
Explanatory note to a review report

Legal name of authorisation holder(s): Chemetall Limited

Authorisation number: UKREACH/21/03/0

Submitted by: Chemetall Limited

Substance: 4-Nonylphenol, branched and linear, ethoxylated

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

Use number: 1

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 Chemetall under EU REACH was transitioned into UK REACH on 4th November 2021 under Authorisation Number UKREACH/21/03/0. The formulation use within the EU AfA was not transitioned as this use takes place within the EU and it thus out of scope.

The scope of use for this UK application has not changed since the EU application for authorisation (AfA) was transitioned from EU REACH to UK REACH. As detailed in the accompanying AoA-SEA whilst the scope of the AfA has not narrowed, there has been significant work carried out regarding assessment of alternatives.

2. Chemical Safety Report (CSR)

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 the CSR now represent an accurate picture for the mixing use in the UK.

In the original EU AfA the number of sites number was approximately 200 across the EU (including at the time of submission the UK), in the review report this number is approximately 30 – 40 UK sites.

In the original EU AfA the volume of substance used was 50 – 350 kg per year across the EU (including at the time of submission the UK), in the review report this number is 40 – 70 kg per year across the UK downstream user sites.

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 NPE to the environment during the two uses applied for are not only minimised but effectively precluded.

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 EU AfA was not successful within the timeline originally put forward.

The shortlisted alternatives within the review report remain the same as those within the original AfA, with Alternative 2 still being considered as the most promising alternative. The substitution of the NPE-based surfactant with a surfactant based upon another substance has not been successfully identified, based on research to date.

R&D Activities

Sections 3.2.1.2 to 3.2.1.4 within the accompanying 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. This effort is summarised in Figure 15, which is confidential and was not included in the original AfA. Figure 15 shows that whilst there has been success in development and prequalification of some alternative sealants, other sealants faced some failures. An example of such a failure case within the R&D process was a sealant reference that failed its prequalification gate in 2020 but succeeded in 2021, and then it failed its qualification gate at the end of 2022 and is currently being evaluated to understand the root cause of failure.

Furthermore, for 2 other sealants alternatives, a significant reason for the delay in the analysis of alternatives work was the discontinuation in Q4 2022 by the supplier of a key polymer used in these alternatives. At an early stage of the whole NPE exchange project, it has been found, that new polymer combinations must be used to compensate for the changed properties of the NPE alternative. The polymer which was now discontinued was chosen due to its very good mechanical properties, which results in high values in some of the key tests of the sealant, e.g., a high peel strength value. By the time of the discontinuation the formulations/recipes of the affected sealant classes alternatives were already fixed and consequently, the recipes of these sealants had to be modified again, and alternatives for the discontinued polymer must be identified. Therefore, all testing with these formulations became obsolete.

It is these R&D issues along with the impact of COVID that have impacted the original substitution timeline

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 NPE 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 6-year review period, to finish on 4th January 2031. Figure 17, which was not included in the original AfA, details a distribution of the sealants across the different phases of substitution process per year since the beginning of the project in 2019 and then during the requested 6-year review period until the beginning 2031. This figure shows how the Applicant aims to structure the substitution effort.

The applicant is seeking an authorisation to enable them to transition to alternatives. The updated estimated timeline for qualifying and implementing a candidate alternative NPE-free sealant is as follows.

- Applicant R&D stage (including pre-tests): estimated end Q4 2026
- Airbus Qualification stage: 18 months, estimated end Q2 2028
- Airbus Industrialisation of newly qualified alternative sealant in Airbus plants and supply chain: 24 months, estimated end Q2 2030

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

Review period proposal:	2024				Y1 2025				Y2 2026				Y3 2027				Y4 2028				Y5 2029				Y6 2030				2031			
PROPOSAL	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	Q1	Q2	Q3	Q4
R&D																																
Qualification by Airbus																																
Industrialisation by Airbus including SUPPLY CHAIN																																
Request Review period																																

There were no conditions included in the Commission’s original decision relating to the AoA

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 6-year review period. This new review period would start from the end of the originally granted review period, e.g., 4th 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.