



Brussels, 16.3.2022
C(2022) 1504 final

COMMISSION IMPLEMENTING DECISION

of 16.3.2022

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, ethoxilated (4-NPnEO)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 16.3.2022

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)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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 2 July 2019, Chemetall GmbH ('the applicant') submitted an application, in accordance with Article 62 of Regulation (EC) No 1907/2006, for authorisation for certain uses of 4-NPnEO². The uses for which authorisation was sought are the formulation of a hardener component containing 4-NPnEO in aerospace two-part polysulphide sealants ('use 1'), and the mixing, by aerospace companies and their associated supply chains, including the applicant, of base polysulphide 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 ('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.
- (4) 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-NPnEO in accordance with Section 6.4 of Annex I to Regulation (EC) No

¹ OJ L 396, 30.12.2006, p. 1.

² Different names and abbreviations are used to refer to the substance, including NPE in the chemical safety report.

³ <https://echa.europa.eu/documents/10162/4d740ff2-dd1b-fdac-518f-6933e44e1b2b>
<https://echa.europa.eu/documents/10162/920b7127-8cc2-8b6b-2d61-cc8a1658cd9b>

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 that substance and authorisations may therefore only be granted with respect to that substance under paragraph 4 of that Article.

- (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 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. In particular, RAC noted that there is no water involved in the formulation process and in the mixing of the base and hardener or in the application of sealant, no wastewater is produced, and all solid waste which had been in contact with 4-NPnEO is collected and disposed as waste for incineration, so that releases to the environmental compartments have been minimised as far as technically and practically possible. Therefore, use 1 and use 2 result in approximately zero emissions of the substance to the environmental compartments. Having evaluated RAC's assessments, the Commission agrees with its conclusion.
- (7) 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 the substance. Taking into account SEAC's assessments, 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 less than 10 kilograms of the substance per year for both uses 1 and 2, the estimated benefits due to avoided profit losses, avoided job losses, avoided relocation costs, avoided additional energy costs and avoided additional costs for quality testing at minimum in the order between billions and tens of billions of euros over the entire review period for uses 1 and 2, the estimated cost of avoiding the remaining releases of the substance in the order between hundreds of millions 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 on maintenance, repair and overhaul activities in the aerospace sector, as well as any relevant distributional impact, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of the continued uses of the substance outweigh the risk to human health and the environment arising from those uses.
- (8) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but those alternatives are 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 opinions on uses 1 and 2, 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 further qualification processes are needed to verify whether the identified alternatives allow for the achievement of the function of adequate dispersion of the curing agent in the

hardener that is necessary to achieve the specific properties of the final polysulfide sealants, including viscosity, adhesion and stability to ensure that the sealants perform in different environments and challenging operating conditions. The Commission therefore considers that it is not yet demonstrated that the identified alternatives allow for the achievement of the functionality needed for the uses 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 use 1 and use 2 as 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-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'.
- (11) 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.
- (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 4 years for use 1 and for 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 substance 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 substance and in particular the significant welfare losses expected in the scenario of non-use of the substance, the absence of a suitable alternative within a shorter time frame, as well as the consideration that the applicant plans to phase out the substance by 2024.
- (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/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 Union limit values.

- (15) This Decision does not affect any obligation to comply with emission limit values 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.
- (16) 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	Authorised use
REACH/22/19/0	Formulation of a hardener component containing 4-NPnEO in aerospace two-part polysulphide sealants
	Mixing of base polysulphide sealant components with 4-

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).

REACH/22/19/1

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 report¹².

Article 2

1. The review period shall expire on 4 January 2025.
2. The authorisation shall cease to be valid on 4 January 2025 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 4 July 2023.

Article 3

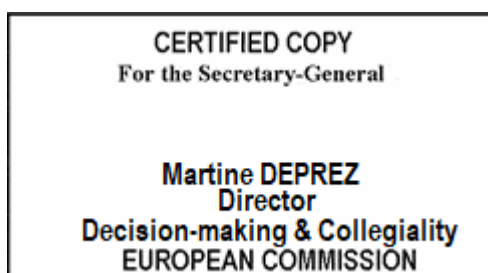
Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place, in an official language of that Member State.

Article 4

This Decision is addressed to Chemetall GmbH, Trakehner Str. 3, 60487 Frankfurt, Germany.

Done at Brussels, 16.3.2022

For the Commission
Thierry BRETON
Member of the Commission



¹² <https://ec.europa.eu/docsroom/documents/44670>