EUROPEAN
COMMISSION

Brussels, 9.11.2021
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COMMISSION IMPLEMENTING DECISION

of 9.11.2021

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Ortho-Clinical Diagnostics France for certain uses 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)(a) of that Regulation.

(2) On 13 February 2019, Ortho-Clinical Diagnostics submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of 4-tert-OPnEO[2]. The use for which authorisation was sought is use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in two in vitro diagnostic VITROS® products used by professional diagnostic laboratories to detect antibodies to human hepatitis A virus and IgG antibodies to rubella virus.

(3) On 11 March 2019, the European Chemicals Agency ('the Agency') received a notification that the application had been transferred from the original applicant Ortho-Clinical Diagnostics to Ortho-Clinical Diagnostics France ('the applicant'). In its assessment, the Agency concluded that the notified changes had no implications for the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the Agency. The Commission agrees with that conclusion.

(4) On 23 October 2019, the Commission received the opinion on the application adopted by RAC and SEAC[3] and sent to it pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

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1 OJ L 396, 30.12.2006, p. 1.

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

3 https://echa.europa.eu/documents/10162/c6247102-56c6-ffc1-b370-e7366c5b98ad

(5) RAC concluded in its opinion 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)(a) of that Regulation. As a result, paragraph 2 of Article 60 of Regulation (EC) No 1907/2006 does not apply to that substance and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

(6) 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.

(7) In its opinion, 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 posed by that use. RAC therefore recommended as a condition for authorisation to collect all liquid waste for adequate treatment which minimises releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible, specifying that release to the municipal sewage treatment plant does not constitute adequate treatment. In line with this condition, RAC also recommended that the applicant should include in the review report a new representative survey concerning the downstream users' effort to collect the liquid waste for adequate treatment and used treatment methods. Having evaluated the RAC assessment, the Commission agrees with that conclusion and recommendations.

(8) In its opinion, 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 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 grams of the substance per year, the estimated benefits due to avoided producer surplus loss, avoided cost for new equipments and avoided loss of jobs at minimum in the order of tens of millions of euros over the entire review period, the estimated cost of avoiding the remaining releases of 4-tert-OPnEO in the order of tens of millions of euros per kg, the qualitatively assessed additional socio-economic benefits of the continued use due to avoided unavailability or reduced availability of in vitro diagnostics ('IVD') kits for certain diseases, 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 outweigh the risk to human health and the environment arising from that use.

(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. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for.

(10) In its opinion, SEAC concluded that there are no available alternative substances or technologies by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that the identified

alternatives do not achieve the required minimisation of non-specific bindings of unwanted biomolecules on the wall of the micro-vessels without denaturing the essential proteins, which is necessary for the manufacturing of the IVD kits. The Commission therefore considers that the identified alternatives do not 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 use of 4-tert-OPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006 as well as the conditions set out in this Decision, are fully applied.

(12) 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.

(13) SEAC recommended in its opinion that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 10 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the time necessary for the reformulation of the two in vitro diagnostic VITROS® products, including the time needed for testing, the clinical trials, and the new regulatory approvals.

(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 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.

(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],

[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).

92/85/EEC[6], 94/33/EC[7] and 98/24/EC as well as 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 any other regulatory requirements including emission limit values 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 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 use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO):

Authorisation number	Authorised use
REACH/21/6/0	As Triton X-100 in two in vitro diagnostic VITROS® products used by professional diagnostic laboratories to detect antibodies to human hepatitis A virus and IgG antibodies to rubella virus

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).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12] as well as to the condition laid down in Article 2.

Article 2

The authorisation shall be subject to the following condition: the authorisation holder and its downstream users shall collect all liquid waste for adequate treatment. The treatment shall minimise releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible.

Article 3

The review period shall expire on 4 January 2031.

The authorisation shall cease to be valid on 4 January 2031 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2029.

Article 4

In the event that the authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall include a new representative survey concerning the downstream users' effort to collect the liquid waste for adequate treatment and used treatment methods.

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

12 https://ec.europa.eu/docsroom/documents/37882

Article 6

This Decision is addressed to Ortho-Clinical Diagnostics France, 1500, Boulevard Sébastien Brant B.P 30335, 676411 Illkirch, France.

Done at Brussels, 9.11.2021

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION