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: AfA054-01, AfA054-02

Authorised use

Use 1: The formulation of a hardener component containing 4-tert-OPnEO within Aerospace two-part polysulfide sealants for use by Airbus and their associated supply chains.

Use 2: Mixing, by Airbus and their associated supply chains, including the Authorisation Holder, of base polysulfide sealant components with 4-tert-OPnEO-containing hardener, resulting in mixtures containing < 0.1% weight per weight (w/w) of 4-tert-OPnEO for Aerospace.

UK REACH authorisation number:

Authorisation number	Authorisation holder
UKREACH/25/15/00	PPG Industries (UK) Ltd
UKREACH/25/15/01	PPG Industries (UK) Ltd

Preliminary Matters

- The substance, 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (4-tert-OPnEO), 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-tert-OPnEO is subject to the authorisation requirement referred to in Article 56(1) of UK REACH.

- The substance, 4-tert-OPnEO, 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 probable serious effects to the environment from its endocrine-disrupting properties when it degrades into : 4-tert-Octyl Phenol (4-tert-OP) (which 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.
- PPG Industries (UK) Ltd., with company number 02110620, whose registered office is at Needham Road, Stowmarket, Suffolk, United Kingdom, IP14 2AD (the 'Authorisation Holder'), has been granted authorisations in accordance with Article 60(4), with authorisation numbers UKREACH/21/02/0 and UKREACH/21/02/3 (the 'Existing Authorisations'). On 30 June 2023, the Authorisation Holder submitted a review report in relation to the Existing Authorisations (the 'Review Report'), to the Health and Safety Executive (the 'Agency'), with respect to the following continued uses:
    a) The formulation of a hardener component containing 4-tert-OPnEO within Aerospace two-part polysulfide sealants for use by Airbus and their associated supply chains (Use 1); and
    b) Mixing, by Airbus and their associated supply chains, including the Authorisation Holder, of base polysulfide sealant components with 4-tert-OPnEO-containing hardener, resulting in mixtures containing < 0.1% w/w of 4-tert-OPnEO for Aerospace uses (Use 2)
- On 12 December 2024, the Agency sent its opinions for Use 1 and Use 2 (the 'Opinion for Use 1' and 'Opinion for Use 2' respectively, together the 'Opinions') 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 authorisations set out below shall apply instead of the Existing Authorisations.
3. For the avoidance of doubt, the Existing Authorisations will continue to apply to relevant activities which took place before 4 January 2025.

[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

4. Authorisation is granted to the Authorisation Holder for the following uses, under the following Authorisation numbers:

    a. UKREACH/25/15/00 (Use 1): The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants for use by Airbus and their associated supply chains; and

    b. UKREACH/25/15/01 (Use 2): Mixing, by Airbus and their associated supply chains, including the Authorisation Holder, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of 4-tert-OPnEO 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 for both uses. 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 for both uses 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 for both uses is not subject to any monitoring arrangements.

8. This authorisation for both uses 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. chemical safety report; and

    d. the applicable uses of the 4-tert-OP

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

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[2] This is a reference to the chemical safety report dated 30 June 2023 submitted by PPG Industries (UK) Ltd as part of the Review Report. The risk management measures, and operational conditions are described in sections 9 (exposure assessment) and 10 (risk characterisation related to combined exposure).

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

    a. the Existing Authorisations (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 Opinions;

    e. any change of circumstances detailed in the Review Report, which if known at the time of granting the Existing Authorisations, would have affected the decision to grant the Existing Authorisations or the terms of the Existing Authorisations.

Reasons

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

Uses

13. In the Review Report, the Authorisation Holder detailed updated uses of 4-tert-OP, which were narrower than the uses covered by the Existing Authorisations. To reflect this change of circumstances, the authorised uses above have been narrowed accordingly, as the authorised uses in the Existing Authorisations are no longer applicable.

Risk to the environment

14. The degradation product of 4-tert-OPnEO, 4-tert-OP, presents a risk to aquatic life when present in water. The substance can adversely affect the endocrine systems of marine vertebrates in both uses. I conclude that the associated risk is low as once the 4-tert-OPnEO containing hardener has been mixed, the concentration of 4-tert-OPnEO drops below 0.1% w/w and is no longer subject to authorisation, as per Article 56(6)(a) of UK REACH.

15. In its Review Report, the Authorisation Holder stated that for both uses, combined across all sites, 50 to 150 kg of 4-tert-OPnEO 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 for both uses, due to the nature of the use and the OCs and RMMs in place. The OCs and RMMs have not changed since the granting of the Existing Authorisations. In its Opinions, the Agency agrees with the Authorisation Holder that releases to air, water and soil are likely to be

prevented for both uses, and that the Authorisation Holder's OCs and RMMs continue to significantly reduce the likelihood of releases to wastewater.

16. In its Review Report, the Authorisation Holder stated that for both uses, there are no releases to air during the use of 4-tert-OPnEO as the uses take place within controlled areas, and the substance possesses a low vapour pressure. In its Opinions, 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.

17. In its Opinions for both uses, the Agency concluded that, as no water is used within the process (including during waste management), there is no direct route of release to wastewater or surface water for both uses. In its Review Report for Use 1, the floor in the production area and filling room is coated with a chemically resistant antistatic coating, in which any spills are reported to be cleaned up promptly. Additionally, the Authorisation Holder noted in their Review Report for Use 2 that the substance is used in controlled environments that typically do not have water sources or drainage within the immediate vicinity. The Agency therefore agrees with the Authorisation Holder's assertion that any releases to the environment continue to be negligible.

18. 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-tert-OPnEO to nearby soils, and any releases to agricultural soil are likely to be negligible due to the lack of release to wastewater. In its Opinions, 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 released to water, air or soil. The Authorisation Holder stated in its Review Report that any waste generated is separated 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 Opinions, the Agency considers that the method for disposing of hazardous waste is satisfactory and continues to limit releases to the environment.

19. In its Review Report, the Authorisation Holder noted that they have surveyed several downstream user sites to verify the OCs and RMMs for Use 2. Additionally, two sites in Great Britain were verified through a site visit where the potential for releases to water, air, soil and waste was assessed for Use 2. In its Review Report, the Authorisation Holder did not specify 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 locations where the use takes place, and other 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 for Use 2, the Agency concluded that the OCs and RMMs described by the Authorisation Holder are unchanged from the Original Application.

20. In its Opinions, 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 even under a worst-case assumption, negligible emissions may occur for both uses. The Agency expects that the uses applied for will result in 0 kg of emissions of 4-tert-OPnEO 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.

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

22. 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 Authorisations. Accordingly, it remains appropriate for both uses that no additional conditions, monitoring arrangements or recommendations are required.

Socio-economic analysis

23. In its Opinions, the Agency assessed the socio-economic benefits arising from both uses 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 social costs of unemployment, which the Agency estimated to be between £2 million to £5 million over 4 years for each use, based on the lower bound of negative socio-economic impacts which would occur in the case of withdrawing the applicable authorisation.[3] Other potential costs were not quantified.

24. The monetised figure was based on a large loss of full-term equivalent (FTE) workers at the Authorisation Holder's site if authorisation is withdrawn (avoided social cost of unemployment). The Authorisation Holder has estimated that the same loss of FTE workers at its site would result if the authorisation for either use was withdrawn.

25. If the authorisation for Use 2 was withdrawn, Use 1 could not continue as the hardener component containing 4-tert-OP would not be required, with pre-mixed sealant and frozen sealants being imported into GB in its place.

[3] In its Opinions, the Agency noted that whilst the economic assessment has been conducted based on a 4-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 are not offset by an increase in risks. Thus, the benefits presented above would represent an underestimate.

Withdrawing the authorisation for Use 2 would therefore reasonably result in the full loss of FTE workers submitted by the Authorisation Holder.

26. If the authorisation for Use 1 was withdrawn however, the Authorisation Holder has not detailed why the Use 2 mixing activities at its site could not continue to some degree using imported hardener component containing 4-tert-OP, in place of the hardener component it previously had produced pursuant to Use 1. Accordingly, I have concluded there is a reasonable possibility that a lower FTE worker loss could occur with respect to withdrawing the authorisation for Use 1, in comparison to the FTE worker loss that could occur if the authorisation for Use 2 was withdrawn.

27. Given, the risks are however negligible, I can conclude with confidence that given some FTE worker loss would occur in both cases, that the socioeconomic benefits of continued authorisation of both uses still comfortably outweigh the applicable negligible risks to the environment, based on the updated analysis submitted.

28. In its Opinions, the Agency also assessed qualitative socio-economic benefits of continued authorisation. This consists of avoided producer surplus losses to the Authorisation Holder and the downstream user Airbus, avoided social cost of unemployment to downstream users, avoided requalification costs, asset acquisition costs for Airbus for cold storage freezers and back-up generators, avoided operation costs by Airbus, and avoided external environmental costs. The Authorisation Holder does not provide a monetised estimate of producer surplus losses with respect to itself. Additionally, the monetised estimate of the producer surplus loss for Airbus (and its associated supply chains) could not be taken into account as the Agency did not accept the methodology used by the Authorisation Holder as its use of Airbus' global EBIT (earnings before interest and taxes) were not deemed appropriate to be used for Airbus' UK EBIT.

29. 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

30. In its Opinions, the Agency concluded that the Authorisation Holder has demonstrated that the socio-economic benefits of continued authorisation (between £2 million to £5 million) for each use, is higher than the risk to the environment (negligible) over a 4-year review period.

31. I consider that the Authorisation holder has shown that the socio-economic benefits of continued authorisation of both uses outweigh the risk to the environment because of:

a. the likely quantitative benefits in respect of the avoided social cost of unemployment;

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-tert-OPnEO.

Alternatives

32. With respect to Use 1, no assessment of alternatives was conducted, and no substitution plan was submitted. This was because the Authorisation Holder stated that the substance that can be used in the formulation stage, is determined by the requirements of Use 2. The Agency agrees with this rationale.

33. In its Opinion of Use 2, 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 for both uses, by the expiry date of their review period specified under the Existing Authorisations (4 January 2025), based on the updated analysis of alternatives submitted. No comments were received from the public consultation on alternatives.

34. 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. In addition, key physical properties required were demonstrated for use of the sealants, such as viscosity, cure times, pot-life, and shelf life. In its Review Report, the Authorisation Holder explained previously tested alternatives did not meet technical requirements showing unanticipated issues and failures with the peel strength, slumping, and 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.

35. The Authorisation Holder established three possible alternatives to 4-tert-OPnEO. Reformulated sealants forms the basis of the future work on alternatives as two general classes of sealant have been developed which have passed initial tests. In its Opinion for Use 2, 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.

36. 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 also consider 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

37. In its Opinions, the Agency recommended the review period referred to in Article 60(9)(e) of UK REACH should be set at 7 years for both uses.

38. In its Review Report, the Authorisation Holder initially requested a review period of 4 years. This is largely due to the Authorisation Holder's assumption that their favoured alternative would be successful in the remaining tests and trials. Nevertheless, members of the REACH Independent Scientific Expert Pool (RISEP)[4] noted during the Challenge Panel that a 4-year review period could be optimistic despite some contingency being built in, as the Authorisation Holder would need to be absolutely certain that they achieve transition before submitting a review report, and that a 7-year review period may be more appropriate. This was based on the late-stage failure of the previous substitute in the Existing Authorisation[5] which meant it could not transition all its customers over to alternatives within the 4-year review period of the Existing Authorisations, and expert views on substitutions in the Aerospace sector. In view of this advice, the Authorisation Holder amended their requested review period to 7 years.

39. In its Opinions, the Agency agreed 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 Opinions, the Agency concluded that as there are effectively no releases associated with both uses, the additional time increases the benefits without increasing the risks.

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[4] REACH Independent Scientific Expert Pool (RISEP) is a pool of experts that can be used to provide advice independent of the Agency, and are responsible for scrutinising and challenging draft opinions at challenge panels.

[5] The Existing Authorisation granted authorisation for a 4-year review period, which ended on 4 January 2025. Although the Authorisation Holder's attempts to replace the 4-tert-OPnEO-containing surfactant in the hardener formulation was successful in some cases, testing for Airbus was unsuccessful.

40. Having evaluated the Agency's assessment, I agree that while a transition to an alternative within 4 years may be possible, achieving a transition to an alternative within this time period 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 between 4 to 7 years, for these specific reasons.

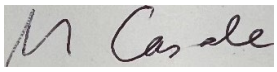
41. In reaching this decision I have taken into account that there is no indication that there is likely to be a material change in the assessment of risks and benefits during a 7-year review period, in comparison to a 4-year review period.

Conclusion

42. For the reasons set out above, I conclude that the socio-economic benefits outweigh the risk to the environment for both uses of 4-tert-OPnEO referred to in paragraph 2, and that there are no suitable alternative substances or technologies.

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

44. In accordance with the provisions of Article 61(1), the Existing Authorisations are amended as outlined, effective from 4 January 2025.



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Deputy Director, Chemicals, Pesticides and Hazardous Waste

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