EUROPEAN
COMMISSION

Brussels, 20.3.2023
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COMMISSION IMPLEMENTING DECISION

of 20.3.2023

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

(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') and 4-nonylphenol, branched and linear, ethoxylated ('4-NPnEO') are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of those substances are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 20 May 2019, Bio-Rad ('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 and a use of 4-NPnEO[2]. The uses for which authorisation was sought are industrial uses of 4-tert-OPnEO and 4-NPnEO for their non-ionic detergent properties in view of controlling reactions and chromatography support saturation required in the production of highly specific and sensitive in vitro immunoassays dedicated to the diagnosis of viral (HIV, HCV, Dengue) and parasitic infections ('use 1'); industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of in vitro reagents dedicated to high-performance microbiological and immunological assays supported on microplates or magnetic particles ('use 2'); industrial use of 4-tert-OPnEO for its detergent properties used for extraction, viral inactivation and purification of biological material further formulated and /or coated on articles intended for IVD applications ('use 3'); industrial use of raw material containing 4-tert-OPnEO for protein stabilisation for veterinary in vitro diagnostic application ('use 4').

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

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

(3) On 15 September 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 and 4-NPnEO for the environment in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 4-tert-OPnEO and 4-NPnEO are substances 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 those substances and authorisations may therefore only be granted with respect to them 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 substances as a proxy for the risk.

(6) In its opinions on all uses, 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, although all solid waste which had been in contact with 4-tert-OPnEO is collected and disposed of for incineration, wastewater containing residual amounts of 4-tert-OPnEO and 4-NPnEO from the washing steps was released untreated to the collective sewage system. Nevertheless, the Commission acknowledged that the applicant successfully finalised the implementation of the procedures of collection of wastewater as well as the new risk management measures and operational conditions, which were initially recommended by RAC as condition for authorisation, with the aim at reducing their emission to a level as low as technically and practically possible. The new measures are reflected in an updated chemical safety report notified to RAC in September 2022. Moreover, RAC recommended monitoring programmes in order to provide information on the trends in emissions over the authorisation period as well as to verify the effectiveness of the measures. Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(7) In its opinions on all uses, 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 uses of the substances. 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 substances, the estimated combined emissions from one site in the order of a few kilograms of the substances over the entire review period per year, the estimated combined benefits due to avoided profit losses and job losses at minimum in the order of tens of millions of euro to hundreds of millions of euro over the review period, the estimated combined costs of avoiding the remaining releases of the substances in the order of tens of millions of euro, the qualitatively assessed additional socio-economic benefits of the continued uses of the substances due to the availability of diagnostics kits for human infectious diseases and avoided penalties for non-

[3] https://echa.europa.eu/documents/10162/73fe3888-3702-af51-6208-a3745cfeeaf1
https://echa.europa.eu/documents/10162/7e60e549-dd44-bd7e-caca-844b8a71cb6d
https://echa.europa.eu/documents/10162/2d77aa22-c5dc-d1fb-bc6b-cd3e26b86278
https://echa.europa.eu/documents/10162/9823792f-13d2-2ba3-8d8b-c0658995bc96

compliance for customer supply contracts, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of the substances outweigh the risk to human health or the environment arising from those uses.

(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 which authorisation is sought should be considered to be technically feasible.

(9) 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 the shortlisted alternatives fulfil the mild detergency, virus inactivation, membrane lysis, protein stabilisation standards and have the ability to prevent non-specific reactions required to meet customer requirements as well as to obtain the necessary regulatory approvals. The Commission therefore considers that it cannot be deemed that the identified alternatives allow the functionality needed for the uses applied for. Thus, 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 uses of 4-tert-OPnEO and 4-NPnEO 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.

(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 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 the generation of additional emission information.

(12) SEAC recommended in its opinions on uses 1, 2 and 3 that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 12 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 level of emissions, the lack of suitable alternatives within a shorter timeline, the long investment cycles, as well as the high performance requirements, testing, and lengthy regulatory approvals necessary for medicinal products.

(13) SEAC recommended in its opinion on use 4 that 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, the socio-economic benefits, the level of emissions, the lack of suitable alternatives within a shorter timeline, the long investment cycles, the registration processes in the veterinary sector,

as well as the high performance requirements, testing, and lengthy regulatory approvals for veterinary products.

(14) 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 uses take 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.

(15) 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[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 Union limit values.

(16) 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

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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).

environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(17) 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') and 4-nonylphenol, branched and linear, ethoxylated ('4-NPnEO'):

Authorisation number	Authorised use
REACH/23/9/0	Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in view of controlling reactions and chromatography support saturation required in the production of highly specific and sensitive in vitro immunoassays dedicated to the diagnosis of viral (HIV, HCV, Dengue) and parasitic infections
REACH/23/9/1	Industrial use of 4-NPnEO for its non-ionic detergent properties in view of controlling reactions and chromatography support saturation required in the production of highly specific and sensitive in vitro immunoassays dedicated to the diagnosis of viral (HIV, HCV, Dengue) and parasitic infections
REACH/23/9/2	Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of in vitro reagents dedicated to high-performance microbiological and immunological assays supported on microplates or magnetic particles
REACH/23/9/3	Industrial use of 4-tert-OPnEO for its detergent properties used for extraction, viral inactivation and purification of biological material further formulated and /or coated on articles intended for IVD applications
REACH/22/9/4	Industrial use of raw material containing 4-tert-OPnEO for protein stabilization for veterinary in vitro diagnostic application

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

[12] https://ec.europa.eu/docsroom/documents/43144

Article 2

1. The authorisation shall be subject to the conditions set out in paragraphs 2 to 6.

2. The authorisation holder shall carry out a mass balance analysis. That analysis shall:

   (a) be carried out for the first time by 20 June 2023 and afterwards annually;

   (b) include the details of the calculations carried out;

   (c) include the assumptions made, if any;

   (d) include the corresponding release values.

3. The authorisation holder shall carry out a monitoring programme measuring 4-tert-OPnEO and 4-NPnEO and their principal degradation products in the wastewater prior to its release to the municipal sewage treatment plant. The monitoring programme shall:

   (a) be carried out at least 4 times per year and during the time of operation. The frequency of the measurements shall be such as to capture the variability in concentrations of 4-tert-OPnEO and 4-NPnEO and their 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 substances and their principal degradation products in the waste water at an appropriately low limit of quantifications;

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

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

5. The authorisation holder shall finalise by 20 March 2024 and afterwards when new information becomes available, a study to assess the feasibility to implement an adequate treatment of residual wastewater and shall act in accordance with the outcome of that study. The treatment shall minimise releases of 4-tert-OPnEO and 4-NPnEO to environmental compartments as far as technically and practically possible.

6. The authorisation holder shall document and keep the information obtained from the monitoring programme referred to in paragraphs 2 and 3, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 4, together with the information collected and any action taken pursuant to paragraph 5. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where an authorised use takes place.

Article 3

1. As regards the authorisation bearing numbers REACH/23/9/0, REACH/23/9/1, REACH/23/9/2 and REACH/23/9/3, the review period shall expire on 4 January 2033.

The authorisation shall cease to be valid on 4 January 2033 with regard to uses bearing numbers REACH/23/9/0, REACH/23/9/1, REACH/23/9/2 or REACH23/9/3 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.

2. As regards the authorisation bearing number REACH/23/9/4, the review period shall expire on 4 January 2028.

The authorisation shall cease to be valid on 4 January 2028 with regard to use bearing number REACH/23/9/4, 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 2026.

Article 4

The following monitoring arrangement shall apply: the authorisation holder shall ensure that the in vitro assays and related products containing 4-tert-OPnEO or 4-NPnEO are provided to the downstream users with instructions on the correct disposal of those assays and related products.

Article 5

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

(a) the information referred to in Article 2(6);

(b) a representative survey of the downstream users' methods of collection and treatment of the in vitro assays and related products containing 4-tert-OPnEO or 4-NPnEO. The survey shall specify whether the instructions referred to in Article 4 have been followed.

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 Bio-Rad, 3 Boulevard Raymond Poincaré, 92430 Marnes-la-Coquette, France.

Done at Brussels, 20.3.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION