



Department
for Environment
Food & Rural Affairs

Authorisation Decision

by Rebecca Pow MP

Parliamentary Under Secretary of State

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

Decision date: 11 August 2021

Application Ref: ID 0203-01, ID 0203-02

UK REACH authorisation numbers:

Authorisation number	Authorisation holder	Authorised use
UKREACH/21/02/0 UKREACH/21/02/1 UKREACH/21/02/2	PPG Industries (UK) Ltd. Boeing Distribution (UK) Inc. Wesco Aircraft EMEA, LTD (UK)	The formulation of a hardener component containing 4-tert-OPnEO in aerospace and defence two-part polysulphide sealants (use 1).
UKREACH/21/02/3 UKREACH/21/02/4 UKREACH/21/02/5	PPG Industries (UK) Ltd. Boeing Distribution (UK) Inc. Wesco Aircraft EMEA, LTD (UK)	Mixing, by aerospace and defence companies, and their associated supply chains, including the Applicants, 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 and defence uses that are exempt from authorisation under Art. 56(6)(a) of EUR 2006/1907 (use 2).

Preliminary Matters

- 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (hereinafter referred to as ‘4-tert-OPnEO’) is listed in Annex 14 to EUR 2006/1907 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)¹. As such, 4-tert-OPnEO is subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- 4-tert-OPnEO 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:
 - a. PPG Industries (UK) Ltd. of PPO BOX 162 Needham Road, Stowmarket, Suffolk, IP14 2AD, United Kingdom
 - b. Boeing Distribution (UK) Inc. of 25 Victoria Street, SW1H 0EX, Westminster, United Kingdom (following the submission of the application on 2 July 2019, Aviall Services Inc. was re-named Boeing Distribution, Inc.)
 - c. Wesco Aircraft EMEA, LTD (UK) of Lawrence House, Riverside Drive, Cleckheaton, West Yorkshire, BD19 4DH, United Kingdom(‘the Applicants’)
- On 2 July 2019, the Applicants made an application for authorisation (‘the Original Application’) to the European Chemicals Agency (ECHA) for the uses of 4-tert-OPnEO in:
 - I. The formulation of a hardener component containing 4-tert-OPnEO in aerospace and defence two-part polysulphide sealants (use 1).
 - II. Mixing, by aerospace and defence companies, and their associated supply chains, including the Applicants, 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 and defence uses that are exempt from authorisation under Art. 56(6)(a) of Regulation (EC) No 1907/2006 (use 2)³.
- 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 EU Commission.

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>

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

³ 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.

- On 17 February 2021, the Applicants notified the Secretary of State of the Original Application in accordance with Article 127G of EUR 2006/1907.
- The Original Application related to the uses of 4-tert-OPnEO across the European Union, Norway, Iceland and Lichtenstein.
 - a. Use 1 was applied for in respect of two sites: one located in Great Britain and one located in France.
 - b. Use 2 was applied for in respect of at least 200 sites across the European Union, Norway, Iceland and Lichtenstein. In further information provided by the Applicants, they estimate that 70-100 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 Applicants.
2. Authorisations are granted in accordance with Article 60(4) of EUR 2006/1907 for the following uses of 4-tert-OPnEO as set out in the table above titled 'UK REACH authorisation numbers':
 - Use 1: The formulation of a hardener component containing 4-tert-OPnEO in aerospace and defence two-part polysulphide sealants.
 - Use 2: Mixing, by aerospace and defence companies, and their associated supply chains, including the Applicants, 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 and defence uses that are exempt from authorisation under Art. 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 for both uses. The authorisations 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 authorisations are 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):
 - For both uses: The authorisation holders must adhere to the risk management measures and operational conditions described

in the chemical safety report⁴ referred to in Article 62(4)(d) of EUR 2006/1907

5. The authorisations are 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 each use.
 - d. Further information provided by the Applicants regarding the risks and benefits arising from uses 1 and 2 within Great Britain (England, Wales and Scotland).

Reasons

8. In the Original Application, the Applicants derived predicted no effect concentrations (PNECs). The RAC Opinion concluded that the Applicants have not demonstrated a threshold level for the endocrine disrupting properties for the environment of 4-tert-OPnEO. 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 for 4-tert-OPnEO 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 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

⁴ This is a reference to the chemical safety report dated 28 June 2019 submitted by PPG Europe B.V 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).

technologies. A suitable alternative should be safer, available, and technically and economically feasible.

Risks to the environment

11. The RAC Opinions for uses 1 and 2 concluded that the Applicants have demonstrated that releases to the 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 processes and the collection of all waste contaminated with 4-tert-OPnEO for incineration. RAC concluded that the release of 4-tert-OPnEO to the environment from the formulation of the hardener component (use 1) is zero. RAC also concluded that there was a very low potential for release to the environment during the process of mixing the hardener component with the base component to make the final sealant (use 2). Having evaluated RAC's assessment, I agree with its conclusion that releases to the 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 for use 2 considered the Applicants' very low estimated level of emissions from the service life of the sealant to be a worst-case release of 4-tert-OPnEO. 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-tert-OPnEO at the surface that may be released to the environment.
13. The Applicants 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 Applicants have assessed that half 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 Applicants, I agree that these estimated emissions can be considered a worst-case scenario for the release of 4-tert-OPnEO in Great Britain.
14. 4-tert-OPnEO 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-tert-OPnEO are 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-tert-OPnEO it contains.
15. The RAC Opinions for uses 1 and 2 concluded that the operational conditions and risk management measures as described in the application are

appropriate and effective in limiting the environmental risk, provided they are adhered to. RAC therefore did not propose any additional conditions to those described by the Applicants, 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-tert-OPnEO in Great Britain.

Socio-economic analysis

16. The SEAC Opinions for uses 1 and 2 concluded that it has no substantial reservations on the quantitative and qualitative elements of the Applicants' assessment of the benefits and the risks to the environment associated with the continued use of 4-tert-OPnEO. I agree with this conclusion and I consider it applicable to the benefits and risks in respect of Great Britain.
17. The SEAC Opinions for uses 1 and 2 estimated that the quantitative benefits, such as avoided profit losses and job losses would be at least a billion euros⁵ per year. SEAC agreed with the Applicants that there were also qualitatively assessed socio-economic benefits such as avoided negative impacts on maintenance repair and overhaul shops, aircraft operators, the defence industry, flight passengers and companies relying on air cargo.
18. When considering Great Britain only, the Applicants provided further information that the potential service life emissions, economic activity and qualitatively assessed benefits linked to these uses decrease proportionately. The Applicants provided additional information that the benefits to Great Britain were approximately one third of those related to the Original Application. Having considered the information provided by the Applicants 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 euros⁶ per kilogram of emissions. In addition, I conclude that the qualitatively assessed benefits described in the Original Application are relevant to Great Britain.

Conclusion on whether the benefits outweigh the risks

19. I consider that the Applicants have shown that the socio-economic benefits outweigh the risk to the environment because:
 - a. There are likely to be no emissions during formulation (use 1) and a very low potential for release to the environment during mixing (use 2);

⁵ The Original Application was submitted to ECHA while the UK was still an EU member state and therefore provided all monetary calculations in euros. At the date of decision, the Bank of England exchange rate was EUR/GBP = 0.8464.

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- b. Although there are potential emissions from the use of the final sealant, these are likely to be very low even in a worst-case scenario. They also 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 job losses;
- d. There are likely to be significant qualitative benefits such as avoided negative impacts to actors across the aerospace and defence supply chains.

Alternatives

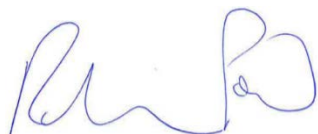
- 20. The SEAC Opinions for uses 1 and 2 concluded that there are no available alternative substances or technologies with the same function and similar level of performance that are safer and technically and economically feasible for the Applicants and their downstream users by the sunset date. SEAC agreed with the Applicants that alternative substances already on the market would not be technically feasible for the Applicants by the sunset date because the interchangeability of the 4-tert-OPnEO-free alternative needs to be confirmed by the downstream users.
- 21. Having evaluated SEAC's assessment, I agree that the Applicants have discharged their burden of proof in demonstrating the absence of suitable alternatives. In reaching this conclusion for both uses, 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 Opinions for uses 1 and 2 recommended 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 Applicants includes time for: (1) the development testing phase for the 4-tert-OPnEO-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.
- 23. SEAC agreed with the Applicants that the steps in the substitution plan need to occur before a conclusion can be reached the suitability of the 4-tert-OPnEO-free formulation. SEAC also agreed that the timeframes proposed in the substitution plan are credible. SEAC also concluded that it is credible that the formulator (PPG Industries (UK) Ltd) will replace 4-tert-OPnEO in all the formulations covered by use 1 by the end of the authorisation period. I agree with SEAC's recommendation that the review period should be set at 4 years. I also agree with SEAC's conclusions and 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 uses of 4-tert-OPnEO 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.



Rebecca Pow MP

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