taken and shall make that documentation available, 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 information referred to in Article 2(7) as well as in Article 4.

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. The brief summary shall be drafted in an official language of that Member State.

Article 7

Implementing Decision C(2022) 6922 is amended as follows:

(1) In Article 1, the following reference is deleted:

‘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’

(2) Article 2(1) is amended as follows:

‘As regards the authorisation bearing number REACH/22/28/1, the conditions set out in paragraphs 2 to 4 shall apply.’;

(a) Article 3(2) is repealed.

(b) Article 5(a) is replaced by the following:

‘as regards the authorisation bearing number REACH/22/28/1, the information referred to in Article 2(4);’.

Article 8

This Decision is addressed to:

BioMérieux SA, 376 Chemin de l’Orme, 69280, Marcy-l’Etoile, France.

Done at Brussels, 23.5.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION