



Department
for Environment
Food & Rural Affairs

Authorisation Decision

by Jo Churchill MP

Parliamentary Under Secretary of State

On behalf of the Secretary of State for Environment, Food and Rural Affairs

Decision date: 4 November 2021

Application Ref: ID 0207-02

UK REACH authorisation number:

Authorisation number	Authorisation holder	Authorised use
UKREACH/21/03/0	Chemetall Limited	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 Art. 56(6)(a) of EUR 2006/1907.

Preliminary Matters

- 4-Nonylphenol, branched and linear, ethoxylated ('4-NPnEO') is listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)¹. As such, 4-NPnEO is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.

¹ References to "EUR 2006/1907" are to the retained version of Regulation (EC) No 1907/2006, as amended. The retained version of that Regulation is available online at <https://www.legislation.gov.uk/eur/2006/1907/contents>

- 4-NPnEO was included in Annex XIV to Regulation (EC) No 1907/2006² because there is scientific evidence of probable serious effects to the environment from its endocrine-disrupting properties when it degrades.
- The application is made by Chemetall Limited³ of Napier House, Auckland Park, Bletchley, Milton Keynes, MK1 1BU, United Kingdom ('the Applicant').
- On 2 July 2019, the Applicant made an application for authorisation ('the Original Application') to the European Chemicals Agency (ECHA) for the use of 4-NPnEO in:
 - a. 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 Art. 56(6)(a) of Regulation (EC) No 1907/2006⁴.
- On 24 December 2020, ECHA sent the Consolidated Opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-Economic Analysis (SEAC) ('the RAC Opinion' and 'the SEAC Opinion', respectively) for each use to the European Commission.
- On 5 March 2021, the Applicant notified the Secretary of State of the Original Application in accordance with Article 127G of EUR 2006/1907.
- The Original Application related to the use of 4-NPnEO in respect of approximately 200 sites across the European Union, Norway, Iceland and Lichtenstein. In further information provided by the Applicant, they estimated that 40-60 of these sites are located within Great Britain.
- In reaching this decision I have considered the likely emissions to the environment and the likely socio-economic benefits in respect of Great Britain.

Decision

1. This decision is addressed to the Applicant.
2. An Authorisation is granted in accordance with Article 60(4) of EUR 2006/1907 for the following use of 4-NPnEO:

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 Art. 56(6)(a) of EUR 2006/1907.

² References to "Regulation (EC) No 1907/2006" are to that Regulation as it has effect in EU law.

³ The Applicant listed on the Original Application was Chemetall PLC. The Applicant name was corrected to Chemetall Limited on 8 June 2020.

⁴ In the Original Application, this use referred to Article 56(6)(a) of Regulation (EC) No 1907/2006, rather than Article 56(6)(a) of EUR 2006/1907.

3. The review period referred to in Article 60(9)(e) of EUR 2006/1907 is set at 4 years. The authorisation will cease to be valid on 4 January 2025 unless the authorisation holder submits a review report in accordance with Article 61(1) by 4 July 2023.
4. The authorisation is subject to the following condition (as well as the requirement in Article 60(10) of EUR 2006/1907 to ensure exposure is reduced to as low a level as is technically and practically possible):
 - a. The authorisation holder must adhere to the risk management measures and operational conditions described in the chemical safety report⁵ referred to in Article 62(4)(d) of EUR 2006/1907.
5. The authorisation is not subject to any monitoring arrangements.

Background

6. This decision is made under Article 64(8) of EUR 2006/1907.
7. In making this decision, I have taken into account:
 - a. The Original Application.
 - b. The elements referred to in Article 60(4)(a) to (d) of EUR 2006/1907, and the aspects referred to in Article 60(5).
 - c. The RAC Opinion and the SEAC Opinion for the use.
 - d. Further information provided by the Applicant regarding the risks and benefits arising from the use within Great Britain (England, Wales and Scotland).

Reasons

8. In the Original Application, the Applicant derived predicted no effect concentrations (PNECs). The RAC Opinion concluded that the Applicant did not demonstrate a threshold level for the environmental impacts of the endocrine disrupting properties of 4-NPnEO. Therefore, the RAC Opinion concluded that for the purposes of the assessment of this application it is not possible to determine PNECs 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.
9. In accordance with Article 60(3)(a) of EUR 2006/1907, this means that Article 60(2) of that Regulation does not apply to this application. Article 60(2) does not apply to substances for which it is not possible to determine a threshold in

⁵ This is a reference to the chemical safety report dated 1 July 2019 submitted by Chemetall GmbH on 2 July 2019 as part of the Original Application. The risk management measures and operational conditions are described in sections 9 (EXPOSURE ASSESSMENT (and related risk characterisation)) and 10 (RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE).

accordance with Section 6.4 of Annex 1. Therefore, an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

10. An authorisation may only be granted under Article 60(4) of EUR 2006/1907 if it is shown that the socio-economic benefits outweigh the risks to human health or the environment and there are no suitable alternative substances or technologies. A suitable alternative should be safer, available, and technically and economically feasible.

Risks to the environment

11. The RAC Opinion concluded that the Applicant has demonstrated that the releases to environmental compartments (air, water and soil) have been prevented or minimised as far as technically and practically possible. In reaching this conclusion, RAC noted the waterless process and the collection of all waste contaminated with 4-NPnEO for incineration. RAC considered the potential for release to the environment during the use to be very low. Having evaluated RAC's assessment, I agree with its conclusion that releases to environmental compartments have been prevented or minimised as far as technically and practically possible and I consider this conclusion to be applicable to the analysis of releases in respect of Great Britain.
12. The RAC Opinion considered the very low estimated level of emissions from the service life of the sealant to be a worst-case release of 4-NPnEO. This estimate covered the potential emissions during the period that the sealant is in use, from the point of application until the end of the product's lifetime. This estimate was based on a conservative worst-case model for release which considered the fraction of sealant that might be exposed to water at the outer surface of the product and the fraction of 4-NPnEO at the surface that may be released to the environment.
13. The Applicant stated that, considering the wide dispersive nature of the release, the predicted concentration even under the worst-case model is negligible and below both background levels and currently available analytical detection levels. The Applicant assessed that approximately less than a third of the estimated level of service life emissions would result from products used by downstream users in Great Britain. Having considered RAC's assessment and the further information provided by the Applicant, I agree that these estimated emissions can be considered a worst-case scenario for the release of 4-NPnEO in Great Britain.
14. 4-NPnEO presents a risk to aquatic life when it degrades in water. When degraded, it can adversely affect the endocrine systems of aquatic organisms. I note that these risks cannot be excluded even at low levels. However, I conclude that the risk is low because the estimated worst-case service life emissions of 4-NPnEO are very low. I also note that these emissions relate to the use of the final sealant which is not subject to authorisation due to the very low concentration of 4-NPnEO it contains.

15. The RAC Opinion concluded that the operational conditions and risk management measures as described in the application are appropriate and effective in limiting the environmental risk, provided that they are adhered to. RAC therefore did not propose any conditions in addition to those described by the Applicant, or any monitoring arrangements. Having evaluated RAC's assessment and the operational conditions and risk management measures described in the Original Application, I agree that no additional conditions or monitoring arrangements are required. In reaching this conclusion, I have considered the need for risk management measures and operational conditions in respect of the use of 4-NPnEO in Great Britain.

Socio-economic analysis

16. The SEAC Opinion concluded that SEAC has no substantial reservations on the quantitative and qualitative elements of the Applicant's assessment of the benefits and the risks to the environment associated with the continued use of 4-NPnEO. I agree with this conclusion, and I consider it applicable to the benefits and risks in respect of Great Britain.
17. The SEAC Opinion estimated that the quantitative benefits, such as avoided profit losses, would be at least a billion euros⁶ per year. SEAC agreed with the Applicant that there were also qualitatively assessed socio-economic benefits such as avoided negative impacts on maintenance repair and overhaul shops, aircraft operators, flight passengers and companies relying on air cargo.
18. When considering Great Britain only, the Applicant provided additional information that the quantitative benefits in respect of Great Britain were approximately a quarter of those related to the Original Application. Having considered the information provided by the Applicant and SEAC's conclusions, I conclude that the quantitative benefits in respect of Great Britain are likely to be in the order of hundreds of millions of euros⁷ per year. In addition, I conclude that the qualitatively assessed benefits are relevant to Great Britain.

Conclusion on whether the benefits outweigh the risks

19. I consider that the Applicant has shown that the socio-economic benefits outweigh the risk to the environment because:
- a. The potential for release to the environment during the use is very low;
 - b. Although there are potential emissions after the use of the final sealant, these are likely to be very low even in a worst-case scenario. They also

⁶ The Original Application was submitted to ECHA while the UK was still an EU member state and therefore provided all monetary calculations in euros. On 3 November 2021, the Bank of England exchange rate was EUR/GBP = 0.8481

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relate to the use of the final sealant which would not require authorisation;

- c. There are likely to be significant quantitative benefits such as avoided profit losses; and
- d. There are likely to be significant qualitative benefits such as avoided negative impacts to actors across the aerospace supply chain.

Alternatives

- 20. The SEAC Opinion concluded that there are no available alternative substances or technologies with the same function and similar level of performance that are safer and technically and economically feasible for the Applicant and their downstream users by the sunset date. SEAC agreed with the Applicant that alternative substances already on the market would not be technically feasible for the Applicant by the sunset date because the interchangeability of the 4-NPnEO-free alternative needs to be confirmed by the downstream users.
- 21. Having evaluated SEAC's assessment, I agree that the Applicant has sufficiently discharged its burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion, I have considered SEAC's assessment of the technical feasibility of alternative substances already on the market and I consider this applicable to Great Britain.

Review period

- 22. The SEAC Opinion recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at 4 years. The substitution plan submitted by the Applicant includes time for: (1) the research and development testing phase for the 4-NPnEO-free formulation; (2) validation of the changed formulation by downstream users to ensure that it meets their performance specifications; and (3) adaption of the relevant processes and documentation by downstream users to reflect this change. The substitution to a 4-NPnEO-free alternative would need to occur during formulation of the hardener component that is used in the mixing process. This formulation occurs at one site in Germany by the formulator (Chemetall GmbH) and does not require authorisation under UK REACH.
- 23. SEAC agreed with the Applicant that the steps in the substitution plan outlined above, in the sequence and timeframes described in the Original Application, need to occur before a conclusion can be reached on the suitability of the 4-NPnEO-free formulation. SEAC also concluded that it is credible that the formulator (Chemetall GmbH) will replace 4-NPnEO in all the formulations by the end of the authorisation period. I agree with SEAC's conclusion and recommendation that the review period should be set at 4 years and I consider them applicable to Great Britain.

Conclusion

24. For the reasons set out above I conclude that the socio-economic benefits outweigh the risk to the environment for the use of 4-NPnEO referred to in paragraph 2 and that there are no suitable alternative substances or technologies.
25. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with Articles 4A and 64(8) of EUR 2006/1907.

A handwritten signature in black ink, appearing to read 'Jo Churchill', with a stylized, cursive script.

Jo Churchill MP

On behalf of the Secretary of State for Environment, Food and Rural Affairs