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COMMISSION IMPLEMENTING DECISION

of 5.1.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to PPG Europe B.V. and others 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/EC¹, 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 2 July 2019, PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc., Sealants Europe SAS, PPG Industries (UK) Ltd., Boeing Distribution Inc. and Wesco Aircraft EMEA Ltd ('the applicants'), submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for certain uses of 4-tert-OPnEO². The uses for which authorisation was sought are the formulation of a hardener component containing 4-tert-OPnEO in aerospace and defence two-part polysulphide sealants ('use 1'), and the mixing, by the aerospace and defence sector and the associated supply chains, of base polysulfide sealant components with 4-tert-OPnEO-containing hardener, resulting in mixtures containing less than 0,1 % w/w of 4-tert-OPnEO for aerospace and defence uses that are exempt from authorisation under REACH Article 56(6), point (a) ('use 2').
- (3) On 15 January 2021, 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 Agency³ and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

¹ OJ L 396, 30.12.2006, p. 1.

² Different names and abbreviations are used to refer to the substance, including 'OPE' in the chemical safety report and in the application for authorisation.

³ <https://echa.europa.eu/documents/10162/685cedb3-416b-8ed4-2495-66a711e740ec>
<https://echa.europa.eu/documents/10162/3a98b027-e5ac-b566-9122-5212df25c6fc>

- (4) On 30 November 2020, the Agency received a notification that the application had been transferred from the original applicant Wesco Aircraft EMEA Ltd to Haas Group International SP. Z.O.O. In its assessment, the Agency concluded that the notified change had no implications for the RAC and SEAC opinions. The Commission agrees with that conclusion.
- (5) On 17 December 2020, the Agency received a notification that the application had been transferred from the original applicant PPG Industries (UK) Ltd. to PPG Europe B.V. In its assessment, the Agency concluded that the notified change had no implications for the RAC and SEAC opinions. The Commission agrees with that conclusion.
- (6) RAC concluded in its opinions 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 substance and authorisations may therefore only be granted with respect to that substance under Article 60(4).
- (7) 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.
- (8) In its opinions on uses 1 and 2, 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. RAC noted that there is no water involved in the formulation process as regards use 1 and in the mixing of the base and hardener and application of sealant as regards use 2, that no wastewater is produced, and that all solid waste which had been in contact with 4-tert-OPnEO is collected and disposed of as waste for incineration, so that releases to the environmental compartments have been minimized as far as technically and practically possible. Having evaluated RAC's assessment, the Commission agrees with its conclusions.
- (9) 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 applicants' assessment of the socio-economic benefits and the risk to the environment associated with the continued uses 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 uses of the substance, the estimated remaining emissions of a few kilograms per year during the service life of the equipment, the estimated benefits due to the avoided social cost of job losses at the formulator's facilities and the avoided profit losses for the downstream users in the order of billions of euros over the entire review period, the estimated cost of avoiding the remaining releases of the substance in the order of between hundreds of millions of euros and billions of euros per kilogram, the qualitatively assessed additional socio-economic benefits of the uses due to avoided negative impacts associated with the unavailability of the sealants in the production, maintenance, repair and overhaul activities performed in the aviation and defence industry at over 200 downstream users' sites, as well as any relevant distributional impact on other economic actors, the Commission concludes that the applicants have demonstrated that the socio-economic benefits of the uses of the substance outweigh the risk to human health and the environment arising from those uses.

- (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 applied for should be considered to be technically feasible.
- (11) In its opinions on uses 1 and 2, SEAC concluded that there were no suitable alternative substances or technologies available by the sunset date. The Commission, having evaluated SEAC's assessment and all relevant information available, concludes that the downstream users still need to verify whether the most promising alternative that has been identified allows an adequate dispersion of the curing agent in the hardener for the final polysulfide sealants to perform in different environments and challenging operating conditions, as well as to obtain the required qualification and industrialisation by original equipment manufacturers. The Commission therefore considers that it is not yet demonstrated that the identified alternatives allow achieving the functionality of the substance. Thus, the Commission agrees with SEAC's conclusion and considers that the applicants have discharged their 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 are fully applied. However, for the sake of legal clarity, the description of use 2 authorised by this Decision should be 'mixing of base polysulfide sealant components with 4-tert-OPnEO containing hardener, resulting in mixtures containing less than 0,1 % w/w of 4-tert-OPnEO for aerospace and defences uses that are exempt from authorisation under Article 56(6), point (a), of Regulation (EC) No 1907/2006, in the aerospace and defence sector and associated supply chains'.
- (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.
- (14) SEAC recommended in its opinions that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 should be set at 4 years for use 1 and use 2. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, the conclusion that the releases of the substances to the environment have been prevented or minimised as far as technically and practically possible, the significant socio-economic benefits of the continued uses of the substances and, in particular, the significant societal welfare losses expected in the scenario of non-use of the substance, the absence of an alternative within a shorter time frame, the time required for qualification and industrialisation of the most promising alternative by the downstream users, as well as the consideration that the applicants plan to phase out the substance in all their 25 formulations by 2024.
- (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 holders 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 holders 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 holders 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/EC⁴. 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/EEC⁵, 92/85/EEC⁶, 94/33/EC⁷, 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 Council⁸ or Directive 2010/75/EU of the European Parliament and of the Council⁹, 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 Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. 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,

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).

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 to the following persons for the following uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO):

| Authorisation number | Authorisation holder | Authorised use |
|----------------------|---|--|
| REACH/22/40/0 | PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc. - OR5 | Formulation of a hardener component containing 4-tert-OPnEO in aerospace and defence two-part polysulphide sealants |
| REACH/22/40/1 | Sealants Europe SAS | |
| REACH/22/40/2 | PPG Europe B.V. in its legal capacity as Only Representative of PPG Industries (UK) Ltd. - OR23 | |
| REACH/22/40/3 | Boeing Distribution, Inc. | |
| REACH/22/40/4 | Haas Group International SP. Z.O.O. | |
| REACH/22/40/5 | PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc. - OR5 | Mixing of base polysulfide sealant components with 4-tert-OPnEO-containing hardener, resulting in mixtures containing less than 0,1 % w/w of 4-tert-OPnEO for aerospace and defence uses that are exempt from authorisation under REACH Article 56(6), point (a), in the aerospace and defence sector and associated supply chains |
| REACH/22/40/6 | Sealants Europe SAS | |
| REACH/22/40/7 | PPG Europe B.V. in its legal capacity as Only Representative | |

4. Haas Group International SP. Z.O.O., ul Ryszarda Chomicza, Nowa Wieś Wrocławska, 13 - E, 55 – 080 Wrocławska, Wrocław, Poland.

Done at Brussels, 5.1.2023

For the Commission
Thierry BRETON
Member of the Commission

