# SUBSTITUTION PLAN

***Non-Confidential Version***

| | |
|---|---|
| **Legal name of applicant(s):** | *PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc. – OR5*<br>*PPG Industries (UK) Ltd.*<br>*Sealants Europe SAS*<br>*Aviall Services Inc.*<br>*Aviall UK Inc.*<br>*Wesco Aircraft EMEA, LTD (UK)*<br>*Wesco Aircraft EMEA Ltd (Poland)* |
| **Submitted by:** | *PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc. – OR5]* |
| **Substance:** | *4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated* |
| **Use title:** | *Use 1: The formulation of a hardener component containing OPE in Aerospace and Defence (A&D) two-part sealants*<br><br>*Use 2: Mixing, by Aerospace and Defence (A&D) Companies, and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace and Defence (A&D) uses that are exempt from authorisation under REACH Art. 56(6)(a).* |
| **Use number:** | *1 and 2* |

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| A&D | Aerospace and Defence |
| AfA | Application for Authorisation |
| AMS | Aerospace Materials Specifications |
| AoA | Analysis of Alternatives |
| ASD | Aerospace and Defence Industries Association of Europe |
| CSR | Chemical Safety Report |
| EAAC | Ethoxylates in Aerospace Authorisation Consortium |
| EASA | European Aviation Safety Agency |
| ECHA | European Chemicals Agency |
| EEA | European Economic Area |
| EU | European Union |
| $MnO_2$ | Manganese dioxide |
| MIL | United States Defense Military Standard / Specification |
| MRO | Maintenance, Repair & Overhaul |
| OEM | Original Equipment Manufacturer |
| OPE | Octylphenol ethoxylate(s) |
| Q1 | First quarter of a given calendar year |
| Q2 | Second quarter of a given calendar year |
| Q3 | Third quarter of a given calendar year |
| Q4 | Fourth quarter of a given calendar year |
| R&D | Research and Development |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| SEA | Socio Economic Assessment |

## LIST OF DEFINITIONS

| Term | Definition |
|---|---|
| Acceptance | Acceptance of a product by either authoritative body or customer. |
| Aerospace | Relating to Aerospace and Defence (A&D) products, including aircraft, rockets, missiles, space vehicles, etc., that fly or operate in the atmosphere and space beyond. |
| Aerospace & Defence (A&D) | Business sector of companies producing hardware and services for aerospace and defence and their associated supply chains. Abbreviated in this document as A&D. |

| Term | Definition |
|---|---|
| Aerospace & Defence (A&D) application | General term for all aerospace & defence components, hardware and/or end products. |
| Aircraft on Ground | Aircraft product not in an airworthy condition, therefore not authorised to fly, typically at an airport gate. |
| Alternative | A candidate alternative that has been tested, qualified, certified and fully industrialised and implemented, by the Aerospace OEM. This definition is used only for the final classification of evaluated alternatives. |
| Approval | Written acceptance by an authorised representative of the authority or customer that a product/service/person or organization is suitable and accepted. |
| Assembly | Several components or subassemblies of hardware which are fitted together to make an identifiable unit or article capable of disassembly, such as equipment, a machine or an A&D product. |
| Base | The larger quantity component of a 2-part sealant that contains the sealant mixture. When the sealant base and hardener are mixed together, the sealant starts to cure (polymerize). |
| Candidate Alternative | In the context of this Application for Authorisation, this is the most promising potential alternative, as evaluated by the formulator, that can be provided to the Aerospace & Defence OEM for their evaluation. |
| Certification | The procedure by which a party (Authorities or MOD/Space customer) gives written assurance that all components, equipment, hardware, service or processes have satisfied the specific requirements. These are usually defined in the Certification Specifications, documented in technical standards or specifications. |
| Component | Hardware or software, sub-assembly or assembly which is uniquely identified and qualified.<br>*NOTE 1: Hardware components may be further divided (sometimes given names such as subassemblies), components, processes, and data.* |
| Corrosion | The process of an unwanted chemical reaction between a metal surface or item and its environment, for example, oxidation of a metal part leading to loss of constituent part. |
| Defence | Market sector that produces and maintains hardware/components/sub-assemblies/assemblies for the primary purpose of national security, including defence products also fulfilling the definition of “aerospace”. Non-aerospace defence product examples include, but are not limited to, land-based radar, weapon systems, launchers, and naval vessels. |
| Design | A set of information that defines the characteristics of a component. (adapted from EN 13701:2001) |

| Term | Definition |
|---|---|
| Design authority | The "owner" of the type certificate data sheet, engineering and flight test reports and design. |
| Design parameters | Those dimensional, visual, functional, mechanical, and features or properties, which describe and constitute the design of the component or assembly as specified by Drawing requirements. These characteristics can be measured, inspected tested, or verified to determine conformance to the design requirements. |
| Development | Process by which the capability to adequately implement a technology or design or requirement is established before series production. NOTE 1: This process can include the building of various partial or complete models of the A&D system and assessment of their performance. (adapted from EN 13701:2001) |
| Drawing | Graphical or written representation of forms or objects with supporting data to provide a design definition. |
| Equipment | Sub-system assemblies intended to achieve a defined final objective. For example, a radar system in an aircraft, an engine, wing assemblage, etc. |
| Evaluation | Process of appraising the performance of a formulation, process, hardware or system. |
| Failure | Termination of the ability of a formulation, component, part or hardware to perform a required function. |
| Faying surface | Surfaces which are placed in intimate contact with each other when assembled. |
| Formulation | A mixture of specific substances, in specific ratios, in a specific form. |
| Hardener | May also be referred to as “accelerator”. The hardener is one of two components in a sealant kit. The hardener and base components are mixed together and applied to the area of the part/assembly as a mixed sealant. |
| Industrialisation | The process by which the use of sealants in actual production and maintenance operations is defined and implemented. This includes all sourcing, transport, storage, handling, usage on products, and disposal activities. After having passed qualification, validation and certification, the next phase is to implement or industrialise the qualified formulation, hardware or process in all relevant activities and operations of production, maintenance and the supply chain. |
| Industry Standard | A documented set of criteria, forming the generally accepted requirements, within an industry relating to the functioning and carrying out of operations in the respective fields of production. |
| Inspection | Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging |

| Term | Definition |
|---|---|
| Interchangeability | Attribute of design that enables exchanged formulations or hardware to be installed due to absence of impact on form, fit and function of final component or system. |
| Maintenance, Repair & Overhaul (MRO) | Performance of tasks required to ensure the continuing compliance with applicable regulations of an A&D product or A&D component, or function of A&D component/hardware/assembly including any one or combination of overhaul, inspection, alternative, defect rectification, and the embodiment of a modification or repair. |
| Mixture | A mixture or solution of two or more substances. |
| Original Equipment Manufacturer | Organization that designs, integrates, and is responsible for certification of new top-level systems (e.g. aircraft, radars systems, missiles). |
| Part | Distinct component, possibly consisting of two or more pieces permanently joined together, that can be separated from or attached to an assembly.<br>*NOTE 1: Hardware item that cannot be disassembled without destroying the capability to perform its required function.* |
| Potential Alternative | in the context of this Application for Authorisation, this is a possible alternative being evaluated in the labs of formulators. |
| Product | In this document, product means any final A&D assembly (e.g. aircraft, engine, propeller, airframe part, radar antenna) performing a specific function (e.g. controlling flight, radiating RF energy) in an A&D system. |
| Qualification | OEM testing and verification that the formulation, process or part meets generic engineering technical performance requirements detailed in technical standards or specifications. Documented demonstration of the ability to fulfil specified requirements. |
| Repair | The restoration of an aerospace, defence, or space product to a condition compliant with applicable regulations, that ensure that the A&D product continues to comply with the design aspects of the appropriate applicable requirements used for the issuance of the certification for the respective A&D product type, after it has been damaged or subjected to wear. |
| Sealant | A formulation used to fill voids of various sizes providing a continuous film to prevent the passage of liquids or gaseous media. It prevents the passage of fluids along the surface of or through the joints or seams of structures and piping. It may also be used as an adhesive in some applications. |
| Specification | Document stating requirements. |

| Term | Definition |
|---|---|
| | NOTE: A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (e.g. product specification, performance specification and drawing). |
| Specification custodian | Term used for A&D supply chain members, typically OEMs, who develop and own their own specification(s). |
| Sub-tier supplier | Supplier not working under a direct purchase order from the OEM but performing work on related products at a lower level in the supply chain (contracted by the OEM's supplier or sub supplier). |
| Supply chain | Network created by customer, OEM, subcontractors and sub-tier suppliers producing, handling, and/or distributing a specific product. |
| Type Certificate | Document issued by an Aviation Authority certifying that an Aerospace product type of a specific design and construction meets the appropriate airworthiness requirements. |
| Validation | Detailed part-specific qualification and verification that the formulation, process or part meets the engineering technical performance requirements detailed in technical standards or specifications. Documented demonstration of the ability to fulfil specified requirements. The term qualification is often used when describing the combined qualification and detailed validation testing. |

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On 7 March 2019, the General Court of the European Union annulled a Commission decision granting an authorisation for certain uses of two lead chromate pigments (Case T-837/16, Sweden v. Commission). As regards the assessment of the suitability of alternatives under Article 60(4) of REACH, it follows from the judgment that if suitable alternatives are available in general, albeit not technically or economically feasible for the applicant, and if the applicant demonstrates that the socio-economic benefits of continued use outweigh the risk to human health and the environment, an authorisation may be granted if the applicant submits a substitution plan."

The applicant wishes to clarify that a substitution plan was purposefully not submitted as part of the application for authorisation. Based on REACH Article 62(4)(f) with due reference to Article 60(5), submission of a substitution plan within the application is required only when a suitable alternative is available to the applicant, which is explicitly not the case in relation to this application.

This following plan is therefore submitted by the applicant in response to ECHA's request and cannot be interpreted as substitution plan in accordance with REACH Article 62(4)(f), as no qualified alternative is available yet. As the qualification of polysulfide sealants is a complex process relying on satisfactory completion of various tests, the plan presented herewith cannot be binding on the applicants with regards to its success and timelines.

## INTRODUCTION

This document has been prepared in response to a specific request by ECHA. It sets out the substitution strategy for the use of octylphenol ethoxylate (OPE) in the formulation and mixing of a range of two-part specialty polysulfide sealants manufactured by PPG for use in the aerospace and defence (A&D) industry sector.

PPG, as the submitting applicant, and Ethoxylates in Aerospace Authorisation Consortium (EAAC) member companies, including Boeing Distribution, Inc. (formerly Aviall Services Inc.) and Wesco Aircraft, which are acting as co-applicants, submitted an Application for Authorisation (AfA) for use of OPE as described above. PPG customers[1], their suppliers and customers such as airlines, rely on these specific polysulfide sealants during production and maintenance, repair, and overhaul (MRO) of A&D components and completed products (e.g. civil and defence aircraft, including helicopters; fixed wing and rotorcraft air-based defence; actuators; missiles; missile launchers; satellite launchers; ground-based military radar and communication systems; satellite systems; naval sonar systems; etc.). Without these polysulfide sealants (i.e. in case an authorisation is not granted), it will not be possible to manufacture, maintain, or repair A&D components and systems in the EEA. The Applicants' customers rely on polysulfide sealants containing very low volumes and concentrations of OPE to ensure reliable and safe performance of A&D systems that are vital to the EEA economy. MRO organisations, including EEA airlines and defence operations, also need access to the formulations to comply with OEM design requirements/specifications for the maintenance and repair of A&D systems.

The substitution strategy refers to information presented in the combined Analysis of Alternatives (AoA) and Socioeconomic Analysis (SEA) document and takes into account regulatory requirements affecting substitution, past efforts associated with substitution, and key milestones affecting the substitution. For clarity, we have referred to relevant sections of the combined AoA and SEA rather than duplicate contextual information not specifically required as part of the substitution strategy in this document.

### Use of octylphenol ethoxylate (OPE)

This application for authorisation covers two closely related uses.

The first, is to use OPE in the formulation of the hardener part of two-part polysulfide sealants, that are specified for use in the A&D industry. PPG formulates and manufactures several different types of hardener/sealant for use in A&D products, each with different specific applications and performance characteristics (as described in detail in Section 4.3 of the combined AoA and SEA).

The second use applied for covers the mixing of the hardener and base parts of the polysulfide sealants prior to their application on A&D products. This is carried out by the applicants and their customers in the A&D industry.

### Regulatory Imperatives relating to substitution of Octylphenol Ethoxylate

[1] Including members of the Ethoxylates in Aerospace Authorisation Consortium (EAAC)

A&D products are subjected to some of the most aggressive and corrosive environments around the world. They must operate successfully in extremes of altitude, temperature, and precipitation, while having to fulfil the highest possible technical reliability and safety requirements. To ensure aircraft safety, comprehensive airworthiness regulations[2] have been in place in the European Union (as well as around the world) for decades. These regulations require qualification/validation of all materials and processes according to a systematic and rigorous process to meet stringent safety requirements that are ultimately subject to independent certification and approval. Parallel requirements[3] are in place to ensure airworthiness for defence systems in Europe. Ground and sea-based defence systems are subject to similar rigorous qualification/validation requirements. Space systems must also meet the highest specifications for consistent reliability and performance in extreme environments over many years, since repair or maintenance is practically impossible once the technology is launched.

Considering these requirements and the role of OPE in polysulfide sealants, the preferred substitution strategy for this specific case of the polysulfide sealants involves developing reformulated 'OPE-free' products that are completely interchangeable with the products they are intended to replace. To achieve this, the OPE-free sealants must perform in the same way and be applied following the same process instructions as the currently certified sealants. When this is the case, no part design changes (e.g. no drawing, part number, or specification changes, or external approval from the certification authorities) are needed, and conformance to existing certification requirements can be maintained. When this is not the case, far more extensive effort is required to qualify, validate and certify its use in each A&D application. Polysulfide sealants containing OPE, specified for use in A&D systems, can only be substituted when the reformulated product has been shown through rigorous and repeatable testing to meet all relevant process and performance requirements. Such interchangeability must be demonstrated for each product in each A&D application before it can be industrialised for use by the OEM and its supply chain.

The testing criteria are determined by the design authority (e.g. the OEM) and/or approval authority on a case-by-case (i.e. application-by-application) basis, with due regard to the design and performance requirements of each component and system. In the case of the polysulfide sealants, testing for a range of parameters in a relevant environment over an appropriate timescale is necessary, and the results must prove the reformulated sealant meets the performance criteria and can be used interchangeably with the current OPE-containing formulation. This typically requires an appropriate suite of testing on samples of the reformulated sealant, even when only very small volumes of the sealant are used. This process must be successfully completed for each of the polysulfide sealant products within the scope of this AfA.

PPG, as formulator, is responsible for developing and performing the preliminary assessment of a reformulated product/potential alternative's viability. However, only the OEM design owner can determine when a candidate alternative is fully qualified (and validated, if required), and is therefore in line with airworthiness or comparable performance requirements for each of their A&D applications.

[2] E.g. European Union (EU) Regulation No 216/2008 and the EASA CS-25 and EASA CS-E in the EU

[3] The European Aviation Requirements (EMARs) established by the European Defence Agency (EDA) Airworthiness Authorities (MAWA) Forum

**Alternatives Analysis**

Qualified alternatives for OPE-containing polysulfide sealants are not yet available. The formulator, PPG, has undertaken significant research and development (R&D) activities that have focused on removing, rather than replacing, the low concentration (<0.5% w/w) of OPE in the hardener formulation. The work by PPG indicates adequate dispersion of the manganese dioxide curing agent can be achieved by mechanical means and that the final sealants utilising the reformulated OPE-free hardener are expected to meet the performance requirements set out in the industry and OEM-specific specifications. However, not all testing is complete at this time. Performance of each reformulated OPE-free sealant must be evaluated against the original sealant through systematic comparison of the batch release test requirements to demonstrate that any changes in the properties and performance of the sealants are technically insignificant. This work programme is still in progress. A&D OEMs will evaluate the test data from the formulator against their own specifications that define acceptable performance criteria of the sealants in their own applications, and perform additional testing as required.

PPG is preparing production scale batches of these reformulated two-part sealants without OPE in the hardener. Samples are being sent to OEM customers covered by this Authorisation to commence qualification activities for rigorous testing against their own relevant performance requirements, as described above. These performance requirements can be more exacting than those to which the formulator tests when developing the product. The reformulated hardener/sealants must successfully and repeatedly satisfy each of the relevant criteria to complete the qualification process and be introduced as alternatives for any application by an OEM.

**Substitution Strategy**

The substitution strategy for the specific case of the polysulfide sealants involves developing reformulated OPE-free products that are completely interchangeable with the product they are developed to replace. Such reformulated polysulfide sealants must be shown through the qualification process to meet the technical requirements documented in OEM specifications and thus suitable and safe for use in accordance with the relevant airworthiness regulations or comparable performance requirements.

The process to develop and test new formulations that meet these specifications involves several stages. The most promising alternative is the removal of OPE from the formulations. PPG forecasts that representative samples of all variants of affected polysulfide sealants will be provided between Q2 2019 and Q2 2020 to OEM customers needing to be covered by this Authorisation.

Once the reformulated sealant is available, the OEMs can start their own technical qualification process. Qualification testing is extensive, and multiple testing runs under different relevant conditions and for different substrates may be required. Ideally, the testing will demonstrate the reformulated product and the current sealant are interchangeable, as this result will greatly simplify the substitution process[4]. Testing to industry specifications by the formulator has been positive and

[4] In this event, additional certification from EASA or defence or space certification authorities is not needed as the OEM-held data for certification of the sealant containing OPE will still be valid and can be read across to support use of the OPE-free reformulated sealant without changes to specifications or drawings.

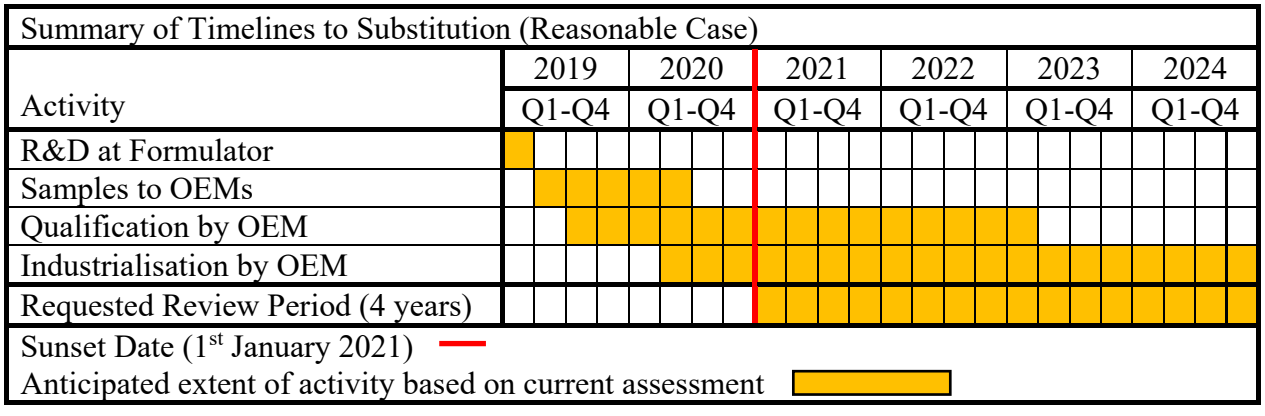
indicates OEMs may be able to demonstrate interchangeability between the original and these reformulated sealants in accordance with their own OEM-specific requirements. However, this is by no means a foregone conclusion and can only be confirmed through appropriate and adequate testing by each OEM to confirm that the reformulated sealant has the same properties and performance, including compliance to relevant industry and OEM proprietary specifications, as the current sealant containing OPE.

Materials for which interchangeability between the existing and re-formulated product cannot be demonstrated, and the change cannot be considered as a one to one replacement, may require validation/certification activities prior to implementation. Further iterations may be needed to refine the OPE-free formulation until an interchangeable alternative is qualified. The cost of such changes may be prohibitive and would significantly extend the timeline to replace the sealants in A&D products.

The OEMs currently estimate that the necessary time to complete qualification testing, if successful on the first attempt, is 9 to 32 months from availability of the reformulated sealant. Qualification would be completed between Q3 2019 and Q1 2023, according to the current schedule. However, success at this stage is by no means assured and the timeline could be longer. Even when the formulation passes initial tests, subsequent tests may fail.

Once qualification activities have been completed and interchangeability of the OPE-free formulations has been established, the qualified alternative sealant must then be industrialised throughout the OEM manufacturing sites and throughout the wider supporting supply chain. It is currently estimated that industrialisation of the reformulated sealant after successful sealant qualification would potentially take up to 18 months. In the overall scheme foreseen by individual OEMs, and assuming qualification is successful, industrialisation would occur between Q2 2020 and Q4 2024. This schedule does not account for any slippage.

Based on this substitution strategy, a review period of four years was requested to allow sufficient time for the process to be completed to ensure compliance with the relevant regulations and safety of the final A&D product.




*Note: This schedule considers an aggregated view of all the OEMs considering each are going to receive samples for testing at different times.*

# 1. FACTORS AFFECTING SUBSTITUTION

The following sections include excerpts from Section 4.3 of the combined AoA and SEA; and details factors, including technical requirements and product specifications, affecting the substitution of OPE.

## 1.1 Description of the technical requirements that must be achieved by the product(s) made with the substance

A&D systems are subject to a variety of onerous requirements flowed down from governmental organisations, for example, regulators, Ministries of Defence and Space Agencies. Every A&D system is subject to one or more sets of these requirements. Further details on the regulatory situation for A&D products is provided in Annex C to the combined AoA and SEA.

The European Aviation Safety Agency (EASA) established Airworthiness regulations to ensure the highest common level of safety for EU citizens. The industry must also cooperate with numerous international actors (e.g. US FAA) to achieve the same level of safety for EU citizens globally. These regulations cover every aspect of design, maintenance, repair, overhaul and safe operation of commercial aerospace products. Defence products must comply with member state specific regulations, and the European Military Aviation Requirements (EMARs) when used in member states participating in the European Defence Agency (EDA) Airworthiness Authorities (MAWA) Forum. Non-defence space application products face stringent requirements and processes regarding change acceptance and qualification (with respect to both performance and manufacturing, assembly, integration and test processes) by European or national agencies and customers. The regulations of European Space Agency (ESA) are supported by wider frame UN General Assembly Resolutions on space activities.

The regulatory requirements and responsibility placed upon OEM companies drives the need for creation, implementation and maintenance of agreed industry and internal specifications relating to all elements of the component or material, which controls what can be used in A&D manufacture. The specifications detail the criteria the material must comply with to be considered as suitable for use and can include details on testing that is conducted to verify if it meets the specified criteria. See Section 1.1.2 below.

All changes to the materials, components, or manufacturing processes used in complex A&D systems are subject to the highest level of scrutiny. No change is so minor that it does not require some degree of substantiation (see Figure 1 for process overview). Any change must be qualified to prove it meets specification performance requirements. Formal systems are in place to manage change, whereby all the impacts of the change are analysed, and the evidence for justifications/substantiations to support the qualification, validation and certification of the change can take many forms.

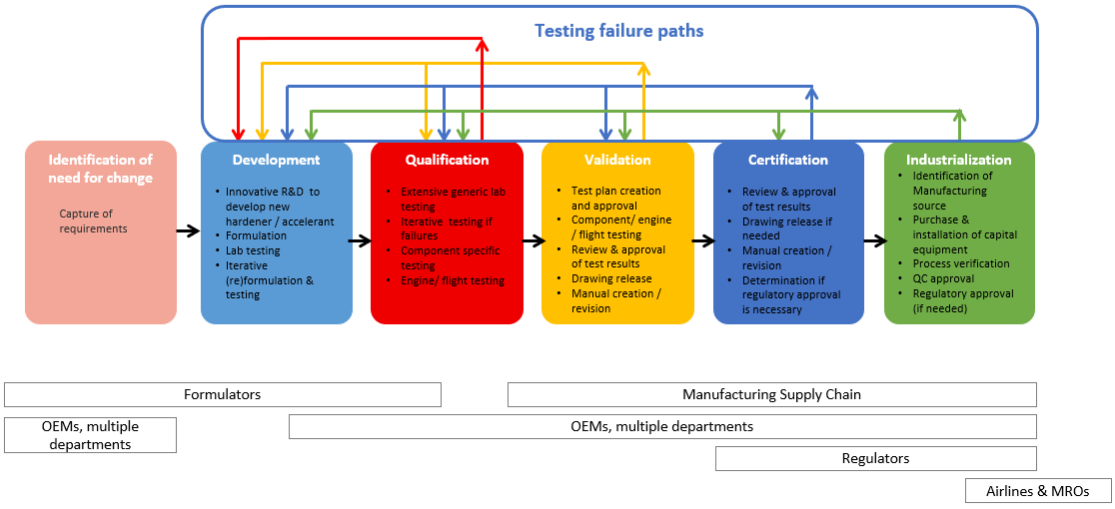



**Figure 1: Key Phases of Introducing A Chemical Substance Change into Production Hardware Manufacture**

In the case of the replacement programme for sealants containing OPE, the performance requirements remain as documented in the relevant specifications. The reformulated alternative sealants will need to meet the same performance requirements as the existing sealants for each category.

### 1.1.1 New Formulation Development

The development of a formulation is complex, and several years are often necessary. Once a reformulation or substitution project is launched, technical specialists, from engineering and manufacturing departments, must align the numerous regulatory, performance and technical requirements that an alternative must fulfil.

In the development of new formulations, or changes to an existing formulation, it is important to note that many iterations are typically rejected in the formulator's laboratory and do not reach sufficient maturity to proceed to OEM qualification testing. In the case of providing candidate alternative polysulfide sealants without OPE to OEMs to commence qualification testing, the provision of OPE-free polysulfide sealant samples is expected to be concluded by Q2 2020, as discussed further in Section 2.2.2.

Qualification through industrialisation is required to:

- Ensure that only reliably performing materials, components, and processes are approved for use to produce, maintain and repair A&D components.
- Ensure that the product, the process or method is compliant with both Industry Regulations and A&D component manufacturer requirements to fulfil specified functions.
- Provide a very high level of confidence for both the use of the product and the resulting A&D end components.
- Ensure consistent quality of materials being introduced.

- Ensure consistent use of the new or alternative formulations between different users of the formulations, and to guarantee production and management system robustness, throughout the supply chain.
- Fulfil requirements of the Airworthiness Authorities (EASA), and applicable Defence and Space requirements.

Technical qualification typically requires a minimum of 1 to 3 years to complete, depending on the ease of meeting all the performance requirements that were established. This duration estimate assumes that the qualification process is successful, which may not always be the case. In the event of failure, qualification will be stopped, and the development phase must start again from the beginning.

Figure 2 highlights the progressive complexity of materials substitution from a change that is deemed interchangeable for any part (least complex) to a change where a unique alternative is required for all uses and no interchangeability is allowed (most complex).

| | Paths | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| **Change context** | Materials interchangeable for any part | Materials interchangeability limited to these parts | Loss of material interchangeability for these parts |
| Impact on **material spec** | Material interchangeability is managed at the spec level* | As many spec as materials | As many spec as materials |
| Impact on **drawing** | No change | Drawing of these parts shall call out the interchangeable materials | Drawing of these parts shall call out the relevant material (with potential consequential impacts on parts drawing) |
| Impact on **part number** | Not changed for any part | Not changed for these parts | Changed for these parts |
| **Mean of traceability** | On production documentation | On production documentation | On drawing |

**Figure 2: Materials Change Path**[5]

As no component design changes (e.g. no formulation name, specification, drawing, or part number changes) are expected in the case of the reformulated polysulfide sealants, the changes at OEMs are anticipated to fall in Path 1 of Figure 2. The newly qualified sealants are expected to perform in the same way as current sealants and to follow the existing process instructions. Interchangeability is achieved where the alternative product is proven to be a one to one replacement, and Path 1 is followed. (Re)Certification will not be required if no change to the specifications or drawings are necessary.

[5] ASD. REACH Design changes best practices, pg. 9. s.l. : ASD, 2019. ASD19003 Issue 1.

In the case of the polysulfide sealants in scope of the AfA, no change to the formulation name is anticipated, as the OPE-containing and OPE-free formulations are expected to be interchangeable.

For materials for which interchangeability between the existing and re-formulated product cannot be demonstrated, and the change cannot be considered as a one to one replacement, it may be necessary to undertake validation/certification activities, following Path 2 or 3 in Figure 2 above, prior to implementation.

Qualification testing by the OEM will commence once candidate alternative OPE-free polysulfide sealants are available from the formulator, anticipated by Q2 2020. In line with best estimates for the degree of testing that will be required, the qualification stage is anticipated to conclude by Q1 2023, at the latest. However, once these activities have been completed and interchangeability of the OPE-free formulations has been established, the qualified alternative sealant must then be industrialised throughout the OEM manufacturing sites and throughout the wider supporting supply chain. If interchangeability is not achieved, then industrialisation may be significantly delayed.

Further details on the regulatory situation for A&D products and the required steps to implement a new or modified formulation in the A&D industry is provided in Annex C to the combined AoA and SEA.

### 1.1.2 Specifications of Polysulfide Sealants

Specifications play an important role in capturing the requirements that sealants must fulfil for use in different A&D applications, and these can range from widely accepted industry standards to OEM proprietary specifications for formulations or processes.

Whilst there are industry-wide specifications relating to sealants used in aerospace (partly as detailed below e.g. Aerospace Materials Specifications, ISO standards, etc.), it is the OEM specifications that will be most relevant for the sealants in question. The OEM specification documents detail the performance requirements and quality level which need to be met per sealant type, including test methods, for that specific company. They specify the physical, chemical and technical characteristics of formulations according to the type of sealant (e.g. general purpose, fuel tank, low adhesion, transparencies)[6]. In addition, OEM process specification documents can identify the engineering requirements in terms of performance requirements to be met as output of the sealant application process. This defines the key characteristics of the process and the formulation and defines mandatory series production inspections imposed by engineering, for each OEM company. These are proprietary to each OEM company and therefore the details of the specifications cannot be disclosed in this document.

The industry standards and criteria applicable to the affected PPG sealants, as identified by EAAC member companies, are as follows:

[6] The description of the polysulfide sealants resulting from the use of OPE is elaborated in Section 4.3.3 of the combined AoA and SEA document.

- AMS 3265: Sealing Compound, Polysulfide (T) Rubber Nonchromated, Corrosion Inhibiting for Intermittent Use to 360°C (182°F)
- AMS 3269: Sealing Compound, Polysulfide (T) Synthetic Rubber for Integral Fuel Tank and Fuel Cell Cavities High Strength, for Intermittent Use to 360°F (182°C)
- AMS 3276: Sealing Compound, Integral Fuel Tanks and General Purpose, Intermittent Use to 360°F (182°C)
- AMS-S-8802: Sealing Compound, Temperature Resistant, Integral Fuel Tanks and Fuel Cell Cavities, High Adhesion
- AMS 3281: Sealing Compound, Polysulfide (T) Synthetic Rubber for Integral Fuel Tank and Fuel Cell Cavities Low Density (1.20 to 1.35 sp gr), for Intermittent Use to 360°F (182°C)
- AMS3284: Sealing Compound, Low Adhesion, for Removable Panels and Fuel Tank Inspection Plates
- AMS-S-83318: Sealing Compound, Polysulfide Type, Low Temperature Curing, Quick Repair, Integral Fuel Tanks and Fuel Cell Cavities
- MIL-PRF-81733: Performance Specification: Sealing and Coating Compound, Corrosion Inhibitive

It should be noted that these are not the only requirements that the replacement sealants will need to meet but are provided to illustrate the preliminary requirements to qualify any alternative sealants.

Specifications typically define test requirements to demonstrate that the relevant criteria[7] are met.

There is a range of different sealant formulations currently on the market, to meet the different specification requirements of the A&D OEMs. Each sealant has several variants (e.g., PR-1440 Class A-1/2, PR-1440 Class A-2, PR-1440 Class B-1/2, PR-1440 Class B-2, etc.) (see Table 1), with each variant providing different specific processing criteria that relate to the different application methods (e.g. extrusion, spatula), working life and cure times that are required by OEMs. It is important that OEMs have access to a product range of sealants comprising these variants with different processing properties, reflecting the different sealant types that are required in the A&D industry (e.g. fillet, injection, faying surface, etc.) and the different manufacturing processes in which the sealants may need to be used. For example, Class A sealants are less viscous and suitable for application by brush, Class B can be applied using an extrusion gun or spatula and Class C can be applied using a brush, extrusion gun, roller or spatula for faying surface sealing where long work life is required. In general, the formulation variants use the following naming convention, although it should be noted that these are common examples only, and there may be some exceptions to the product naming.

**Table 1. Sealant variations**

| Class (viscosity) | Dash number | |
|---|---|---|
| | Work life (in hours) | Cure Time (Room temperature) |
| A | 1/2 | Approx. 6-24 hrs |
| | 2 | Approx. 10-72 hrs |

[7] For further details, see Sections 4.3.5.2 and 4.3.5.3 in the combined AoA and SEA.

| Class (viscosity) | Dash number | |
|---|---|---|
| | Work life (in hours) | Cure Time (Room temperature) |
| | 4 | Approx. 24 – 72 hrs |
| B | 1/2 | Approx. 6 – 24 hrs |
| | 2 | Approx. 10 – 72 hrs |
| C | 1/2 | Approx. 6 – 24 hrs |
| | 2 | Approx. 10 – 72 hrs |
| | 12 | Approx. 7 – 10 days |
| | 48 | Approx. 21 – 49 days |
| | 96 (C70 highest variety common in Europe) | Approx. 49 – 70 days for C70 |

The following table compares some example testing requirements by the formulator for two fuel tank sealants, PR-1750 A1/2 and PR-1750 B1/2, which only differ in the sealant class.

**Table 2. Sealant testing requirement comparison**

| Test | PR-1750 A1/2 Requirements | PR-1750 B1/2 Requirements |
|---|---|---|
| Base Viscosity (Poise) | 100 - 600 | 9,000 - 16,000 |
| Working life (hrs) | 1/2 minimum | 1/2 minimum |
| Tack Free Time (hrs) | 10 Maximum | 10 Maximum |
| 14 Day Hardness (Degrees Shore A / Durometer A) | 40 Minimum | 40 Minimum |
| Standard Cure (hrs, time to reach 30 Durometer A) | 30 Maximum | 30 Maximum |
| Immersed Cure Rate @120hrs (Degrees Shore A / Durometer A) | 35 Minimum | 35 Minimum |
| Immersed Cure Rate @48hrs (Degrees Shore A / Durometer A) | 25 Minimum | 25 Minimum |
| Non-volatile Content (%) | 85 Minimum | 96 Minimum |

Table 3 lists the sealants manufactured or sold in the EEA that are in the scope of the AfA. The sealants listed in this table have been identified as in scope, as currently known by the EAAC OEM members and Formulator Applicant[8]. Sealants can perform and be used in functions other than the named "title" function of the sealant. The sealant nomenclature typically comes from its primary use but does not preclude it from use on other hardware. It should also be noted that the uses listed are examples only and are not the only applicable usages of the sealants identified. For example, a fuel tank sealant may be used in applications other than fuel tanks, if the fuel tank sealant's process and performance capabilities can satisfy other OEM or MRO needs.

**Table 3. A&D sealant use examples**

| Formulation | Aerospace and Defence Use Examples |
|---|---|
| PR-1425CF | Glazing/windshield |

[8] Note: this table reflects current knowledge of affected sealants containing OPE manufactured by the Formulator, PPG. The possibility of additions to the list at a later date, if further formulations are identified as containing OPE prior to the Sunset Date, cannot be disregarded but this is currently considered an unlikely possibility.

| Formulation | Aerospace and Defence Use Examples |
|---|---|
| PR-1428 | Low adhesion - form in place (e.g. access doors, hatches) |
| PR-1440 | Fuel tank and general sealant |
| PR-1440M | |
| PR-1448 | Void filling sealant |
| PR-1460 Q2 | Potting compound for electrical purposes |
| PR-1750 | Fuel tank and general sealant |
| PR 1764M | Corrosion inhibiting conductive sealant |
| PR-1770 | Fuel Tank (elevated temps) and general sealant |
| PR-1771 | Corrosion inhibiting gap filling sealant |
| PR 1772 | Fuel tank sealant |
| PR-1773 | Corrosion inhibiting access door sealant |
| PR-1775 | Corrosion inhibiting for dissimilar substrates/surfaces |
| PR-1776 | Fuel tank and general sealant |
| PR1776 LW | |
| PR-1776 M | |
| PR-1782 | |
| PR-1783 | |
| PR-1784 | Windshield and canopy sealant |
| PR-2007 | Fuel tank (low density/low tolerance) |
| PS 860 | Fuel tank repair |
| PS 890 | Fuel tank and general sealant |
| PS 890 F | |
| PS 890 M | |
| PS890 N | |

## 2. LIST OF ACTIONS AND TIMETABLE WITH MILESTONES

The following sections include pertinent information provided in Sections 5.1 to 5.3 of the combined AoA and SEA. Further details on the individual alternative assessments can be found in Section 5.3 of the combined AoA and SEA but have not been included in this substitution plan.

The preparation of this Substitution Plan has been supported by the Applicants and OEMs in the supply chain of polysulfide sealants under the auspices of the EAAC. The products are manufactured by an EEA Applicant and used on A&D products in the EEA, as well as the rest of the world. The sealant formulations covered by the AfA are themselves proprietary and confidential.

### 2.1 Substitution of OPE in Aerospace and Defence Industry Products

Any alternative or reformulated sealants must comply with the previously summarised requirements and undergo qualification testing, prior to being approved as a viable alternative.

Following appropriate qualification steps, including successfully completing all necessary testing measures for sealants in each specific A&D application, is highly important, so that OEM companies

are certain of the performance of the sealant being used on the A&D hardware. When performance cannot be assured, successful qualification is not possible, and the formulation cannot be used.

Even after successful completion of testing during the qualification process and industrialisation, problems can be identified with the performance of the formulations. This is because the testing simulates, but does not reproduce, actual service conditions. Under real conditions, formulations, which performed successfully in laboratory tests, may fail. For this reason, performance of newly approved formulations is closely monitored until there is adequate evidence of performance under operational conditions. In this AfA, the focus has rested largely on the OPE-containing polysulfide sealants that are used in key applications by the A&D industry[9], rather than on the specific use of the substance in the Authorisation entry. As previously outlined, thorough assessment of hardener reformulations must demonstrate the sealant continues to meet its performance requirements. Changes to the hardener could result in a change to the delivery or concentration of the manganese dioxide to the base when mixing. This could potentially result in viscosity changes, change in cure time, etc., which could impact the sealant usage in the wider A&D component manufacture and MRO activities. This is further elaborated in Section 2.2.2 below.

This reiterates the importance of undertaking stringent change control activities, and the need for adequate testing of alternatives by OEMs prior to industrialisation across the industry supply chain.

The following section will present the efforts made by EAAC to identify potential alternatives to the OPE-containing polysulfide sealants for the applications previously identified in A&D industry.

## 2.2 Research and Development

### 2.2.1 Relationship between Formulators and Industry

Formulators and the A&D Industry often communicate processing and performance requirements between one another using sealant specifications. As previously discussed in Section 1.1.2, specifications define the characteristics and performance capabilities of a sealant/ adhesive (e.g. AMS-S-8802). A specification custodian is the term used for A&D supply chain members, typically OEMs, who develop their own specification(s). Industry standards, such as Aerospace Materials Specifications (AMS) are authored and maintained by different Aerospace Quality Committees of SAE International (standardisation body in the US) and represent widely accepted requirements.

In the context of this document, the relevant specifications can be A&D OEM company proprietary specifications that contain the requirements sealants must meet for each OEM's specific applications, as well as industry standards (e.g. AMS and MIL). An OEM may need to test to industry specifications, to their own internal specifications or use both when evaluating new or reformulated sealant performance, and this varies across the A&D industry.

Typically, formulators qualify reformulated sealant to industry standards, and then work with OEMs who carry out testing to further internal, often more stringent requirements. Therefore, reformulation is often a process of iterative reformulation and repetitive testing until the new formulation satisfies

[9] As discussed in detail in Section 4.3.3.1 of the combined AoA and SEA

all the specifications (industry standard, custodial specifications, and OEM internal specifications) currently met by the original formulation (see Figure 3 Relationship of formulators and OEMs).

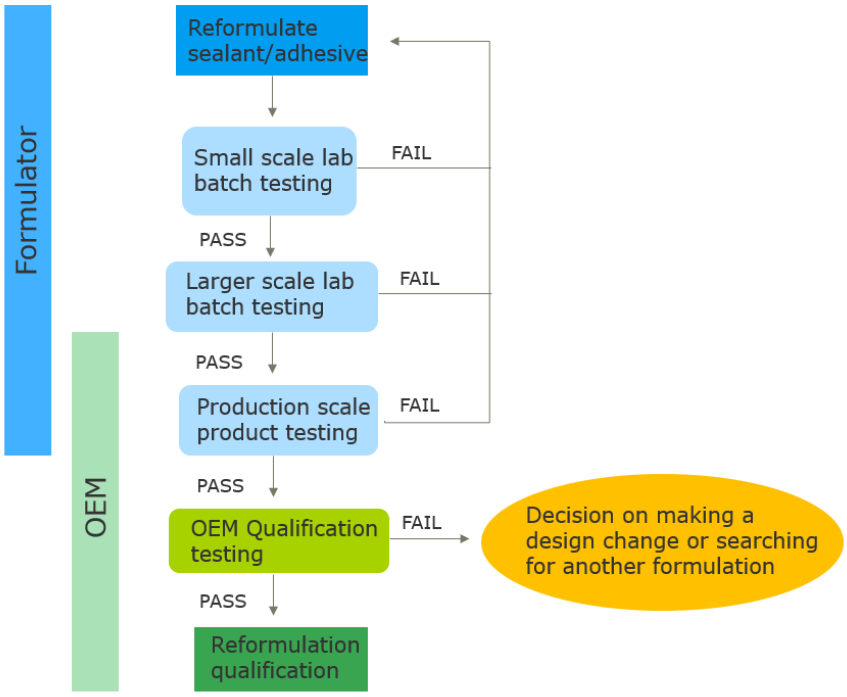



**Figure 3: Relationship of formulators and OEMs**

### 2.2.2 Research and Development Activities by Formulator

Aerospace and defence polysulfide sealants come in two parts known as the base and the hardener. The base is composed primarily of a sulfide polymer with additives, such as resins, acetates and other batch chemicals, present at <10%. The hardener is composed of manganese dioxide ($MnO_2$) and other formulator-specific constituents.

When the hardener and base are combined, the $MnO_2$ in the hardener and the base mix together and start to chemically react to change the state of the sealant from a paste to a rubber-like solid over time. This is known as curing the sealant. Depending on the specific hardener and base combination, the curing reaction time can vary. Typically, the proportions of the two parts used are 1 (Hardener): 10 (Base). This curing reaction can take place at room temperature but can be further accelerated by elevated temperatures. Once the sealant is mixed, the OPE is present at <0.1% w/w in the mixture and further use of the mixture is exempt from authorisation requirements. Under the current knowledge of the formulator, the OPE present does not play a role in the chemical curing reaction and is inert in the sealant after cure.

Sealants with different working lives and cure times are required to meet all the varying process requirements across A&D manufacturing and MRO operations. Ensuring adequate dispersion of the $MnO_2$ within the base when mixing is key to achieving the desired cure and properties of the final

sealant. The specific hardener and base combination control the speed of the cure reaction, but also has an impact on important functionalities, such as viscosity of the sealant and its working life. When a fast cure hardener is used, there is a higher concentration of the $MnO_2$ constituent in the sealant mixture. There is a faster curing reaction, the viscosity increases more rapidly, causing the working life to decrease. Workers must apply a fast cure sealant within a shorter space of time than when using slower cure sealants, which can impact manufacturing time and processes.

Conversely, if there is not enough $MnO_2$ mixed into the base as a result of inadequate mixing of the two parts, the cure time may be much longer than expected, or the mixture may not cure at all. Both could lead to the sealant not functioning as required. For example, it may be easier to peel off due to poor adhesion or it may not provide adequate resistance to corrosive fluids for the expected lifetime of the A&D product use. Any alternative formulations must ensure the same key criteria[10] and function[11] in the sealants.

Historically, OPE was added to the original sealant hardener formulations to assist in dispersing the $MnO_2$, a critical constituent in the hardener, and not to provide a function in the final formulation for either the application of the sealant on A&D components or in the cured sealant during the lifecycle of the A&D components.

Importantly, as the formulator's mixing processes evolved and improved, it was found that the OPE is no longer thought to be necessary for the required dispersion of the $MnO_2$. The evaluation undertaken so far indicates that, for the A&D sealants in scope of the AfA, current process methods do not require OPE in the hardener formulation to achieve the same results and removal of OPE from the sealant formulation is expected to be a viable alternative.

The Formulator monitors SVHC listings and conducts reformulation activities when necessary. To determine how a formulation should be changed to adapt to the regulatory situation and still provide OEM customers with required formulations to specification, it goes through a detailed and extensive R&D process. In the case of the polysulfide sealants containing OPE, the R&D for the reformulations of the sealant products has followed the below process for all affected products. The provision of OPE-free polysulfide sealant samples is expected to conclude by Q2 2020 at the latest.

#### 2.2.2.1 Laboratory Scale Development and Testing

The first stage of R&D is laboratory scale development and testing of potential alternatives. In the case of the polysulfide sealants, the removal of OPE from the sealant formulations was the first alternative tested. This proceeded through the following stages:

1. Validate that $MnO_2$ powder can be fully dispersed into the hardener formulation.
2. Manufacture identical hardener formulations with and without OPE.
3. Select candidate sealants to evaluate comparisons between original and OPE-free hardener formulations.
4. Design laboratory scale experiments to test and compare the original and OPE-free sealant versions.

[10] For more detail, see Table 2 in Section 4.3.5.2 of the combined AoA and SEA.

[11] For more detail, see Table 3 in Section 4.3.5.3 of the combined AoA and SEA.

5. Test the raw hardener constituents for physical and reactive properties.
6. Test the combinations and blending properties to ensure finished formulations can be achieved from the constituents.
7. Validate this work in three separate laboratory locations (USA, France & UK).
8. Determine regional 'favorite/most used products of customers' for initial tests.
9. Retain samples for stability checks later in the work program.
10. Share results internally and, if successful, obtain 'Gate Approval' to proceed to operational trials.

#### 2.2.2.2 Pilot/Small Scale Production Testing

After the potential alternative has successfully proceeded through the laboratory stage, and 'Gate Approval' has been obtained for reformulation, steps 1 through 10 are repeated, using small scale production equipment or minimum batch capability of standard equipment, to ensure repeatability of results under small scale pilot production/manufacture test conditions.

Once complete, the potential alternative formulation proceeds to testing of the following manufacturing parameters:

1. Ensure pumping capability of the alternative formulation on:
   a. transfer pumps in production
   b. filling equipment used to dose metered shots into final packs
   c. meter-mixing equipment used for pre-mixed and frozen operations.
2. Launch mid – long term accelerated, and natural aging stability checks of OPE-free intermediates and blended hardeners.
3. Allocate material for initial product-by-product evaluation and initial customer sampling.

#### 2.2.2.3 Production Scale Batch Testing

If the small-scale production testing is successful, the potential alternative proceeds to full production scale batch testing. This repeats all previous test stages, but at full manufacture scale on standard production equipment, and is done across the three manufacturing locations (USA, France & UK). Once this stage of testing is completed, OPE-free potential alternative hardener samples are rolled out for an extensive work program, testing the OPE-free hardener on a product-by-product evaluation. Further samples can now also be provided to customers to commence their own qualification testing.

#### 2.2.2.4 Customer / Industry Evaluation

Once production scale batch testing of the reformulated hardener and subsequent sealants has been conducted, the formulation change is sent out for evaluation by external parties.

In the case of the polysulfide sealants, validation of the formulation change was sought from SAE International (standardisation body in the US for industry standards). SAE International has indicated no objection to the change and it is understood by PPG that its $MnO_2$-cured polysulfide sealants currently approved to AMS specifications have now been updated on the SAE qualified products list (QPL), with the reason for change cited as removal of OPE. It must be noted that whilst some OEM companies use industry standards, others do not, so not all A&D OEMs will refer to the SAE qualified

products list. A third-party laboratory was also commissioned to independently test performance against the original formulation.

In parallel, the formulator plans that test results of each reformulated OPE-free sealant will be evaluated against the original sealant containing OPE through systematic comparison of the batch release test requirements, aiming to validate that the effects or changes in properties and performance of the sealants are technically insignificant. Over time, each sealant produced in all three of the plants will receive this parallel evaluation, but this work program is still in progress.

Now that PPG has a high level of confidence that the testing results of the reformulated hardener formulation will be acceptable to OEM customers, the reformulated samples can be distributed to the OEMs, as requested, to start qualification activities against their own specifications.

As previously discussed in Section 2.2.2, OPE was historically used as a nonreactive dispersing aid in certain $MnO_2$ hardener intermediate formulations. The evaluation and process analysis undertaken indicates that, for the A&D polysulfide sealants in scope of this AfA, current process methods do not require OPE in the hardener formulation to achieve the same mixing results, and removal of OPE from the sealant formulation is expected to be a viable alternative.

### 2.2.3 Research and Development Activities by OEM

Development of A&D systems is a complex process that must consider not only the design of the part, but also its performance, durability and reliability in varied climates and service environments. Every part is designed and manufactured with consideration to performance as well as component and system level interactions/interfaces and the needs for long-term inspection and maintenance. In a complex system, change introduces new forms of risk and uncertainties, which must be managed to avoid failures.

In broad terms, substitution of affected technologies in the A&D industry can be broken down into the distinct phases of qualification, validation, certification and industrialisation, as described previously in Figure 1. New or reformulated sealants must achieve the criteria required by each phase before they can proceed to the next. If a sealant does not pass the criteria, then further development testing is not continued unless changes (sealant reformulation or technology adaptation) are made to address the shortcomings. For chemical formulations such as sealants, paints, primers, adhesives, etc., the development and some of the qualification phases are typically owned by formulators, as discussed in Section 2.2.2 above. However, A&D OEMs perform additional qualification tests prior to proceeding further.

Qualification testing may include more general requirements (e.g. standard adhesion and temperature resistance testing). Validation testing becomes more specific to the design and operational parameters, (physical and environmental conditions that are relevant for an A&D component while in-service) and begins after successful completion of initial qualification testing. The operational condition parameters include, but are not limited to, fluid exposures; external environment including temperature extremes, humidity, wind/rain erosion, etc.; functional characteristics; service life requirements; etc. These parameters are specific to each individual component and each individual use of a component. They can therefore vary between company and application.

Testing ranges from laboratory testing to testing using methods to simulate performance in a 'relevant environment' that is designed to emulate lifetime performance, for example, exposure to humidity and thermal cycling as well as exposure to fluids likely to be present in the part location.

Determining the extent of testing required to implement a new or reformulated sealant formulation, component or technology is done on a case-by-case basis due to the many performance requirements and operational conditions to be considered to fully validate the substitution for each specific use in the A&D system. These include but are not limited to:

1. Design of the part or assembly (e.g. substrate material, proximity to dissimilar substrate materials or faying surfaces, crevices that can entrap liquids, structural stress and strain environment, etc.)
2. Environmental conditions within the A&D product (e.g. location, potential presence of condensation or liquids, entrapment of liquids, temperature range, microbial growth, etc.)
3. External environmental conditions (humidity, pollution, wind / rain erosion, impact from runways, exposure to fluids like fuel, deicers, and hydraulic fluids, etc.)
4. Probability of finish deterioration / deterioration of external surface during use (e.g. chipping, scratches, abrasion, corrosion)
5. Historical performance in similar A&D uses
6. Issues with the previous formulations due to variation in maintenance practices
7. Ability to inspect during the lifetime of the A&D product and ability to repair in situ in a non-production environment
8. Severity of the impact if the relevant part(s) fail

Once the reformulated sealant is available, the OEMs can start their own technical qualification process. Qualification testing is extensive, and multiple testing runs under different relevant conditions and for different substrates may be required. As discussed in Section 1.1, ideally the qualification testing will demonstrate the reformulated product and the current sealant are interchangeable, as this result will greatly simplify the substitution process[12]. Testing to industry specifications by the formulator has been positive and indicates OEMs may be able to demonstrate interchangeability between the original and these reformulated sealants in accordance with their own OEM-specific requirements. However, this is by no means a foregone conclusion and can only be confirmed through appropriate and adequate testing by each OEM to confirm that the reformulated sealant has the same properties and performance, including compliance to relevant industry and OEM proprietary specifications, as the current sealant containing OPE.

Materials for which interchangeability between the existing and re-formulated product cannot be demonstrated, and the change cannot be considered as a one to one replacement, may require validation/certification activities prior to implementation. Further iterations may be needed to refine the OPE-free formulation until an interchangeable alternative is qualified. A reformulation that was not interchangeable would require a far more extensive effort associated with A&D part design

[12] In this event, additional certification from EASA or defence or space certification authorities is not needed as the OEM-held data for certification of the sealant containing OPE will still be valid and can be read across to support use of the OPE-free reformulated sealant without changes to specifications or drawings.

changes and approvals. The cost of such changes may be prohibitive and would significantly extend the timeline to replace the sealants in A&D products.

Adherence to the technical requirements aims to ensure continued performance and safe operation of A&D systems. Therefore, the requirements always reflect system-level requirements (e.g. airworthiness regulations).

Industrialisation depends on the scale of the modification to the existing, proven design and its relevant requirements due to the alternative formulation, product or technology. It is important to note that the industrialisation step refers to the whole supply chain.

In any case, it takes considerable effort and time to establish the specific testing requirements and funding for an alternative formulation or part design (system or component). In most cases, testing cannot be accelerated, as extrapolation from limited data is unlikely to be accepted as reliable.

In summary, qualification through industrialisation is required to:

- Ensure consistent quality of formulations being introduced.
- Ensure that the formulation, component, the process or method is compliant with both Industry Regulations and A&D component manufacturer requirements to fulfil specified functions.
- Provide a very high level of confidence for both the use of the formulation or component and the resulting A&D end components.
- Ensure consistent use of the new or alternative formulation and to guarantee production and management system robustness throughout the supply chain.
- Ensure that only reliably performing formulations, components, and processes are approved for use to produce A&D components.
- Fulfil requirements of the certifying Authorities (e.g. EASA, Ministries of Defences, European Space Agency).

Further details of this process are found in Annex C to the combined AoA and SEA.

### 2.2.4 Replacement Timeline of OPE in sealants

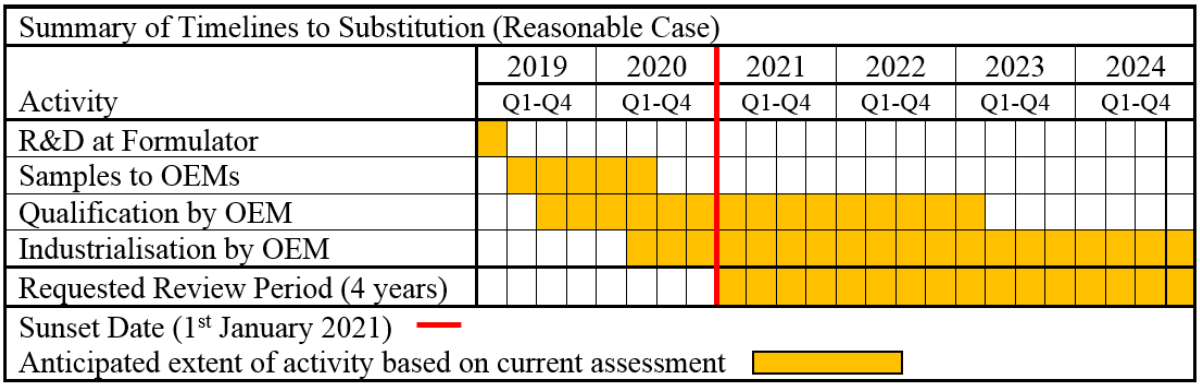
In the A&D industry, the formulator develops formulations to meet the requirements of its customers and tests to industry- and customer-relevant specifications. When the formulator's testing demonstrates that a formulation meets the customer's requirements, the candidate alternative is given to specification custodians (e.g. OEMs) for their own testing.

It is the responsibility of the OEMs, as the design authority, to ensure that materials and processes used on A&D hardware can perform the intended function and are safe for use, in accordance with standards which meet the regulations, as further detailed in Annex C to the combined AoA and SEA. The OEM must qualify each alternative, prior to use and industrialisation through the supply chain. When formulations, such as polysulfide sealants, are used in multiple applications, it must be qualified against the specific criteria for each application, so it may need to be tested against many specifications for any one OEM. A formulation that meets industry requirements may not meet some, or all, the requirements set down by each OEM. Only the individual OEM has access to the design requirements for each of their own applications. In many applications, requirements are not defined

in terms of specific properties of the sealant, but rather as providing a necessary function within a complex assembly. In such cases, verification of acceptability can only be achieved by using the sealant in a representative assembly and demonstrating functionality at the assembly level. Thus, only the OEM can carry out the necessary testing and evaluate the results for their uses and only the OEM can ultimately determine whether a formulation meets the performance requirements for each and all its applications.

The estimated timeline for qualifying and implementing a candidate alternative OPE-free sealant is shown below and in Figure 4. This is under the Path 1 Scenario as described previously in Figure 2.

- R&D by Formulator: The formulator completed its main R&D in Q1 2019.
- Reformulated samples for affected sealants are currently estimated to be provided to OEMs by Q2 2020.
- OEM qualification: 9 to 32 months from receipt of candidate alternative samples
- OEM Industrialisation in OEM supply chains: potentially up to 18 months after successful OEM qualification




*Note: This schedule considers an aggregated view of all the OEMs considering each are going to receive samples for testing at different times.*

**Figure 4: Sealant OPE Removal Timeline**

Considering the planned schedule for each OEM to qualify and industrialise the reformulated samples, the estimated timeframe to complete substitution is two to four years. This timeline has been compiled using information from the formulator, PPG, and EAAC OEM members. Importantly, it assumes the candidate OPE-free sealants will be successfully qualified by OEMs. If a candidate alternative fails qualification testing, this will extend the timeline until a reformulated potential alternative is made available and passes the testing requirements.

As testing results from PPG on representative sealant formulations are indicative that the OPE-free reformulated sealants can be considered as a one-to-one change with the previous formulations, this may mean that the reformulated alternative sealants require a less extensive qualification testing programme, compared to when qualifying and implementing alternative formulations with a more significant change. For materials for which interchangeability between the existing and re-formulated product cannot be demonstrated, and the change cannot be considered as a one to one replacement, it may be necessary to also undertake validation/certification activities prior to implementation.

A review period of four years was requested in the AfA to accommodate the estimated timeframe for qualification and industrialisation of reformulated sealants from time of submission (Q2 2019). This is based on efforts to date that indicate it will be possible to qualify reformulated sealants as a one-to-one replacement for the existing sealant formulations. As such, the timelines estimated for this substitution are significantly shorter than for some A&D substitution activities, due to the expected limited functionality of OPE in the mixed and the subsequently cured sealants.

## 2.3 Identification of known alternatives

### 2.3.1 Removal of OPE from Formulator's sealant formulations

As discussed in Section 2.2.2, the formulator (PPG) has been undertaking extensive R&D activities to determine the viability of reformulating the affected sealants without the OPE, with no other formulation changes. Sealants, determined by the formulator as representative formulations, have gone through the R&D testing cycles by the formulator, and have been provided to limited external third parties for validation of the results, including a large OEM specification custodian. However, this level of formulator testing has not yet been completed for all affected formulations and classes.

The formulator has been in the process of preparing samples of the alternative reformulated sealants, including all affected sealant classes, to provide to customers. Reformulated sealant samples have been made available to specification custodian OEMs from Q2 2019, and all other reformulated alterative sealants will be made available to OEMs upon request by Q2 2020 for qualification testing. The exact date of sample availability is dependent on manufacturing cycle and formulator testing progress, e.g. samples for those representative sealants for which testing has already been completed are expected to be available sooner than those with initial testing still in progress. Once in receipt of the samples, the OEMs will commence their qualification testing process. Testing by each OEM is necessary to determine whether the reformulated sealant meets individual company performance requirements, as captured in OEM-specific specifications and/or industry standards, as applicable to each company.

The Formulator is currently considering no other alternative substances or reformulation options.

Therefore, the primary candidate alternative available to the OEMs is a reformulation of the affected sealants by removal of OPE from the formulations. This is elaborated in Section 5.4.1 of the combined AoA and SEA.

### 2.3.2 Alternative Polysulfide Sealants

In addition to the above, the EAAC OEM member companies have conducted individual analysis of various commercially available OPE-free two-part polysulfide sealant systems, from other formulators, that may be potential alternatives for specific sealant applications[13]. However, it must be recognised that, even though these products appear to be potential replacements for the currently qualified polysulfide products, they cannot be considered alternatives without demonstrating

[13] These candidate products are listed in Table 12 in Section 5.4.2 of the combined AoA and SEA. This list is not exhaustive and may not apply to all OEM companies, as each have unique design and performance criteria.

technical equivalence. Even in the case where there were no initial technical or economic feasibility concerns for an OEM's use case, the testing required to demonstrate a completely new formulation as a viable alternative and qualify it for use would be significantly more onerous than the testing required for the reformulated sealants in progress by PPG. Therefore, to pursue qualification of an alternative polysulfide sealant, rather than a reformulated PPG sealant, the requested review period would need to be much longer than four years to have sufficient time to qualify and implement this alternative option. The alternative polysulfide sealants are further elaborated in Section 5.4.2 of the combined AoA and SEA.

### 2.3.3 Alternative Technologies

As part of the work undertaken by both EAAC OEM and formulator member companies when identifying potential alternatives to the polysulfide sealants containing OPE, the following technologies were identified:

- Polythioether sealants
- Epoxy based sealants
- Silicone sealants
- Polyurethane sealants

However, it must be noted that any alternative technology, if not already present as a qualified and certified alternative on an OEM specification and design, must successfully go through the full qualification, validation, and certification process prior to industrialisation as an alternative, as previously discussed. This process would take far more time than qualifying previously approved sealants where the OPE has been removed. This is elaborated further in Section 5.4.3 of the combined AoA and SEA.

Further, some potential alternative technologies (e.g. redesigning of parts to reduce or eliminate the need for a sealant) have been ruled out from further consideration, as they would be extremely costly to develop and undertake, as well as projected to require a significantly longer timeline. In the majority of cases, a re-design to eliminate the need for sealant would not be technically possible.

### 2.3.4 Summary of Alternatives Assessment

When considering a new formulation for use in an existing design, the more closely the alternative matches the properties of the original formulation, the lower the technical risk, smaller the qualification test plan, and the shorter the expected timeframe necessary to qualify and industrialise the alternative formulation. Therefore, the preferred alternative for the affected polysulfide formulations is to use the PPG reformulations, whose only change to the formulation is the removal of OPE. These reformulated sealants are expected to exhibit properties nearly identical to the original sealants and to successfully proceed through OEM qualification testing. This strategy is currently supported by testing and external third-party test validation of samples of reformulated representative sealants.

The second-best option is to qualify and implement other polysulfide formulations that function with the same sealant chemistry and already do not contain OPE, as these will share many of the important properties of the previously qualified polysulfide sealants containing OPE currently in use. However,

because they are new formulations from different formulators, a far more extensive qualification and validation process will be required.

The least desirable option is to pursue sealants with different chemistries, as these will exhibit the greatest difference in properties from the current polysulfide sealants and will require even more extensive qualification and validation testing than implementing other polysulfide formulations.

Redesign of parts to avoid the need for sealant or use of other sealant technologies was ruled out for further consideration, because it would be extremely costly to develop and timescales to substitution would significantly exceed those indicated by qualifying an OPE-free alternative to the current sealant, which looks achievable in the shortest timeframe, based on initial data available to the OEMs.

These potential alternatives are all treated as unique, despite any similarities in chemical behaviour or composition, because each may have different requirements for the data needed to be obtained and may have different testing requirements for assurance it could place the polysulfide sealants containing OPE currently in use. Therefore, each alternative must be assessed completely against the requirements of the specific performance criteria. These criteria are reflected in the specifications associated with the current use of each sealant type. The alternatives assessed in this section have already undergone considerable R&D efforts, either by the formulator or by other actors within the A&D industry.

With A&D safety and equivalent non-flight defence requirements, the technical performance, foremost, must demonstrate “equal or better” performance with respect to the specification requirements and design parameters. What constitutes "equal or better" can vary from application to application. For example, in an application where rigidity must be maintained, stiffness of the alternate formulation would have to be equal or greater than the baseline. However, in an application where flexibility is important, stiffness of the alternate formulation would have to be equal or less than the baseline. Therefore, unless a given alternative has properties that are identical to the baseline, its suitability can only be determined on a component by component basis. If technical feasibility is assured, then economic feasibility is assessed for further input into the business industrialisation plan.

## 3. MONITORING OF THE IMPLEMENTATION OF THE SUBSTITUTION PLAN

Implementation of the substitution plan (see Figure 4) is actively monitored by the Applicants and OEMs, as described in the following sections.

### 3.1 R&D at Formulator and Samples to OEMs

Samples are being provided to the OEMs and this is forecasted to be complete by the end of the Q2 2020.

PPG will regularly advise relevant OEM(s) whether the formulation and sample distribution program is on track, to report deviations in the program and measures to redress deviations agreed. The substitution status will be updated accordingly and will be made available to the authorities upon request.

### 3.2 Qualification by OEMs

Qualification by the OEMs is ongoing to verify key properties and requirements, as described above in Section 2.2.3. The OEMs will regularly advise PPG whether the qualification program is on track, to report deviations in the program. Measures to redress deviations will be agreed. The substitution status will be updated accordingly and will be made available to the authorities upon request.

### 3.3 Industrialisation by OEMs

Industrialisation (i.e. deployment) of the reformulated OPE-free versions of polysulfide sealants is forecasted to begin the Q2 2020 and will involve numerous OEM manufacturing sites and suppliers' sites. OEMs will advise PPG whether the industrialisation program is on track, to report deviations in the program. Measures to redress deviations will be agreed. The substitution status will be updated accordingly and will be made available to the authorities upon request.

## 4. CONCLUSIONS

The substitution strategy for the specific case of the polysulfide sealants involves developing reformulated OPE-free products that are completely interchangeable with the product they are developed to replace. Such reformulated polysulfide sealants must be shown through the qualification process to meet the technical requirements documented in OEM product and/or process specifications and thus suitable and safe for use in accordance with the relevant airworthiness regulations or comparable performance requirements.

The process to develop and test new formulations that meet these specifications involves several stages. The most promising alternative is the removal of OPE from the formulations. PPG forecasts that representative samples of all variants of affected polysulfide sealants needing to be covered by this Authorisation will be provided to OEM customers between Q2 2019 and Q2 2020.

Once the reformulated sealant is available, the OEMs can start their own technical qualification process. This testing is extensive, and multiple testing runs under different relevant conditions and for different substrates may be required. Ideally, the qualification testing will demonstrate the reformulated product and the current sealant are interchangeable, as this result will greatly simplify the substitution process[14]. Testing to industry specifications by the formulator has been positive and indicates OEMs may be able to demonstrate interchangeability between the original and these reformulated sealants in accordance with their own OEM-specific requirements. However, this is by no means a foregone conclusion and can only be confirmed through appropriate and adequate testing by each OEM to confirm that the reformulated sealant has the same properties and performance, including compliance to relevant industry and OEM proprietary specifications, as the current sealant containing OPE.

The OEMs currently estimate that the necessary time to complete qualification testing, if successful on the first attempt, is 9 to 32 months from availability of the reformulated sealant. Qualification would be completed between Q3 2019 and Q1 2023, according to the current schedule. However,

[14] In this event, additional certification from EASA or defence or space certification authorities is not needed as the OEM-held data for certification of the sealant containing OPE will still be valid and can be read across to support use of the OPE-free reformulated sealant without changes to specifications or drawings.

success at this stage is by no means assured and the timeline could be longer. Even when the formulation passes initial tests, subsequent tests may fail.

In case of failure, further iterations may be needed to refine the OPE-free formulation until an interchangeable alternative is qualified. For materials for which interchangeability between the existing and re-formulated product cannot be demonstrated, it may be necessary to undertake validation/certification activities prior to implementation. Thus, a reformulation that was not interchangeable would require a far more extensive effort associated with A&D part design changes and approvals. The cost of such changes may be prohibitive and would significantly extend the timeline to replace the sealants in A&D products.

Once qualification activities have been completed and interchangeability of the OPE-free formulations has been established, the qualified alternative sealant must then be industrialised throughout the OEM manufacturing sites and throughout the wider supporting supply chain. It is currently estimated that industrialisation of the reformulated sealant after successful sealant qualification would potentially take up to 18 months. In the overall scheme foreseen by individual OEMs, and assuming qualification is successful, industrialisation would occur between Q2 2020 and Q4 2024. This schedule does not account for any slippage.