EUROPEAN
COMMISSION

Brussels, 17.3.2022
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COMMISSION IMPLEMENTING DECISION

of 17.3.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Kedrion S.p.A for a use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

(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 17 May 2019, Kedrion S.p.A ('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 authorisation was sought is use as Triton X-100 as detergent for virus inactivation in the manufacturing process of the human plasma-derived medicinal products Plasmagrade/Plasmasafe and Resusix, as well as Plasminogen (pre-commercialisation name) and any subsequent commercialisation brand.

(3) On 3 June 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 the Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine a predicted no-effect concentration (PNEC) 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), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that

[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://www.echa.europa.eu/documents/10162/a6306d4a-2cef-ddf4-245e-d3a2a768ca39

substance and an authorisation may therefore only be granted with respect to that substance under Article 60(4).

(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 on the use, RAC concluded that the operational conditions and risk management measures in the exposure scenario are appropriate and effective in limiting the risk to the environment posed by that use. In particular, considering that all solid and liquid waste contaminated by 4-tert-OPnEO is collected and disposed of for incineration, RAC considers that releases to environmental compartments have been prevented or minimised as far as technically and practically possible. However, RAC also noted that there are residual releases of 4-tert-OPnEO from the on-site wastewater treatment plant, originating from the rinsing of equipment. Therefore, in order to continue evaluating the effectiveness of the risk management measures and operational conditions and to confirm that emissions are reduced to as low a level as is technically and practically possible, RAC recommended to carry out a monitoring programme as well as a feasibility study for collection of remaining liquid waste. Having evaluated RAC's assessment, the Commission agrees with that conclusion and recommendations.

(7) 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 use of the substance. 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 use of the substance, the estimated emissions up to a maximum of five kilograms of the substance per year by 2035, the estimated benefits due to avoided profit and job losses at minimum in the order of tens of millions of euros for the entire review period, the estimated cost of avoiding the remaining releases of the substance in the order of hundreds of thousands of euros per kilogram, the qualitatively assessed additional socio-economic benefits of the continued use due to the availability of human plasma-derived medicinal products, 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 the substance outweigh the risk to human health and the environment arising from that use.

(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 use applied for should be considered to be technically feasible.

(9) 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 extensive testing is needed to confirm the feasibility of the identified alternatives to achieve the complete inactivation of all relevant viruses, as required to obtain regulatory approvals for the medicinal products at stake. The Commission therefore considers that it cannot be deemed that the identified alternatives 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.

(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 use of 4-tert-OPnEO described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.

(11) The Commission has based its assessment on the relevant scientific evidence currently available, as assessed by RAC and SEAC, and based its conclusions on the existence of a sufficient weight of evidence 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 request that additional exposure and emission information be submitted.

(12) 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, that the operational conditions and risk management measures are expected to be appropriate and effective in limiting the risk to the environment, the level of emissions, the lack of suitable alternatives within a shorter timeline, as well as the regulatory approvals and quality requirements for medicinal products.

(13) 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.

(14) 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.

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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

(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 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.

(16) The measures provided for in this Decision are in accordance with the opinion of the Committee established under 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 (4-tert-OPnEO):

Authorisation number	Authorised use
REACH/22/16/0	As detergent for virus inactivation in the manufacturing process of the human plasma-derived medicinal products Plasmagrade/Plasmasafe and Resusix, as well as Plasminogen (pre-commercialisation name) and any subsequent commercialisation brand

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 for that use in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2031.

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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).

12 https://ec.europa.eu/docsroom/documents/41822

Article 3

1. The monitoring arrangements referred to in paragraphs 2 to 7 shall apply.

2. The authorisation holder shall carry out a monitoring programme of 4-tert-OPnEO and its principal degradation products in the waste streams after on-site treatment and prior to release to the municipal wastewater treatment plant. That monitoring programme shall:

   (a) be 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 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 substance and its principal degradation products in wastewater, with appropriately low limit of quantification;

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

3. The authorisation holder shall use the information gathered in the measurements referred to in paragraph 2 and related contextual information to regularly 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.

4. The authorisation holder shall assess, by 17 March 2023, the feasibility to collect the remaining liquid waste from rinsing reusable equipment for adequate treatment, and act in accordance with the outcome of that study.

5. The authorisation holder shall carry out a mass balance analysis after the implementation of the risk management measures and operational conditions and document it.

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

7. 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 the information in accordance with paragraph 6.

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

Article 5

This Decision is addressed to Kedrion S.p.A, Località Ai Conti s.n.c., Castelvecchio P., 55051 Barga, Lucca, Italy.

Done at Brussels, 17.3.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION