Department for Environment Food & Rural Affairs

Authorisation Decision

by Marc Casale Deputy Director, Chemicals, Pesticides and Hazardous Waste (DEFRA)

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

Decision date: 12 June 2025

Application Ref: AFA053-01

Authorised use

Mixing, by Aerospace Companies and their associated supply chains, including the Authorisation Holder, of base polysulfide sealant components with 4-NPnEO containing hardener, resulting in mixtures containing < 0.1% w/w of 4-NPnEO for Aerospace uses.

UK REACH authorisation number:

Authorisation number	Authorisation holder
UKREACH/25/14/00	Chemetall Limited

Preliminary Matters

- The substance, 4-Nonylphenol, branched and linear, ethoxylated (4-NPnEO), is listed in Annex XIV to assimilated Regulation (EC) No. 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals (UK REACH).[1] As such, 4-NPnEO is subject to the authorisation requirement referred to in Article 56(1) of UK REACH.
- The substance, 4-NPnEO, was included in Annex XIV because it meets the criteria set out in Article 57(f) of UK REACH, that there is scientific evidence of

[1] References to Regulation (EC) No 1907/2006, referred to in this decision as UK REACH, are to the assimilated law available online at https://www.legislation.gov.uk/eur/2006/1907/contents

probable serious effects to the environment from its endocrine-disrupting properties when it degrades into 4-Nonylphenol, branched and linear (4-NP). There are no known associated risks to human health.

- The environmental risk of 4-NPnEO stems from its degradation to an endocrine-disrupting chemical, 4-NP. 4-NP presents a risk to aquatic life and can adversely affect the endocrine systems of aquatic organisms. This risk cannot be excluded even at low levels. There are no known associated risks to human health.
- Chemetall Limited, with company number 00252864, whose registered office is at Napier House, Auckland Park, Bletchley, Milton Keynes, MK1 1BU, England, United Kingdom (the 'Authorisation Holder') has been granted an authorisation in accordance with Article 60(4) with authorisation number (UKREACH/21/03/0) (the 'Existing Authorisation'). On 29 June 2023, the Authorisation Holder submitted a review report in relation to the Existing Authorisation (the 'Review Report') to the Health and Safety Executive (the 'Agency'), with respect to the following continued use:
  a. Mixing, by Aerospace Companies and their associated supply chains, including the Authorisation Holder, of base polysulfide sealant components with 4-NPnEO containing hardener, resulting in mixtures containing < 0.1% w/w of 4-NPnEO for Aerospace uses.
- On 12 December 2024, the Agency sent its opinion (the 'Opinion') for the Review Report to the Secretary of State for Environment, Food and Rural Affairs, and Scottish and Welsh Ministers.

Decision

1. This decision is addressed to the Authorisation Holder.
2. In accordance with Article 61(1) of UK REACH, effective from 4 January 2025, the authorisation set out below shall apply instead of the Existing Authorisation.
3. For the avoidance of doubt, the Existing Authorisation will continue to apply to relevant activities which took place before 4 January 2025.
4. Authorisation is granted to the Authorisation Holder for the following use, under the following Authorisation number:
   a. UKREACH/25/14/00: Mixing, by Aerospace Companies and their associated supply chains, including the Authorisation Holder, of base polysulfide sealant components with 4-NPnEO containing hardener, resulting in mixtures containing < 0.1% w/w of 4-NPnEO for Aerospace uses.

5. Pursuant to Article 60(8) of UK REACH, the review period referred to in Article 60(9)(e) of UK REACH is set at 7 years. The authorisation will cease to be valid on 4 January 2032 unless a review report is submitted in accordance with Article 61(1) of UK REACH by 4 July 2030.

6. This authorisation is subject to the following condition (as well as the requirement in Article 60(10) of UK REACH to ensure exposure is reduced to as low a level as is technically and practically possible):

   a. The Authorisation Holder must adhere to the operational conditions (OCs) and risk management measures (RMMs) described in the chemical safety report referred to in Article 62(4)(d) of UK REACH.[2]

7. This authorisation is not subject to any monitoring arrangements.

8. This authorisation is not subject to any recommendations.

Background

9. In accordance with Article 61(1) of UK Reach, the Authorisation Holder submitted a review report containing updated versions of the following documents initially submitted with respect to the Existing Authorisations:

   a. the analysis of alternatives;

   b. the socio-economic analysis;

   c. the chemical safety report; and

   d. the applicable use of 4-NPnEO.

10. This decision is made pursuant to Article 61 of UK REACH and having obtained the consent of Scottish and Welsh Ministers.

11. In making this decision I have taken into account:

   a. the Existing Authorisation (including associated documentation);

   b. the Review Report submitted to the Agency;

   c. the provisions of Article 60 and Article 61 of UK REACH, including the elements referred to in Article 60(4) and the requirements of Article 60(5) (as applicable);

   d. the Agency's Opinion;

   e. any change of circumstances detailed in the Review Report, which if known at the time of granting the Existing Authorisation, would have

[2] This is a reference to the chemical safety report dated 29 June 2023 submitted by Chemetall Limited as part of the Review Report. 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).

affected the decision to grant the Existing Authorisation or terms of the Existing Authorisation

Reasons

12. In the Review Report, the Authorisation Holder derived a Predicted No Effect Concentration (PNEC) for 4-NPnEO. However, the Agency has not considered the PNEC in its Opinion because the Review Report has not been made on the basis of adequate control.

Risk to the environment

13. The degradation product of 4-NPnEO, 4-NP, presents a risk to aquatic life when it degrades in water. The substance can adversely affect the endocrine systems of marine vertebrates. Once the 4-NPnEO containing hardener has been mixed, the concentration of 4-NPnEO drops below 0.1% w/w and is no longer subject to authorisation, as per Article 56(6)(a) of UK REACH.

14. In its Review Report, the Authorisation Holder stated that, combined across 30 to 40 sites, 40 to 70 kg of 4-NPnEO is used annually. The Authorisation Holder presented a scenario in its Review Report where there are no emissions (or negligible emissions) of the substance to the environment, due to the nature of the use and the OCs and RMMs in place, which remain unchanged since the granting of the Existing Authorisation. In its Opinion, the Agency agrees with the Authorisation Holder that releases to air, water and soil continue to be prevented. Additionally, the Authorisation Holder's OCs and RMMs continue to significantly reduce the likelihood of releases to wastewater.

15. In its Review Report, the Authorisation Holder stated that there are no releases to air during the use of 4-NPnEO as the use process takes place within controlled areas and the substance possesses a low vapour pressure. In its Opinion, the Agency agrees with the Authorisation Holder that any releases to air continue to be prevented through a controlled use environment and as a result of the low vapor pressure of the substance.

16. In their Review Report, the Authorisation Holder noted that the substance is used in controlled environments that do not have water sources or drainage within the immediate vicinity. As such, in its Opinion, the Agency concluded that as no water is used within the process (including during waste management), there is no route of release to wastewater or surface water. The Agency therefore agrees with the Authorisation Holder's assertion that any releases to the environment continue to be negligible.

17. In its Review Report, the Authorisation Holder has concluded that the low vapour pressure and lack of releases to air will limit deposition of 4-NPnEO to nearby soils, and any releases to agricultural soil, via the spreading of sludge

from sewage treatment plants, are likely to be negligible due to the lack of release to wastewater. In its Opinion, the Agency have therefore concluded that the OCs and RMMs in place, and the information provided on the use of the substance, indicate that there is unlikely to be releases to water, air or soil. Any waste generated is segregated as hazardous waste, collected by a licensed third party and then incinerated, significantly reducing the likelihood of release to wastewater, surface water or soils. In its Opinion, the Agency considers that the method for disposing of hazardous waste is satisfactory and continues to limit releases to the environment.

18. In its Review Report, the Authorisation Holder noted that they have surveyed 13 downstream user sites to verify the OCs and RMMs. Additionally, two sites (one in Great Britain and one in Germany)[3] were verified through a site visit where the potential for releases to water, air, soil and waste was assessed. In its Review Report, it is not specified whether the two site visits are part of the downstream user survey that was conducted in 2019 as part of the application submitted for the Existing Authorisations (the 'Original Application'), however, the sites where the use take place, and the general information has not changed since the initial 2019 chemical safety report. The way the substance is used and disposed of has not changed since the Original Application. In its Opinion, the Agency concluded that as the OCs and RMMs described by the Authorisation Holder are unchanged from the Original Application.

19. In its Opinion, the Agency concluded that the OCs and RMMs described in the Review Report continue to be appropriate and effective in limiting the risk to the environment, and that under a worst-case assumption, negligible emissions may occur. The Agency expects that the use applied for will result in 0 kg of emissions of 4-NPnEO to the environment and has not identified any uncertainties that may affect its conclusions. The Agency therefore did not propose any additional conditions or monitoring arrangements for the review period.

20. Having evaluated the Agency's assessment, I agree with its conclusions that the use of 4-NPnEO will continue to have negligible environmental impacts in relation to endocrine disruption.

21. I am therefore of the view that there has been no material change of circumstances with respect to the assessment of risks which would have affected the granting of the Existing Authorisation, and accordingly it remains appropriate that no additional conditions, monitoring arrangements or recommendations are required.

[3] Although the site in Germany is outside the scope of UK REACH, the inclusion of the site in the downstream user survey contributes to a representative demonstration of the OCs and RMMs in place as the OCs and RMMs are very similar across the sector.

Socio-economic analysis

22. In its Opinion, the Agency assessed the socio-economic benefits arising from the applied for use and the socio-economic implications of a refusal to authorise, based on the updated socio-economic analysis submitted. The socio-economic benefits of authorisation consist of avoided relocation cost to the Authorisation Holder, which the Authorisation Holder anticipates being necessary in the event of non-authorisation. The Agency estimated the socio-economic benefits to be at least £8.4 million over 6 years.[4] Other potential costs were not quantified.

23. In its Opinion, the Agency also assessed important qualitative socio-economic benefits of granting an authorisation. This consists of producer and consumer avoided producer surplus loss, avoided producer and consumer surplus loss at downstream user sites, avoided social cost of unemployment and requalification costs for downstream users. The Authorisation Holder did not provide a monetised estimate of producer surplus losses under the non-use scenarios, citing concerns around confidentiality. If the Authorisation Holder had monetised these figures, the monetised benefits would have been greater than stated in paragraph 22. In its Opinion, the Agency accepts the Authorisation Holder's qualitative description of authorisation benefits and concludes that the Authorisation Holder has therefore underestimated the benefits of continued use.

24. Having evaluated the Agency's assessment, I agree with its conclusions on the quantitative and qualitative benefits.

Conclusion on whether the benefits outweigh the risk

25. In its Opinion, the Agency concluded that the Authorisation Holder has demonstrated that the socio-economic benefits of continued authorisation (at least £8.4 million) are higher than the risk to the environment (negligible) over a further 6-year review period.

26. I consider that the Authorisation Holder has shown that the socio-economic benefits outweigh the risk to the environment because of:

    a. the likely quantitative benefits in respect of the avoided relocation costs to the Authorisation Holder;

[4] The economic assessment was conducted based on a 6-year period. This is due to the Authorisation Holder initially requesting a review period of at least 6 years. In its Opinion, the Agency noted that whilst the economic assessment is based on a 6-year period, increasing the review period to 7 years leads to a slight increase in benefits. As the risks are effectively zero in this case, the increase in benefits is not offset by an increase in costs. Thus, the benefits presented above would represent an underestimate.

b. the likely qualitative benefits in respect of avoided negative impacts on the Authorisation Holder and downstream users;

c. the assessed risks from the use of 4-NPnEO.

Alternatives

27. In its Opinion, the Agency concluded that there were no available alternative substances or technologies with the same function and a similar level of performance that were technically and economically feasible for the Authorisation Holder by the expiry date of their current authorisation (4 January 2025), based on the updated analysis of alternatives submitted. No comments were received from the public consultation on alternatives.

28. In its Review Report, the Authorisation Holder detailed the environments and conditions the cured sealants need to perform under, including the presence of fuel and other liquids, extreme temperatures, vibrations and fluctuations in humidity. The key physical properties required for use of the sealants was also provided, including viscosity, cure times, pot-life and shelf life. In its Review Report, the Authorisation Holder explained that although a range of NPnEO-free sealants have been successfully implemented in a portion of the aerospace industry, for a major customer, the NPnEO-free alternatives have not met the performance requirements showing unanticipated issues with the lack of adhesion of the sealant to different substrates during the final testing phase. The Agency did not evaluate the risk of alternatives due to the alternatives not being proven to be technically and economically feasible at this time.

29. There is information available in the Review Report to indicate that there are potential alternatives available that could be technically and economically feasible in Great Britain in the future. The Authorisation Holder noted in their Review Report that further testing is required to demonstrate this and as such have included these alternatives in their recent analysis of alternatives and substitution plan.

30. The Authorisation Holder established four possible alternatives to 4-NPnEO, with initial trials indicating that one of these alternatives will be a successful substitution candidate. In its Opinion, the Agency concluded that the Authorisation Holder provided a comprehensive overview of the aerospace manufacturing process, and key details of the environments and conditions the cured sealants need to perform under. The Agency noted that the scope of the Authorisation Holder’s research on alternatives was logical, broad and included a wide variety of surfactant types. Additionally, in its Review Report, the Authorisation Holder’s research has followed on logically from the research conducted before and during their current review period.

31. Having evaluated the Agency's assessment, I agree with the conclusion that there were no available alternatives by the expiry date of the review period and consider that the Authorisation Holder has discharged its burden of proof in demonstrating the absence of suitable current alternatives. In reaching this conclusion, I have considered the Agency's assessment of the technical and economic feasibility of alternatives and the consistency with the analysis of alternatives provided. I have also considered that the Authorisation Holder's initial trials with the favoured alternative suggest that it will be a successful substitution candidate in due course.

Review period

32. In its Opinion, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 7 years.

33. In the Review Report, the Authorisation Holder initially requested a review period of at least 6 years. This is largely due to the Authorisation Holder's assumption that one of the four alternatives would be successful in the remaining tests and trials. Nevertheless, after some clarification questions and challenge from the REACH Independent Scientific Expert Pool (RISEP) during the Challenge Panel, and after written comments on the draft Opinion from RISEP, the Agency and the Authorisation Holder noted that a 6-year review period could be optimistic, and that a 7-year review period may be more appropriate. Whilst there are currently no major issues to suggest that substitution of 4-NPnEO is not possible within 6 years, this was based on the fact that late-stage failure of a previous alternative in the Existing Authorisation for a major customer occurred, and expert views on substitutions in the aerospace sector.[5] In view of this, the Authorisation Holder amended their requested review period to 7 years.

34. In its Opinion, the Agency consider that a 7-year review period will provide opportunity for the Authorisation Holder to complete their substitution efforts should there be any delays. Additionally, testing of new sealants in a variety of aerospace components and assemblies will be required for full validation of an alternative. These tests could take several years due to the length of some tests and the subsequent regulatory approval required under airworthiness certification procedures. In its Opinion, the Agency concluded that there is no increased risk of providing an extra year for the review period given that there are no expected emissions to the environment.

35. Having evaluated the Agency's assessment, I agree that while a transition to an alternative within 6 years may be possible, achieving a transition to an

[5] The Authorisation Holder's attempts to replace the 4-NPnEO-containing surfactant in the hardener formulation was successful in for some customers during the Existing Authorisation, but not for a major customer due to late-stage technical failures and unanticipated issues with the lack of adhesion of the sealant to different substrates during the final testing phase.

alternative within this time is not realistic taking into account the reasonable prospect of late-stage failure, the high technical requirements which need to be met, and the regulatory process involved in approving any alternative. Accordingly, I have concluded that a 7-year review period would be appropriate, rather than any shorter period, for these specific reasons.

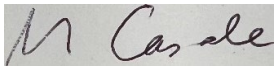
36. In reaching this decision I have taken into account that there is no indication that there is likely to be a material change in the assessment of risks and benefits during a 7-year review period, in comparison to a 6-year review period.

Conclusion

37. 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.

38. The Scottish Ministers and the Welsh Ministers have given their consent to this decision in accordance with the requirements of UK REACH.

39. In accordance with the provisions of Article 61(1), the Existing Authorisation is amended as outlined, effective from 4 January 2025.



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