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COMMISSION IMPLEMENTING DECISION

of 22.5.2025

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Chemetall GmbH for certain uses of 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO) in the context of a review and repealing Implementing Decision C(2022) 1504

(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-Nonylphenol, branched and linear, ethoxylated ('4-NPnEO') 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 16 March 2022, by Commission Implementing Decision C(2022) 1504² an authorisation was granted to Chemetall GmbH, for certain uses of 4-NPnEO, which were the formulation of a hardener component containing 4-NPnEO in aerospace two-part polysulphide sealants ('use 1') and mixing of base polysulfide sealant components with 4-NPnEO-containing hardener, resulting in mixtures containing less than 0,1 % w/w of 4-NPnEO for aerospace uses that are exempt from authorisation under Article 56(6), point (a), of Regulation (EC) No 1907/2006, in the aerospace sector and associated supply chains' ('use 2'). Chemetall GmbH was assigned the authorisation number REACH/22/19/0 for use 1 and REACH/22/19/1 for use 2. The expiry of the review period referred to in Article 60(9), point (e) of Regulation (EC) No 1907/2006 for those authorised uses of 4-NPnEO was set at 4 January 2025.
- (3) On 11 November 2022, Chemetall GmbH submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation for certain uses of 4-NPnEO³. The uses for which authorisation was sought are the formulation of a

¹ OJ L 396, 30.12.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>.

² Commission Implementing Decision of 16 March 2022 granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Chemetall GmbH for certain uses of 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO).

³ Different names and abbreviations are currently used to refer to the substance, including 'NPE' in the chemical safety report.

hardener component containing 4-NPnEO within Aerospace two-part polysulfide sealants ('use 1') and mixing, by aerospace companies and their associated supply chains, including the applicant, of base polysulfide sealant components with 4-NPnEO-containing hardener, resulting in mixtures containing < 0.1 % w/w of 4-NPnEO for Aerospace uses that are exempt from authorisation under REACH Art.56(6)(a) ('use 2').

- (4) The European Chemicals Agency sent the opinions on the review report⁴ adopted by its Committee for Risk Assessment ('RAC') and its Committee for Socio-economic Analysis ('SEAC') to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 23 September 2024, the Commission received the opinions.
- (5) In its opinions, RAC concluded that it is not possible to determine a predicted no-effect concentration for the endocrine disrupting properties for the environment of 4-NPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore 4-NPnEO 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-NPnEO and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.
- (6) RAC noted that despite the absence of a dose-response relation, a risk to the environment cannot be excluded for 4-NPnEO, even at low exposure levels. Consequently, RAC takes the emissions of the substance as a proxy for the risk.
- (7) 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 in limiting the risk to the environment posed by the uses of 4-NPnEO described in the review report. In particular, RAC notes that the uses for which an authorisation is sought result in no releases of the substance to the environment since no water is used in the formulation process and in the mixing of the hardener and base, and all waste which has been in contact with 4-NPnEO is collected and disposed of for incineration. Hence, Chemetall GmbH has demonstrated that emissions have been prevented or reduced to a level as low as technically and practically possible. Having evaluated RAC's assessment, the Commission agrees with its conclusion.
- (8) In its opinions on uses 1 and 2, SEAC concluded that the societal costs of not granting an authorisation are higher than the risk to the environment arising from the use of 4-NPnEO. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that Chemetall GmbH has demonstrated that the benefits of the use outweigh the risk to the environment arising from that use.
- (9) For an alternative to be suitable it needs to 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, the applicant is required by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.

⁴ <https://www.echa.europa.eu/documents/10162/94b31a58-3226-f1f0-9a04-c338c342fb48>
<https://www.echa.europa.eu/documents/10162/c6d6c0fc-e02a-5783-b02c-bff68611e469>

- (10) An alternative that provides the functionality and level of technical performance necessary for the use for which an authorisation is sought should be considered to be technically feasible.
- (11) In its opinions on uses 1 and 2, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant, but that there were technically and economically feasible alternatives in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that, although certain alternatives have been developed within the Union for the use for which an authorisation is sought, they are not yet able to meet the technical requirements concerning, amongst others, viscosity, density or tear strength needed by the applicant. Thus, the Commission considers that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to develop and implement one of the most promising alternatives to make it technically feasible. Therefore, the Commission agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.
- (12) In its opinion, SEAC concluded that the substitution plan is credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the use for which an authorisation is sought and the substitution plan submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.
- (13) 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-NPnEO described in the review report, provided that the risk management measures described in the chemical safety report are applied and that the operational conditions described therein are fulfilled. However, for the sake of legal clarity, the description of uses 1 and 2 authorised by this Decision should be 'the use of surfactant containing 4-NPnEO for formulation of the hardener component of the two-part polysulfide sealants for use in aerospace sector' (use 1); and 'mixing of base polysulfide sealant components with 4-NPnEO-containing hardener, resulting in mixtures containing less than 0,1 % w/w of 4-NPnEO for aerospace uses that are exempt from authorisation under Article 56(6), point (a), of Regulation (EC) No 1907/2006, in the aerospace sector and associated supply chains' (use 2).
- (14) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of a sufficient amount of material and reliable information.
- (15) In its opinions on uses 1 and 2, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 6 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, SEAC's conclusion on the risk to the environment and on the socio-economic benefits of the use of the substance.
- (16) 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.

- (17) This Decision does not affect the obligation of the authorisation holder to ensure that the 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/EC⁵. 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/EEC⁶, 92/85/EEC⁷, 94/33/EC⁸ and 98/24/EC or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.
- (18) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC⁹ or Directive 2010/75/EU¹⁰ 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 Council¹¹ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹². Compliance with the provisions of this Decision does not

⁵ 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, ELI: <http://data.europa.eu/eli/dir/1998/24/oj>).

⁶ 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, ELI: <http://data.europa.eu/eli/dir/1989/391/oj>).

⁷ 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, ELI: <http://data.europa.eu/eli/dir/1992/85/oj>).

⁸ 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, ELI: <http://data.europa.eu/eli/dir/1994/33/oj>).

⁹ 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, ELI: <http://data.europa.eu/eli/dir/2008/50/oj>).

¹⁰ 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, ELI: <http://data.europa.eu/eli/dir/2010/75/oj>).

¹¹ 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, ELI: <http://data.europa.eu/eli/dir/2000/60/oj>).

¹² 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

necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

- (19) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. For reasons of clarity and legal certainty, Implementing Decision C(2022) 1504 should be replaced by this Decision.
- (20) 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-Nonylphenol, branched and linear, ethoxylated ('4-NPnEO'):

Authorisation number	Authorisation holder	Authorised use
REACH/25/27/0/R1	Chemetall GmbH	Use of surfactant containing 4-NPnEO for formulation of the hardener component of the two-part polysulfide sealants for use in aerospace sector
REACH/25/27/1/R1		Mixing of base polysulfide sealant components with 4-NPnEO-containing hardener, resulting in mixtures containing less than 0,1 % w/w of 4-NPnEO for aerospace uses that are exempt from authorisation under Article 56(6), point (a), of Regulation (EC) No 1907/2006, in the aerospace sector and associated supply chains

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹³.

Article 2

The review period shall expire on 4 January 2031.

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

Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84, ELI: <http://data.europa.eu/eli/dir/2008/105/oj>).

¹³ <https://ec.europa.eu/docsroom/documents/61777>

Article 3

The following monitoring arrangements shall apply: the authorisation holder shall document the steps taken to substitute 4-tert-OPnEO in accordance with the substitution plan, including information concerning any deviations from the initial substitution plan and any contingency measures taken and shall make that documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

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. The brief summary shall be drafted in an official language of that Member State.

Article 5

Implementing Decision C(2022) 1504 is repealed.

Article 6

This Decision is addressed to:

Chemetall GmbH, Trakehner Str. 3, 60487 Frankfurt, Germany.

Done at Brussels, 22.5.2025

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

