EUROPEAN
COMMISSION

Brussels, 1.12.2023
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COMMISSION IMPLEMENTING DECISION

of 1.12.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Prionics Lelystad B.V. 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 21 May 2021, Prionics Lelystad B.V. (‘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 4-NPnEO[2]. The use for which the authorisation was sought is as components of buffer solutions to produce antigens (cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of microorganisms that produce targeted antigen and solvent exchange) and in-process and final quality control of antigens intended for use as veterinary and human health laboratory reagents in scientific research and development and in vitro Diagnostic applications.

(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 17 June 2022, the Commission received the opinions.

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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 ‘OPE’ and ‘NPE.

3 https://echa.europa.eu/documents/10162/c411c9c2-ea13-32fe-be8a-7328b638df14

(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 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 4-tert-OPnEO and 4-NPnEO and an authorisation may therefore only be granted with respect to those substances 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 and 4-NPnEO, even at low exposure levels. Consequently, RAC takes the emissions of the substances 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 wastewater are collected and disposed of for incineration so that the uses for which authorisation is sought result in almost no releases of the substances to the environment, and the applicant has demonstrated that emissions have been prevented or reduced to a level as low as technically and practically possible. Having evaluated RAC's assessment, the Commission agrees with its conclusion. Nevertheless, in order to ensure that downstream users dispose used or expired products appropriately, and with the aim to minimise releases to environmental compartments, the Commission considers it appropriate to require that they are provided with instructions on that disposal.

(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 uses of those substances. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the uses outweigh the risk to 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 the uses 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, both for the applicant and in the Union. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that testing, verification and validation of identified alternative substances and methods are still required to confirm their technical feasibility for the entire range of products, in terms of the necessary lysis of the intact cells from the antigen culture, and to obtain the necessary regulatory approvals. Thus, the Commission considers that it cannot be deemed that the shortlisted alternatives allow the functionality needed for the uses 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 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 are fully applied. Nevertheless, for the sake of clarity, the description of the uses authorised by this Decision should be 'as component of buffer solutions with the following purposes: (1) for antigen production (to achieve cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of microorganisms that produce targeted antigen and solvent exchange); and (2) to carry out in-process and final quality control of antigens intended for use as veterinary and human health laboratory reagents in scientific research and development and in vitro diagnostic applications'.

(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.

(12) SEAC recommended in its opinion 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, RAC's conclusion that there are almost no releases of the substances to the environment, the socio-economic benefits of the future uses of the substances, the lack of suitable alternatives within a shorter timeframe and the research and development efforts undertaken by the applicant, as well as the time required to substitute to an alternative, including the time needed to obtain the necessary regulatory approvals.

(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 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.

(14) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substances 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

[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

occupational limit values which may be stricter than the applicable limit values under Union law.

(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 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/23/34/0	4-tert-OPnEO as component of buffer solutions with the following purposes: (1) for antigen production (to achieve cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of microorganisms that produce targeted antigen and solvent exchange) and (2) to carry out in-process and final quality control of antigens intended for use as veterinary and human health laboratory reagents in scientific research and development and in vitro diagnostic applications

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).

REACH/23/34/1	4-NPnEO as component of buffer solutions with the following purposes: (1) for antigen production (to achieve cell extraction, cell lysis, coating of biological antigens onto articles, inactivation of microorganisms that produce targeted antigen and solvent exchange) and (2) to carry out in-process and final quality control of antigens intended for use as veterinary and human health laboratory reagents in scientific research and development and in vitro diagnostic applications

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 4 January 2033.

2. The authorisation shall cease to be valid on 4 January 2033 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 2031.

Article 3

The following monitoring arrangements shall apply: the authorisation holder shall provide the downstream users with instructions on the correct disposal of used or expired products as waste with the aim to minimise release to environmental compartments.

Article 4

Where the authorisation holder submits a review report, it shall include a representative survey of the downstream users' methods of collection and treatment of used or expired products containing 4-tert-OPnEO or 4-NPnEO. The survey shall specify whether the instructions referred to in Article 3 have been followed.

Article 5

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.

[12] https://ec.europa.eu/docsroom/documents/52678

Article 6

This Decision is addressed to Prionics Lelystad B.V., Platinastraat 33, 8211AR, Lelystad, Flevoland, the Netherlands.

Done at Brussels, 1.12.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION