EUROPEAN
COMMISSION

Brussels, 15.11.2023
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COMMISSION IMPLEMENTING DECISION

of 15.11.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to RSI ChemRep Europe Ltd, only representative of OraSure Technologies Inc., for a use 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 25 June 2019, RSI ChemRep Europe Ltd, only representative of OraSure Technologies Inc., ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of 4-tert-OPnEO[2]. The use for which the authorisation was sought is as surfactant in in-vitro diagnostic device developer solution.

(3) The European Chemicals Agency sent the opinions[3] on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the Agency to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 6 April 2021, the Commission received the opinions.

(4) In its opinion, RAC concluded 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 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-

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

[2] Different names and abbreviations are used to refer to the substance, including 'Triton X-100' in the chemical safety report.

[3] https://echa.europa.eu/documents/10162/24c01f34-bceb-2e9a-d879-5f1fd3887f13

OPnEO and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(5) RAC noted that the 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, 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 for exposure scenario 2, whereas they are not appropriate and effective for exposure scenario 1. As regards exposure scenario 2, RAC noted that almost all used products are disposed for incineration, so that emissions are prevented or minimised as far as technically and practically possible. As regards exposure scenario 1, RAC pointed out that releases of the substance may occur from the potential landfilling of used products from consumer uses, or from pouring developer solution of these products into the sink. However, RAC notes that implementing further risk management measures, such as redesigning the kit, would take a significant amount of time, so that substitution is likely to be achieved before the implementation of those measures.

(7) In order to reach that conclusion, RAC took into account SEAC's positive assessment on the applicant's ongoing and planned substitution activities, which are well-described and enable the achievement of most of the substitution targets in the first few years, as well as SEAC's recommendation to carry out the substitution activities according to the substitution plan, as a condition for authorisation. Therefore, RAC did not make any further recommendation for conditions for authorisation. Having evaluated the RAC's and SEAC's assessments, the Commission agrees with their conclusions and recommendations.

(8) Nevertheless, as regards exposure scenario 1, the Commission notes that further actions could be undertaken to improve the collection and treatment of used kits, to prevent their landfilling and aiming at minimising releases to environmental compartments. In this regard, the Commission considers it appropriate to set as conditions for authorisation the obligation for the authorisation holder to carry out a feasibility study to implement a system for the collection and further treatment of used kits following consumer use, to provide consumers with specific instructions on appropriate disposal of used products and to keep track of the return rate of the products from consumers.

(9) In its opinion, 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 the use of 4-tert-OPnEO, the estimated remaining emissions in the order of less than one kilogram of the substance per year, the estimated benefits due to avoided profit losses at minimum in the order between hundreds of thousands of euro to millions of euro over the entire review period, the estimated cost of avoiding the remaining releases of the substance in the order between tens of thousands of euro to hundreds of thousands of euro per kilogram, the qualitatively assessed additional socio-economic benefits of the continued use due to early diagnosis of Human Immunodeficiency Virus and Hepatitis C Virus and treatment of patients, as well as any relevant distributional impact, the Commission concludes that the applicant has

demonstrated that the socio-economic benefits of the continued use of 4-tert-OPnEO described in the application outweigh the risk to human health or the environment arising from that use.

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

(11) In its opinion, SEAC concluded that there were no suitable alternative substances or technologies available by the sunset date for the applicant. The Commission, having evaluated SEAC's assessment and all relevant information available, notes that the identified alternative would still need to undergo extensive end-product performance testing as well as subsequent clinical and non-clinical testing, and transfer of technology in order to obtain the necessary regulatory approvals for the in-vitro diagnostic kits at stake. The Commission therefore considers that it cannot be deemed that the identified alternative allows the functionality needed for the use 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.

(12) 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 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.

(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.

(14) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should 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 level of emissions, the socio-economic benefits, the lack of suitable alternatives within a shorter timeline, as well as the time needed for regulatory approvals.

(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(s) 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[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.

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

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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).

Authorisation number	Authorised use
REACH/23/29/0	As a surfactant in in-vitro diagnostic device developer solution for the diagnosis of Human Immunodeficiency Virus and Hepatitis C Virus

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. As regards exposure scenario 1, the authorisation shall be subject to the conditions set out in paragraphs 2 to 6.
2. The authorisation holder shall follow the substitution steps planned and document them, including, if relevant, any deviations and contingency measures taken. The authorisation holder shall make that documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.
3. The authorisation holder shall carry out, at the latest by 15 November 2024, a study on the feasibility to implement a system for the collection and adequate treatment of used kits 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.
4. The authorisation holder shall act without delay in accordance with the outcome of the study referred to in paragraph 3, document such actions and make those documents available, upon request, to the competent authority of the Member State where the use takes place.
5. Following the implementation of changes in accordance with paragraph 4, the authorisation holder shall provide consumers with specific instructions on appropriate disposal of used products as waste so that releases to environmental compartments are minimised. As regards the developer solution made with 4-tert-OPnEO that can possibly be emptied in the wastewater, the authorisation holder shall ensure that those instructions specify that disposal into wastewater or as domestic waste is not allowed.
6. If a system for the collection and further treatment of used products in accordance with paragraph 3 is implemented, the authorisation holder shall keep track of the return rate of the products from consumers.

Article 3

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

Article 4

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

[12] https://ec.europa.eu/docsroom/documents/45355

the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 5

Where the authorisation holder submits a review report, it shall include the information referred to in Article 2(2), (4) and (6).

Article 6

This Decision is addressed to RSI ChemRep Europe Ltd, only representative of OraSure Technologies Inc., 27-30 Merchants Quay, Merchants House, Dublin 8, Ireland.

Done at Brussels, 15.11.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION