

## Explanatory note to a review report

**Legal name of authorisation holder(s):** PPG Industries (UK) Ltd.

**Authorisation number:** UKREACH/21/02/0 (Use 1) and UKREACH/21/02/3 (Use 2)

**Submitted by:** PPG Industries (UK) Ltd.

**Substance:** 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

**Use title:** The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants for use by Airbus and their associated supply chains

**Use number:** 1

**Use title:** Mixing, by Airbus and their associated supply chains, including the Applicant, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a)

**Use number:** 2

**Date** June 2023

## 1. The scope of the use

Under the European Union (Withdrawal) Act 2018, the EU REACH Regulation was brought into UK law on 1st January 2021 and is known as UK REACH. EU REACH was replicated in the UK with the changes needed to make them operable in a domestic context. As such, all references within this document and accompanying documents of the Review Report (CSR and AoA-SEA) to EU REACH still apply with regards to functionality of UK REACH, such as the reason the substance has been classified as a SVHC in the UK is the same as that in the EU.

Article 127G of the UK REACH Regulation relate to a transitional measure of Authorisation decisions made under EU REACH. Article 127G applies to existing EU AfAs that were submitted by GB-based companies prior to the UK leaving the EU. The initial application by PPG under EU REACH was transitioned into UK REACH on 11<sup>th</sup> August 2021 under Authorisation Number UKREACH/21/02/0 and UKREACH/21/02/3.

The titles for Use 1 and Use 2 within the Original AfA (REACH/22/40/5) were for uses by Aerospace and Defence companies. The scope of use has now been narrowed to only include Airbus and their associated supply chain.

## 2. Chemical Safety Report (CSR)

### a. Use 1

As the original EU AfA was transitioned over to the UK without adapting the volumes and sites impacted by the use there is therefore changes in these values within the Review Report. The numbers presented in below and in the accompanying CSR now represent an accurate picture for the mixing use in the UK.

Change	Original AfA	Review Report
Volume of Substance Used	100 – 300 kg	50 - 150 kg
No. of sites	2 (One in UK and one in EU)	1 (UK Legal Entity)

There have been no changes to:

- The contributing scenario for the applied for use; or
- The Risk Management Measures (RMM) and Operational Controls (OCs) in place for each use.

As per the original CSR the applicant demonstrates that, considering measures in place, emissions of OPE to the environment during the two uses applied for are not only minimised but effectively precluded.

### b. Use 2

As the original EU AfA was transitioned over to the UK without adapting the volumes and sites impacted by the use there is therefore changes in these values within the Review Report. The numbers presented in below and in the accompanying CSR now represent an accurate picture for the mixing use in the UK.

Change	Original AfA	Review Report
Volume of Substance Used	100 – 300 kg	50 - 150 kg
No. of downstream user sites	Approximately 200	Approximately 45

The reduction in the number of sites is predominately due to the narrowing of the focus to only Airbus and their associated supply chains and due to EU downstream users not being within the remit of the Review Report.

There have been no changes to:

- The contributing scenario for this use; or
- The RMM and OCs in place for this use.

For Use 2 Risk Management Measures (RMM) and Operational Controls (OCs) in place remain as per the original CSR and as such the applicant still demonstrates that emissions of OPE to the environment are not only minimised but effectively precluded.

### c. Conditions, Monitoring Arrangement and Enforcement Activities

- There were no conditions or monitoring arrangements within the original decision that had to be complied with.
- No enforcement activities were taken by the UK Member State Competent Authority relating to this Authorisation. Although not within the jurisdiction of this Review Report the Applicant can confirm that no enforcement activities were taken by any EU Member State Competent Authority relating to this Authorisation.

## 3. Analysis of Alternatives (AoA)

As noted within the accompanying AoA-SEA the Applicant and Airbus have continued the substitution efforts outlined in the original application. As a Review Report is being submitted the substitution effort outlined within the original AfA was not successful within the timeline originally put forward due to there being no alternative that met Airbus technical specifications available.

The Applicant has worked with Airbus and identified alternatives sealants that are OPE and hydrogenated terphenyls free (Alternative 2) as the most promising alternative currently under consideration (Section 3.3.2 and 3.4). Alternative 2 sealants are not yet available on the market, but representative product samples have been provided by the Applicant to Airbus for further verification of the initial testing results, and whilst the development of Alternative 2 sealants has been more complex than initially anticipated, there has been significant progress to prove the feasibility of this alternative with all grades of the alternative having successfully passed the development phase. Further reformulation work and testing is required to address the current gaps in knowledge and product performance, with this work scheduled to be completed within the applied for 4-year Review Period ending 4<sup>th</sup> January 2029. Alternative 2 is also considered a long-term sustainable sealant as it will be both OPE and hydrogenated terphenyl free. Hydrogenated terphenyl is a SVHC that was

included on 10<sup>th</sup> Recommendation for Inclusion to the Authorisation List<sup>1</sup> and recommended for restriction<sup>2</sup> in the EU. The UK REACH work programme for 2022/23 stated that the HSE will carry out an assessment to decide if it should recommend that terphenyl, hydrogenated is added to Annex 14 (the Authorisation List) of UK REACH. This assessment will take the form of a Regulatory Management Options Analysis (RMOA). A call for evidence for this RMOA opened on 7<sup>th</sup> Feb 2023 and closed on 8<sup>th</sup> April 2023.

The Applicant and Airbus see any substitution effort that includes hydrogenated terphenyl within the new formulation as at best a “short term” solution that would require a subsequent substitution with a more sustainable formulation later. The intense effort related to substitution would then be doubled in a short period of time, forcing Airbus and its associated supply chain to repeat this high investment in terms of cost, time, and workforce.

Within the original AfA Alternative 1 (formulations already on the market) was highlighted as the most promising alternative available. However, Alternative 1 did not perform as expected during the screening tests and was thus shown to not be technically feasible when assessed against Airbus technical specifications. These screening test failures meant that Alternative 1 could not be qualified and introduced by Airbus.

This Review Report is narrowed to two sealants from the Applicant that contain OPE used by Airbus and their associated supply-chain (Table 6 in the AoA-SEA document), which is a reduction in the number of impacted sealants from the original AfA.

### **R&D Activities**

Section 3.2.1 and Figure 16 within the AoA-SEA detail the R&D and substitution activities that have been carried out in the time since submission of the original AfA and submission of this Review Report. In this section the substitution progress made by the Applicant and Airbus is shown, such as when the sealants successfully passed the decision gates, as well as the events that caused delays to the substitutions such as gates failed, Covid crisis, decision to change the sealants names or to reformulate.

### **Substitution Timeline**

In the original AfA a 4-year review period was requested. The Applicant was of the opinion at the time of submission that this review period would provide sufficient time to substitute OPE from the formulations used in Aerospace.

The substitution effort has not been 100% successful within the original review period hence the submission of this Review Report. The Applicant is applying for a further 4-year review period, to finish on 4<sup>th</sup> January 2029. The applicant is seeking an authorisation to enable them to transition to an alternative. The updated estimated timeline for qualifying and implementing a candidate alternative OPE-free sealant is as follows.

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<sup>1</sup> <https://echa.europa.eu/recommendations-for-inclusion-in-the-authorisation-list/-/dislist/details/0b0236e1846dd2e9>

<sup>2</sup> <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1862d9f6a>

- Applicant and Airbus R&D stage (including pre-tests): estimated end Q2 2025
- Airbus Qualification stage: 18 months, estimated end Q4 2026
- Airbus Industrialisation of newly qualified alternative sealant in Airbus plants and supply chain: 24 months, estimated end Q4 2028

Updated worker training and manufacturing documentation may be required to adapt Airbus aerospace manufacturing processes.

PROPOSAL	2023				2024				2025				2026				2027				2028				2029				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
R&D												Q2 2025																	
Qualification by Airbus																18	End 2026												
Industrialisation by Airbus incl. Supply chain																												24	End 2028
Request Review period																												48	End 2028

There were no conditions included in the Commission's original decision relating to the AoA, or in the decision grandfathered by the UK authority.

#### 4. Socio-economic Analysis (SEA; if relevant)

The significant change within the SEA submitted as part of this Review Report compared to the SEA included within the original AfA is that the Applicant is requesting a further 4-year review period but **only** for Airbus and their associated supply chain (not for all Aerospace and Defence companies as applied for in the original AfA). This new review period would start from the end of the originally granted review period, e.g., 4<sup>th</sup> January 2025. The reasons for this updated review period are outlined above (3. Analysis of Alternatives including *R&D Activities* and *Substitution Timeline*) and within the accompanying AoA-SEA document.

This Review Report focus is the SEA impact to the UK market and not the wider EU market within the original application. Although the UK market is smaller than the EU market there was no significant changes to the SEA methodology since the submission of the original AfA with assessments and conclusions relating to the non-use scenarios and benefits of continued use remaining similar.

There were no conditions included in the Commission's original decision regarding the SEA, or in the decision grandfathered by the UK authority.