EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 23.2.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Wallac Oy 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), point (a), of that Regulation.

(2) On 19 June 2019, Wallac Oy ('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[2]. The uses for which authorisation was sought are the formulation of 4-tert-OPnEO (as Triton X-100) for use in the assay buffer for the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1- phosphate uridyl transferase (GALT) activity ('use 1'), and the use of 4-tert-OPnEO (as Triton X100) in the assay buffer of the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity ('use 2').

(3) On 17 December 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 for the environment of 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://www.echa.europa.eu/documents/10162/d29ebb2a-4b6b-63b7-ddfe-c5c0eae2e88a https://www.echa.europa.eu/documents/10162/c360a752-7dba-2855-8a9f-9c87aac9e643

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 that substance and authorisations may therefore only be granted with respect to that substance under Article 60(4) of that Regulation.

(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 substance as a proxy for the risk.

(6) In its opinion on use 1, 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 noted that, although most of the contaminated water originates from one analytical instrument, the Genetic Screening Processor (GSP), and is collected and disposed of as liquid waste, residual releases with very low concentration of 4-tert-OPnEO to wastewater still occur during that process. Therefore, RAC recommended as a condition for authorisation that the applicant should collect wastewater originating during quality control of in vitro diagnostic kits and research and development processes for adequate treatment, which minimises releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Moreover, in order to evaluate the effectiveness of the risk management measures and operational conditions as well as to confirm that emissions are reduced to as low a level as technically and practically possible, RAC recommended to carry out a monitoring programme. Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(7) In its opinion on use 2, 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 noted that the applicant did not impose specific requirements towards downstream users to collect wastewater for adequate treatment. Therefore, RAC recommended as a condition for authorisation that the applicant and its downstream users should collect all wastewater for adequate treatment, which minimises releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations.

(8) In its opinions on uses 1 and 2, 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 assessment, the lack of scientific knowledge at present to quantify or monetise the risk to the environment associated with the uses of 4-tert-OPnEO, the combined estimated emissions of around one hundred grams per year, the combined estimated benefits due to avoided profit losses at minimum in the order of EUR 1 million over the review period, the combined estimated cost of avoiding the remaining releases of the substance in the order of millions of euro per kilogram, the qualitatively assessed additional socio-economic benefits of the continued uses due to avoided additional costs for hospitals and laboratories, avoided potential disruptions in neonatal screening, and avoided potential relocation of neonatal kit research and production outside of the EEA, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of 4-tert-OPnEO outweigh the risk to to human health or the environment arising from those uses.

(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. 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.

(10) In its opinion on use 1, SEAC concluded that there were no suitable alternative substances or technologies available for the applicant by the sunset date. SEAC noted that there is no function *per se* provided by the substance in use 1 for which authorisation is sought, since that use covers the use of 4-tert-OPnEO for formulation of mixtures intended exclusively for use 2, thus the function of the substance is not relevant in this case. Therefore, due to the interlink with use 2, SEAC concluded that the assessment of alternatives for use 1 should rely on the one concerning use 2. The Commission, having evaluated SEAC's assessment, agrees with that conclusion.

(11) In its opinion on use 2, 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, concludes that further research and development, testing as well as regulatory approvals are required to verify whether the identified alternative allows the necessary reduction of the floating of sample dried blood spot disks in neonatal GALT assay buffers. The Commission therefore considers that it cannot be deemed that the identified alternative allows the functionality of 4-tert-OPnEO needed for the uses for which authorisation is sought. 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.

(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 uses 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 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 emissions information.

(14) In its opinions, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 5 years for uses 1 and 2. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the estimated emissions, the socio-economic benefits of the continued uses of the substance and, in particular, the societal welfare losses expected in the scenario of non-use of the substance, the absence of an alternative within a shorter timeframe, the applicant's current research and development effort to phase out the substance from its products, and the time required to perform the necessary testing and obtain 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 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 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 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 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.

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

Authorisation number	Authorised use
REACH/23/5/0	Formulation of 4-tert-OPnEO (as Triton X-100) for use in the assay buffer for the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity
REACH/23/5/1	In the assay buffer of the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity

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 conditions set out in Articles 2 and 3.

Article 2

1. As regards the authorisation bearing number REACH/23/5/0, the authorisation shall be subject to the conditions set out in paragraph 2 to 5.

2. The authorisation holder shall collect wastewater contaminated with 4-tert-OPnEO, occurring during the quality control of in vitro diagnostics kits and research and development processes, for adequate treatment. The adequate treatment shall minimise releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Release into the sewage system or to surface waters does not constitute adequate treatment.

3. The authorisation holder shall carry out a monitoring programme of 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the off-site wastewater treatment plant. That monitoring programme shall be:

   (a) carried out at least four 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 the substance and its principal

[12] https://ec.europa.eu/docsroom/documents/44384

degradation products in the wastewater due to changes or operational fluctuations in the process;

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

(c) 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 paragraph 3 and related contextual information to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions and, if needed, to introduce measures to further reduce emissions of 4-tert-OPnEO to a level as low as technically and practically possible.

5. The authorisation holder shall document and keep the information obtained in accordance with paragraph 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. The authorisation holder shall submit that information, upon request, to the competent authority of the Member State where the authorised uses take place.

Article 3

As regards the authorisation bearing number REACH/23/5/1, the authorisation shall be subject to the following condition: the authorisation holder and its downstream users shall collect all solid waste and wastewater contaminated with 4-tert-OPnEO for adequate treatment. The treatment shall minimise releases of 4-tert-OPnEO to environmental compartments as far as technically and practically possible. Release into the sewage system or to surface waters does not constitute adequate treatment.

Article 4

The review period shall expire on 4 January 2026.

The authorisation shall cease to be valid on 4 January 2026 with respect to an authorised use 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 2024.

Article 5

Where the authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall include the following:

(a) as regards the authorisation bearing number REACH/23/5/0, the information pursuant to Article 2(5);

(b) as regards the authorisation bearing number REACH/23/5/1, a representative survey concerning the downstream users' treatment methods of solid waste and of wastewater contaminated with 4-tert-OPnEO.

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 Wallac Oy, Mustionkatu 6, 20750 Turku, Finland.

Done at Brussels, 23.2.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION