ANALYSIS OF ALTERNATIVES

and

SOCIO-ECONOMIC ANALYSIS
AS PART OF A REVIEW REPORT

Legal name of applicant(s):	Chemetall Limited
Submitted by:	Chemetall Limited
Date:	June 2023
Substance:	4-Nonylphenol, branched and linear, ethoxylated
Use 1:	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 EU REACH Art. 56(6)(a) and as Grandfathered into UK REACH.
Use number:	1

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FIGURES

LIST OF ABBREVIATIONS

AIMS	Airbus Material Specification
AIPI	Airbus Process Instruction
AOA	Analysis of Alternatives
AOG	Aircraft on Ground
BOM	Bill of Materials
CSR	Chemical Safety Report
DU	Downstream Use
EASA	European Aviation Safety Agency
EEA	European Economic Area
IPDA	Instruction de Procédés Documentation Avions
MRO	Maintenance, Repair & Overhaul
N/A	Not Applicable
NPE	Nonylphenol ethoxylate
NPV	Net Present Value
NUS	Non-Use Scenario
OC	Operational Control
OEM	Original Equipment Manufacturer
PBT	Persistent Bio accumulative and Toxic
PMF	Pre-mixed and Frozen
PPE	Personal Protective Equipment
R&D	Research and Development
RMM	Risk Management Measures
SDS	Safety Data Sheet
SEA	Socio Economic Assessment
SME	Small or Medium sized Enterprise
SOI	Standard Operating Instruction, more generally called “work instructions”
SVHC	Substance of Very High Concern
TWA	Time Weighted Average
vPvB	Very Persistent and Very Bio accumulative

LIST OF DEFINITIONS

Term	Definition
Adhesion promotion	Enhancement of the tendency of dissimilar constituents or surfaces to cling to one another (for example adhesion of sealant to substrate, adhesion of paint to sealant and/or substrate).
Aerodynamic/aero smoothing	Exterior sealing to achieve aerodynamic smoothness is important as it reduces the drag of the aircraft as it flies and thus reduces the amount of fuel used. Typical exterior areas where aerodynamic sealant is applied include fuselage, rudders, windows, wings and antennas.
Aerospace	Business sector of companies producing products and services for aerospace and their associated supply chains relating to aircraft (both civil and military incl. helicopters and unmanned aerial systems and launchers), etc., that fly or operate in the atmosphere.
Airbus	Airbus Commercial, Airbus Helicopters and Airbus Defence and Space including all Affiliates and Subsidiaries
Aircraft on Ground	Aircraft (incl. helicopters) not in an airworthy condition, therefore not authorized to fly, typically at an airport gate.
Alternative	A candidate alternative that has been tested, qualified, fully industrialised, and certified by Airbus and their associated supply chains. This definition is used only for the final classification of evaluated alternatives.
Approval	Written acceptance by an authorized representative of the customer or authority that a product/service/person or organization is suitable and accepted.
Assembly	Procedure of fitting together several components, or subassemblies of a product to make an identifiable unit capable of disassembly, such as equipment, a machine or an aircraft. *NOTE 1: An assembly also is the resulting product of fitting components together*
Base	The larger quantity component of a 2-part sealant that contains the sealant polymer. When the sealant base and hardener are mixed together, the sealant starts to cure (polymerize).
Candidate Alternative	Potential alternative provided to Airbus for their evaluation and will have already been evaluated in the labs of the formulator.
Certificate	Document attesting that a formulation/service/organization conforms to specified requirements.
Certification	The procedure by which a party gives written assurance that all components, equipment, products, service or processes have met or exceeded the specific requirements, defined in the Certification Specifications, documented in technical standards or specifications.
Chemical resistance	The ability of solids to resist damage by chemical exposure.
Civil aerospace	Subsector of 'aerospace' relating to non-military aircraft.
Compatibility (with substrate/or other coatings)	Suitability of formulations, processes or services for use together under specific conditions to fulfil relevant requirements without causing unacceptable interactions (ISO Guide 2:2004)
Competent authority	The authority or authorities or bodies established by the EU or UK Member States to carry out the obligations arising from the REACH Regulation

Compliance verification	Confirmation by the approving agency that all documentation provided to demonstrate fulfilment of requirements is satisfactory. *NOTE 1: See also Part 21 Subpart J Design Assurance System GM No. 1 to 21A.239(a) (b) 3.1.3*
Component	Hardware or software product, sub-assembly or assembly which is uniquely identified and qualified. *NOTE 1: Hardware components may be further divided into lower tier products (sometimes given names such as subassemblies), components, processes, and data. software components may be further divided into additional components and/or software units (adapted from MIL-STD499C and MIL-STD-973)*
Components list	List of components, usually issued by the Design Organization, necessary to manufacture, assemble or maintain a product
Configuration	Interrelated functional and physical characteristics of a product (hardware/software) defined in product design or build information.
Corrosion	The process of an unwanted chemical reaction between an item and its environment, for example, oxidation of a metal part leading to loss of constituents.
Corrosion resistance	The resistance an item offers against reaction with adverse environmental factors that can degrade it.
Design	Mixture of a set of information that defines the characteristics of a product. (adapted from EN 13701:2001)
Design parameters	Those dimensional, visual, functional, mechanical, and features or properties, which describe and constitute the design of the article 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 products and assessment of their performance.
Downstream processes	Those processes occurring after an activity e.g. the transport of a manufactured product from a factory to customer, end user or distributor cf. upstream.
Downstream user (REACH)	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, during his industrial or professional activities. (A distributor or a consumer is not a downstream user. In addition, an assembler of articles, or a user of articles is not a downstream user as defined in REACH.)
Drawing	Graphical representation of forms or objects with supporting data to provide a design definition.
Endocrine disruptors	Any chemical verified by testing to exhibit endocrine disruptive properties using the proper toxicological methodology and regulated specifically as an endocrine disruptor by a national regulatory agency.
End user	Same as final customer in the complete supply chain
Equipment	Associated assemblies intended to achieve a defined final objective.
Erosion	Gradual breaking down; the gradual destruction or reduction and weakening of something by physical or chemical forces.

Evaluation	Process of appraising the performance of a person, process, product or system.
Exposure pathways	Existing or hypothetical routes by which chemicals in soil, water or other media can encounter humans, animals or plants.
Failure	Termination of the ability of an item to perform a required function. *NOTE 1: After failure, the item has a fault.* *(IEC Multilingual Dictionary:2001)*
Faying surface	Surfaces which are placed in intimate contact with each other when assembled.
Faying surface/interfay sealant	Sealant applied to one or more faying surfaces that will be placed in contact during assembly.
Formulation	Chemical product purchased by aerospace industry member and specified for a specific use on aerospace product
Galvanic protection	With reference to sealants, the ability to protect dissimilar metal junctions from galvanic attack through the combined functions of moisture blocking, adhesion, and active corrosion inhibition.
Hardener	The hardener is one of two components in a sealant kit. The hardener and base components are mixed to together and applied to the area of the part/assembly as a mixed sealant.
Hazardous materials	Formulation posing a risk to health, safety, property or the environmental when handled or worked on.
Health risk assessment	A study prepared to assess health and environmental risks due to potential exposure to hazardous substances.
Identified use	A use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain (including his own use) or that is made known to him in writing by an immediate downstream user.
Implementation	After having passed qualification and certification, the next phase is to implement or industrialise the qualified formulation, component or process in all relevant activities and operations of production, maintenance and the supply chain.
Inspection	Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.
Interchangeability	Attribute of design that enables exchanged products to be installed.
Life cycle (of a product)	All stages of a product's development, from raw materials manufacturing through to consumption and ultimate disposal.
Maintenance, Repair & Overhaul	Organization/company that performs maintenance and repair activities on aerospace hardware, components and end products. MRO activities include performance of tasks required to ensure the continuing airworthiness of an aircraft or aircraft component, or function of aerospace component/hardware/assembly including any one or combination of overhaul, inspection, replacement, defect rectification, and the embodiment of a modification or repair. NOTE 1: for civil: the overhaul, repair, inspection, replacement, modification or defect rectification of an aircraft or an aircraft component that is performed after completion of manufacturing
Material	Raw, semi-finished or finished purchased item (gaseous, liquid and solid) of given characteristics from which processing into a functional element of the product is undertaken

Mixture	A solution of two or more substances that do not react.
Non-confirming product	Product that does not meet the design, production or maintenance requirements.
Operator	Individual or team who physically performs the process. "Approved Operators" are Self-Verification qualified individuals or teams. These may also be referred to through terminology considered suitable by the organization's program focus, cultural and customer environment, i.e. "Approved Technicians", "Certified/Approved process Team Members".
Original Equipment Manufacturer (OEM)	Defines the performance requirements of the components and the materials and processes used in manufacturing and maintenance. OEMs are responsible for the integration and certification of the final product.
Part	Distinct component, possibly consisting of two or more pieces permanently joined together, that can be separated from or attached to an assembly. *NOTE 1: Hardware item that cannot be disassembled without destroying the capability to perform its required function.*
Potential Alternative	A possible alternative being evaluated in the labs of the Formulator.
Product	In this document product means any final aerospace assembly, engine, propeller, airframe part or equipment (within that assembly) to be used in operating or controlling an aircraft in flight or other aerospace vehicle in use. The result of a process, which in the context of this Standard includes finished detailed components and assemblies. It also includes forgings and castings. In the context of this document, products are purchased as components and/or sold as finished goods.
Product acceptance	Acceptance of a product by either customer or authoritative body.
Qualification	OEM as Airbus validation that the formulation, process or part meets the engineering technical performance requirements detailed in Qualification Specifications, documented in technical standards or specifications. Documented demonstration of the ability to fulfil specified requirements.
Qualification certificate	Certificate attesting the qualified status.
Regulatory authority	Authority responsible for and competent in a specific matter. In the context of this document this refers to Airworthiness and Defence Authorities (e.g. EASA, MoD etc.).
Repair	The restoration of an aerospace product to an airworthy condition to ensure that the aircraft it continues to comply with the design aspects of the appropriate airworthiness requirements used for the issuance of the Type Certificate for the respective aircraft 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.
Shore A Hardness	A measure of the resistance of a material to the penetration of a needle under a defined spring force. It is determined as a number from 0 to 100 on the scales A or D using a durometer. The higher the number, the higher the hardness (1).
Site (REACH)	A single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared.
Specification	Document stating requirements.

	NOTE 1: A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (e.g. product specification, performance specification, process specification).
Sub-tier supplier	Supplier not working under a direct purchase order from the prime contractor but performing work on related products at a lower level in the supply chain (via purchase order cascade).
Supply chain	Network created by customer, prime contractor, subcontractors and sub-tier suppliers producing, handling, and/or distributing a specific product.
Type Certificate	Document issued by an Aviation Authority to define the design of an aircraft type and to certify that the design meets the appropriate airworthiness requirements.
Type model	Top level configuration designator for the end item and for civil aircraft having Approved Design Data approval by a regulatory authority.

DECLARATION

The Applicant is aware of the fact that further evidence might be requested by UK HSE to support the information provided in this document.

Also, we request that the information blanked out in the "public version" of the Analysis of Alternatives and Socio-economic Analysis is not disclosed. We hereby declare that, to the best of our knowledge as of today 26th June 2023, the information is not publicly available, and, in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature:
FeltenC

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Date, Place:
26.06.2023, Frankfurt am Main

1. SUMMARY

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, and related legislation, were replicated in the UK with the changes needed to make it operable in a domestic context. All references within this document to the EU REACH legislation still apply with regards to UK REACH and the reason the substance has been classified as a SVHC in the UK is the same as that in the EU.

Authorisation decisions made under Article 127G of the UK REACH Regulation relate to a transitional measure of UK REACH. Article 127G applies to certain authorisation applications that were submitted by GB-based companies under EU REACH. The initial application by Chemetall under EU REACH was grandfathered into UK REACH on 4th November 2021 under Authorisation Number UKREACH/21/03/0.

This Review Report covers the use of nonylphenol ethoxylate (NPE) in the mixing of a range of specialty two-part polysulfide sealants manufactured by Chemetall GmbH (Chemetall) for use in the Aerospace industry sector. Formulation of the two-part polysulfide sealants takes place in the EU and is therefore out of the scope of this Review Report.

This Review Report is submitted by Chemetall as specialist formulator for the Aerospace industry. Airbus and their suppliers and customers such as airlines (together representing most sales, 89 – 99% (> [redacted]%)), rely on these specific polysulfide sealants during production and maintenance, repair, and overhaul (MRO) of civil and military aerospace components and completed products. CBI 1

The total tonnage of NPE covered by this application is low (much less than 1 tonne per annum). However, without these polysulfide sealants it will not be possible for Airbus and their associated supply chain to manufacture, maintain, or repair aerospace components in the UK. Airbus and their associated supply chains, including MRO organisations (such as UK airlines and military aircraft operations) rely on polysulfide sealants to ensure reliable and safe performance of critical aerospace systems that are vital to the UK economy.

Use 1

The mixing by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with the hardener containing NPE. The specific base and hardener are packaged together and distributed as a unit. The hardener causes the sealant to polymerise and cure, with full strength typically attained after several days. Subsequent use of the polysulfide sealants is exempt from authorisation according to REACH Art. 56(6)(a), as the concentrations of NPE in the mixed polysulfide sealant is less than 0.1% w/w.

A further description of the uses applied for, and the functional requirements of the sealants, can be found in Section 3.1 and 3.1.3 of this document.

Analysis of Alternatives

No alternative identified in this AoA-SEA can be substituted prior to the end of the Review Period. The Applicant, as the EU based formulator, has undertaken significant research and development activities (Section 3.2). During early reformulation activities, it was identified that surfactants that are not derived from NPE substances are not as efficient at bonding the curing agent into the rest of the liquid hardener mix. It was also determined that, contrary to initial expectations, it is not a straight-forward process to find a suitable alternative surfactant that works to the same standard but does not contain NPE.

The Applicant has screened >100 different surfactants and has been investigating suitable alternatives for NPE surfactants in its polysulfide sealants. The Applicant had previously identified and developed a promising candidate alternative sealant formulation, but it did not pass technical qualification testing by Airbus, due to unanticipated issues with the lack of adhesion of the sealant to different substrates during the final testing phase[1]. The remaining four potential alternatives are the focus of the Applicant's assessment and still being investigated and tested for suitability, and these are discussed in more detail in this report (Section 3.3). Once the Applicant has completed their assessment the alternative formulation (if feasible) would be provided to Airbus to commence qualification testing.

Most of the grades (except 2 sealants references) of the preferred Alternative (Alternative 2) have successfully passed the development phase at laboratory level. Therefore, even though a significant development effort is still required to reach a sufficient level of maturity, which may translate into slight formula modifications, it can be considered that the feasibility of these alternatives has been fundamentally proven. These differences in technical feasibility could still impact the performance of the end sealant, the manufacturing process, the method of application, and the quality of the manufactured part and in the in-service behaviour. The Alternative also still needs to go through the full qualification and validation process with the OEMs for each end application that it may be required to fulfil as an alternative to the sealants currently in use. For 2 sealants references, due to raw material shortage of the initial selected alternative formula, development has been restarted end of December 2022. Therefore, a low level of maturity is currently achieved for these 2 references and would need significant re-testing and adaptation of the formula to fulfil Airbus requirements.

The Applicant had stockpiled enough NPE to account for the 4-year review period applied for within the original EU AfA. The Applicant has sufficient surfactant supplies to continue sealant manufacture until 2025. To allow for the sealants to continue to be placed on the market post 2025 the Applicant has sourced a new non-EU supplier of NPE. An AfA has been submitted to the European Chemicals Agency (ECHA) to allow for continued formulation within the EU, thus allowing for continued supply of the polysulfide sealant formulations to the UK market.

Alternatives in General, Substitution Plan and Continued Use Scenario (CUS)

[1] This demonstrates the importance of the qualification process to ensure the candidate alternative(s) fully meet performance requirements, as per specifications.

There are suitable alternatives in general[2] to the Applicant, but these alternatives are not technically feasible. As such, a substitution plan has been included within this AoA-SEA (see Section 4.1.3). Within the Substitution Plan the Applicant has provided a timetable of works associated with the substitution of NPE from the relevant sealants. Based on this timetable the Applicant has requested a Review Period of 6 years, running to the beginning of 2031 (4th January 2031), in order to try complete the substitution effort. Based on the above the CUS is for the Applicant to continue their substitution efforts, with support from Airbus.

Non-Use Scenario (NUS)

There are no immediate technically suitable available alternatives to polysulfide sealant formulations currently qualified for use in aerospace applications covered by the scope of this Review Report. Flight safety, airworthiness or comparable performance requirements mean it is not an option to use another product or formulation that is not qualified.

If this Review Report is not accepted the least disruptive NUS assumes logistics and processes for all aerospace operations in the UK can be adapted to allow use of pre-mixed and frozen (PMF) polysulfide sealants. Full details of the NUS are in Section 4.3. However, there are substantial doubts about the technical feasibility of this NUS and even if these can be overcome there would have to significant investment required (e.g., new low cold storage freezers, back-up generators and other relevant equipment needed at by all DUs in the UK) and considerable logistical challenges (customs, refrigerated air freight etc.) to address. The energy requirements and increased CO_2 emissions associated with the NUS are also substantially greater than the current situation and as there is no potential for release of NPE to the environment under the authorised use, the NUS does not represent an improvement from an environmental perspective. **Considering the greater energy use required the NUS has a far more substantial negative environmental impact than the authorised use.**

Socio-Economic Analysis

The Applicants employed a conservative approach to the economic assessment based on the NUS above and accounting for only those impacts within that NUS that can be reliably quantified with available hard data. Even so, the assessment demonstrates the NUS would involve socio-economic costs in the range of 1 114 – 2 185 million GBP, while the volume of NPE-containing sealants would not decrease at all. In addition, environmental impacts associated with the NUS would be greater than the baseline, due to substantial additional energy costs associated with the need to refrigerate the PMF sealant, and to transport by air.

The economic impacts to customers of the aerospace industry and those that rely on these industries will also be substantial. Interruptions in aerospace product and service (maintenance and repair) availability during the expected period where no aircraft production takes place while production is moved outside the UK, will bring disruption to commercial and defence aerospace industries, with widespread implications. These implications are outlined in detail in Section 5.

[2] EU General Court judgment of 7 March 2019 in Case T-837/16, Sweden v. Commission

Considering these downstream economic impacts during the quantitative assessment would greatly influence the ratio between economic benefits and safety and security impacts, further distinguishing the benefits of authorisation.

As indicated above, there are substantial doubts about the technical feasibility of this NUS. In this case, production of Airbus and Airbus related products and components (for instance, sealant is required for final assembly of aircraft) that require NPE-containing sealants in the UK would stop. Airbus Aircraft could not be assembled in the UK and MRO activities that require these sealants would also stop.

The SEA shows, in case it is not possible to establish use of imported PMF in the medium term, the impact of stopping operations is estimated to be more than 1 114 – 4 204 million GBP.

Conclusion

The Applicant is of the opinion that the societal costs of discontinuing the use of the Annex XIV Substance do outweigh the imperceptible risks to the environment associated with the continued use. This review report has been prepared to address the specific circumstances relating to the use by aerospace companies of polysulfide sealants that are formulated by Chemetall. The scope and content of this application should not be considered relevant for other applications for authorisation and associated review reports, and vice versa.

2. AIMS AND SCOPE

2.1. AIMS

The preparation of this Review Report has been supported by Chemetall (the Applicant) and Airbus. This Review Report covers the mixing of a range of specialty formulations referred to as polysulfide sealants manufactured by Chemetall for use in the Aerospace industry sector. These polysulfide sealants are comprised of a base component and a hardener component, which are mixed together in a typical ratio of 10 parts to 1 (by weight) respectively when mixed according to the Technical Data Sheet. The hardener component, which is used in far smaller volumes than the base, contains very low concentrations (< 0.6%) of NPE. The base component does not contain NPE. The concentration of NPE (after combining the two components) in the mixed sealant is less than 0.1% w/w.

The NPE present in low concentrations in the hardener component of the sealant is within the scope of Entry 43 of Annex XIV of EU REACH, and is thus within the remit of UK REACH as per the explanation above regarding transition of EU REACH to UK REACH and therefore the subject of this analysis of alternatives (AoA) and socio-economic analysis (SEA).

#	Substance	Intrinsic property(ies)[3]	Latest application date[4]	Sunset date[5]
43	4-Nonylphenol, branched and linear, ethoxylated substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof	Endocrine disrupting properties (Article 57(f) - environment)	04/07/2019	04/01/2021

The specialty formulations covered by this application for authorisation (AfA) of NPE are proprietary products manufactured inside the EU by one Applicant company. The formulation of these products is out of the scope of this Review Report. These formulations are supplied to the UK for use in the production, maintenance, repair and overhaul (MRO) of aerospace components and completed products.

This AfA is submitted by the Applicant to support Airbus and its suppliers/customers (together representing 89 – 99 ([redacted]) % of sales) for continued use of affected polysulfide sealants in aerospace applications until such time a fully qualified NPE-free alternative CBI 1

[3] Referred to in Article 57 of Regulation (EC) No. 1907/2006

[4] Date referred to in Article 58(1)(c)(ii) of Regulation (EC) No. 1907/2006

[5] Date referred to in Article 58(1)(c)(i) of Regulation (EC) No. 1907/2006

sealant is available. The scope of the application is limited to these companies and the use of these sealants in the aerospace industry.

An upstream application is necessary to allow the use of these sealants by the various manufacturing, airline and MRO facilities that rely on them, and facilitates a harmonised approach to supply, use and regulation of the products. Due to the complex and inter-dependent supply chain, inability to access these sealants to support the planned manufacturing, Airline and MRO activities at important points in the supply chain will have very clear and substantial consequences, as explained in both the description of the Non-Use Scenarios (Section 4.3) and Annex C (Aerospace Industry – Background Information) herein. Without an upstream application, multiple downstream user applications for authorisation utilising different approaches, assumptions and terminology as well as substance and product risk management measures and practices are unavoidable. Such differences would present challenges for implementation of authorisation within the supply chain. Additionally, managing multiple authorisations for the same substance uses within facilities would cause difficulties for enforcement authorities across the EEA.

Aerospace assemblies are complex and are required to meet stringent standards for performance, accounting for use in varied climates and considering the different types of services provided (civil and military). An aerospace product, for instance, is exposed to massive forces within a flight envelope, large variations in environmental conditions, and extremely high stress levels due to high velocities. Therefore, every part is designed, tested, and manufactured to strict performance and manufacturing specifications, and must undergo lengthy and rigorous testing programmes before being certified for use in production.

This combination of design complexity and extremely high-performance standards requires great controls in management of change in the Aerospace sector, which is described in Annex C. As described in Section 4.1.3, the estimated timeframe (including risk margin) for provision of NPE-free sealant alternatives by the formulator is Q4 2026. This is followed by the Airbus qualification testing, which is expected to complete by end Q2 2028, and industrialisation of the qualified alternative sealants could continue throughout 2030. Therefore, the Analysis of Alternatives (AoA) demonstrates that an updated review period of at least 6 years is warranted for the highly complex aerospace assemblies described and addressed in this Review Report for NPE. As noted, the formulation use is not within the scope of this AfA as it takes place within the EU. However, when assessing alternatives this use has to be accounted for as any delay in the formulation process will impact the substitution effort by Airbus.

The Socio-Economic Assessment will demonstrate that the net benefit of a decision to allow continued use of these products until such time that they can be safely replaced is substantial. The accompanying CSR discusses the way in which these polysulfide sealants are used such that there is no potential for release of NPE to the environment during the use of these sealants as a component of the aerospace components, sub-assemblies and assemblies.

2.2. SCOPE

The preparation of this AfA has been supported by Chemetall (the Applicant) and Airbus.

An introduction to the aerospace industry, with an explanation of the regulatory requirements that must be complied with and an overview on the process of implementing new or replacement formulations on aircraft is provided in Annex C.

As noted in Section 3.1.3, the concentration of NPE in the mixed polysulfide sealant is below 0.1% w/w. Use of the mixed sealant itself is exempt from authorisation according to REACH Article 56, 6 (a)[6]. Nonetheless, information regarding the usage of the mixed sealant is vital to the rationale for the requested review period and the SEA and is discussed in this document and the accompanying CSR. The technical requirements placed on sealant components, mixed sealants (both cured and uncured), and usage conditions, must be validated for conformance before potential alternative products can be industrialised throughout the aerospace industry, and these are described in Section 3.1.3.

This AfA is the result of the efforts to share data and prepare a comprehensive and reliable assessment of alternatives that is representative for the Downstream Users that will rely on it. Airbus (whose supply chain represents 89 – 99 ([redacted]) % of Chemetall sales of these products) have reviewed and validated the findings in detail. As such, the Applicant considers the information presented in this Review Report as reliable and representative of its customers' use of polysulfide sealants containing NPE.

CBI 1

6 Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations: (a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0.1 % weight by weight (w/w)

3. ANALYSIS OF ALTERNATIVES

3.1. SVHC use applied for

The aerospace industry relies on approved and niche formulators for several 'specialty' formulations used during the manufacture and MRO of aerospace products. These formulators have extensive expertise in the development and production of these formulations for the aerospace industry, their formulations have been developed over many years of continuous testing and development and the formulations themselves are the intellectual property of those companies. The choice of formulations is very limited. In addition, the formulations are protected by patents and are the only products qualified to be used and certified/approved for use on aerospace products. Only the mixing use is covered by this review report.

3.1.1. Use 1 – Mixing of Sealants before Downstream Use

In the use applied for, the applicant is applying for authorisation for 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 EU REACH Art. 56(6)(a). There is a limited amount of time during which the mixed sealant can be applied to the hardware before the extent of curing changes the processing properties needed to properly apply the sealant to hardware (e.g., main frame and all parts attached to an airplane, helicopter, etc.). This requires that the end users (OEM, supplier, MRO facility, airline, etc.) mix the two components together just prior to applying it on the hardware. In limited cases, mixing is also performed by the formulator, when manufacturing pre-mixed frozen (PMF) products.

For further details on the areas of use and the functioning of the polysulfide sealants, please refer to Section 3.1.3. The aerospace regulatory setting and the process for developing, qualifying, and implementing alternative formulations are summarised within this AoA-SEA and Annex C.

3.1.2. Market analysis of products manufactured with the Annex XIV substance

3.1.2.1. About the products relevant for this application

The products affected under this Review Report comprise the NPE-containing hardener component of two-part polysulfide sealants for use in the Aerospace sector. This section further provides an overview of market trends in the European and thus UK civil Aerospace as an example of downstream use of polysulfide sealants in the Aerospace industry, amongst others.

3.1.2.2. About the applicant and its structure

Chemetall is one of the leading global suppliers of quality products and services with surface treatment and chemical treatment of metal surfaces being a core competence. The applicant focuses on worldwide surface treatment applications associated with the development and implementation of customized technology and system solutions. The products are developed for cleaning, corrosion protection, sealing, improving paint adhesion, and facilitating the formation and treatment of metals.

The applicant is headquartered in Frankfurt am Main, Germany with 2 500 employees, 40 subsidiaries and 21 production sites globally. With sales offices, production facilities, service teams, laboratories and warehouses located worldwide, operations are performed in close proximity to its customers. Chemetall Ltd's main office is based in Milton Keynes.

As a leading global supplier of choice for aerospace specialty chemicals, Chemetall provides Naftoseal® polysulfide aircraft sealants for all airframe, aerospace operation and aero-engine OEM and maintenance applications used by Airbus and their associated supply chain, together representing 89 – 99% (>[redacted]%) Chemetall sales share. The inter-relatedness of these customers is further elaborated in a general outline of the aerospace supply chain presented in Section 3.1.2.5. CBI 1

3.1.2.3. Affected production facility and number of employees

In this use applied for, the applicant is applying for authorisation for 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. There are 30 – 40 downstream user sites within the UK that are impacted by this AfA.

3.1.2.4. Financial performance and trends

The applicant has not provided this information due to confidentiality reasons.

3.1.2.5. Supply chain

The supply chain for the aerospace industry is highly complex, spanning many countries and regions, and having evolved over many years of successive investment, innovation, and competition. The supply chain includes but is not limited to, chemical manufacturers, importers, distributors, formulators, processors, component manufacturers and OEMs as well as airlines and MRO companies as final customers (ECHA/EASA, 2014). The complexity of the supply chain can provide a challenge to efficient communication and data gathering. It is difficult to characterise inter-dependency (i.e., the multitude of links/dependencies between companies) within the supply chain; however, the healthy functioning of the entire supply chain is clearly necessary for the health of the aerospace industry. Importantly, the complex structure of the supply chain also influences how quickly and efficiently change can be assuredly affected.

Figure 1 shows, in highly simplified form, the various linkages between actors within the supply chain for the use of polysulfide sealants and shows how the supply chain often crosses borders to meet demands. The separations clarify that these companies are at different levels of production, however, not all the companies are limited to one single level or tier in the supply chain.

To provide a clearer view on the individual actors in the supply chain, a generalised definition of each 'tier' or group of companies involved has been elaborated by the European Aviation Safety Agency (EASA) (ECHA/EASA, 2014) and is provided below.

The actors within the aerospace supply chain are:

- **Manufacturers** that produce the raw materials required by formulators. These formulators for various reasons might acquire the raw material from outside the EEA via **importers**.
- **Formulators**, such as Chemetall, purchase the raw materials from **manufacturers** or **importers** of surfactant containing NPE. As noted, formulation of polysulfide sealants takes place in Germany so is out of the scope of this review report. Formulators develop mixtures (which are proprietary, such that formulation composition is highly confidential) to meet the requirements of their clients in each market and supply formulations containing NPE to meet performance specifications and industrial approvals. Their customers are generally component manufacturers, OEMs, and MRO operations.
- **Distributors** that purchase NPE or polysulfide sealant formulations from the manufacturer or formulator and deliver it to the customer (processors, component manufacturers, OEMs, operators, and maintenance repair and overhaul shops).
- **Processors** that are involved in the process of producing parts or final products to meet the requirements of other companies (OEMs or component manufacturers). They purchase polysulfide sealants to supply the required component parts.
- **Component manufacturers** (e.g., Airbus Qualified Suppliers) that 'build-to-print' (or Airbus design), produce and supply components. The components will be used by OEMs in the final stage of production. When producing parts, they purchase sealants themselves and mix *in situ*.
- **Original equipment manufacturers (OEMs)** (e.g., Airbus) that define the performance requirements of the components and the materials and processes they use in manufacturing and maintenance, or sub-contract to component manufacturers. OEMs are responsible for the integration and certification of the final product.
- **Maintenance repair and overhaul (MRO) shops** (e.g., Airlines and Airbus) that carry out aerospace product maintenance, repair and overhaul activities using polysulfide sealants during their daily activities.
- **Aircraft Operators (airlines)** and **military prime contractors** are the **customers** or end users of products containing or being treated with polysulfide sealants. For example, many airlines are using polysulfide sealants on a daily basis.

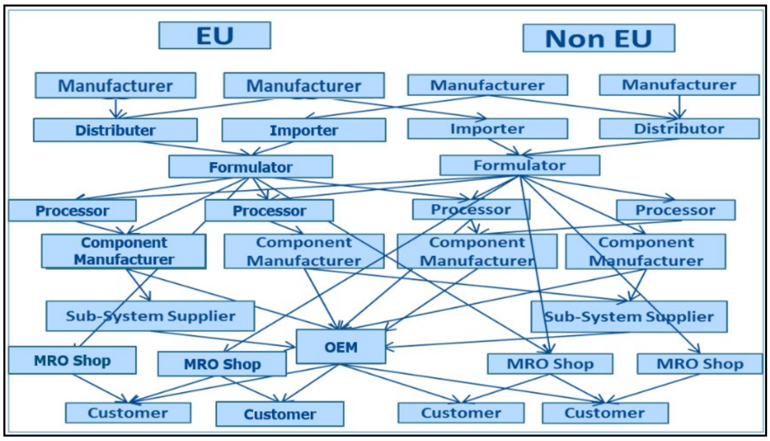


FIGURE 1: TYPICAL SUPPLY CHAIN IN THE AEROSPACE SECTOR (ECHA/EASA, 2014)

Figure 1 represents the supply chain where the use of sealants takes place. In summary this Review Report considers the following actors in the aerospace supply chain:

- Downstream users (DUs), including the Applicant and Airbus and their associated supply chains

3.1.2.6. Markets and competitive dynamics related to the use of the substance

The Aerospace industry can be broken down into different sub-sectors, such as passenger transport and air freight. All these sub-sectors depend on one another to form a functional and profitable aerospace industry. On a global scale, the UK has the second largest aerospace industry right behind the United States and is significantly driven by exports (International Trade Administration, 2022). .

Passenger transport and air freight

In 2021, the aviation sector in the UK directly employed 111,000 people and generated turnover of 22.4 billion GBP. Out of this figure, aircraft with a worth of 15.2 billion GBP, manufactured in the UK are destined for exports to other countries (ADS Group, 2022). Furthermore, airports in the UK were frequented by 73.7 million international and domestic passengers in 2020, which was comparably 75 % less than in 2019 (Department for Transport, 2021). By far the most frequented airport by passengers in the UK is London Heathrow, as it accounts for almost 30 % of total movement. This is followed by Gatwick airport with 46,600 passengers in 2019 and the airport in Manchester with roughly 29,000 passengers (UK Civil Aviation Authority, 2019).

The Aerospace industry must operate in a long-term perspective of at least 20 to 30 years, which is the average lifetime of an individual aircraft, while any aircraft component may be manufactured for as many as 50 years. This demonstrates a healthy and growing industry for decades to come. Accordingly, the regulations that are established today and the respective allocated resources determine the perspectives and performance of the industry for decades to come (Ecorys, 2009).

Reliable air freight is key to the health of the UK's economy, especially when exports play a leading role in the development of the economy. Around 68 % of all air cargo into, within or out of Europe is usually moved across northern European countries, such as Belgium, Germany, France, and the UK (Boeing, 2022). In 2020, air freight set down and picked up in the UK amounted up to two million tons (Statista Research Department, 2023).

Generally, air cargo is more vulnerable than passenger service. Airframes in aircrafts are dependent upon substances, parts and processes that were qualified decades ago. Disruptions in air service due to a non-authorisation of the use of compounds integral to the manufacture, maintenance, repair and overhaul of components and aircraft proven to keep flight airframes effective over many years of future service – compounds such as – NPE containing polysulfide sealants could profoundly impact economies in the UK.

3.1.3. Description of the function(s) of the Annex XIV substance and performance requirements of associated products

The hardener component of polysulfide sealants manufactured by the Applicant includes a surfactant containing 'Nonylphenol, branched, ethoxylated, phosphated' (NPE-phosphate) (CAS 68412-53-3). The NPE-phosphate is not in scope of Annex XIV of the EU REACH Regulation, but contains the residual substance, Nonylphenol ethoxylate (NPE) (CAS 68412-54-4), which is within the scope of Entry 43 to EU Annex XIV, and thus within the scope of UK REACH as per the transitional arrangements outlined earlier. The surfactant is added to other constituents (e.g. manganese dioxide (MnO2), a plasticiser and other additives) and mixed together to form the hardener component. The hardener is then mixed with the base component to form the mixed uncured sealant.

- **NPE concentration in the surfactant is 2.5-10%**
- The surfactant is added up to 6% in the final hardener formulation
- **NPE concentration in the hardener formulation is up to 0.6%.**
- **The NPE concentration in the mixed sealant is <0.1% w/w** (base and hardener combined), when mixed according to the ratio requested in the technical data sheet.

Due to the ethoxylate functional groups, NPE (or similar substances) has a high surface activity and can act as a surface-active agent. This means that it lowers the surface tension of the medium in which it is dissolved, lowering the tension between substances of other phases, and is adsorbed at the liquid-vapour interface and other interfaces. Therefore, these substances are commonly used to fulfil a surfactant role to promote mixing between substances with differing surface tensions, such as between a solid particle and a liquid or between dissimilar liquids.

The choice of surfactant used in the formulation is linked to various factors, such as the type of plasticiser used. The concentrations of the surfactant must be optimised accordingly to avoid negative consequences (adhesion issues etc) of excess surfactant levels on the cured product. Fine tuning is required during product development and testing to obtain the optimum ratio between all key ingredients and ensure all performance requirements are met.

The hardener is manufactured as follows. The surfactant is manually added to the mixing vessel, along with the plasticizer and additional additives, and mixed as required. The solid MnO_2 powder is then weighed into the vessel and a homogenous paste is produced by stirring with the same mixer. Once fully mixed, the paste is automatically pumped directly into a mill. The mixture is then homogenised by mixing again. The whole process is run at ambient temperature and cooling is applied in all mixing and grinding steps, as these activities result in heat from mechanical friction (see CSR). The ratio between plasticizer and MnO_2 in the hardener is about 1:1 by weight and the additives (including the NPE-phosphate based surfactant) sum up to approximately 6% in the mixture. Once completed, an exactly fitting plate is attached to the top of the mill container and pressure is applied so the hardener is dispensed into a container for shipping or for transfer to the filling area where it is extruded out into the relevant compartments for the prefilled cartridge products. This ensures minimal residue of the hardener product remaining on the container.

3.1.3.1. Aerospace Industry Polysulfide Sealants – how they work

Aerospace polysulfide sealants come in two parts referred to as the base and the hardener. The base is composed primarily of a sulphide polymer with additives, such as resins, acetates and other batch chemicals, present at <10%. The hardener is composed of approximately 50% liquid polymer mix of the plasticiser and other additives and 50% solid manganese dioxide (MnO_2) particles. The MnO_2 is a significant component of the sealant.

MnO_2 functions as an agent to cure the polysulfide resins by oxidative crosslinking. It plays a crucial role in the formulation, application and end property development of the polysulfide sealant. The concentration of MnO_2 in the hardener and, following mixing, in the uncured sealant mixture, is important in determining the key properties of the sealant and to meet the specification requirements of the end use application.

Surfactants containing NPE-phosphate, with NPE present as a residual non-phosphated component of the surfactant, are added to the hardener formulation to promote bonding of the MnO_2 particles to the rest of the polymer mix and to ensure adequate dispersion of the MnO_2 particles in the hardener component. The surfactant is important because it is a determining factor for the concentration of the MnO_2 in the hardener. A surfactant that is too weak will not allow sufficient concentration of MnO_2 in the base. This has several important implications for the properties of the sealant. For example, if there is not enough MnO_2 present in the hardener, this affects the curing time of the mixed uncured sealant, as it will take longer to cure with less of the active MnO_2 component in the hardener. If there is too much MnO_2 in the hardener, it will be much thicker and more viscous than specified, so it cannot be pumped into packaging or efficiently processed further.

When the hardener and base components are mixed, the MnO_2 in the hardener and the base component 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. This curing reaction can take place at room temperature and may also be accelerated by taking place under raised temperatures.

The requested mixing proportions as stated in the Technical Data Sheets range from 100 (Base): 9 (Hardener) to 100 (Base): 12 (Hardener).

Without the right surfactant, it is not possible to get enough MnO_2 into the hardener component and subsequently into the end uncured sealant mix. If there is less MnO_2 present in the hardener, then the ratio of hardener to base components would also need to change, as it must stay in proportion to achieve the same sealant properties. For example, if the concentration of MnO_2 in the hardener is reduced, the proportion of hardener in the uncured sealant mix would need to be increased to compensate and keep the sealant cure time the same. This would adjust the MnO_2 proportion, but there also will be more plasticiser from the hardener component introduced to the uncured sealant mix, so the cured sealant is softer and easier to peel off. The sealant applied to aerospace parts must achieve a Shore A Hardness (see Section 3.1.3.7) score of >30 to enable it to be moved or processed further, and the final full cure of the sealants should achieve a Shore A hardness score of 40-50. The MnO_2 content in the hardener and mixed sealant also has an impact on other key parameters, such as viscosity of the sealant pre-cure and application time. Therefore, ensuring adequate concentration and dispersion of the MnO_2 in the hardener is key to the functionality and use of the sealant. As such, the surfactant used to aid this process is an important component and replacement may not be straightforward.

- Sealants are comprised of a base and a hardener which are typically mixed in a 10:1 ratio – the hardener contains 50% solid MnO_2 particles, which functions as the active curing agent for the sealant
- Surfactants are added to the hardener formulation to adequately disperse the MnO_2 particles through the liquid hardener mixture. NPE is present in the surfactant used for these polysulfide sealants
- Inadequate dispersion of the MnO_2, and therefore reduced concentration of the active component in both the hardener and mixed uncured sealant, can impact upon end mixed uncured sealant performance and cured sealant performance during aircraft operational life

3.1.3.2. Sealants and the Aerospace Industry

Sealants are used to fill voids of various sizes, isolate dissimilar metals/substrates, bond two parts and provide a barrier to prevent the passage of liquids or gaseous media. These are just some of the examples of the applications that sealants are used for, as they have a wide range of key uses in the aerospace industry.

Polysulfide sealants are a specific type of sealant, originally developed over 70 years ago. Since then, they have been widely used in a variety of industries, including in aerospace. When used in aerospace applications, sealants add specific functionality to the hardware on which they are used. For example, they are used to protect against corrosion by e.g. preventing ingress of environmental moisture or water and providing an effective firewall in aircraft engines and exhaust assemblies by containing fluids, such as fuel and vapours. Polysulfide sealants are used extensively in, and relied upon by, the aerospace industry sector and are of vital importance for the aerospace sector.

The unique properties of this class of sealants that make it suitable for use in key aerospace applications include, but are not limited to:

- Resistance to degradation by fuel and other chemicals
- Flexibility over a wide range of temperatures, most uniquely extreme cold
- Adhesion to a wide range of substrates without the need for special surface preparation, and sometimes without requiring the use of additional adhesion promoters

- Ability to stress-relax, thereby maintaining adhesion to expanding and contracting substrates, limiting peeling of the sealant during aerospace product normal conditions of use

Due to this unique set of properties, and additionally their compatibility with a wide range of paint and primer systems, these sealants have been employed in innumerable sealing and adhesive uses in aerospace assemblies. These applications include anywhere that a fluid needs to be restricted from passage through, or presence in, some volume or space. Some examples are listed below, but this is by no means the entire list of key applications of these products in aerospace industry;

- Seal structures/components:
    - to keep moisture or other fluids out (e.g.to prevent corrosion or attack of structures/components)
    - to keep fluids in (e.g., fuel, hydraulic fluids, etc.)
    - to prevent airflow to maintain cabin pressure
- Component isolation:
    - to separate dissimilar substrates/metals to prevent corrosion
    - to provide thermal/electrical insulation
- Fill gaps:
    - to create an aerodynamic surface by a process referred to as aero smoothing
    - to eliminate moisture accumulation or traps
- Adhesive applications:
    - in engines and nacelles when flexibility and compatibility with mating gap filler is required
    - in bonding structures requiring flexibility
    - in bonding/sealing of wires
- Electrical potting in connectors, PC boards, circuit boards

Examples of the polysulfide sealants use in aerospace products include on structures, fuel tanks, actuators, electronic controller connections, gyros, wiper blade systems, propeller blades, ball screws for actuators, flight control rudder pedals and joint sealing of general aircraft structures during assembly process, wet installation of fasteners, etc. Other key uses include in flight controls, actuators, controllers, fuel tank (to ensure no leakage), window sealing for air tightness and pressurization of pressurized areas such as passenger cabins. They can also fulfil some adhesive and aircraft coating functions.

The ease of handling of sealants and their ability to adhere to a wide range of substrates, either as they are or with the additional use of an adhesion promotor, make them suitable for use in MRO operations. The ability to use the same formulations in MRO that are used in original manufacture is essential in aerospace assemblies for ensuring continuance of performance, safety of the component or assembly and compatibility between the two sectors.

There is significant overlap in the uses of polysulfide sealants in passenger, commercial and military aircraft assemblies.

The properties of polysulfide sealants have led to their usage beyond sealing. One such important use of sealants is as an adhesive. Polysulfide sealants are not used as structural adhesives, since these sealants are not as adhesively strong, compared to common structural adhesives, such as high strength epoxy-based adhesives where adhesion is the primary function. However, their ability to bond a wide range of substrates and to stress relax has led to their use for bonding where high strength is not a requirement, but reliable adhesion and flexibility at extreme temperatures, and/or reparability are required.

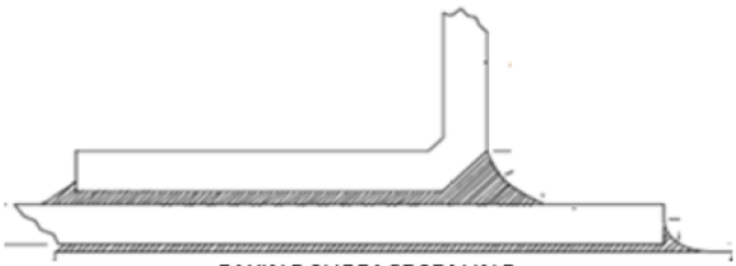
It is difficult to overstate the importance of uses of polysulfide sealants in aerospace assemblies. Virtually every aerospace system incorporates polysulfide sealants in multiple uses, see Figure 8 and Figure 9.

- Polysulfide sealants are widely used and provide specific functions on aerospace hardware
- Polysulfide sealants have varied and unique properties, as well as good adhesion to a variety of substrates, which makes them suitable for a variety of applications in the aerospace industry

3.1.3.3. Polysulfide Sealants – where they are used

Polysulfide sealants are applied in a variety of locations to fulfil key functions, such as;

Faying/Inter Fay Surface Sealant - A mixed sealant installed between two mating (overlapping) surfaces, e.g. between part of a hinge and the door of a cabinet to which it is installed. In aerospace, this includes on internal structural joints as well as exterior and interior surfaces. Faying surface sealants are used to prevent corrosion (e.g. for dissimilar substrates as corrosion resistant steel and aluminium), to protect against fretting and abrasion, and, in conjunction with fillet seals, to prevent a leak path from extending through a faying surface to another area. Additionally, the faying surface sealants prevent debris ingress. Faying surface sealant is used in dry areas as well as in wet fuel containing areas, as per Figure 2.



FAYING SURFACE SEALING

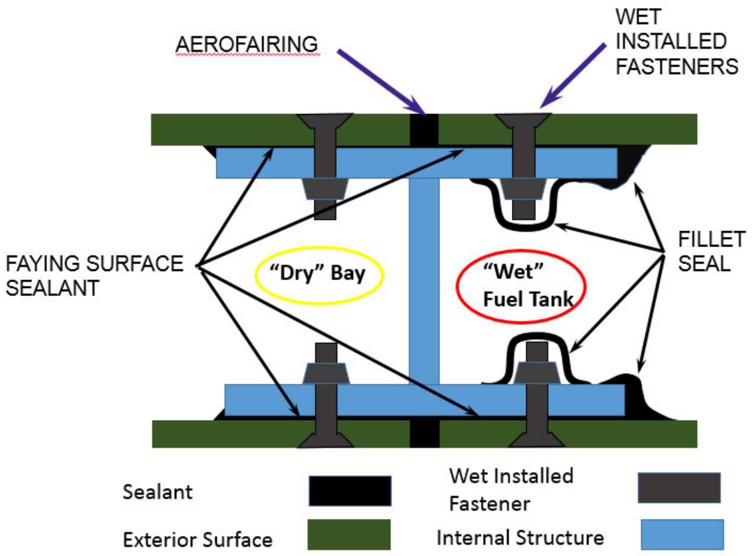
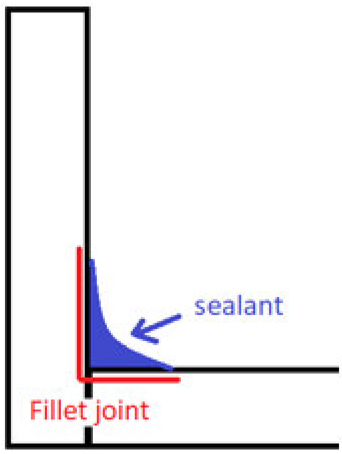


FIGURE 2 DIAGRAM OF FAYING SURFACE SEALANT LOCATION APPLICATIONS

Fillet Seal - A primary seal (post assembly) applied at the juncture of two perpendicular or angled adjoining components (a fillet joint), or surfaces, and along the edges of faying surfaces, as a continuous bead of sealant to create a continuous and smooth surface, see Figure 3. An everyday example of this would be between at the top interface between a wall and a bath. It can be applied over, along the edges of, and between installed components and fasteners. Fillet seals are predominantly used in fuel tanks but are also applied to dry areas that have contact with water, moisture and occasional exposure to other liquids to prevent corrosion.



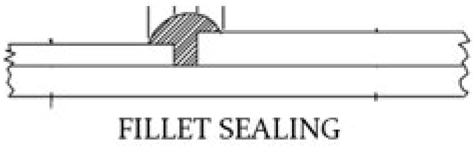


FIGURE 3 FILLET SEALING DIAGRAMS

Wet Installed Fastener - Fasteners that have sealant applied to their shank and under their head prior to installing to provide a corrosion barrier and secondary seal to ensure tightness against fuel, air and moisture.

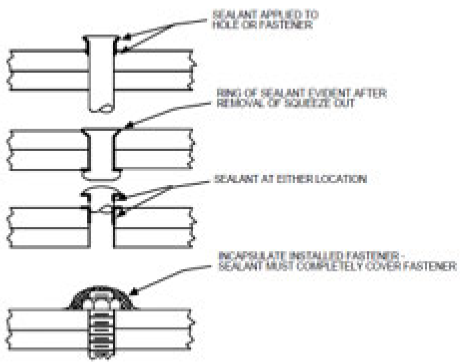


FIGURE 4 WET INSTALLED FASTNER DIAGRAM

Aerodynamic Sealant – Is formulated for filling and smoothing external depressions and seams. This provides smoother airflow across, for example, the fuselage and other external hardware, resulting in better fuel economy. It also enhances aerodynamic properties of the surface and prevents cavitation.

Windshield Sealant – Specifically formulated develop adhesion while not attacking or degrading polycarbonate or acrylic windshields.

Fuel Tank Sealant – Fuel tanks exist as a cavity in a wing or in the fuselage or both, and the sealant is an important part of ensuring fuel containment (see Figure 5).

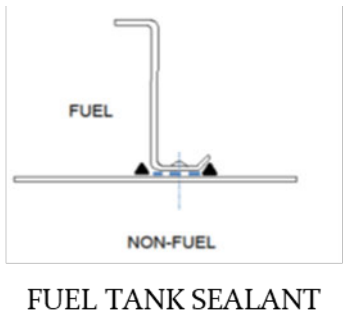


FIGURE 5 FUEL TANK SEALANT DIAGRAM

Firewall Sealant - The sealant is formulated to withstand high flash temperatures (e.g. 2000°F/1100°C) and seal structures against the passage of hot air and vapours.

Cabin Pressure Sealant - Creates an airtight seal on aircraft cabins to prevent pressure leakage and provide resistance to water and weathering.

Sealants can also be used to gap fill holes, act as a barrier to prevent abrasion, seal bonded structures, fill open cavities, in slot and injection sealing, firewall sealing, overlap sealing, etc., as per Figure 6 below. This is not an exhaustive list of uses for the sealants in the aerospace sector but demonstrates how widely they are used throughout the industry.

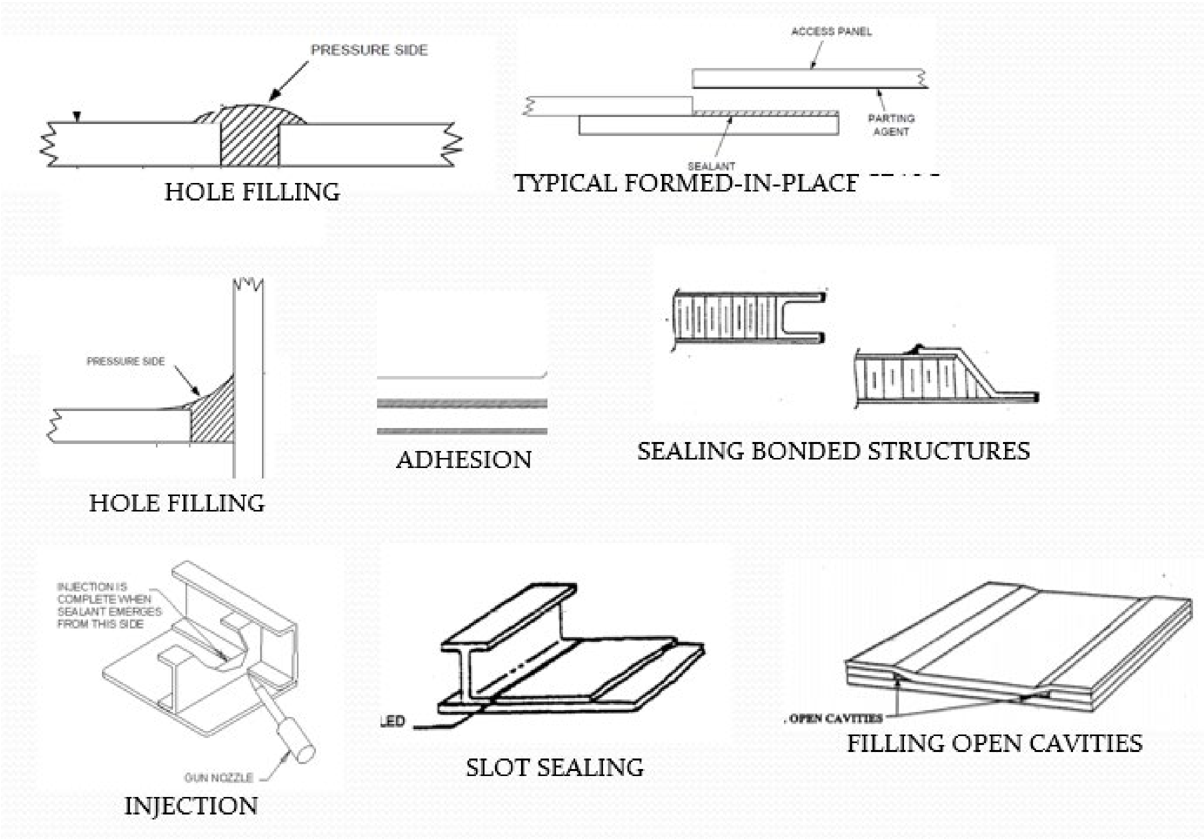


FIGURE 6 OTHER EXAMPLES OF SEALANT APPLICATIONS

Sealants are applied and bonded to aerospace components on the outside and inside of the aircraft, as they are typically applied between most mating joints and most fasteners during assembly of the structures, illustrated for aircraft (per Figure 7) below; although, it should be noted that corrosion protection is required all over the aircraft.

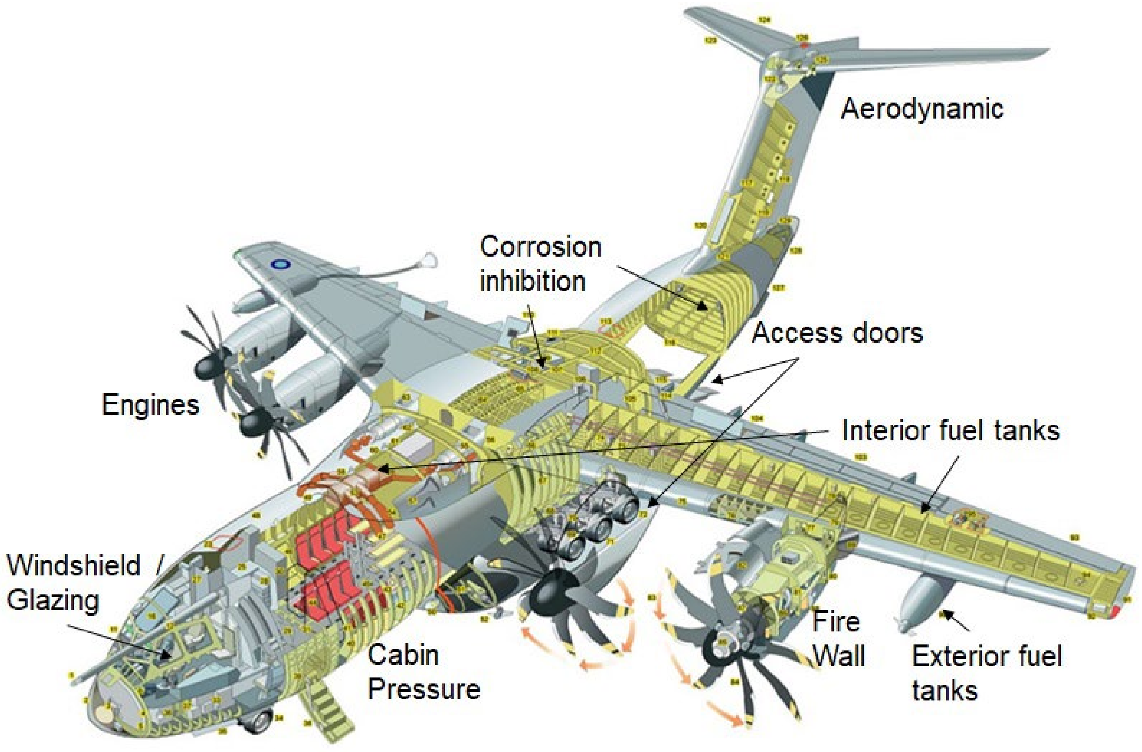


FIGURE 7 DIAGRAM OF TYPICAL SEALANT LOCATIONS ON MILITARY AIRCRAFT

3.1.3.4. Sealants – Packaging Methods

Sealants used by the aerospace industry are supplied in a variety of packages, but the most common are,

- two-part kit sets (which are available pre-packaged either in cans for smaller scale mixing or drums for bulk mixing),
- pre-metered two-part disposable cartridge-based systems (stores, mixes and applies multiple component adhesives/sealants)
- premixed and frozen (PMF) sealant

The different packaging methods have been developed over time, to not only optimise the product quality and performance to specification of the sealant, but to provide options to customers depending on their own requirements and manufacturing processes. Some Airbus plants may be using high volumes when manufacturing, so the two-part kit sets, which can be delivered in greatest volume, might be more appropriate than individual smaller volume cartridge systems.

For all the packaging methods, the hardener is required to be mixed into the base component prior to application. Product mixing is completed in a clean environment under room temperature conditions and in a controlled manner, to ensure thorough mixing in accordance with manufacturer's procedures.

The mixing activity is within the scope of Authorisation, due to the concentration of NPE in the hardener component (max. 0.6% w/w). Once the two components are mixed, the concentration of NPE in the mixture is <0.1%w/w and the application or further use of the uncured mixed sealant is outside the scope of Authorisation, see Figure 10.

Two-Part Kits

All sealants consist of a base and hardener, but for the two-part kits, it is delivered in two containers that are attached together and clearly labelled. Each container has the base and hardener components premeasured for the standard mixing ratio for that product (e.g. 10 Base:1 Hardener), ready to be mixed together. The volume in these kits can vary from smaller scale can kits to drums.

Each part is first mixed separately to uniformity, using a disposable spatula or tool for even consistency, as constituents of the hardener and base can occasionally settle. The hardener is added to the base and slowly, but thoroughly, mixed together, taking care to avoid leaving unmixed areas, particularly around the sides or bottom of the mixing container. This can be done manually or by machine for can kits or by machine for bulk mixing, as in Figure 8.

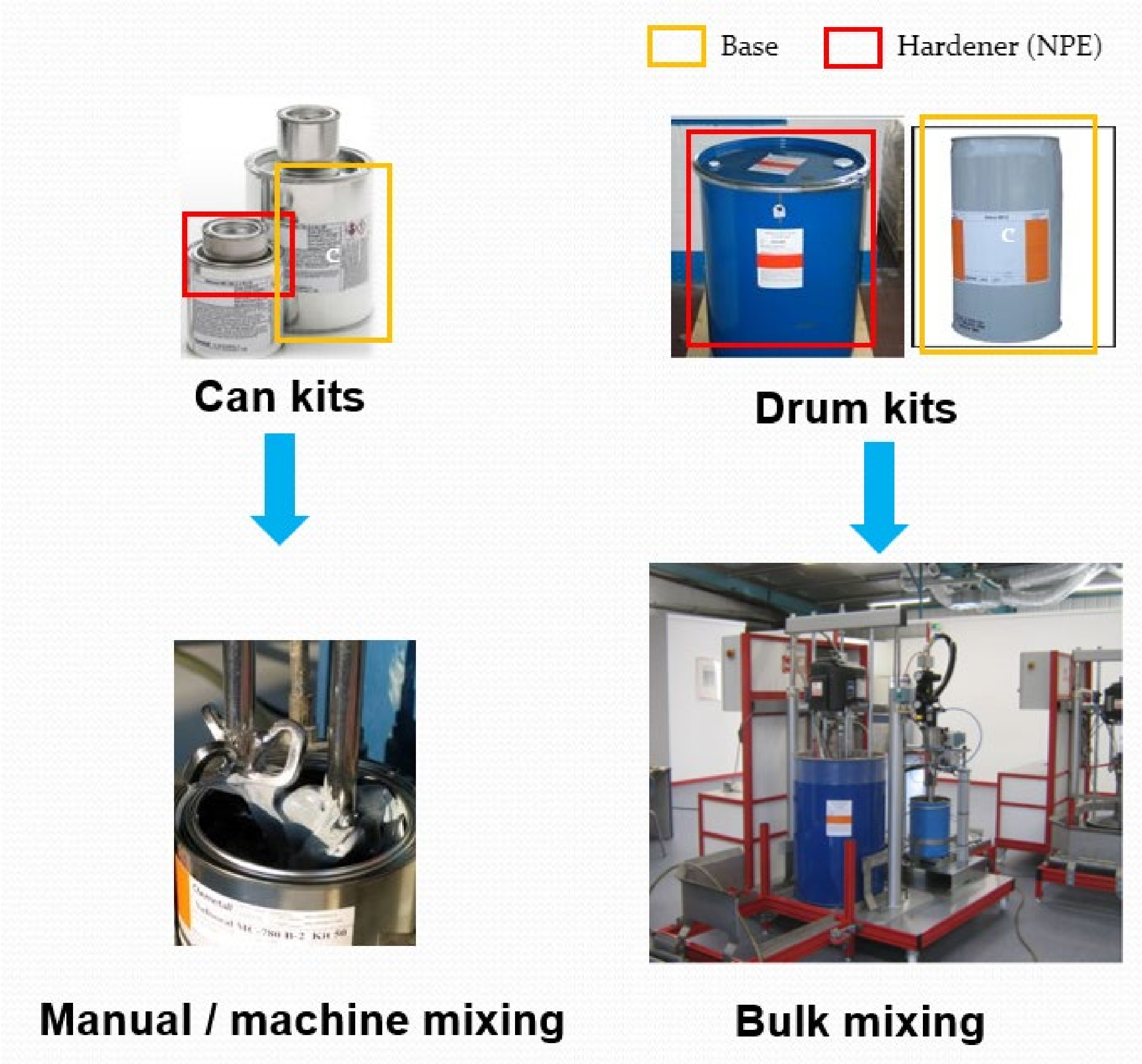


FIGURE 8 PICTORAL OVERVIEW OF TWO-PART SEALANT KIT MIXING

The mixed sealant is then applied to previously cleaned and pre-treated surfaces (e.g., by means of a dedicated adhesion promoter), for example at the interface between two pieces of structure, or adjacent to the joint, if a fillet seal is being applied, etc. It is applied within the pot life/working lifetime and per work instructions. In general, shorter working life is preferred due to the shorter time to produce full setting or cure of the sealant. Some sealants are self-levelling and suitable for brush application methods, and others are suitable for loading into an extrusion gun or onto a disposable spatula. Some designs require the use of bond primer or adhesion promotor to improve adhesion of the sealant to the surface.

Pre-metered Cartridges

In this case the sealant is stored, mixed and dispensed from a single cartridge where the base and hardener are pre-metered. When ready to be used, the internal mixing rod is pushed through the barrier separating the two parts and is repeatedly plunged the length of the syringe barrel, whilst being rotated to ensure an even mix of the sealant, see Figure 9. This can be done manually or by machine to ensure a uniform and repeatable standard of mix of the sealant. The mixed sealant is pushed from the kit via a plunger at the back and applied directly to the surface or gap through the cartridge nozzle or with a pneumatic gun.

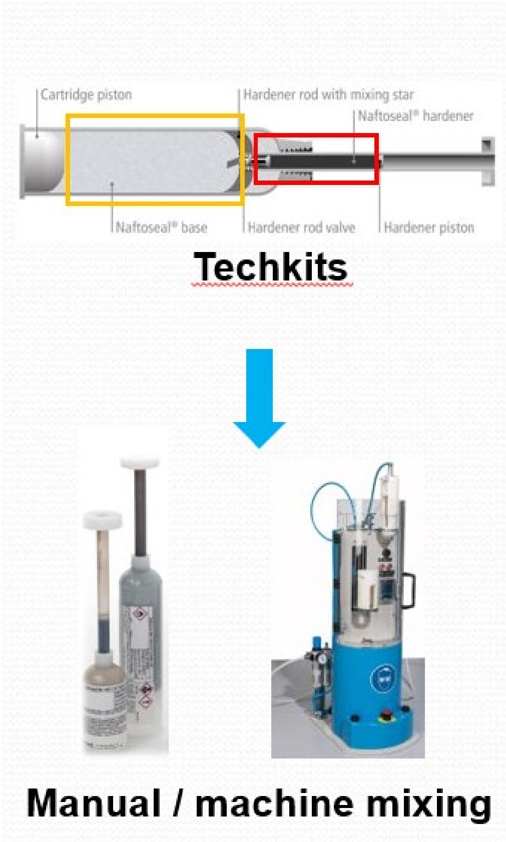


FIGURE 9 PRE-METERED CARTRIDGE MIXING METHODS

Premixed and Frozen (PMF)

PMF products have the mixing stages completed by the Formulator or downstream user and are placed into dispensing syringes and frozen before the sealant can cure. These must be stored at extremely low temperatures (typically below -70°C) and shipped in temperature-controlled (typically below -40°C) packaging and stored in speciality low temperature freezers to ensure the mixed sealant does not prematurely cure before it can be applied. These products have a maximum shelf life after deep freezing of 35 days and this option is limited to sealants with longer work life and longer cure time. Sealants with a short work life or fast cure products cannot be frozen due to the reduction of work life that freezing causes. Upon receipt, the Downstream User can then thaw the PMF dispensing syringes to room temperature and can then expel the mixed sealant directly to the surface or gap through the cartridge nozzle, in the same way as in the ready to mix cartridge systems. PMF is further discussed in Section 4.3.2.1 (NUS Scenario 1).

PMF sealant can be provided in more specialist packaging methods, such as:

- Sealant strips: premixed sealant is shaped as required either cured or with PMF uncured sealant, then placed where required and left to cure
- Seal caps: the manufacturer creates moulded caps of cured sealant with a hollow inside, either filled with PMF uncured sealant or provided to the downstream user unfilled. These are thawed or filled for use and placed over bolts/fasteners to quickly and easily create a capping seal that can be left to cure

After applying the sealant, regardless of the method of application to the hardware, the surface is left undisturbed until the sealant is tack free, to allow the sealant to cure sufficiently before the part can be moved, and further assembly or maintenance activities can be undertaken. The other manufacturing or MRO activities can continue in the time between the sealant achieving a tack free surface and full sealant cure. Excess uncured sealant needs to be removed prior to cure to avoid fit issues.

Time taken to cure the sealant is dependent on the specific sealant and factors, such as temperature and relative humidity used. For example, 2 hrs might be possible for some sealants under oven conditions, whereas complete cure may require up to 90 days at room temperature. Over the course of the curing process, the sealant will have transformed from a liquid/paste consistency to a solid rubber. See Figure 10 for an overview of the process.

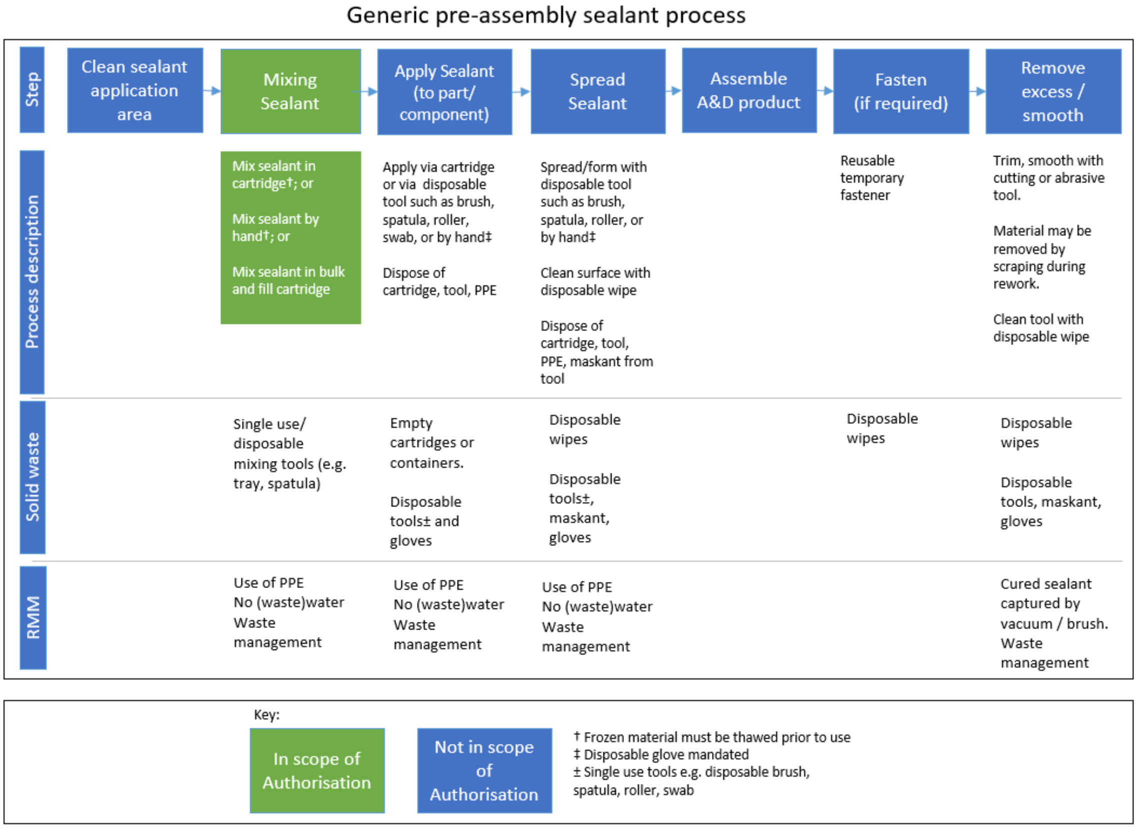


FIGURE 10 GENERIC PRE-ASSEMBLY PROCESSS OF SEALANT USE

The process for post-assembly sealant use is the same as in Figure 10 above, except cured sealant is first removed as part of the cleaning sealant application area activities. In the context of this application, and as highlighted in Figure 10, it is the mixing of the two parts of the sealant that is within the scope of the Authorisation.

3.1.3.5. Description of the technical requirements that must be achieved by the products(s) made with the substance

The European Aviation Safety Agency (EASA) established airworthiness regulations to ensure the highest common level of safety and environmental protection for EU citizens in civil aerospace. The European Military Aviation Requirements (EMARs) were created by the European Defence Agency (EDA) Military Airworthiness Authorities (MAWA) Forum to promote harmonisation of European military airworthiness regulations.

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. These specifications inform which component(s) or material(s) are suitable to be used in aircraft manufacture. The specifications detail the performance criteria the material must comply with to be considered as suitable for use and can include details on testing to verify if it meets the specified criteria (see Section 3.1.3.7).

All changes to the materials, components, or manufacturing processes used in complex aerospace assemblies are subject to the highest level of scrutiny. No change is so minor that it does not require some degree of substantiation. Figure 11 provides a process overview, however, it must be noted that this is an indicative illustration and not all companies use the same wording to describe each stage. For example, validation can be included in technical qualification in some cases. Any change to the components, materials, or manufacturing or maintenance processes must be qualified to prove it meets specifications performance requirement. Formal processes are in place to manage the change, and justifications/evidence provided for the qualification and certification of the change can take many forms. It is the responsibility of the OEMs, as design authority or Type Certificate Holder, to ensure that formulations used in key applications, or on aerospace parts or assemblies, are suitable and safe for use, in accordance with the airworthiness regulations (as detailed in Annex C) and to agree the approach to certification (if needed) with relevant authorities.

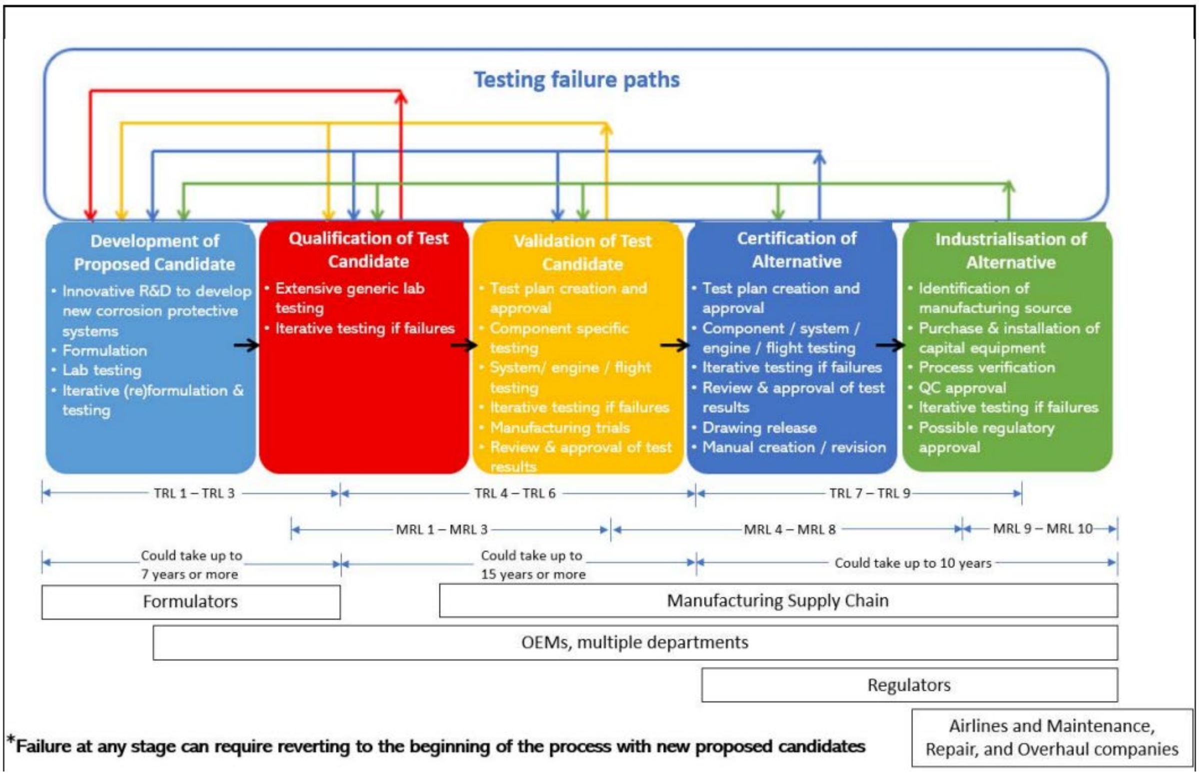


FIGURE 11 KEY PHASES OF INTRODUCING A CHEMICAL SUBSTANCE CHANGE INTO PRODUCTION HARDWARE MANUFACTURE[7]

In the case of the replacement programme for polysulfide sealants containing NPE for each individual change, compliance with specifications, process instructions, and maintenance manuals provides the evidence that the alternative sealant is interchangeable and thus is airworthy. As a result, there is no need for an additional certification step or validation from EASA or relevant military certification authorities. This is crucial, since additional certification or validation from the relevant authority involves a much more extensive

[7] *Source: Adapted from "Use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains", Application for Authorisation 0117-01, GCCA (2017)*

effort associated with aircraft part design changes (e.g. drawing, part number, and/or name changes). The reformulated alternative sealant will need to meet the same performance requirements as the existing sealants for each category.

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 rejected in the Applicant's laboratory and do not reach sufficient maturity to proceed to Airbus qualification testing.

Qualification through industrialisation is required to:

- Ensure that only reliably performing materials, components, and processes are approved for use to produce aerospace components.
- Ensure that the product, the process or method is compliant with both relevant Regulations and aerospace component manufacturer requirements to fulfil specified functions.
- Provide a very high level of confidence for both the use of the product and the resulting AD end components.
- Ensure consistent quality of materials being introduced.
- Ensure consistent use of the new or alternative product between different product or component suppliers, and to guarantee production and management system robustness, throughout the supply chain.
- Fulfil requirements of the Airworthiness Authorities and applicable military requirements.

Technical qualification for the polysulfide sealants by Airbus is anticipated to require 18 months 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, product qualification will be stopped, and the development phase must start again from the beginning.

The newly qualified sealants must perform in the same way as current sealants and will be applied using the same process instruction. In this way, the alternative product can be considered a one-to-one replacement. When the alternative product is a one-to-one replacement, the interchangeability principle will be applicable.

Figure 12 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) (54)."[8] As no component design changes (e.g. no drawing or part number changes), are expected in the case of the reformulated sealants, the changes at OEMs are anticipated to fall in Path 1. The newly qualified sealants are expected to perform in the same way as

[8] ASD19003 Issue 1: REACH Design changes best practices (17th April 2019), pg. 9

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 are necessary.

	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 12 MATERIALS CHANGE PATH (ASD A. A., 2019)

Initially no change of name was planned because the reformulation was supposed to be a minor change in the formula. By keeping the same product name this would have allowed to avoid a documentation update that is time consuming and expensive. However, after a certain amount of development tests it was realized that the reformulation was considered a major change as several modification in the composition occurred. Due to the risk of confusion between formulations the decision to change name was made in October 2019, after the submission of the initial AfA. Despite the major formulation change, there is still no impact on products interchangeability, e.g., the NPE-containing and NPE-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 12 above, prior to implementation.

Once the new formulation is qualified and ready for deployment in manufacturing plants, the industrialisation stage can commence.

Industrialisation may be scheduled to follow a stepwise approach to minimize the technical risks and to benefit from lessons learned (see below). This means that changes may not be implemented universally or simultaneously across all sites and at all suppliers but rather via a phased introduction.

In the case of providing candidate alternative polysulfide sealants without NPE to Airbus to commence qualification testing, this development stage has been ongoing since 2017 and is expected to be concluded by Q4 2026. In line with best estimates about the degree of qualification testing that will be required, including a risk margin of safety, the qualification stage is expected to be able to conclude by Q2 2028 as discussed further in Section 4.1.3.

Further details on the regulatory situation for aircraft and the required steps to implement a new or modified formulation in the aerospace industry is provided in Annex C.

3.1.3.6. Sealants – Service Life

Sealants are required to perform as specified for the lifetime of the part for aerospace assembly equipment. Sometimes, due to the location or performance requirements of the part the sealant must maintain its properties (as described in Section 3.1.3.7) for the lifetime of the system itself. Aerospace components containing polysulfide sealant perform over a wide range of service environments and face a variety of challenging operating conditions when cured, such as:

- extreme high and low temperature exposures
- vibration
- mechanical shock
- high and low ambient humidity
- exposure to fluids including jet fuel, coolants, cleaning agents, de-icing fluid, lubricating oils, seawater, etc.
- exposure to sunlight, ozone and weathering

The long service life of aerospace assemblies drives MRO activities over their entire service lives, sometimes requiring the localized removal and replacement of the sealants where access to the equipment that requires repair may not be possible without removal of components (e.g. around access doors and panels, etc.). Upon repair, some of the old polysulfide sealant may remain, requiring the new sealant used at the time of repair to be compatible with previously cured sealants. This characteristic is commonly required across numerous aerospace assemblies.

Physicochemical/process/operational conditions for usage of sealants

The key technical criteria for selection and usage of sealants to meet manufacturing and industrialisation criteria, which affect the suitability of alternatives to using NPE in polysulfide sealants, as identified by Airbus, are included below. This list in Table 2 is indicative and should not be considered exhaustive.

TABLE 1 KEY TECHNICAL CRITERIA – PHYSICOCHEMICAL/PROCESS/OPERATIONAL CONDITIONS

Key Technical Criteria	Description
Viscosity	Viscosity is defined as the magnitude of internal friction and the resistance to uniform flow of a fluid; the greater the resistance to flow in the fluid, the more viscous it is and the more the fluid behaves cohesively. The viscosity of a sealant is very important, as this can affect the method of physically applying the sealant and the suitability of the sealant to the area in question. For example, a sealant with very low viscosity could be uniformly applied to a level surface and not to any curved components, or the underside of a part. A sealant that is very viscous may not be suitable for extrusion using a cartridge and may have to be applied using a spatula or brush. Different sealants may fulfil a similar function but have different viscosities requirements, depending on the intended use and method of applying the sealant to the hardware (e.g. brush, extrusion, etc.).

Key Technical Criteria	Description
Density	Density is defined as the item's mass per its specific volume. For sealants, where usually the component it is being applied to defines the required amount in volume, the sealant density will play a role in the overall weight of the component. The sealant density therefore has a direct influence on the efficiency and fuel-consumption of an aircraft. On the other hand, lowering the density of a sealant, e.g. by including gas-filled balloons into the material matrix, might result in a decrease of mechanical properties, e.g. cohesive strength.
Pot Life / Working Life/ Application time	Pot life/working life/application time can be characterised as the period where reactive chemicals remain usable after mixing, until the viscosity of the mixed sealant is such that the sealant is no longer usable. This can be taken as the maximum length of time available to apply the sealant after the sealant is mixed or thawed, and remove any excess, which is determined by Standard Test Conditions. This can also give a rough indication of the curing time for the mixed sealant as those with a longer pot life/working life/application time take a longer time to cure. For different sealants, different working life times may be specified to ensure an optimal balance between consumption and throughput. This can be identified in the name of the sealant (e.g. MC-238 A-1/2; the numerical suffix (1/2 in this example) refers to the working life time in hours). If reformulated sealants have different working lives, it can adversely impact OEM manufacturing processes and usage efficiency.
Cure Time and Temperature	The cure temperature is a key criterion for sealants, as this is one of the main controls on the time the sealant takes to fully cure and can currently be completed at either ambient temperature or elevated temperatures using heat lamps or other heat sources. The time taken to cure is important for the OEM manufacturing facility, as this will affect the overall manufacturing process, if incorporating into a larger aerospace system, and impact upon delivery of final equipment pieces. It is also important for either civil or military aircraft repairs if the aircraft is not located near a repair facility. Any alternative sealants must not adversely impact the curing time and must be able to be cured under the same temperature conditions as the original formulation, otherwise the manufacturing and MRO processes will be impacted.
Tack Free Time	The tack free time is considered as the minimum length of time until the sealant can resist damage after some degree of contact to the surface (e.g. will not easily dent under gentle pressure) and can resist contamination with airborne particles or dirt. Therefore, the tack free time also is a measure of the minimum length of time the aerospace part in question must be left undisturbed before it can be moved or incorporated into a larger aerospace system in manufacture or repair. For example, a product may have a tack free time of 20 hrs, but a full cure time of 50 hrs, and a product with a tack free time of 10 hrs may have a full cure of 40 hrs or less. These examples illustrate that this is an important parameter for the planning and manufacturing/MRO process to assist avoiding unnecessary delays in continuing with the manufacturing and repair of the part.
Shelf Life	The shelf life of a product is the length of time that a product can be kept before it is no longer suitable for use. It is key that the sealant purchased retains its quality (e.g. has the same performance capabilities at the end of the shelf life as at the beginning) and is still in good condition to use when required. Settling or degradation of key ingredients over time would be unacceptable, as this can affect the end mixed sealant performance. Depending on the needs of the OEM manufacturing or MRO facility, it may be necessary to keep the sealant components or cartridges on site for several months, as there may be fluctuation for amount required during manufacture or repair of the aerospace components.

Sealant performance parameters for article lifecycle

The final cured sealant also must meet the following key technical criteria, to ensure adequate aerodynamic and bonded structure sealing of aerospace components which affect the suitability of alternatives. These are as identified by Airbus. As above, this list in Table 3 is indicative and should not be considered exhaustive of all requirements. These properties may not all simultaneously apply to one sealant, as some properties may be more relevant than others and this can vary between products.

TABLE 2 SEALANT PERFORMANCE PARAMETERS

Performance Parameters	**Description**
Hardness	The hardness of a sealant is defined as the resistance to permanent deformation (otherwise known as "plastic deformation"). It is measured by means of indentation, and for rubber-type compounds, this is typically measured against the Durometer Shore A hardness scale. The higher the score on the Shore A hardness scale, the harder the sealant and the greater its resistance to deformation. This is important when used in aerodynamic, faying sealant and overcoating uses to protect the system component and its integrity.
Tensile Strength / Tear strength	Tensile strength is the ability to withstand stress, measured (usually in force per unit of cross-sectional area) by the greatest load pulling in a single direction that a given item can stand without breaking). For example, the amount of force it takes to pull and break an elastic band. Tear strength is the related measure of how much tensile stress an item can withstand, when a tear is introduced. In the aerospace industry, components may have to withstand strong mechanical forces and, therefore, any sealants or coatings that are forming a resistance barrier or coating must not reduce the shear resistance of the component or aerospace system they are applied to, to ensure structural integrity is as specified and as expected. Any replacement products must also provide the necessary performance for this parameter and perform to current standards or better.
Bond Shear Strength	Shear strength is the strength against yielding or structural failure when unaligned forced push one part of a body in one specific direction, and another part of the body in the opposite direction. For example, cutting paper is performed by applying unaligned forces, resulting in the paper failing in shear. Aerospace components may have to withstand strong mechanical forces and, therefore, any sealants or coatings that are part of a component must not reduce the shear resistance of the component to which they are applied, to ensure that structural integrity of the overall component is as specified. Any replacement products must also provide the necessary performance for this parameter and perform to current standards or better.
Galvanic Isolation	Galvanic isolation is the principle of isolating different substrates/surfaces from each other to prevent electrical current flow between them. By isolating the substrates/surfaces in this way, it prevents unwanted electrical build up and galvanic corrosion between dissimilar components. Sealant is utilised for this purpose as it is electrically inert and can act as an insulator.
Adhesion – subsequent coatings	Adhesion is the ability of different particles or surfaces to adhere to one another and is essential for long term performance. Many aerospace components are exposed to harsh environmental conditions, encounter other metallic components, and/or must withstand strong mechanical forces. The requirements for adhesion vary within the aerospace industry and depend on the required function, and location of the part. A variety of screening tests are used to evaluate coating adhesion. Even where such a test is successfully completed, extensive further testing is required to substantiate and certify that the new formulation provides the necessary performance for the relevant design parameters.
Chemical Resistance & Water Resistance	Water resistance is defined as the ability of a solid to resist penetration or destruction by liquid and will instead repel the liquid. This is similar to chemical resistance, which is defined as the ability of solids to resist damage by chemical exposure. Aerospace components are often exposed to water and liquids, such as jet fuel, hot oil, de-icing fluids, hydraulic fluid, and other chemicals. Consequently, the candidate alternative sealant must be unaffected by prolonged exposure to these fluids during use. Water, fuel, hot oil and other fluid immersion tests called out in specifications are tools for screening suitability of proposed alternative compositions. Any suitable candidate alternative coating must provide the necessary performance for the relevant design parameters.

Performance Parameters	Description
Corrosion Resistance	Corrosion describes the process of oxidation of a metal due to chemical reactions with its surroundings, or chemical reactions with environmental compounds (e.g. water or hydraulic fluid), and which can create corrosive electrolytes through the presence of other dissolved substances. In this context, corrosion resistance means the ability of a metal to withstand gradual destruction by chemical reaction with its environment. For aerospace, this parameter is one of the most important, since meeting its minimum requirements plays a key role in assuring the longest possible life cycle of aerospace assemblies and all the implicit components, the feasibility of repairing and maintenance activities and most importantly, continued safety and reliability of aerospace components during use. Ideally, the corrosion-inhibiting substances/systems are applicable in all surface treatment processes, compatible with subsequent layers and perform effectively on all major metal substrates. Furthermore, it must guarantee product stability (chemically and thermally) and must reinforce the useful sealant properties.
Thermal cycling resistance	This parameter describes the ability of a sealant to withstand repeated low and high temperature cycling. For the same reasons stated above, it is indispensable that components and sealants perform their functions optimally at all temperatures encountered during their service life. In general, different test methods are available within the aerospace industry, where aerospace components must meet test requirements to operate at both sub-zero and elevated temperatures. Thermal cycling requirements are tightly controlled by company and industry specifications.
Compatibility with substrates/ other coatings	Compatibility with a wide range of substrates and other formulations such as primers, topcoats, specialty coatings, adhesives and other sealants is a key performance characteristic for sealants used within the aerospace industry. To determine the compatibility between the sealant and other substrates/products, adhesion testing is carried out according to company and industry specification requirements.
Slump Resistance	The resistance of a sealant to slump is the measure by which after application, it retains its position and shape under its own weight and is linked to viscosity properties. This is necessary for application of sealant on vertical and overhead position, e.g. to overcoat fastener, and important for usage of sealant. A sealant with low slump resistance applied in vertical or overhead positions is unlikely to hold to the surface required and the sealant may drop, meaning that it would have to be re-applied.

3.1.3.7. Specifications of Polysulfide Sealants

A change in formulation needs to be qualified, validated and certified to ensure that the new formulation provides the necessary performance for the relevant design parameters and that the formulation performs as specified[9].

Whilst there are industry-wide specifications relating to sealants used in aerospace (e.g. Aerospace Materials Specifications, ISO standards, etc.), it is the Airbus specifications that are most relevant for the sealants in question. The Airbus specification documents detail the performance requirements and quality level which need to be met per sealant type, including test methods. 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. In addition, Airbus process specification documents can identify the engineering requirements in terms of performance requirements to be met as output

[9] When the candidate alternative can be demonstrated to be "interchangeable" with the one currently in use, it may not be necessary to seek external formal certification of the change in formulation, as described in Annex C.

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. Further examples are provided below:

Airbus Materials Specifications: defines the requirements for the approval of a formulations for a defined use for aerospace application e.g.:

- low, medium and high-density general-purpose sealants;
- low, medium and high-density fuel tank sealants;
- low adhesion sealants;
- lightweight general-purpose sealants;
- lightweight high-performance fuel tank sealants;
- sealants containing a particulate foam filler that enables it to fill large cavities where conventional sealant would show unacceptable levels of slump; and
- two-part reaction polysulfide, curing at room temperature, non-structural bonding application.

Airbus Process Instructions: defines the detailed work instructions for a defined process e.g. instructions on:

- Sealing of aircraft structure
- Wet installation of fasteners
- Process for the manufacture of form-in-place seals using sealant
- Application of low adhesion sealants
- Cap, retainer, bolt head and nut, installation specification / Installation of Injection Nut Caps and Head Caps
- Application of Cavity-Filler Sealant for filling of major gaps within structure
- Defrosting - Preparation - Application of sealants

Airbus Process Specifications: defines the engineering requirements for a defined process e.g. for:

- wet installation of fasteners;
- manufacture of form-in-place seals using sealant; and
- application of low adhesion sealants.

Some of the example criteria to comply with these Airbus specification requirements are detailed in Table 4 and Table 5 below. The parameters described in the tables below are examples only and are not the full list of specification requirements that a sealant may be required to perform to.

TABLE 3 EXAMPLE PROPERTIES OF CURED SEALANT PRIOR TO ENVIRONMENTAL EXPOSURE TO MEET AIRBUS SPECIFICATION REQUIREMENTS

Property	Unit	Requirement
Density	g/cm3	Max 1.65
Lap shear strength	MPa	1.5 min. 100% cohesive failure
Lap shear strength with adhesion promoter		

Property	Unit	Requirement
Peel strength	N/25mm	90 - 120 min. 100% cohesive failure
Peel strength with adhesion promoter		
Tensile strength	MPa	1.5 min.
Tensile elongation	%	200 min.
Low temperature properties	NA	Pass 10% min.
Hardness	Shore A	40 min.

TABLE 4 EXAMPLE PROPERTIES OF CURED SEALANT AFTER ENVIRONMENTAL EXPOSURE TO MEET AIRBUS SPECIFICATION REQUIREMENTS

Environmental Exposure	Property	Unit	Requirement
Fuel immersion, 4500 hours at (23±2) ºC	Peel strength	N/25mm	120 min.100% cohesive failure
	Peel strength with adhesion promoter		
	Hardness	Shore A	35 min.
	Tensile strength	MPa	1.5 min.
	Tensile elongation	%	200 min.
	Tensile strength after 1-day air dry at 60ºC	MPa	1.5 min.
	Tensile elongation after 1-day air dry at 60ºC	%	200 min.
	Peel strength after 1-day air dry at 60ºC	N/25mm	120 min.
Fuel immersion, 336 hours at 100ºC	Peel strength	N/25mm	120 min100% cohesive failure
	Hardness	Shore A	30 min.
Water immersion, 1000 hours at 35ºC	Peel strength	N/25mm	120 min 100% cohesive failure
	Peel strength with adhesion promoter		
	Hardness	Shore A	30 min
	Tensile strength	MPa	1 min
	Tensile elongation	%	200 min

Environmental Exposure	Property	Unit	Requirement
Corrosion prevention capability	N/A	N/A	Pass
Air exposure 2000 hours at 80ºC	Peel strength	N/25mm	65 min 100%cohesive failure
	Peel strength with adhesion promoter		
	Tensile strength	MPa	1 min
	Tensile elongation	%	125 min
De-icing fluid immersion, after 168 hours at 23ºC	Peel strength	N/25mm	120 min 100% cohesive failure
	Peel strength with adhesion promoter		
	Tensile strength	MPa	1 min
	Tensile elongation	%	150 min

There are a wide range of sealant formulations to meet the different, highly refined specification requirements of Airbus reflecting the different sealant applications that are required in the aerospace industry. Each sealant has several variants (e.g. MC-216 A-2, MC-216 B-2, MC-238 A-1/2, MC-238 A-2 etc.), considering the processing and performance criteria the sealants are required to meet by Airbus, and depending on usage area of the sealant. As shown in Table 6, there can be different requirements that the products must demonstrably meet, even across the same product name and class range. The example below is for illustrative purposes only and other sealant variants could have different application/cure times.

TABLE 5 APPLICATION LIFE AND CURE TIME COMPAIRSON OF PRODUCT RANGE MC-238 CLASS A AT 23ºC / 50% RELATIVE HUMIDITY

Product Type	Min. Application Time	Tack-Free Time	Time to Shore A Hardness 35
MC-238 A-1/2	0.5 hrs	≤ 10 hrs	≤ 30 hrs
MC-238 A-2	2 hrs	≤ 12 hrs	≤ 48 hrs
MC-238 A-4	4 hrs	≤ 18 hrs	≤ 48 hrs

This wide range of products with unique processing and performance requirements adds substantial complexity to the challenges faced when attempting to source and qualify new or replacement products.

The affected sealants containing the NPE-phosphate surfactant with NPE in the hardener component above the Authorisation threshold (≥0.1% w/w) that require reformulation and are manufactured and sold in the UK include, but may not be limited to, products identified in Table 7. The products listed in this table have been identified as within the scope of this application for authorisation, as they are currently known by Airbus and Applicant. It should also be noted that the uses listed are examples only and are not the only applicable usages of the products in question, and do not include each variation based on application time, as in Table 6. For example, a fuel tank sealant may not only be used in fuel tanks, depending on the OEM or MRO company.

TABLE 6 NON-EXHAUSTIVE LIST OF AFFECTED SEALANT PRODUCTS MANUFACTURED BY THE APPLICANT

Formulation	Aerospace Use Examples
Naftoseal MC-238 Class A	Fuel tank and fuselage sealant
Naftoseal MC-238 Class B	Fuel tank and fuselage sealant
Naftoseal MC-780 Class A	Fuel tank and fuselage sealant
Naftoseal MC-780 Class B	Fuel tank and fuselage sealant
Naftoseal MC-780 Class C	Fuel tank and fuselage sealant
Naftoseal MC-216 Class A	Low adhesion sealant
Naftoseal MC-216 Class B	Low adhesion sealant
Naftoseal MC-790 Class B	Cavity Filler
Naftoseal MC-630 Class A	Fuel tank and fuselage sealant
Naftoseal MC-630 Class C	Fuel tank and fuselage sealant
Naftoseal MC-650 Class B	Fuel tank and fuselage sealant
Naftoseal MC-340 Class B	Fuel tank sealant also used for aerodynamic smoothing and protection of landing gears
Naftoseal MC-770 B-2 Grey	Fuel tank and fuselage sealant

As shown in 3.1.3.5, specifically the section on New Formulation Development, NPE has been removed from MC-216, however due to documentation issues quantification was delayed which further impacted the timeframe for industrialisation.

3.1.4. Annual volume of the SVHC used

The average tonnage of NPE used in sealants for the UK aerospace industry is 40 - 70 kg per year.

3.2. Efforts made to identify alternatives

The preparation of this Review Report has been supported by the Applicant and Airbus. The products are manufactured by an EEA Applicant and used on aerospace products in the UK, as well as the rest of the world. The sealant formulations covered by this Review Report are themselves proprietary and confidential.

As described in Section 3.2.1 extensive research of products that are used in the aerospace supply chain was undertaken as part of the initial process of assessing the potential need for an Application for Authorisation for NPE. This assisted members in the identification of products for which alternative products were not readily available and already qualified, or otherwise in use in aerospace manufacture, MRO or supplier activities.

Here, the distinction between a change in a process chemical/formulation and a formulation that is part of a final delivered aerospace product is important. For process-only chemical formulations, alternatives must be evaluated to ensure they provide equivalent results (e.g., the replacement cleaner performs as well as its predecessor and meets cleanliness requirements). For a chemical formulation that forms part of a final delivered aerospace product (e.g., sealants), testing to confirm equivalent properties is just the first step, as additional evaluations are needed to verify long-term performance of the impacted aerospace component and related assemblies. Both formulation types are important to the aerospace industry and require extensive evaluation and qualification. However, evaluation of anything that forms part of the final delivered product has the additional burden of understanding its properties and performance over the entire life of the aerospace system, including inspect-ability and repair-ability. This additional burden significantly complicates the evaluation required.

Airbus worked with Chemetall, as the formulator of identified NPE-containing polysulfide sealant formulations, to determine the status of NPE within the formulations. The hardeners required for certain polysulfide sealants manufactured by Chemetall were identified in the initial assessment as formulations that contain NPE, are incorporated onto end aerospace assemblies, and for which alternatives were not be available in time for full qualification prior to the Sunset Date and submission of the original EU AfA. These alternatives were addressed in the original EU AfA and further addressed in the review report, as discussed further below.

3.2.1. Research and development

3.2.1.1. Relationship between Formulators and Industry

The formulator qualifies the reformulated sealant against Airbus material specifications. Some tests are managed by the formulators and others are managed or duplicated by Airbus. Therefore, reformulation is often a process of iterative reformulation and repetitive testing until the new formulation satisfies the specifications currently met by the original formulation, as shown in Figure 13.

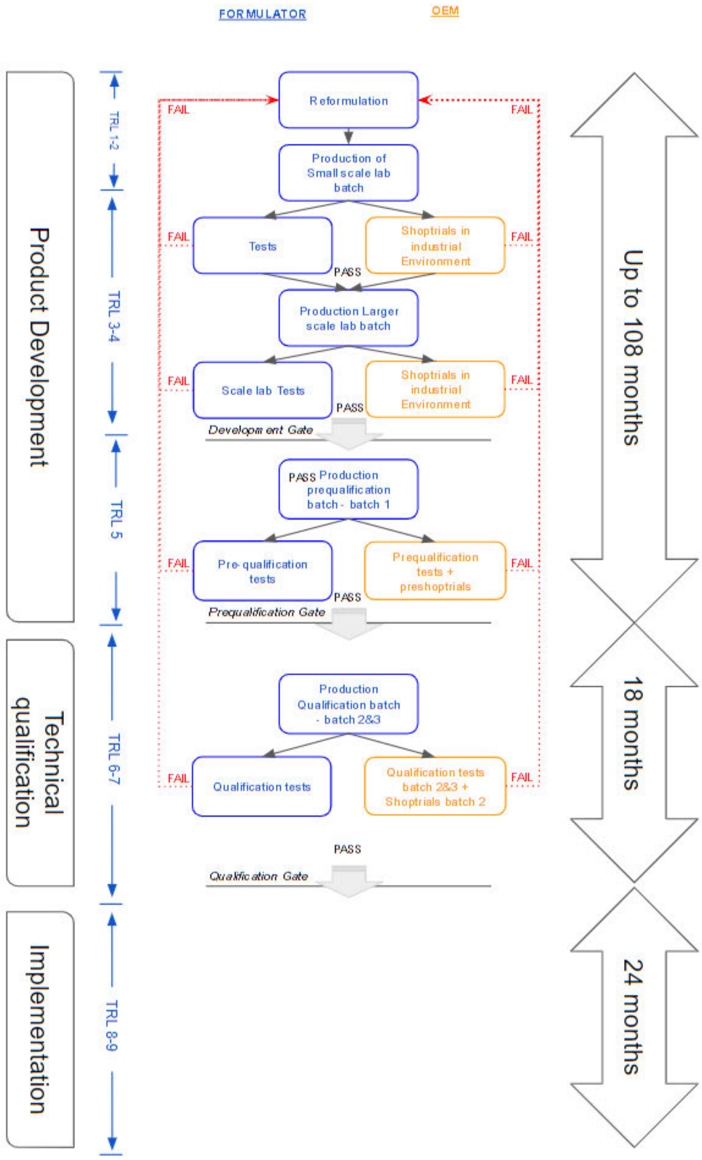


FIGURE 13 RELATIONSHIP BETWEEN CHEMETALL AND AIRBUS TESTING WITH TIMELINE

Go/No Go gates have been implemented in the iterative process of the new formulation qualification between Chemetall and Airbus.

As shown in Figure 13 the Development phase is validated by a Development gate and a Pre-qualification gate. The Qualification gate is passed at the end of the Technical Qualification phase. During the Go/No Go gates, the performances measured by both Chemetall and Airbus are examined and a decision is made to go further in the qualification process if all the performances are met or to go back to the previous step if one or several performances is not reached. This way of working between formulator and industry allows to align the expectation on materials requirements and focus effort from all parties to reach a common goal. For example, during the shop trials that take place at Development in an Airbus production site, Chemetall can witness the test and understand what is really expected as manufacturability criteria.

The collaborative approach will be implemented across the full substitution project for each sealant referenced until an NPE free alternative is completely deployed in all the impacted production sites.

3.2.1.2. Research and Development Activities by Formulator

The Applicant has undertaken significant research and development activities. The Applicant is the formulator of the final products, with formulation taking place in the EU. Whilst the formulation use is not within the scope of this Review Report the impacts of changes to the formulation are crucial when assessing research and development activities, available alternatives, and substitution timelines. Therefore, this AoA-SEA will address these efforts carried out by the Applicant in the EU.

As noted in the original AfA there is a vast variety of surfactants in the market based on different chemistries. Unfortunately, many of them develop their full potential only in aqueous environments or water-rich formulations (e. g. dish detergents). Surfactants for emulsions (oil in water / water in oil) or dispersions (solids in liquids) differ significantly in their impact on product performance and require specific designs. During preliminary reformulation activities, it was identified that surfactants that are not derived from NPE substance are not as efficient at bonding the MnO_2 particles into the rest of the liquid hardener mix. It was also determined that, contrary to initial expectations, it is not a straight-forward process to find a suitable alternative surfactant that works to the same standard but does not contain NPE. The Applicant stated in the original AfA that this could be due to competition between the surfactant constituent and the adhesion promotor constituent of the formulation, both of which are surface active. As adhesion is a key property of the sealants for Chemetall customers, the Applicant is also continuing the assessment of reformulating the adhesion promotor constituent of the formulation for these products separately.

The Applicant has screened >100 different surfactants and has been investigating suitable alternatives for NPE surfactants in its polysulfide sealants containing NPE. The first step of a surfactant screening involved a desk-based exercise. The experts checked the chemical basis of the surfactant and estimated its probability of success in the formulation. In addition, the EHS rating of the substance was evaluated, and only acceptable substances were considered for further testing. Chemetall also asked suppliers of surfactant products to recommend types of surfactants that might fulfil the intended purpose. As Chemetall formulations contain many [redacted]) ingredients in total, even the best chemists cannot reliably predict based on theory alone whether a surfactant will work in the formulation or not. For this reason, many trial-and-error type screenings in the laboratory are also essential. CBI 2

The chemical nature of the surfactants varies [redacted]). In many cases, the full chemical nature of the surfactant tested was not available to Chemetall due to confidentiality of the supplier. The best candidates in the trial-and-error screenings are then implemented in a hardener formulation and thoroughly tested according to target customers specifications and other parameters, such as optical appearance, homogeneity, storage stability and others. CBI 2

As noted in the original EU AfA the Applicant had previously identified and developed a promising candidate alternative sealant formulation, but it did not pass technical qualification testing by the OEMs for all the sealants formulations, due to unanticipated issues with the lack of adhesion of the sealant to different substrates during the final testing phase. This demonstrates the importance of undertaking the requalification activities, both for the Applicant and for OEMs, and that unanticipated failures can occur, resulting in the potential for several testing iterations to ensure the candidate alternative(s) fully meet OEM performance requirements, as per specifications.

The remaining potential alternatives originally identified in the EU AfA are still being investigated and tested for suitability, and the initial testing procedures can take a significant amount of time, as there are testing parameters that cannot be accelerated or amended and are dependent on each other to proceed. For example, a candidate alternative sealant could require several weeks to fully cure, which must occur as per the specification timeframe and with no other performance issues, before the cured candidate alternative sealant can then be strength tested and undergo environmental exposure testing as well.

The potential alternative formulation is initially assessed against environmental, health and safety (EHS) criteria to reduce the likelihood of new formulations containing substances that may be subject to later regulatory measures. Initial basic tests are conducted on the reformulation at laboratory phase, such as stability, and are duplicated to demonstrate that the results are repeatable.

If the reformulation passes the initial laboratory testing, the R&D testing process proceeds to the production phase, in which initial small (bench) scale testing is completed and then progresses on to full scale batch production testing, to identify issues in the manufacturing of the hardener component of the sealant that may result from the change in formulation. If the reformulation fails at the laboratory or production phase, then no further R&D activity or testing is carried out. However, if it passes these stages, the reformulated hardener and mixed sealant is tested to relevant sealant specifications, which can vary according to the OEM specifications. For example, some specifications require immersion testing in fuel for 2 weeks at higher temperatures, whereas other customers request 1000-hour (42-day) immersion testing in fuel at lower temperatures. The longest test runtime required for some customers is immersion in fuel for 4,500 hours (half a year). The Applicant has identified that the water penetration and fuel immersion tests are the most important and, therefore, if the alternative does not pass the adhesion/lamination criteria for those tests, then further research and development is not conducted on that option. Where possible, different specification testing is run in parallel to complete the process as quickly as possible. Even with testing completed in this way, it generally takes approximately 2.5 months to complete initial testing and, considering that tests must be run in duplicate to ensure repeatable and robust results, testing can generally take 5-6 months in total. Additionally, new composites used in aerospace parts have been recently introduced that also need to be tested to confirm compatibility with the reformulated sealants, and this also takes time. As per Section 3.2, the product development process is not strictly linear, as some pre-qualification testing can be done by the OEM, before the alternative sealant proceeds to the Technical Qualification phase.

In the original AfA the Applicant stated they aimed to introduce an NPE-free reformulated candidate alternative polysulfide sealant to the OEMs ready to commence technical qualification by Q2 2021. However, it was noted with the same AfA that such an outcome was by no means assured and it must be noted that previous efforts were not successful. By submitting this review report the Applicant can confirm that timeline for substitution of NPE within sealants used by Airbus as its largest customer was not successful.

3.2.1.3. Research and Development Activities by Airbus

Development of aerospace assemblies and end products is a complex process that must consider not only the design of the part, but also its use and maintenance history in varied climates and service environments.

Determining the extent of the testing required to qualify and implement a new or alternative formulation, product or technology is on a case-by-case basis, due to the many design parameters considered to quantify the risks of substitution for each specific use of the alternative in the aerospace system. These include but are not limited to:

1. Design of the part or assembly (e.g. substrate, inclusion or proximity to dissimilar substrates or mating surfaces, crevices that can entrap liquids, structural stress and strain environment, etc.)
2. Environmental conditions within the aerospace product (e.g. location, presence of condensation or liquids, entrapment of liquids, temperature range, microbial growth, etc.)
3. External environmental conditions (humidity, wind / rain erosion, impact from runways, exposure to fluids like de-icers and hydraulic fluids, etc.)
4. Probability of finish deterioration during use (e.g. chipping, scratches, abrasion, erosion, corrosion, etc.)
5. Historical performance in similar aerospace uses
6. Previous issues due to variation in maintenance practices
7. Ability to inspect during the lifetime of the product

Materials specialists, in conjunction with manufacturing engineering, develop extensive qualification test programmes performed in laboratories and in industrial conditions to cover material properties and requirements, as well as process parameters, as per specifications, considering design and maintenance aspects.

During the Product Development phase, the formulator runs some qualification testing on the reformulation to verify key properties and requirements until a NPE free sealant is found. Once the formulator's production samples of NPE-free sealants are available, Airbus will proceed with preliminary shoptrials to ensure the new formulations can be applied in the industrial environment in the same way, i.e. following the same process steps, parameters and equipment as with the existing formulations (in Figure 13: In Product Development phase: Shoptrials in industrial environment). If Airbus's requirements are met the Development gate is successfully passed and the Prequalification can commence.

The first Airbus test campaign includes tests on requirements prior and after environmental exposure (e.g. fuel immersion, water immersion…), as previously illustrated in Table 3 and Table 4 (in Figure 13: at the end of Product Development phase: Prequalification tests). Typically, the required level of performance for main properties, such as peel strength, tensile strength, hardness, etc. will be checked. Some immersion tests in fuel, water, de-icing fluid, as well as air exposure tests, will be also conducted in Airbus laboratories. Some tests, such as water immersion, have long lead times and require a minimum of 3 months to complete, including preparation, test duration and analysis.

In parallel, preliminary shoptrials consisting of several checks for key process parameters, such as mixing ability, appearance, curing time, roller application in different positions, fillet application, covering of fastener, reparability, shrinkage, etc., will also be carried out (in Figure 13: at the end of Product Development phase: Pre-shoptrials).

Once all key requirements, properties and behaviours in a laboratory environment have been tested successfully, the formulations and key process parameters are fixed, the Prequalification gate is successfully passed and the official technical qualification testing programme can commence with formulators site-specific production batches (batches coming from a production line, not a lab environment). A comprehensive test program is then conducted in laboratories at Airbus and Chemetall, and extensive industrial trials at Airbus facilities are also repeated with these new production batch samples to confirm shop floor acceptance and repeatability (in Figure 13: In Technical Qualification phase: Qualification tests and Shoptrials).

3.2.1.4. Summary of Past R&D Activities

Volume of tests

There are 7 sealant references ([redacted] etc.) and each sealant reference has several variants or application times ([redacted]). In total there are 24 sealant variants to reformulate and qualify to Airbus material specification requirements. Two sealant references have completed their qualification test programme (representing 4 sealants variants). It is anticipated that over 20 new formulation variants will be tested in Airbus in at least a dozen sites (laboratory and in facilities) as part of the qualification test programme supporting NPE sealant replacement. This testing will be carried out in the UK and EU, but as the products will be used in the UK results from EU testing are relevant. CBI 2

The number of tests for all sealants variants and for the complete qualification program have been estimated for each phase and indicated in Figure 14 below.

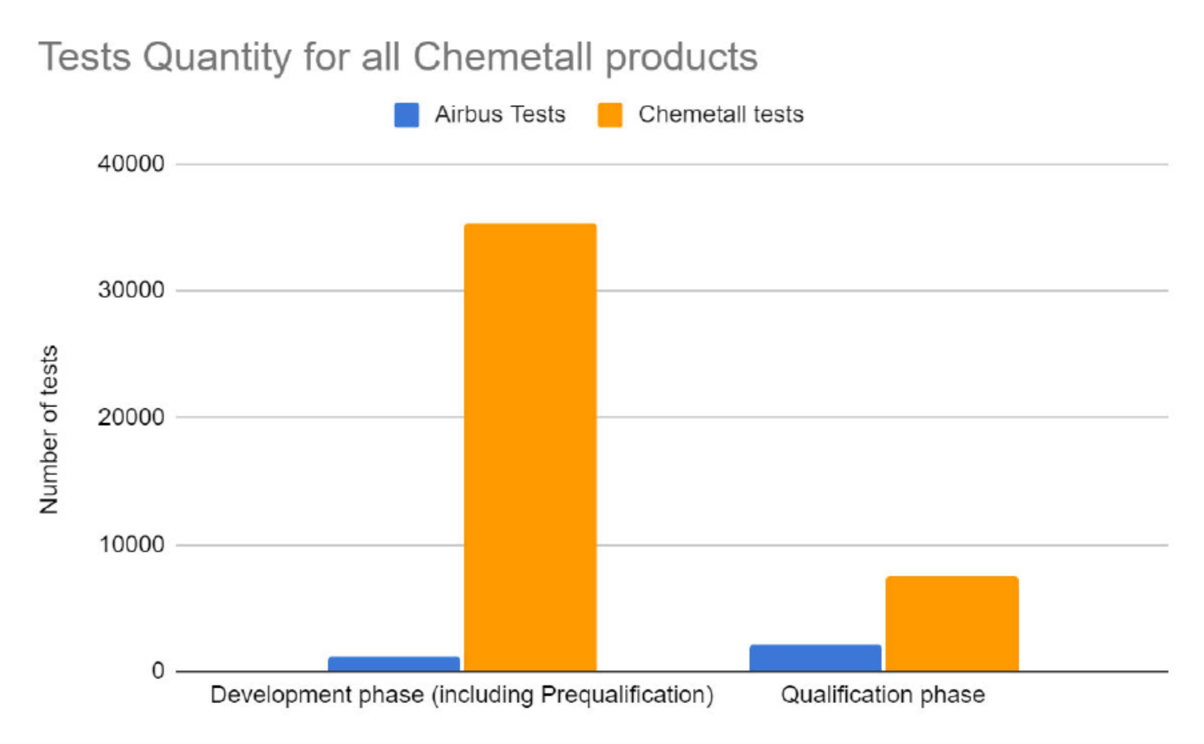


FIGURE 14 NUMBER OF TESTS PER PHASE FOR THE COMPLETE PROJECT

During development (including Pre-qualification), the performance testing represents around 30,000 to 40,000 tests led by Chemetall and 1,000 to 1,500 tests led by Airbus.

During the Qualification phase, around 7 000 to 10 000 engineering tests are led by Chemetall; and 2 000 to 2 500 tests led by Airbus.

Overall, for the complete NPE Development and Qualification test programme it is expected that between 40 000 to 50 000 engineering tests will be done and around 1 000 to 1 500 cartridges will have been tested for the shoptrials in Airbus.

These figures include an approximation of 20% test iterations needed in the event of failures.

The qualification compliance documentation will be issued only when the qualification test campaign has demonstrated that the reformulated alternative sealant is meeting the performance requirements, as per the relevant specifications, see Figure 13.

Summary on main progresses achieved by end of 2022

Sealants produced by the Applicant are complex two component systems comprising of a hardener and base material. Combined they consist of more than 20 different ingredients.

The exchange of one of these ingredients can have various and unpredictable effects on the properties of the finished product. In addition to that, many of the properties of the sealant are of a contrary nature. That means, when some ingredient has a positive influence on the elongation of the sealant, it can be disadvantageous for the tensile strength and vice versa. In the end, the formulated sealant is a very sensitive composition and already small changes can have a big influence on the properties. That fact given, even an "easy" raw material exchange can end up being a difficult task when taking into account the huge number of tests to be fulfilled and the time needed to process the workstream.

The Covid pandemic and consequently all of the restrictions that were implemented in the daily work business caused a major delay in the reformulation, development and testing process. For a couple of months almost all workers were forced to work from home, where no suitable testing and laboratory equipment was available. Any worker who was not mandated to work from home had to adhere to the social distancing requirements, limiting the maximum number of people in a room, thus further impacting the schedule. In addition, there was higher than usual time loss due to illness due to positive Covid test results within the workforce and the required quarantine times associated with such tests.

In Q4/2022 one of the key polymers used in two sealant classes alternatives (Naftoseal [redacted]) was discontinued by the supplier. 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. CBI 2

The formulations/recipes of the affected sealant classes alternatives (Naftoseal [redacted]) were already fixed at the time of the discontinuation. Consequently, the recipes of these sealants have to be modified again, and alternatives for the discontinued polymer have to be identified. Therefore, all testing with these formulations became obsolete. CBI 2

To identify a new polymer combination, which leads to acceptable results in all tests, a screening must be conducted in the laboratory. Research and evaluation of data must be done, and after that samples of polymers have to be ordered. These samples will be formulated into the affected sealants and comprehensive testing will be conducted.

Research of polymer alternatives, the lead time for new samples to arrive, the testing including test verifications have to be taken into account for the creation of a new time plan for the development of the affected sealants.

As noted above, in the initial AfA, a significant amount of R&D work has been carried out to substitute the NPE sealants. Figure 15 presents the timeline of all the achievements from the start of the process to the end of 2022. It highlights the progress when the sealants successfully passed the gates or started to be implemented in plants, but also the events outlined above that caused delays to the substitutions such as gates failed, Covid pandemic, and the decision to change the sealants names or to reformulate.

[redacted]

CBI 2

FIGURE 15 CHEMETALL NPE REFORMULATION PROGRESS

At the end of 2022, 4 references out of 7 had completed their development and pre-qualification phases; 3 references were in qualification phase and 2 references were almost completely deployed in Airbus plants. Despite the successful gates passed for certain sealants, other sealants faced some failures. They could either fail a gate or pass it under certain conditions until iterations of reformulation or tests showing successful results. For example, a sealant reference [[redacted]] 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. Another example of delay that can occur during development is the need to reformulate, and this can happen several times in the process.

CBI 2

3.2.1.5. Summary of Past Industrial Activities

[redacted] *industrialisation (deployment) in plants:*

CBI 2

At the time of redaction of this review report, [redacted] (see Table 6) have completed their technical qualification. These 2 sealants have almost successfully completed their industrialisation across a dozen Airbus manufacturing plants. However, [redacted] is blocked in one Airbus production site because of a specific application that cannot allow use of the new qualified product.

<u>Specific application:</u>

[redacted]

[redacted]

CBI 2

CBI 2

[redacted]

[redacted]

[redacted]

3.2.2. Consultations with customers and suppliers of alternatives

A communication was sent in 2021 to inform the Airbus qualified suppliers with general information regarding the submitted AfA, namely Authorisation period, the obligation to comply to Authorisation conditions, and on the strategy for substitution (including the impacted sealants references and alternatives with the expected new names; rationalization; impacted process specifications; industrialisation and next qualifications).

In addition, Airbus included a questionnaire in this communication where the suppliers should report which sealant references they use and their applications. To decrease the risks during industrialisation and to anticipate problems, this questionnaire enabled Airbus to identify suppliers using sealants in exotic applications and set up an action plan and evaluate the risk of the use of specific sealants in the supply chain.

This communication and questionnaire were sent to more than 400 qualified suppliers across the EU and UK in May 2021.

3.2.3. Data searches

The sections above and the original AfA outline the data searches carried out by the Applicant. The alternatives outlined in the section below were initially provided in the initial AfA and are still the best solutions currently available.

3.2.4. Identification of alternatives

The focus regarding alternatives within the review report, as per the original AfA, has been on alternative surfactants that could be used in NPE free sealant hardener formulations. The R&D effort and criteria for accepting an alternative have been outlined in the Sections above. The potential alternative surfactants are detailed in Section 3.2.6 and the assessment of these alternatives is detailed in Section 3.3.

As per the original AfA there has been no further assessment of alternative products or alternative technologies as no alternative existing sealant products that could replace the current NPE-containing sealant products and no alternative technologies that could be implemented to compensate for the lack of NPE in the sealants were identified.

3.2.5. Assessment of rejected alternatives

Table 7 below details the alternative substances that were initially considered but have since been eliminated from further consideration during the R&D phase, due to test failures or issues encountered during testing, so will not be discussed further in this chapter.

TABLE 7 LIST OF POTENTIAL SURFACTANT REPLACEMENTS THAT ARE NO LONGER IN CONSIDERATION

Alternative Substance to NPE	Technical limitations	Economic considerations	Regulatory and Safety concerns	Further R&D?
Poly(oxy-1,2-ethandiyl) alpha-isotridecyl)-omega-hydroxy-phosphate	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	*none*	*GHS H411*	No, the influence on the mechanical properties was too big
Modified Polyester derivative	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Phosphoric acid salt of a copolymer	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	GHS H410	No, the influence on the mechanical properties was too big
Copolymer with pigment affine groups	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Highly crosslinked polyester	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Block-copolymer with pigment affine groups	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big
Solution of an unsaturated poly carbonic acid polymer	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, it was not compatible with other raw materials in the formulation
Modified natural oil	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	none	none	No, the influence on the mechanical properties was too big

3.2.5.1. Manganese Dioxide

As part of the original AfA submission the ECHA Socio-Economic Assessment Committee (SEAC) questioned the possibility of using a different particle size of MnO_2 or replacing MnO_2 with a different curing agent.

With regards to the use of a differing particle size MnO_2 can only be used as a curing agent for polysulfide sealants in a special grade. It needs to be activated with alkali (sodium hydroxide) and in a narrow particle size range. Only a few grades which fulfill the requirements for such a use are available on the market. As the amount of Manganese Dioxide in the hardener for the sealants is very high, all of the available grades need to be combined with a surfactant. Otherwise, it is not possible to guarantee a homogenous distribution of the particles in the plasticizer system of the hardener. The mechanism of dispersal of manganese dioxide within the hardener is outlined in Section 3.1.3.

Regarding the use of a different curing agent, theoretically it is possible to use other oxidizing agents to cure the polysulfide polymer, e.g. organic peroxides, permanganates, lead dioxide or cerium dioxide. Unfortunately, none of these alternative oxidizing agents can provide an equivalent performance level compared to the manganese dioxide curing system. Additionally, some alternative oxidizing agents have other considerations when conducting substitution activities, such as greater hazardous labelling or other health risks. As the sealants are intended for the very demanding Aerospace Market, it is not possible to allow a lower performance level, as reformulated products must meet the many and varied specifications required (see Section 3.1.3.5).

As outlined within this Review Report the Applicant are developing sealants based on a chemistry other than NPE-phosphate, which should not require the dispersing of MnO_2 in a hardener for curing. However, as shown in the sections below these alternatives are not available therefore the Applicant will have to make sure MnO_2 cured material can be produced and provided to Airbus.

From Airbus's perspective, currently there are no suitable alternatives to polysulfide sealant formulations currently qualified for use in aerospace applications. Compliance with safety, airworthiness and technical performance requirements must be demonstrated through qualification. It is therefore not an option to use another product or formulation that is not qualified.

3.2.6. Shortlist of alternatives

Due to the confidential nature of the formulations and OEM-specific uses, for the purposes of qualification, the potential alternatives are each treated as unique, despite similarities in chemical behaviour or composition. Therefore, each re-formulation option must be tested completely for the requirements of its specific design parameters. The potential alternatives assessed in this section have already undergone considerable R&D efforts within the aerospace industry and testing is still ongoing to determine the most suitable alternative to provide as a candidate alternative to Airbus for qualification testing.

The Applicant considers that substitution of the NPE-based surfactant with a surfactant based upon another substance is feasible, although such a substitution has not been successfully identified, based on research to date. Several of the potential surfactant replacements allow for the possibility to produce the hardeners in a similar manner, so equipment/process changes would be minimised. This belief is in part based on the results provided in Section 3.2.1.5 where the Applicant has replaced NPE from one family of sealant. However, as a two-component sealant is a very complex system, with, in total, more than 20 ingredients, unpredicted reactions or interactions between raw materials are always possible. Therefore, comprehensive testing of an amended formulation is always mandatory. With flight safety at stake, the technical performance of any reformulated products, foremost, must demonstrate "equal or better" capabilities with respect to design parameters. As discussed in Section 3.1.3.5, insufficient quantities of MnO_2 being mixed into the hardener component during formulation, and then also during mixing of the hardener and base sealant components, can cause performance issues. For example, this can affect the viscosity of the mixed uncured sealant (which in turn can affect delivery method) and the overall cure time of the sealant, which are both key technical parameters that a candidate alternative product must demonstrate adequate equivalent performance with to pass that test criteria.

At the current state of knowledge, it is not clear which potential alternative(s), will be successful and possibly implemented for aerospace applications within the scope of the AfA and, at what point in time this may be the case. During initial testing, the Applicant has observed the influence of the surfactants used in the hardener component on different sealant properties, such as adhesion, viscosity, aging behaviour, tensile strength and others, and has selected alternative surfactants for the sealant reformulation test programme. That does not necessarily mean that these cannot successfully be used as alternatives to the NPE-containing surfactant, but that at the very least, the amended formulations need to be further adjusted according to the different behaviour of the alternative surfactant in the reformulation. However, it may be the case that even after such adjustments, the reformulated product will not meet performance specifications. This reformulation and testing process can take a significant amount of time, as sealants are complex and sensitive systems (see above). For example, in the experience of the Applicant when assessing replacement surfactants, it may be that the alternative NPE-free surfactant is used and there are no issues with manufacture of the hardener, but when the base and hardener components are mixed and samples prepared for initial testing, it is likely that there will be a failure in a key performance parameter (such as adhesion, application time, etc.). Therefore, further adjustments are required, such as increasing the active hardener component or modifying the adhesion promotors in the hardener, so that when the test is re-run with the adjusted hardener formulation, the mixed sealant meets the required specifications. It can also be the case that in making these adjustments, the mixed sealant then fails on other criteria, such as the viscosity is now too high, and the elongation parameter (degree of strain a sealant can undergo before tensile failure) is affected. This illustrates that the process of creating a candidate reformulated sealant hardener that meets all required specifications can be very iterative and responsive, depending on the initial testing outcomes, and that this can take a significant period.

The following chapter provides a description of the most promising potential alternatives. Table 8 provides an overview and summary results. These alternative surfactants that are based on other substances have been, or are currently, the focus of the Applicant and Airbus, through the continued development and testing of various confidential formulations.

Table 8 is the same list of alternatives provided within the original AfA. The Applicant is still of the opinion that these are the best candidates for substitution but certain events since submission of the original AfA have slowed the assessment process, these have been expanded upon in Section 3.2.1.4. There have also been issues in completing all the reformulations necessary to fulfil the specifications completely.

As such, the Applicant will continue with the assessment of the four alternatives mentioned below.

TABLE 8: SHORTLISTED ALTERNATIVES

Number	**Alternative name**	**Description of alternative**	**Further R&D**
1	Polyglycolether	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes

2	Polyetherphosphate	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes
3	Alkylammonium salt of a copolymer with acidic groups	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes
4	Anionic aliphatic ester	Influence on the viscosity and the aging behaviour, as well as on the mechanical properties	Yes

3.3. Assessment of shortlisted alternatives

3.3.1. Alternative 1: Polyglycol ethers

3.3.1.1. General description of Alternative 1

Trade Name: [redacted]

CBI 2

Polyglycol ethers are polymers composed of glycol ethers. They represent a group of solvents based on alkyl ethers of ethylene glycol or propylene glycol and contain both an ether and alcohol functional group in the same molecule. These functional groups allow for additional sites for hydrogen bonding and compatibility with other substances and, therefore, these substances have good solubility properties and chemical stability. These properties are why these substances are considered as such useful organic solvents, and why they can be used as chemical manufacturing intermediates. Depending on whether they are manufactured from ethylene oxide or propylene oxide, they are categorised into either ‘e-series’ or ‘p-series’ glycol ethers, respectively. P-series glycol ethers are more commonly used in surfactant formulations, such as degreasers or cleaning agents. Most glycol ethers are water-soluble, biodegradable and generally have no or low hazard classifications. The surfactant containing polyglycol ether currently being assessed by the Applicant has a flash point >100 °C and it creates a relatively pH neutral solution (pH 5-7) when mixed with water.

3.3.1.2. Availability of Alternative 1

The surfactant product based on polyglycol ether is commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener components utilising this surfactant option, this is controlled primarily by the outcome of the Applicant’s technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with Airbus.

3.3.1.3. Safety considerations related to using Alternative 1

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure the replacement surfactants do not contain any other substances that may be subject to UK regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 1, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

3.3.1.4. Technical feasibility of Alternative 1

Alternative 1, through initial tests, has demonstrated that it fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previous formulation containing NPE. However, use of Alternative 1 results in significant impacts on the mixed sealant mechanical properties, viscosity and adhesion properties to some substrates and is not currently considered as satisfactorily meeting the performance criteria on all tested substrates. It has been observed to increase or otherwise affect the viscosity of the hardener component, which in turn affects the performance and stability of the hardener over time, as well as impacting shelf life of this sealant component. Through these R&D activities, it has been determined that Alternative 1 is not suitable for use in all sealant hardener formulations.

Therefore, further reformulation work is required before Alternative 1 can be considered as a technically viable alternative, as any sealants containing reformulated hardener components must comply with the appropriate specifications and product performance parameters to be considered as a viable, interchangeable alternative product. At this stage, whilst the Applicant's R&D team is positive that these technical challenges could be overcome in time through further formulation adjustment, it is unclear if this potential alternative will be carried forward for further R&D activities, depending on the testing outcomes of the other potential alternatives.

A further risk for Alternative 1 is the chance that the reformulated hardener may not be successfully approved by Airbus, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by Airbus. If this situation occurs, this will negatively impact upon the timeline and delay the replacement of the current sealants with NPE free versions.

3.3.1.5. Economic feasibility of Alternative 1

The economic impact due to changes in raw material prices is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost profile. It is also not expected that there will be any manufacturing equipment changes due to changes in surfactant. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 (£171,500 approx.) per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate alternative, but even so, the cost of conducting laboratory and production phase testing is significant.

For Airbus, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, sub-assemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants, to ensure that the replacement product meets Airbus specifications and performs as expected. Overall, the replacement costs for the entire operation are estimated to be several millions of euros. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant, to replace the NPE in the hardener component of the sealant.

3.3.1.6. Suitability of Alternative 1 for the applicant and in general

There are no concerns on availability of Alternative 1 or any further UK regulatory controls expected for components of this surfactant blend, as currently known. There is no significant economic impact on the Applicant for switching to use of Alternative 1 and this is not expected to impact upon the final pricing of the sealants. The primary economic impact of Alternative 1 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 (£171,500 approx.) per month for the Applicant. Once there is a reformulated product using the most successful candidate alternative, there will also be a cost to Airbus to conduct the qualification of the reformulated sealant. These economic impacts are not specific to Alternative 1 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing polyglycol ethers instead of NPE has been shown in initial laboratory testing to suitably disperse MnO2 particles in the hardener formulation but has been shown to cause significant impacts on the mechanical, adhesion, curing and viscosity properties of the mixed sealant, as well as causing issues with the stability and viscosity of the hardener over time. Despite this Alternative not currently meeting the definition of a technically feasible alternative, the Applicant is still conducting some reformulation work and laboratory testing is still ongoing. It is anticipated that the issues with adhesion, curing and performance over time can be addressed, but further progression of Alternative 1 is also dependant on the outcomes of laboratory testing for the other potential alternatives. The Formulator believes that NPE will be able to be successfully replaced, either with Alternative 1 or another potential alternative, in the sealants and provided to Airbus to commence qualification testing by Q4 2026.

The timeline for qualification and industrialisation of the reformulated products is provided in Section 4.1.3. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3.5 years (18 months for qualification following sealant formulation development and 24 months for industrialisation). However, the possibility that the reformulated products may not be successfully approved due to a product, or several products, not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current sealants is complete. The intent of this Review Report is to allow enough time to successfully complete qualification, industrialization and supply chain implementation of the NPE-free sealant versions.

3.3.2. Alternative 2: Polyether phosphate

3.3.2.1. General description of Alternative 2

Trade Name: [redacted]

CBI 2

Polyether phosphate esters are esters of phosphoric acid with polyalkylene glycol ether(s), with a generic formula of R-(AO)n-P(O)(OH)3-n, where n is an integer from 1 to 3. They can be prepared by reacting a polyalkylene glycol ether with a phosphating agent. These phosphate esters, and salts thereof, are useful as extreme pressure/anti-wear additives. The flash point of the substance is above 100 °C and it has an acidic pH when mixed with water (1.5-2.5 pH).

3.3.2.2. Availability of Alternative 2

The surfactant product based on polyether phosphate is readily and commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener components utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with Airbus.

3.3.2.3. Safety considerations related to using Alternative 2

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure the replacement surfactants do not contain any other substances that may be subject to UK regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 2, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

3.3.2.4. Technical feasibility of Alternative 2

Through initial tests, it has been demonstrated that Alternative 2 fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previously used NPE-phosphate based surfactant. Use of this Alternative in the hardener formulation has been demonstrated in laboratory testing to have improved the viscosity and stability of the hardener, compared to the NPE-phosphate based surfactant. This Alternative has been shown to be suitable for use in all hardener formulations and has equivalent performance with the NPE-phosphate surfactant in relation to the viscosity, curing, adhesion and mechanical properties of the mixed sealant, when used in the hardener formulation.

This is currently the most technically feasible alternative out of the different potential alternatives listed, and only final adjustments are thought to be required for use of this Alternative in hardener formulations going forward.

A further risk for Alternative 2 is the chance that the reformulated hardener may not be successfully approved by Airbus, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by Airbus. If this situation occurs, this will negatively impact upon the timeline and delay the replacement of the current sealants with NPE free versions.

3.3.2.5. Economic feasibility of Alternative 2

Similarly, to Alternative 1, the economic impact due to changes in raw material prices for Alternative 2 is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost. It is also not expected that there will be any manufacturing equipment changes due to changes in surfactant. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 (£171,500 approx.) per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate, but even so, the cost of conducting laboratory and production phase testing is significant.

For Airbus, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or to the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, subs-assemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants to ensure that the replacement formulation meets the Airbus specifications and performs as expected. Overall, the replacement costs for the entire operation is to be several million euros. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant to replace the NPE in the hardener component of the sealant.

3.3.2.6. Suitability of Alternative 2 for the applicant and in general

There are no concerns on availability of Alternative 2 or any further UK regulatory controls expected for components of this surfactant blend, as currently known. There is no significant economic impact on the Applicant for switching to use of Alternative 2, and this is not expected to impact upon the final pricing of the sealants. The primary economic impact of Alternative 2 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 (£171,500 approx.) per month for the Applicant. Once there is a reformulated product using the most successful alternative, there will also be a cost to Airbus to conduct the qualification testing for the reformulated sealant. These economic impacts are not specific to Alternative 2 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing polyether phosphate, instead of NPE, has been shown in initial laboratory testing to suitably disperse MnO_2 particles in the hardener formulation, not to cause any issues during manufacture, and to not adversely affect the viscosity and sealant of the hardener. Equivalent performance of mixed sealant using hardeners containing Alternative 2 has also been demonstrated for the mechanical, adhesion, curing and viscosity properties of the mixed sealant. Alternative 2 is currently considered as the most promising potential alternative, as it works in all sealant hardeners and most results are within specification, but final formulation adjustments are needed. The Applicant believes that NPE will be able to be successfully replaced, and this is currently thought to be most likely with Alternative 2, in the sealants and provided to Airbus to commence qualification testing by Q4 2026.

The timeline for qualification and industrialisation of the reformulated products is provided in Section 4.1.3. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3.5 years (18 months for qualification following sealant formulation development and 24 months for industrialisation). However, the possibility that the reformulated products may not be successfully approved due to a product, or several products, not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current sealants is complete. The intent of this Review Report is to allow enough time to successfully complete qualification, industrialization and supply chain implementation of the NPE-free sealant versions.

3.3.3. Alternative 3: Alkylammonium salt of a copolymer with acidic groups

3.3.3.1. General description of Alternative 3

Trade Name: [redacted] CBI 2

"Alkylammonium salt of a copolymer with acidic groups" is a type of quaternary ammonium salt (QAS), which are commonly used in anti-microbial disinfectants and surfactants, due to the high solubility of these compounds in water. These are typically formed of alkyl groups in a long hydrocarbon chain, with different functionalities, e.g. methacrylic acid copolymer containing pendant carboxylic acid groups.

3.3.3.2. Availability of Alternative 3

The surfactant product based on alkylammonium salt of a copolymer with acidic groups is readily and commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener components utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with Airbus.

3.3.3.3. Safety considerations related to using Alternative 3

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure that the replacement surfactants do not contain any other substances that may be subject to UK regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 3, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

3.3.3.4. Technical feasibility of Alternative 3

Alternative 3, through initial tests, has demonstrated that it fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previously used NPE-phosphate surfactant. Alternative 3 is considered suitable for use in all hardeners and no issues with the viscosity of the hardener have been encountered. However, use of Alternative 3 has a slight impact upon the stability of the hardener, and further work is required to match the efficiency of the NPE phosphate surfactant in this respect. Use of Alternative 3 has been demonstrated to have slight negative impacts upon the curing, adhesion and viscosity of the mixed sealant, and significant impacts on the other mechanical properties of the sealant.

However, despite these issues, Alternative 3 is considered one of the more technically feasible alternatives after Alternative 2. Further reformulation work is required before Alternative 3 can be considered as a technically viable alternative, as any sealants containing reformulated hardener components must comply with the appropriate specifications and product performance parameters to be considered as a viable, interchangeable alternative product. At this stage, whilst the Applicant's R&D team is positive that these technical challenges could be overcome in time through further formulation adjustment, it is unclear if this potential alternative will be carried forward for further R&D activities, depending on the testing outcomes of the other potential alternatives.

A further risk for Alternative 3 is the chance that the reformulated hardener may not be successfully approved by Airbus, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by Airbus. If this situation occurs, this will negatively impact upon the timeline and delay the replacement of the current sealants with NPE free versions.

3.3.3.5. Economic feasibility of Alternative 3

Similarly, to Alternatives 1 and 2, the economic impact due to changes in raw material prices for Alternative 3 is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost profile. It is also not expected that there will be any manufacturing equipment changes due to changes in surfactant. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 (£171,500 approx.) per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate, but even so, the cost of conducting laboratory and production phase testing is significant.

For Airbus, it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, subassemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants, to ensure that the replacement formulation meets Airbus specifications and performs as expected. Overall, the replacement costs for the entire operation is to be several million euros. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant, to replace the NPE in the hardener component of the sealant.

3.3.3.6. Suitability of Alternative 3 for the applicant and in general

There are no concerns on availability of Alternative 3 or any further UK regulatory controls expected for components of this surfactant blend, as currently known. There is no significant economic impact on the Applicant for switching to use of Alternative 3, and this is not expected to impact upon the final pricing of the sealants. The primary economic impact of Alternative 3 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 (£171,500 approx.) per month for the Applicant. Once there is a reformulated product using the most successful alternative, there will also be a cost to Airbus to conduct the qualification testing of the reformulated sealant. These economic impacts are not specific to Alternative 3 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing an alkylammonium salt of a copolymer with acidic groups has been shown in initial laboratory testing to disperse MnO_2 particles equivalently to the previously used NPE-phosphate surfactant, no issues with the viscosity of the hardener have been encountered and is considered as suitable for use in all hardener formulations. However, use of Alternative 3 has a slight impact upon the stability of the hardener, and use of Alternative 3 has been demonstrated to have slight negative impacts upon the curing, adhesion and viscosity of the mixed sealant, and significant impacts on the other mechanical properties of the sealant. Alternative 3 is currently considered as the second most promising potential alternative, as it works in all sealant hardeners and most results are within specification, but further reformulation work and testing is required to address the current gaps in performance. The Applicant believes that NPE will be able to be successfully replaced, and this is currently thought to be most likely with Alternative 2, in the sealants and provided to Airbus to commence qualification testing by Q2 2026.

The timeline for qualification and industrialisation of the reformulated products is provided in Section 4.1.3. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3.5 years (18 months for qualification following sealant formulation development and 24 months for industrialisation). However, the possibility that the reformulated products may not be successfully approved due to a product, or several products, not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current sealants is complete. The intent of this Review Report is to allow enough time to successfully complete qualification, industrialization and supply chain implementation of the NPE-free sealant versions.

3.3.4. Alternative 4: Anionic aliphatic ester

3.3.4.1. General description of Alternative 4

Chemical Name: [redacted] CBI 2

Trade Name: [redacted]

An anionic aliphatic ester is an open hydrocarbon chain with alkyl functional groups and an overall negative charge. These substances are derived from an alcohol that is reacted with an acid (organic or inorganic) resulting in at least one –OH (hydroxyl) group being replaced by an –O–alkyl (alkoxy) group. These additional alkyl functional groups allow for additional sites for hydrogen bonding and promote compatibility and solubility with other substances, which is why they are included in surfactant blends. The surfactant currently being assessed by the Applicant contains Dioleyl maleate (CAS 105-73-7), which has a flash point > 275 °C and is not classified as hazardous.

3.3.4.2. Availability of Alternative 4

The surfactant product based on anionic aliphatic ester is readily and commercially available, and the Applicant has confirmed that the suppliers for this surfactant have no plans to withdraw the surfactant from the market in the foreseeable future. Therefore, there are no anticipated issues with the availability of this alternative surfactant. Regarding availability of ensuing sealant hardener component utilising this surfactant option, this is controlled primarily by the outcome of the Applicant's technical and performance parameter testing, before determining if this alternative will proceed to the next phase of qualification testing with Airbus.

3.3.4.3. Safety considerations related to using Alternative 4

Any alternative surfactant product that is considered as a potential alternative to the current one in use that contains NPE, has gone through initial EHS assessment to ensure that the replacement surfactants do not contain any other substances that may be subject to UK regulatory control in the foreseeable future. Therefore, only surfactants with non-hazardous labelling requirements have been considered. The ingredients already present in the hardener and base components of the sealant have undergone similar assessment in the past, and as such, use of Alternative 4, instead of the current surfactant containing NPE, would result in a hardener that has reduced environmental hazard risk, and is not expected to be subject to any further regulatory control measures at the current state of knowledge. This is true for any of the Alternatives listed.

3.3.4.4. Technical feasibility of Alternative 4

Alternative 4, through initial tests, has demonstrated that it fulfils the performance criteria of facilitating adequate dispersion of the MnO_2 in the plasticiser liquid during manufacture of the hardener, equivalent to the previously used NPE-phosphate surfactant. However, use of Alternative 4 results in significant impacts on the mixed sealant mechanical properties, viscosity and adhesion properties to some substrates and is not currently considered as satisfactorily meeting the performance criteria on all tested substrates. It has been observed to increase or otherwise affect the viscosity of the hardener component, which in turn affects the performance and stability of the hardener over time, as well as impacting shelf life of this sealant component. Through these R&D activities, it has been determined that Alternative 4 is not suitable for use in all sealant hardener formulations.

Therefore, further reformulation work is required before Alternative 4 can be considered as a technically viable alternative, as any sealants containing reformulated hardener components must comply with the appropriate specifications and product performance parameters to be considered as a viable, interchangeable alternative product. At this stage, whilst the Applicant's R&D team is positive that these technical challenges could be overcome in time through further formulation adjustment, it is unclear if this potential alternative will be carried forward for further R&D activities, depending on the testing outcomes of the other potential alternatives.

A further risk for Alternative 4 is the chance that the reformulated hardener may not be successfully approved by Airbus, if the hardener component or end sealant does not meet the technical and performance specifications as expected. This is not anticipated to be the case, but it remains a small risk. If there was a gap in performance compared to the specifications, the Applicant may need to conduct another round of R&D work and reformulate the hardener further until the sealant criteria were met, and the new formulation was qualified by Airbus. If this situation occurs, this will negatively impact upon the timeline and delay the replacement of the current sealants with NPE free versions.

3.3.4.5. Economic feasibility of Alternative 4

The economic impact due to changes in raw material prices is not expected to be significant, as these surfactants are used in low concentrations in the overall formulation and have a relatively equivalent cost profile. Due to the differences in mechanical properties of the hardener manufactured with this potential alternative surfactant, it is possible that use of Alternative 4 may require manufacturing process or equipment changes, which will inherently incur additional cost. However, a more significant economic impact on the Applicant is the investment undertaken in the current engagement of personnel in the evaluation and testing of alternatives. This must be done for almost all formulations and against all relevant specifications. The R&D costs to the Applicant for alternative substance screening, formulation and testing of potential alternatives are approximately €200,000 (£171,500 approx.) per month. Once a candidate alternative has been identified as the most feasible option, it is expected that these costs will reduce, as the efforts and any further testing would then be focussed on one candidate, but even so, the cost of conducting laboratory and production phase testing is significant.

For Airbus it is not expected that the change in surfactant will have any significant impact upon the price of the sealants or the different forms in which the product is currently made available. This product reformulation is not expected to influence the end cost of the aerospace products, sub-assemblies or assemblies. As with the Applicant, the primary economic impact is due to the qualification testing that must be conducted on any reformulated sealants, to ensure that the replacement formulation meets Airbus specifications and performs as expected. Overall, the replacement costs for the entire operation is to be several million euros. This cost would be required for any reformulated product, regardless of which Alternative is chosen by the Applicant to replace the NPE in the hardener component of the sealant.

3.3.4.6. Suitability of Alternative 4 for the applicant and in general

There are no concerns on availability of Alternative 4 or any further UK regulatory controls expected for components of this surfactant blend, as currently known. There may be impacts on the manufacture process or equipment resulting from switching to use of Alternative 4, which would incur additional cost on the Applicant. However, the primary economic impact of Alternative 4 is the cost and work involved in the screening, formulation and testing of potential alternatives, which is estimated at a cost of €200,000 (£171,500 approx.) per month for the Applicant. Once there is a reformulated product using the most successful alternative, there will also be a cost to Airbus to conduct the qualification testing of the reformulated sealant. These economic impacts are not specific to Alternative 4 and would apply to any of the potential alternatives currently under assessment.

Use of a surfactant containing anionic aliphatic ester instead of NPE has been shown in initial laboratory testing to suitably disperse MnO_2 particles in the hardener formulation but has been shown to cause significant impacts on the mechanical, adhesion, curing and viscosity properties of the mixed sealant, as well as causing issues with the stability and viscosity of the hardener over time. Despite this Alternative not currently meeting the definition of a technically feasible alternative, the Applicant is still conducting some reformulation work and laboratory testing is still ongoing. It is anticipated that the issues with adhesion, curing and performance over time can be addressed, but further progression of Alternative 4 is also dependant on the outcomes of laboratory testing for the other potential alternatives. The Applicant believes that NPE will be able to be successfully replaced, either with Alternative 4 or another potential alternative, in the sealants and provided to Airbus to commence qualification testing by Q2 2026.

The timeline for qualification and industrialisation of the reformulated products is provided in Section 4.1.3. It is expected that the process to introduce the reformulated sealant in some specific or less common applications will require more extensive testing. The length of time required to complete the product qualification and industrialisation is estimated to take approximately 3.5 years (18 months for qualification following sealant formulation development and 24 months for industrialisation). However, the possibility that the reformulated products may not be successfully approved due to a product, or several products, not meeting the required performance specifications as expected, cannot be discounted. This would negatively impact the substitution timeline until full requalification and replacement of the current sealants is complete. The intent of this Review Report is to allow enough time to successfully complete qualification, industrialization and supply chain implementation of the NPE-free sealant versions.

3.4. Conclusion on shortlisted alternatives

The assessment of the potential alternatives as replacements for the NPE-phosphate based surfactant is summarised in Table 9. This is the same conclusion that was reached in the initial AfA. The maturity levels of the candidate alternatives are categorised as follows:

- 1 = most promising potential alternative, works in all sealant hardeners, most results are within specification, final adjustments needed
- 2 = promising potential alternative, higher amount is needed, which means higher cost and bigger influence on the whole system, adjustments of the formulation ongoing to compensate
- 3 & 4 = potential alternatives which require further and deeper re-formulation work, however R&D is positive about the feasibility to use the alternatives in the end

TABLE 9: ASSESSMENT OF POTENTIAL ALTERNATIVE OPTIONS

Key Parameter	Potential Alt 1 - Polyglycol ethers	Potential Alt 2 - Polyether phosphate	Potential Alt 3 - Alkylammonium salt of a copolymer with acidic groups	Potential Alt 4 - Anionic aliphatic ester
MnO_2 dispersion properties / Ease of manufacture of hardener	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant
Viscosity of the hardener	OK, but twice the amount is needed to reach the efficiency of the NPE phosphate surfactant	Improved in comparison to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant
Stability of the hardener	poor - viscosity increase over time	Improved in comparison to NPE phosphate surfactant	ok, but a little bit more is needed to reach the efficiency of the NPE phosphate surfactant	poor - viscosity increase over time
Suitable for all sealant hardeners?	no	yes	yes	no

Key Parameter	**Potential Alt 1 - Polyglycol ethers**	**Potential Alt 2 - Polyether phosphate**	**Potential Alt 3 - Alkylammonium salt of a copolymer with acidic groups**	**Potential Alt 4 - Anionic aliphatic ester**
Impacts on mechanical properties of the mixed sealant	significant impact	significant impact	significant impact	significant impact
Impacts on mechanical properties of the mixed sealant after adjustment of the base/hardener formulation	slight impact	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	slight impact
Impacts on the curing behaviour of the mixed sealant	slight impact	equivalent to NPE phosphate surfactant	slight impact	slight impact
Impacts on the viscosity of the mixed sealant	significant impact	equivalent to NPE phosphate surfactant	slight impact	significant impact
Impacts on the adhesion of the mixed sealant	significant impact	significant impact	significant impact	significant impact
Impacts on the adhesion of the mixed sealant after adjustment of the base/hardener formulation	significant impact	equivalent to NPE phosphate surfactant	equivalent to NPE phosphate surfactant	significant impact
Maturity Level	**3**	**1**	**2**	**4**

Overall, the Applicant believes that it will most likely be able to introduce a fully working NPE-free reformulated alternative sealant product to Airbus, ready to commence technical qualification, by Q4 2026. As summarised above potential Alternative 2 (Polyether phosphate) is currently considered as the most mature candidate and will be focussed on as a priority. This alternative is the most likely to successfully complete the development testing phase, before reformulated sealant samples are made available to Airbus for testing. However, the other potential alternatives are undergoing similar development tests, and in the case of multiple viable potential alternatives, the Formulator may use multiple surfactants in sealant formulations going forward to avoid dependence on a single surfactant source. The R&D work with the formulator is still ongoing and is expected to end Q4 2026.

4. Socio-Economic Analysis

4.1. Continued use scenario

4.1.1. Summary of substitution activities

As outlined in Sections 3.2, 3.3 and 3.4 significant R&D substitution activities have been carried out by the Applicant and Airbus.

Within the original AfA a substitution plan was submitted with the aim to have removed NPE from the formulations by 2024. By submitting this review report it is clear that this timeline was not achieved with regards to the sealants meeting Airbus material specifications. As such, a new estimated timeline for qualifying and implementing a candidate alternative NPE-free sealant has been developed. This is provided below:

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

As noted in Section 3.2.6 the Applicant is still of the opinion that the alternatives highlighted within this review report are the best candidates for substitution. In the initial EU AfA and subsequent follow up questions from SEAC the Applicant confirmed that the bulk of the formulator R&D activities would take place in 2020-21. Unfortunately, certain events since the submission of the original AfA have slowed the substitution effort. One such key event was the Covid Pandemic which inevitably slowed down the R&D effort due to resourcing issues due to social distancing guidelines as well as impacting raw material availability, which further impacted the substitution delivery timeline. There have also been issues in completing all the reformulations necessary to fulfil the specifications completely. This is not to say there has not been efforts to complete substitution, as the case study on MC-216 provided in the New Formulation Development chapter of Section 3.2.1.5 shows.

4.1.2. Conclusion on suitability of available alternatives in general

As detailed in the European Commission document on Assessment of Alternatives[10]Article 60(4) of the REACH Regulation stipulates, for the granting of an authorisation under the socio-economic route, two conditions: (1) that the socio-economic benefits outweigh the risk to human health or the environment resulting from that use, and (2) that there are no suitable alternatives. Regarding the second condition, the lead chromate pigments judgment[11] introduced a new element in the assessment of alternatives, i.e. the question whether there are suitable alternatives available in general (SAAG), which was previously not considered.

The General Court clarified that if suitable alternatives are available in general but those alternatives are not technically or economically feasible for the applicant, and if it is shown

[10] https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1

[11] EU General Court judgment of 7 March 2019 in Case T-837/16, Sweden v. Commission

that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, an authorisation may be granted if the applicant submits a substitution plan. In other words, if there are SAAG for the use applied for but the applicant has demonstrated that these alternatives are not feasible for them or their downstream users, then they must also submit a substitution plan.

The General Court provided certain key criteria to identify what is a suitable alternative, these are summarised below
Criteria 'suitable alternative' [par. 72-76 lead chromates judgement]

- Risk reduction: the alternative should be safer.
- Suitability in the EU, the alternative should:
    - not be an alternative suitable *in abstracto* or in laboratory or conditions that are of exceptional nature;
    - be technically and economically feasible in the EU; and
    - be available, from the perspective of production capacities of alternative substances, or of feasibility of the alternative technology, and in light of the legal and factual requirements for placing them on the market.
- Feasibility for the applicant: *'In the context of the socio-economic procedure, it is also necessary […] to determine whether the alternatives established during the authorisation procedure are technically and economically feasible for the applicant.'*

If suitable alternatives are available in general, but they are not feasible for the applicant and their downstream users, an authorisation may still be granted if the applicant submits a substitution plan. The availability of a SAAG, as defined above, that is not feasible for the applicant or its downstream users, is *de facto* a trigger for the requirement to submit a substitution plan.

As outlined in Sections 3.2 – 3.4 there are suitable alternatives in general to the Applicant but these alternatives are not technically feasible. As such, a substitution plan has been included (see Section 4.1.3).

4.1.3. Substitution plan

4.1.3.1. Factors affecting substitution

The key factor affecting substitution is the reformulated sealant adhering to Airbus material specifications. The process for this is described in detail in Section 3.2.1. If Airbus material specifications are not met then substitution cannot happen.

Newly qualified alternative sealants, modified or reformulated sealant, must perform in the same way as current sealants and must be applied following the same process instruction. The interchangeability principle will be applicable, as the alternative product must be a one-to-one replacement. Initially no change of name was planned because the reformulation was supposed to be a minor change in the formula. By keeping the same product name this would have allowed to avoid a documentation update that is time consuming and expensive. However, after a certain amount of development tests it was realized that the reformulation was considered a major change as several modifications in the composition occurred. Due to the risk of confusion between formulations the decision to change name was made in October 2019, after the submission of the initial AfA. Despite the major formulation change, there is still no impact on products interchangeability, e.g., the NPE-containing and NPE-free formulations are expected to be interchangeable. As a result, no aircraft part design changes, e.g. no drawing or part number changes are expected once a candidate alternative sealant successfully completes the qualification process and there is no need for an additional certification step or validation from EASA or relevant military certification authorities.

The technical qualification is usually followed by an industrial qualification of the Applicant's production site to ensure compliance with quality standard EN9100 (e.g. check reproducibility criteria) via a first article inspection (first commercial batch). Once all compliance documentation is available, the deployment of the alternative reformulated sealant in Airbus manufacturing plants and at suppliers can begin. The product can then be used on the aircraft or aerospace equipment and industrialized in production, following relevant internal procedures to trigger the change of product.

The deployment of the reformulated NPE-free versions of polysulfide sealants impacted by this Review Report will concern dozens of Airbus manufacturing sites, and around 150 - 200 suppliers' sites in the UK and EU. A stepwise approach may be utilized, and formulation changes may not be implemented simultaneously across all sites and suppliers, but rather through a phased introduction to minimize technical risks and to benefit from lessons learned. It is currently estimated that the industrialisation step will require 24 months to complete.

4.1.3.2. List of actions and timetable with milestones

The Applicant is applying for a 6-year review period, to finish at the beginning of 2031. The applicant is seeking an authorisation to enable them to transition to an alternative within the requested review period. The updated estimated timeline for qualifying and implementing a candidate alternative NPE-free sealant is as follows (also see Figure 16).

- 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.

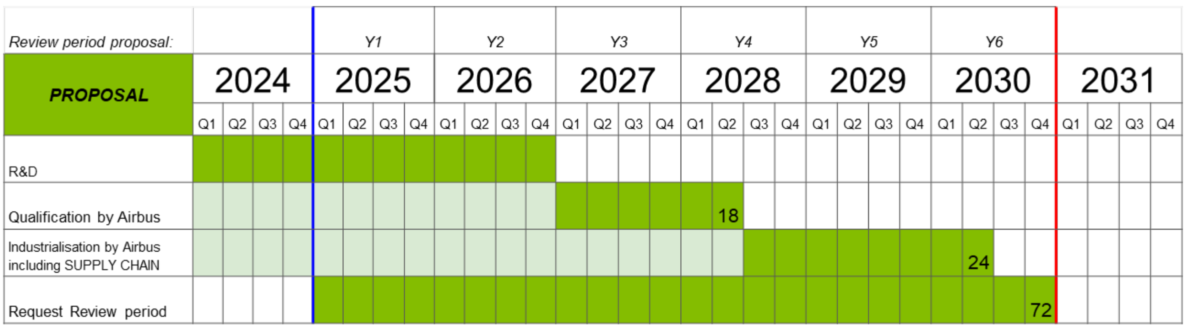


FIGURE 16 NPE REPLACEMENT TIMETABLE

The activities required, and the timelines associated, for the Qualification and Industrialisation steps are detailed below.

Figure 17 shows a distribution of the sealants across the different phases of substitution per year since the beginning of the project in 2019 and during the requested review period until the beginning 2031.

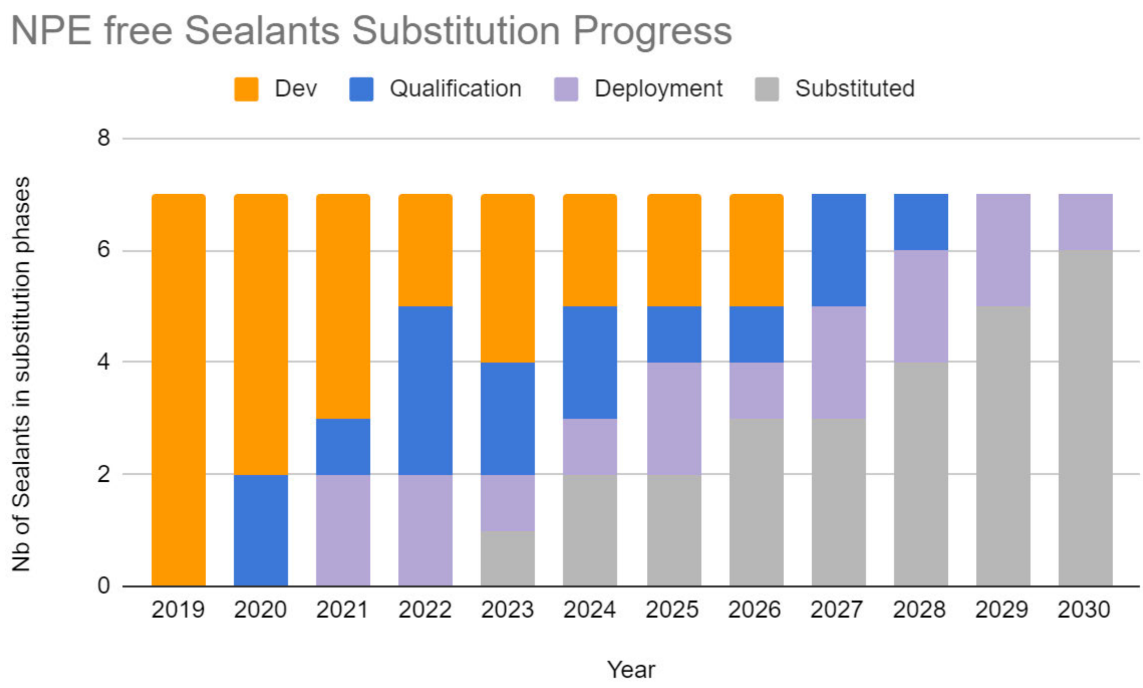


FIGURE 17 EXPECTED PROGRESS OF NPE SUBSTITUTION, BY YEAR

During the 6 years review period (2025-2031) it is expected that 5 (out of 7) NPE free sealants will have completed their development by 2024, and the 2 remaining sealants (MC780MA&C) will end their development phase in 2025-2026. It is expected that 3 sealants will complete their qualification phase (MC780M A, B & C) during the first half of the review period. The industrialisation phase (deployment in plants) will be the main portion of activities during the review period, with 5 NPE free sealants being deployed in plants across the 6 years. Therefore, the use of NPE sealants will be gradually decreased during the review period, especially during the second half of the review period, until reduced to zero use.

However, Figure 17 includes some margins to reasonably cover eventual unexpected delays caused by failures or external events such as raw material discontinued or specific case application requiring a design modification. In the optimised case scenario, the developments, qualifications and deployments phases could be completed sooner than presented in Figure 17 and it is the intention of the Applicants and Airbus to make all efforts to complete substitution before the end of the requested 6 years review period.

R&D (including pre-test)

The R&D work to be done on the sealants consists of different procedures. At first, a screening to determine alternative surfactants (NPE free) as possible alternatives to the affected NPE-containing surfactant used in the sealants. This step is already done, and a number of alternatives have been identified and are described in the document. The main alternative used to exchange NPE in all re-formulated sealants remained the same since the beginning of the project.

One of the main challenges of the R&D work is to tackle the complex combinations of raw materials and to compensate for the effect on properties of the exchanged surfactant. At the beginning of the project the effect of the surfactant on the properties of the sealant, and the capability of fulfilling all tests within the specifications was considered low. It turns out that this is not the case, and that the situation is much more complex.

Lots of raw material screenings, in many different types and classes e.g., fillers, adhesion promoters, additives and polymers had to be performed. The raw materials have to be carefully evaluated, and not only the technical capability within the complex formulation of the sealants is to be considered, but also EHS properties, such as labelling, availability, possible reactions with other ingredients and also the foreseeable future of the material with regards to REACH and other legislation authorities.

Compared to the original qualification of the sealants in the early 2000´s there were also significant changes in the testing and especially in the substrate portfolio used by the customers. The re-formulated sealant has to build up adhesion on many different coatings, metals and also materials like carbon fibre composite. In addition to that, also values in the specification, in particular regarding technological times like tack-free time and curing behaviour were changed in a more demanding way. The re-formulated sealants have to cure much faster than the original versions to enable the optimized application procedures at the customer facilities.

Furthermore, due to dramatically increased energy cost and other reasons, Chemetall faced a crisis like situation on the raw material market. Not only did the prices increase significantly, but also in some cases the availability of raw materials was problematic, resulting in increased lead times or sometimes in discontinuation of raw materials. This overall situation with decreased choice of alternatives makes the re-formulation of sealants even more difficult.

To make a formulation ready for the pre- or qualification process at the customer, the formulation must be tested a couple of times at the formulator. Given the nature of polysulfide-based systems, there is always a deviation of properties and performance from batch to batch. That means all sealants have to be tested thoroughly and with different raw material batches to ensure a reliable quality of the product once the recipe is fixed.

Taking into account the vast number of tests to be performed with each sealant, also considering the number of different substrates, there are lots of potential points for failures. Especially when looking at the contrary effect of changes in the recipe of one of the many ingredients. That means, in many cases after a full set of tests was performed, slight adjustments to the formulation were needed. After these adjustments, all tests had to be performed again. And even in case of a full success, these results have to be verified, to ensure a robust quality of the product.

Qualification

For the Airbus, Qualification usually includes:

- technical qualification of the product; and

- an industrial qualification of Applicant's production site (Chemetall)

Qualification activities are defined as those undertaken by Airbus to validate and document that the changed or new formulation, process or part meets the engineering technical performance requirements detailed in their Qualification Specifications, documented in technical standards or specifications. These activities can include:

- Extensive generic lab testing: testing against the technical requirements of the formulation in a laboratory setting e.g., viscosity, density, working life, tack free time, shelf life, cure time, cure temperature.
- Specific use testing e.g., use as aero fairing/ aero smoothing/aerodynamic coating, use as a fuselage sealant, use as an adhesive.
- Testing of the technical requirement and specific use under different controlled conditions, to simulate the varied conditions the formulation must perform under e.g., compatibility with a wide range of paint and primer systems, resistance to degradation by fuel and other chemicals, use and continued function over a wide range of temperatures, most uniquely extreme cold.
- Component specific testing e.g., use as a faying surface sealant between part of a hinge and the door, can be internal or external.
- Customer specific testing e.g., if a set of customers have very particular different requirements for the end system, and the formulation must function in a specific way to meet those requirements.
- Repeats of the tests to ensure consistency; depending on the complexity of the changes, the qualification process may require more than 100 runs on any test
- Iterative testing in the event of failures. If the formulation does not perform to the specified minimum requirements, then reformulation by the formulator to improve the performance may be required. Qualification continues in an iterative process until successful.
- Engine / flight testing: once passed all other qualification testing requirements, testing, use of the formulation in a final system under controlled conditions may be required before certification will be given.

Each OEM is responsible, according to airworthiness regulations or MOD customer requirements, for its own product qualification, validation and certification. Within a single OEM, even ostensibly 'similar' components or hardware used in different systems/aircraft/engine models have unique design parameters and performance requirements. Whilst there are industry-wide specifications relating to sealants used in aerospace (e.g., Aerospace Materials Specifications, ISO standards, etc.), Qualification Specifications and technical standards for the affected part or entire product typically differs between OEMs, and the process to satisfy those specifications is usually developed within an OEM company and is proprietary information. Therefore, different OEMs may apply different testing methods, or have different qualification activities, according to the variation in qualification specifications and requirements for the new or changed formulation/part or the end component/system. For example, the process for qualifying a unique enclosure that requires a long term, reliable seal must be undertaken by building the unit, exposing it to accelerated life testing, and then performing a leak test. This is an example of a specific test that is not required of other hardware using the sealants.

Qualification is always required when implementing a new or changed formulation, process or part; no change is so minor that it does not require some degree of substantiation. To ensure aircraft safety, comprehensive airworthiness regulations have been in place in the European Union (as well as around the world) for decades. These regulations require qualification 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. However, the time required to complete these systematic checks can vary depending on the type of change. For example, where changing a formulation, if it can act as completely interchangeable, and demonstrate in qualification testing that it can perform to the same level or better than the previous product for all applications under all test conditions, then no further part or design changes (e.g., no drawing, part number, or specification changes, or external approval from the certification authorities) are required. This is a much less extensive type of change, but the qualification activity is still required to be rigorous, and the testing is still thorough. If the new or changed product is not able to act completely interchangeably, then the qualification activities take more time as testing is repeated, with tweaks to potentially affecting factors (e.g., method of application, use with other products etc.) are tested out as well, or iterative reformulation is conducted, until it satisfies the qualification specifications requirements.

Technical Qualification: The target of technical qualification is to compare performance of the new or updated formulation against specification(s). At the qualification stage, the process parameters and formulation are frozen. Tests – according to a qualification test programs – are performed on industrial batches of the formulation. Testing required for qualification of NPE free sealants cannot be accelerated or amended; qualification will take considerable time. Some examples of activities that qualification includes are:

- Preparation of samples for testing by the manufacturer: sealants production at industrial level, including packaging and shipping to the laboratory testing – 3 months.
- Cure of sealants before testing - a candidate alternative sealant could require several weeks or months to fully cure before it can be strength tested and undergo environmental exposure testing. For example with MC780-C48 it could take around 2.5 to 3 months to cure before testing.
- Testing according to specification - the immersion in fuel tests may require 4,500 hours = 6 months.
- Testing the main application – shop trials on plants. It could take around 2 months to test the application for a dozen plants.
- Validation of the results, editing the qualification test report and update of the relevant documents for completed the qualification – 4 to 6 months.

Some sealant applications require frozen sealants, also called premixed and frozen (PMF). These formats of sealant product provide options to the users depending on their requirements and manufacturing processes. Some specific NPE free sealant versions will be tested to validate the mixing, freezing and defrosting processes. The tests on PMF will be performed by the formulator/applicant and by Airbus in parallel with the technical qualification and before deployment in Airbus manufacturing sites The preparation of samples consists in receiving the base and hardener in bulk, mixing them together, filling cartridges and syringes with the mix and freezing them. Then the parameters of mixing, freezing and defrosting are tested on these cartridges and syringes under a complete manufacturing shoptrial test programme.

The volume of sealant needed to perform these tests is estimated to around 300 litres and around a hundred tests are planned. This estimation does not consider the test programme set-up that could require additional material and tests. This test program adds up to the volumetry of material to be produced by the formulator, shipped to the Airbus sites, processed and tested. As at all stages of testing, if any failure is detected potential adaptation or reformulation in the worst case may be needed.

Industrial Qualification of the Applicant's (Formulator) Manufacturing Site: Industrial Qualification is undertaken to ensure that the industrial processes used by the supplier to develop, manufacture and deliver formulations that comply with applicable requirements and the resulting formulations continuously conform to applicable technical data.

Production Process Verification is a Quality standard used to demonstrate the ability of a given Manufacturing System to produce conforming items in serial mode. It refers and answers to EN9100 and EN9102 requirements regarding Production Process Verification. Production Process Verification uses the declarations within the First Article Inspection (FAI) process to provide confidence/objective evidence that product realization processes can produce parts that meet engineering requirements.

Main activities of this step can include:

- Validating the supplier's Industrial qualification dossier and Supply Chain Dossier.
- Checking Quality Assurance Plan if applicable.
- Performing Product audits for product complexity high and/or industrial risks upon Supply Chain and Quality Leader decision.
- Checking Supplier's FAI: The FAI is a documented review of the physical and functional processes conducted by the suppliers to validate that the Production System is capable and to document the product As-Built is conforming to As-Defined. FAI documentation and Quality Management System enables Production System.

The first activities of the Industrial qualification can be performed in parallel of the technical qualification. FAI can only be done, once the technical qualification is completed. Industrial qualification usually takes around 6 months to complete

Documentation Update

Even if the alternatives are interchangeable, Individual Product Specifications (IPS) need to be changed. For example, it is estimated that more than 50 IPS[12] would need to be updated for Airbus Commercial. The specifications and therefore qualification process can vary even within a single company; for Airbus' divisions, the testing methods are similar

[12] identifies a material from a manufacturer that has been successfully qualified to the relevant Material Specification. It specifies individual requirements, which describe the specific performance of the material, as demonstrated by the qualification, and which have to be considered for procurement and use, together with the Material Specification.

but each of division needs to test and validate the qualification under their own specifications.

The Airbus documentation structure is complex, with multiple interdependent organizations and owners depending on each department and production site. Some processes of documentation updates are continuously improved to reach harmonisation. The documentation update of the sealant substitution project, being one of multiple projects to involve documentation update, has to adapt to the local ways of working.

After each new product qualification, all the technical documents impacted by the new sealant reference must be updated with the new product name and specific technical data, when applicable. The following groups of documents are impacted:

- Qualification documents to be updated by Engineering:
  - Create new IPS
  - Withdraw the old IPS at the end of the project

- Process specifications & Instructions to be updated by Manufacturing Engineering or by Engineering depending on the Airbus site
  - Update AIPI & IPDA
  - Update all National process specifications

- Local Manufacturing Engineering documentation to be updated by Manufacturing Engineering
  - Create New Standard & Specified Items (NSPI) requests to standardise the products for the designers and to notify procurement to allow new ordering,
  - Work instructions and other local documentation
  - MNIs, other local documents, etc.

- Customer Support documentation
  - CML (Consumable Material List)
  - SRM (Structure repair manual)
  - PMS (Process & Material Specification)

The estimated number of documents to be updated due to the change of sealants names is very high. In addition to the central documents such as the Engineering documents linked to the technical qualification, the department most impacted by the documentation update is production. For manufacturing engineering documents, a minimum of 5000 to 10000 Work Instructions and 3000 to 5000 routings also named Bill of Materials (BOM) have to be updated through all the production sites. In addition, other manufacturing documents such as Airbus Process Instruction (AIPI), Instruction de Procédés Documentation Avions (IPDA), Kamban and other local documents such as traceability sheets must be updated through all the production plants.

As first estimation, using approximation and some hypothesis (such 2 to 4 iterations of updates per document), the cost due to documentation update of new qualified sealants represents an increase of several million euros.

An example of the impact of documentation on substitution timelines can be seen in the case of formulation MC216M. A delay of approximately 5 to 7 months was experienced at the end of MC216M technical qualification phase in order to update the Airbus material specifications. The Airbus material specifications had to be updated in order to remove an historic requirement of low adhesion to primer that was considered not aircraft relevant. This decision could be made only after all qualification tests were completed. Industrialization in plants could start only once all Engineering documentation was completed. This process, due to the high volume of manufacturing documents to update in all the plants, added approximately 3 to 5 months to MC216M industrialization phase.

Industrialization

Once qualification is complete, the qualified alternative sealant formulation must be industrialized throughout the OEM manufacturing sites and throughout the wider supporting supply chain (30 – 40 UK suppliers).

Industrialisation is 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 (if required), 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.

Even with an interchangeable product that requires no major modifications at industrial sites, this is still an extensive activity to go through and ensure that all actors within the manufacturing process, repair operations and supply chain are switched over to the correct formulation.

The introduction of an alternative formulation in the industrialisation stage is complex and can involve many tiers of the supply chain that provide components that go into the final system. As such, the entire supply chain may be impacted by the alternative formulation, which must be implemented in accordance with the stringent safety procedures in place.

Industrialisation may be scheduled to follow a stepwise approach to minimise the technical risks and to benefit from lessons learned. This means that changes may not be implemented universally or simultaneously across all sites and at all suppliers but rather via a phased introduction. For example, Airbus operates dozens of manufacturing sites / final assembly lines worldwide. For existing production, long-term agreements (contracts) are often in place with suppliers. When a change is made to a product design to incorporate a new alternative, the contract with the supplier may need to be renegotiated as well.

Industrialisation is estimated to take up to 24 months; it may be completed more rapidly in some cases. Although the Applicant, Airbus are optimistic that the alternatives for sealant formulations covered by this Review Report will be relatively easy to implement and industrialise, this is by no means assured until all the testing and evaluations have been successfully completed. At Airbus manufacturing sites, the process of industrialization can be described as in the diagram below. This is for each site (plant where sealants must be replaced) and each is a project by itself.

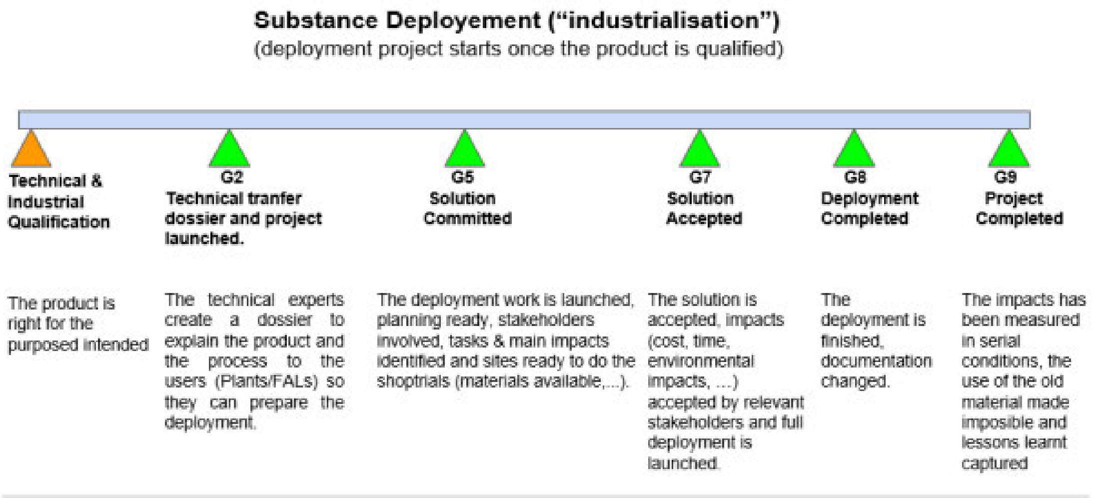


FIGURE 18 SUBSTANCE DEPLOYMENT - INDUSTRIALISATION

Main Activities

G2 Activities:

- Preparation of the technical Dossier: minimum information must be put together so the plants can thoroughly analyse the impacts in their scope and prepare the activity. This is prepared right after the qualification activity completes.

G5 Activities:

- Preparation and involvement of the team (manufacturing engineering, production, H&S, Environment) for all the lines
- Preparation of the project; identify what, why, when and how the deployment will be done and communicate it to the relevant areas.
- First view on the impacts of the solution for the specific site in terms of time, budget needed, material needed (or adaptation in industrial means and tools), documentation impacted.
- Awareness and agreement of the involved stakeholders.
- Ensure that the material and means are available to start shop trials, what means include the new materials in the systems and to make it available in the different areas and to define what are the industrial means needed (e.g. suitable bulk mixers, or other equipment)
- After G5, the main aim is to have a complete and comprehensive view of what the new solution means for the plant and what must be changed

G7 Activities:

- Shop trials needed to have a complete view on the performance and impacts of the solution in the plant (quantity of material needed, time of application and curing, need of special new means).
- The Plants/FALs accept the solution and commits to deploy now that there is a good and comprehensive view on what the change means for the area.

- From this moment, the full deployment starts (change of all manufacturing documentation, process documentation, etc.).
- Based on the interchangeability principal drawings will not be changed but local manufacturing documentations would need to be updated. At each site, local manufacturing documentation must be updated to consider the new qualified products & new references.
- Examples of manufacturing documents:
    - Routings: lists all the Standard Operation instruction and product names that will be used to do the operation described in the work orders
    - Standard Operation Instruction: based on the design/assembly drawing, it instructs the operator in detail how to assemble the parts for one step of the process, with visual support such as 3D view or pictures.

G8 Activities:

- In G8 the deployment is finished and checks to ensure that the change has been completed (all the areas using new material, the industrial means including new machines or other industrial means are in place & running, that the personnel has been properly trained, etc.).

G9 Activities:

- In G9 it is ensured that the change is irreversible, and impacts are measured in real conditions (impacts that were identified in G5 and measured in shop trials in G7) and close the project.
- Ensure that the purchase of the previous material is not possible by removing the product from Procurement Systems
- Ensure no purchase of the old material has been done after G8 The industrialization process generally lasts 1 year for each site in order to ensure proper control of the process, parameters and documentation update. Figure 19 provides a simple Gantt chart Airbus is using for the substitution of the sealants in their facilities.

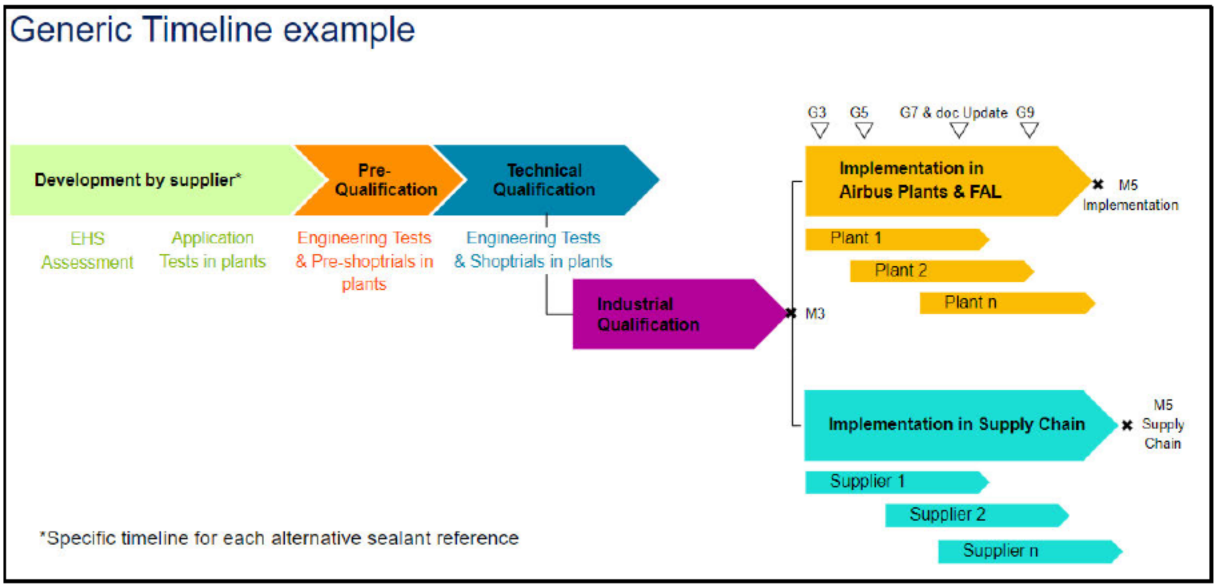


FIGURE 19 AIRBUS SUBSTITUTION GANTT CHART

Important workload in plants: In plants, the same manufacturing teams are involved for shoptrials occurring in various phases such as development, pre-qualification or qualification, and for the activities linked to the industrialisation. In addition, these teams must manage other manufacturing projects not related to the sealant substitution project. Therefore, they have to deal with multiple activities that often occur simultaneously, which can eventually slow down the global substitution rhythm.

During the industrialization (deployment) in the UK Airbus production sites, all the impacted workstations have to stop using the former sealant references and start using the new qualified NPE free sealants instead. For the complete substitution of all NPE sealant references in the 2 UK Airbus sites it was estimated that around 40-50 workstations are impacted by a substitution (some workstations are counted several times when impacted by several substituted references). For the MC216M (2 sealant references) already deployed, around 5 workstations were impacted during deployment. In comparison with the next sealants to be industrialized, MC238M and MC780M (5 sealant references) will impact 30-40 workstations, increasing the workload and the risk that a new sealant does not fit one or several specific application case(s). Compared with the EU Airbus production sites, the number of UK workstations is quite low, however UK sites deployment will be synchronized with the EU sites, since they depend on the end of technical qualification of the products.

This estimation is only valid for Airbus, but all the associated supply chains also have many workstations to deploy with the new NPE free sealants, with proportional risks.

The Applicant had stockpiled enough NPE to account for the 4-year review period applied for within the original AfA. The Applicant has sufficient surfactant supplies to continue sealant manufacture until 2025. To allow for the sealants to be continued to be placed on the market post 2025 the Applicant has sourced a new non-EU supplier of NPE to allow for continued formulation in the EU, and thus continued supply to the UK.

4.1.3.3. Monitoring of the implementation of the substitution plan

Each line in Figure 16 is a deemed a key milestone within the substitution plan. The Applicant and Airbus project team will attempt to adhere to the plan and meet the timeline set above.

4.1.3.4. Conclusions

The Applicant is committed to the substitution of NPE from its products and is working with Airbus to achieve this goal. The Applicant and Airbus believe the substitution plan outlined above is achievable but that safety is of paramount importance and cannot be compromised, as such if the sealant produced with an alternative does not meet with Airbus material specifications then substitution of the product cannot occur.

4.1.3.5. References

Not applicable

4.2. Risks associated with continued use

A comprehensive analysis in the CSR points out specific risk management measures (RMMs) and operational controls (OCs) performed by the Applicant and Airbus at their respective sites.

4.2.1. Implemented risk management measures and resulting emissions

4.2.1.1. Use 1 – Mixing of Sealants before Downstream Use

The process of mixing the hardener through the base component can be carried out in three ways:

- Mixing within a two-compartment kit; or,
- Mixing in small scale batches by hand; or,
- Bulk mixing by machine.

Due to the contained nature of the cartridge, no exposure of the NPE containing hardener component to the environment is possible under typical operation of the cartridge. Whether mixed by hand or machine, the operators wear the relevant PPE. After mixing, any disposable PPE are disposed of as hazardous solid waste in a bin on site. These scenarios are each introduced in the CSR and described further in detail.

A worker risk assessment is not required in line Article 62(4)(d) of the REACH regulation. Workers' activities are summarised below, to the extent that they are relevant for an assessment of release to the environment. For example, explanation of measures relating to PPE are only described to the extent necessary to demonstrate absence of incidental environmental exposure from contaminated worker clothing. In case PPE is contaminated with hardener during the process, the material is carefully captured and removed with a rag or wipe, which is disposed of as hazardous waste.

The polysulfide sealants contain multiple ingredients. A range of environmental hazards is associated with these materials. The RMMs and OCs in place at the facility therefore have to adequately manage the range of hazards associated with all constituents. Consequently, the overall level of protection is high, and RMMs and OCs are in place so that the mixing processes do not result in potential release to the environment of NPE. Risk management measures are in place to avoid contamination of clothing. Therefore, there is no significant residual contamination on overalls. Overalls are cleaned regularly in line with normal hygiene.

The RMMs below are observed during all activities involving handling and mixing the hardener component. When mixing sealant, workers wear gloves, protective overalls, and eye protection. A disposable apron may also be worn over the overalls.

- During handling and mixing of the hardener, workers will wear a combination of disposable and reusable PPE. After use, disposable PPE is removed carefully by the worker and disposed of to the hazardous waste containers in the production area.
- Reusable PPE would, if contaminated with either NPE or formulated hardener, be cleaned with a rag soaked in solvent. The rags are subsequently disposed of to the hazardous waste containers in the production area. Once clean, the reusable PPE is returned to storage for future use.
- Waste that may be generated during formulation and mixing of the hardener include disposable PPE, waste two compartment kits, waste containers from the two container kits and rags with solvent that are used to clean equipment. The rags are handled and disposed as hazardous waste.

- Hazardous waste bins are labelled with the waste description and waste code. Materials in the bins are consigned as hazardous and subsequently removed by licensed third party waste contractors in line with applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

TABLE 10: LOCAL RELEASES TO THE ENVIRONMENT ASSOCIATED WITH USE 1

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing operator controls and risk management measures	**Initial release factor**: 0 % **Final release factor**: 0 % **Local release rate**: 0 kg/day **Explanation / Justification**: There is no release to wastewater on site. RMMs and OCs in place on site to prevent any release to the environment of the NPE containing hardener or sealant.

4.2.2. Impacts on humans

No impacts on human health are anticipated.

4.2.2. Impacts on environmental compartments

According to the Annex XV dossier on the identification of SVHC, the primary environmental compartment of interest for NPE is the aquatic environment. Degradation of NPE to the respective alkylphenol (NP) is expected to occur in wastewater treatment plants, surface water and soils, and more slowly in sediments. Thus, the qualitative assessment focused on use of water and/or discharge of wastewater and/or generation of waste materials (solid, liquid) in the formulation or mixing process or in ancillary processes, such as cleaning and maintenance. The qualitative exposure assessment concludes that there is no potential for releases or emissions to the environment from the uses covered by this review report. OCs and RMMs in place, are effective in preventing release of NPE to the environment. The applicant's and downstream users' compliance with the requirements of the Exposure Scenarios described in the CSR and relevant OCs and RMMs included in the SDS supplied by the formulator, respectively, allows for a high level of certainty that there is no potential for emissions to the environment.

Given the above reasoning, there is no potential for releases to the environment of the NPE-containing hardener component of the two-part sealant during mixing within the two-compartment kit, in small scale batches by hand or bulk mixing by machine, in line with the above RMMs and OCs. Accordingly, there is no potential risk to the environment from the uses mentioned above.

4.2.3. Monetised damage of environmental impacts

According to the results of the CSR, a quantitative analysis of environmental media, including water, air, sediment, and soil, was considered, but not conducted. Since no emission/exposure is assumed, it is implied that the operational controls and risk management measures in place preclude the release to the environment.

The findings of the emissions assessment were such that the need for a detailed exposure assessment was deemed unnecessary and the exposure assessment can be carried out using qualitative approaches. Since exposure is not predicted, the risk assessment was carried out based on a simple comparison of the findings of the exposure assessment with the outcome of the hazard assessment. Subsequently, no quantitative assessment of the environmental impacts of the applied for use scenarios are performed in the related sections of this AoA/SEA. For other technical reasons, please refer to section 9 of the CSR.

4.2.4. Compilation of environmental impacts

The applicant demonstrates that, considering measures in place, emissions of NPE to the environment during the use applied for (as discussed within section 9.0.1 of the CSR) are not only minimised but effectively precluded. Airbus and their associated supply chains require good manufacturing practices, including compliance with standard operating procedures, and Exposure Scenarios communicated by the Applicant, in place at all Downstream User sites carrying out the activities associated with the exposure scenarios covered within the CSR. This is necessary to ensure aerospace equipment is safe to use and delivers environmental protection. Adherence to these requirements means that release of NPE to the environment during use is precluded.

Thus, it is considered that use of NPE containing sealants as described within this AfA poses no risk to the environment.

TABLE 11: SUMMARY OF REMAINING RELEASES TO THE ENVIRONMENT.

	[Per year] [Over 6 years]
Total releases/emissions (in kg per period)	No releases

4.3. Non-use scenario

4.3.1. Identification of plausible non-use scenarios

As shown in the AoA, there is no alternative readily available for use at all the DU sites in the UK. DU sites covered by this review report comprise all UK sites of Airbus, as well as their suppliers and customers, including MROs and airlines. Naturally, the use of a worse performing alternative is not an option due to flight safety and airworthiness requirements. Therefore, as will be outlined in the following sections, two different non-use scenarios have been found to be most likely, should an authorisation not be granted. As outlined in the following sections, NUS 1 represents the lower bound and NUS 2 represents the upper bound in terms of negative socio-economic impacts that need to be considered in the case of non-authorisation. Figure 20 shows the causal chain for the most likely NUS.

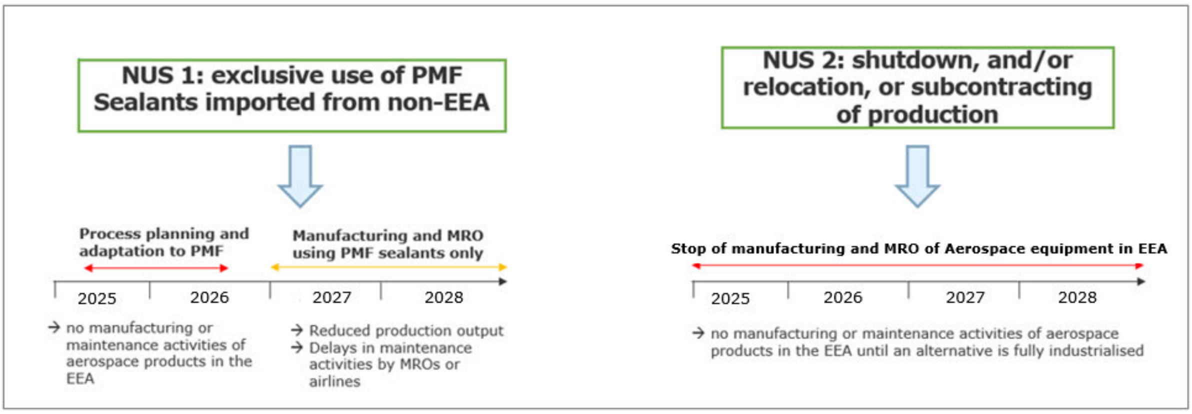


FIGURE 20: CAUSAL CHAIN FOR NUS 1 AND NUS 2

NUS 1 refers to a situation where all processes of all aerospace operations in the UK would be changed to the exclusive use of PMF sealants, with all technical and procedural drawbacks. In this scenario, the total volume of sealants needed within the UK would be pre-mixed and frozen in a non-UK country and imported to the UK via refrigerated airfreight. This NUS would entail a period of 1 to 2 years where no manufacturing or MRO of aerospace equipment would be possible in the UK, due to unavailability of NPE-containing sealants. This period would be followed by a period of 2 to 3 years with reduced production output, increased operational costs and drastically decreased operability of aerospace products, due to MRO delays, until an alternative is fully industrialised at all UK DU aerospace operations. For the sake of this assessment, it is assumed that necessary amounts of PMF sealant can be readily delivered as soon as all processes at Airbus and its suppliers, as well as MRO operations, have been adapted to the use of PMF sealants only.

Although two-part sealants can theoretically be replaced by PMF sealants, the applicability of this NUS is highly questionable for different reasons (see Limitation of NUS 1 listed in Section 4.3.2.1). Therefore, a situation as described in the following **NUS 2** could materialise.

NUS 2 refers to a situation where manufacturing and MRO of aerospace equipment would need to be stopped until an NPE-free alternative is fully industrialised at all DU sites in the UK.

The sections below present an overview of NUS 1 and NUS 2; the following sub-sections describe the scenario for the DU sites.

4.3.2. Conclusion on the most likely non-use scenario

4.3.2.1. NUS 1 – Exclusive Use of PMF Sealants

As an alternative to the preparation of the polysulfide sealants directly before use, sealants with application time > 0.5 hours can theoretically be pre-mixed, frozen, and stored at -45°C for a maximum of 35 days for later use. Pre-mixing can take place either directly at the DU site or at the formulator site. Pre-Mixed and Frozen (PMF) sealants are therefore an alternative method of delivering polysulfide sealants to the point of use inside a DU facility.

The NUS presented here considers a hypothetical situation where the total sealant volume is mixed outside of the UK by the DU sites themselves or via subcontractors. The PMF sealant is then imported into the UK and used at the DU sites.

Production of PMF sealants will take place outside the UK until an NPE-free alternative is developed, qualified, and industrialized by the affected OEMs. Since PMF sealants can only be transported and stored in small packaging (cartridges), a large volume of PMF cartridges will need to be produced to substitute the large quantities of sealants that are used in aerospace equipment manufacturing and MRO. This will require investments in infrastructure by the UK DU sites to meet the demand for increased production and storage of PMF sealants. Installation of additional cold storage freezers, back-up generators and other relevant equipment will be required by DU sites in the UK. The installation of this equipment and the need to immediately store PMF sealants at the requisite temperature after production will create the need for additional cold storage freezers at the site of formulation and downstream use. The provision of these extended cold storage freezers will require additional infrastructure by either upgrading the existing facility or acquisition of new land.

As a result of this relocation outside the UK, job losses can be expected at all UK DU sites.

To maintain the quality standards and the short-term functionality of the PMF sealants, it is crucial to maintain low temperatures during the entire process from mixing until end use. Different steps during the supply chain will require different temperature specifications to preserve the PMF sealants. For instance, the freezing process will require an ambient temperature of less than -70°C. Prior to distribution, it should be preserved at an ambient temperature of -60°C ± 4°C and during transportation, it must be preserved at an ambient temperature of -44°C ± 4°C. It will require the PMF sealants to be packaged using dry ice in small containers and further transported via refrigerated air freight to the site of end use in the UK at a constant temperature matching the specifications. Transport via air freight is mandatory due to the requirement to maintain very low temperature as well as due to the limited shelf life of PMF sealants. Consequently, additional logistical costs of transporting the PMF sealants from outside the UK to a UK DU facility of use will be incurred by the DU.

Figure 21 shows the stages involved in this scenario. As it can be seen in this non-use scenario, the sealant is manufactured outside the UK by mixing of hardener and base and subsequent freezing and packaging. This is done by the applicant at their EU facility or by a non-UK site of an aerospace company. The PMF sealant is then transported via refrigerated air freight to the point of use in the UK.

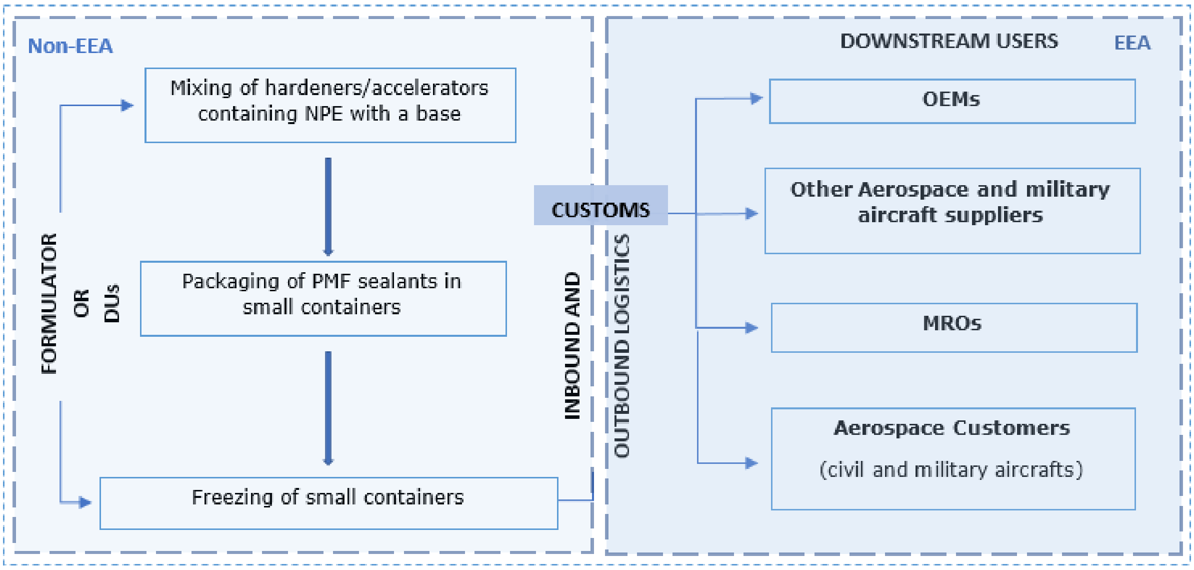


FIGURE 21: DIAGRAMMATIC REPRESENTATION OF THE NON-USE SCENARIO

Use 1 – Mixing of Sealants before Downstream Use

Following the relocation of formulation outside the UK, the DU sites would start importing the PMF sealants after the following steps have been completed:

- Requalification of longer cure sealants containing NPE to be used to replace fast cure PMF sealants

The time required for the completion of such regulatory requirements would be approximately 1 to 2 years, leading to a production stop. As a result of this interruption, delays in the manufacture, maintenance and repair of aerospace products would be experienced due to unavailability of sealants. However, these processes are assumed to commence after the regulatory requirements have been fulfilled.

Most importantly, costs for process adaptations and related production stops, as well as supply disruptions and potentially significant process delays and output reductions at DU sites, must be considered in this NUS.

For MRO activities, such a scenario would be difficult to implement, especially for the line maintenance activities or unscheduled repairs, where the amount of sealant required cannot be forecasted. Field repairs (e.g., on-wing or fuselage repairs) usually require the use of fast cure sealants with a short working life. An on-site repair requires the immediate use of these sealants wherever an aircraft lands, in case of a defect. While non-MRO operations could theoretically cope with longer cure times of PMF sealants (provided process adaptations are successful), such a scenario is deemed infeasible, especially for unscheduled MRO operations, where a short cure time for sealants is essential to avoid prolonged aircraft on ground (AOG) times and related costs and impacts (see Case Study 1 in Annex).

Limitations of NUS 1

It is important to re-iterate that there are substantial doubts about the technical feasibility of NUS 1. As mentioned in the introduction to NUS 1, this scenario was developed to provide an alternative, less costly scenario, compared to the "total shutdown of all Aerospace operations in the UK-scenario" with all its tremendous consequences for the UK Economy and Society.

In addition to that, the following must be considered when evaluating this NUS.

- The entire process of producing pre-mixed and frozen sealants has several limitations, which are discussed in greater detail in the subsequent sections. Being able to only use PMF sealants in this scenario will be especially problematic for applications where currently fast-cure sealants are used. Fast-cure sealants have an application time of only several minutes or less and can therefore not be supplied as a PMF sealant (the freezing and unfreezing steps reduce the application time even further, inhibiting later use of the sealant, i.e., the sealant cures during freezing and thawing, making it unusable). For this reason, the processes requiring fast cure sealants will have to be adapted. The possibility to switch from fast cure sealants to sealants with a longer cure time, allowing the use of pre-mixed and frozen sealants, will depend on each application on a case-by-case basis and may jeopardize the complete process flow in the assemblies. The time required for switching from fast cure sealants to PMF sealants with a relatively longer cure time is individual to each DU application.
- Theoretically these fast cure sealants can be replaced by products that can be imported as PMF; however, this will slow down the processes at the DU sites. For MROs and airlines, this can result in increased AOG times with all related consequences, as laid out in Case Study 1 in Annex A. Curing might also be subject to weather, such that it depends on outside temperature and humidity. The colder and more humid the weather, the longer it takes for the sealant to cure. Therefore, fast-cure sealants are often used in cold climates and in winter, when using normal products in such a climate, curing/hardening would require a much longer time.
- This scenario would not only imply investment costs, but also high transport (and energy costs, to maintain the cold storage freezers at a specific temperature at all times.

- Besides that, there is a constant need to maintain the sealants at -45°C to protect its functionality and applicability. To maintain such low temperatures while transporting PMF sealants in small containers, transportation would be carried out using dry ice at -70°C (large containers cannot be deployed for such packaging, noting the non-uniform freezing of large quantities of PMF sealants resulting in poor quality and increased freezing time versus freezing of small quantities of PMF sealants). A complete cooling to about -45°C must be ensured from production to end customer. Subsequent external environmental costs associated with increased CO_2 emissions and generation of plastic packaging waste are expected, which will be borne by society.

As shown in Figure 21, importing the pre-mixed sealants in a frozen form from outside the UK would imply customs clearance. Holding the package at customs could intensify the difficulty of maintaining low temperatures for the pre-mixed and frozen sealants containing NPE. An inability to do so could result in the possibility of air entering the material, consequently leading to loss of adhesion properties, rendering the sealants unfit for use on an aircraft.

A comparison of this scenario with the applied for use scenario highlights the **tremendous economic and procedural downsides** of importing and using PMF sealants, providing no environmental benefit. Indeed, there is no potential to reduce **NPE emissions, which are already, at worst, precluded** throughout the life cycle of an aircraft. Additionally, high external environmental costs related to packaging waste and **increased CO_2 emissions from transport** would be incurred in this non-use scenario.

In conclusion, this scenario would involve socio-economic while the volume of NPE containing sealants would increase, due to higher storage volumes and subsequent scrapping of unused sealants at the end of their shelf life.

For the reasons outlined above, which might render this NUS infeasible, an additional NUS (**NUS 2**) is presented in the following to provide an upper bound of socio-economic impacts that can be expected, should an authorisation not be granted.

4.3.2.2. NUS 2 – Shutdown/Relocation/Subcontracting to outside the UK

As outlined, this scenario is relevant when more detailed analyses conclude that a temporary change to PMF sealants would take equally long or technical/procedural limitations of change to PMF sealants could not be overcome.

Use 2 – Mixing of Sealants before Downstream Use

The DU sites would be forced to stop production of aerospace products and components (including civil and military aircraft) that require NPE containing sealants in the production process in the UK.

The NUS for MRO activities needs to be distinguished between scheduled activities (so called 'letter' checks (A-, B-, C-, D-)) and unscheduled activities which may be required at any time at any place. Unscheduled activities are either executed *in situ* for parts that cannot be disassembled (e.g., on the fuselage) or activities that do not necessarily require moving the aircraft to a hangar (e.g., can be performed at the gate and therefore allow minimised interruptions of the flight plan), or *ex situ,* which describes all activities for which parts need to be taken off the aircraft.

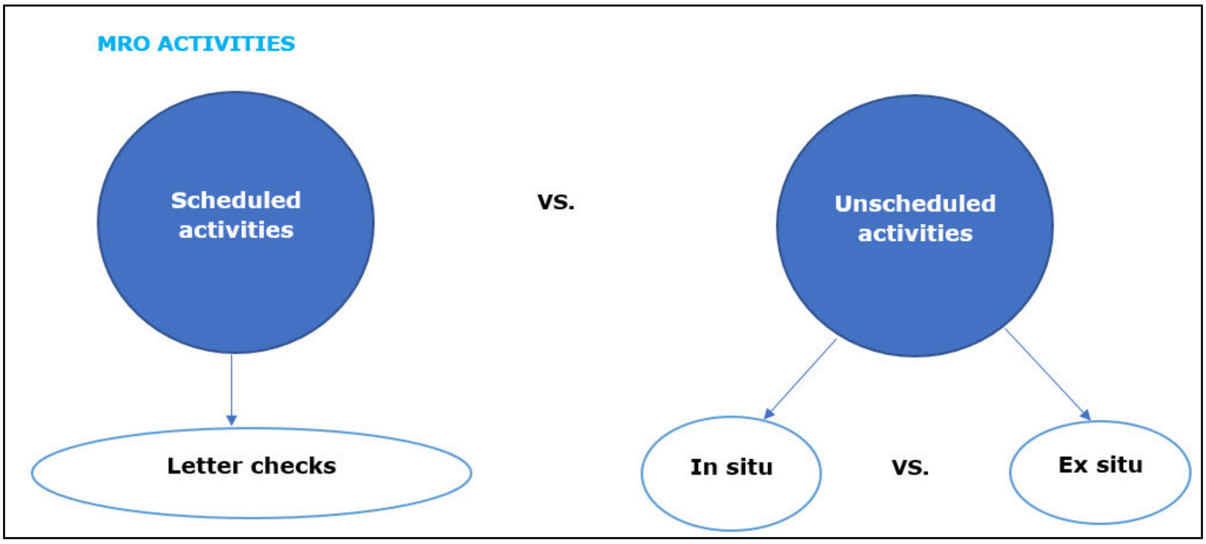


FIGURE 22: SCHEDULED AND UNSCHEDULED MRO ACTIVITIES

1. Scheduled MRO activities

The Letter checks need to be executed on a regular basis. The following numbers provide typical intervals of these checks and required working efforts to perform the MRO activities:

A-check:

- every 400-600 flight hours or 200–300 cycles
- MRO activities take 50-70 man-hours

B-check:

- every 6-8 months
- MRO activities take 160-180 man-hours

C-check:

- every 20–24 months
- MRO activities take up to 6,000-man hours and the time needed is at least 1–2 weeks

D-check:

- every 6-10 years
- MRO activities take up to 50,000 man-hours and 2 months to complete

Like production activities, a partial shutdown of MRO activities would be necessary, relocating repair and maintenance of aerospace products requiring the use of NPE containing polysulfide sealants to outside the UK, again assuming that capacity would be available, at least in the short term. If capacity was not immediately available, then delays in the maintenance and repair of aerospace products could be expected. MROs could still perform maintenance and repair activities but would lose the ability to use these sealants. However, no maintenance of airframes and other components would be possible, causing all such maintenance to be moved outside of the UK.

Clearly, with only component replacement and non-usage of NPE in polysulfide sealants for maintenance of components and aircraft and other aerospace products being possible in the UK, the economic viability of UK-based maintenance and repair operations would be significantly affected. The most likely scenario for MROs is that the maintenance facilities in the UK would be closed (at least eventually) and relocated to outside the UK, where possible.

While this scenario might be theoretically feasible, with all the related negative impacts, it is completely unfeasible for some small aircrafts. Smaller aircrafts (e.g., jets, turboprops) used by airline operations (and freight companies) for regional and national flights are only certified to fly a limited distance from an airport, due to their limited fuel supply. Considering this scenario, these planes would need to 'hop' overland by a series of shorter flights to other countries (e.g., within the EU, Turkey, Egypt etc.) for scheduled maintenance and then fly back, already shortening the time between the next letter check due to additional flight cycles. In practice, this would be practically, financially, and environmentally unfeasible for such aircrafts.

2. **Unscheduled MRO activities**

Unscheduled activities are either executed *in situ* for parts that cannot be disassembled (e.g., on the fuselage) or activities that do not necessarily require moving the aircraft to a hangar (e.g., can be performed at the gate and therefore allow minimised interruptions of the flight plan) or can be performed *ex situ.*

The following non-exhaustive incidents may result in unscheduled MRO activities:

- Damage from foreign objects like
  - Ramps
  - Bridges
  - Fuel trucks
  - Baggage loaders
  - Bird strike
  - Hail
- Hard landing

Unscheduled MRO activities (in situ)

In situ or 'on-wing' repairs are necessary where the part cannot or does not need to be disassembled. For time-essential repairs, as much work is completed 'on-wing' as possible to minimise turnaround time for the airline.

The non-use scenario would require grounding of the aircraft (as permission to flight is lost) and shipping it outside the UK for repair and then flying it back to the UK. As an assembled aircraft cannot just be loaded onto a truck and be transferred somewhere else, this is, if at all, a very costly scenario. Airlines would need to massively increase their fleet with mostly unused aircraft to continue their services at any time. This contrasts with current repair cases, which allow putting the aircraft into service again after a short time.

Unscheduled MRO activities (ex situ)

Ex situ or 'off-wing' repairs apply to the repair of parts that need to be taken off the aircraft. Parts that are typically removed for unscheduled repair include engine parts that require bond repairs and autoclave or oven cure, etc. Parts that are not typically removed for unscheduled repair but could conceivably be removed through a complex process of disassembly, if so needed, include landing gear, gearbox, fan case, air seals, bleed valve, etc.

For unexpected/unscheduled maintenance, the aircraft would have to be grounded (as permission to flight is lost) and physically shipped outside of the UK for repair and then flown back to the UK, thereby extremely extending the AOG time, or flown with a special permit (permit to fly) issued by the state of registration for the aircraft outside the UK for maintenance. This would require airlines to massively increase their fleet with mostly unused aircraft to continue their services at any time.

Further, although moving *ex situ* repairs or 'base maintenance activities' (letter checks) to a location outside the UK is a comparatively easy step to make, as repair facilities exist in numerous other regions, this could never be justified in the case of 'line maintenance activities' or *in situ* repairs (i.e., day-to-day activities, including defect rectification). This is because being unable to undertake these activities where an aircraft land would basically imply suspending the operation of the aircraft every time there is a defect, disassembling the aircraft, shipping it outside the UK for repair, and flying it back to UK again. This would decrease both performance/compliance/availability of the products, as well as significantly increase cost. Normal operation of revenue aircraft would be impossible under these circumstances, with consequent drastic implications for the entire commercial aviation industry, and in the end, on the UK Economy and Society (ECHA/EASA, 2014).

Manufacturers of components used in aerospace products would need to stop the production of parts treated with NPE-containing sealants in the UKA as a NUS. Companies that have the capability of relocating the production facilities outside the UK might do so, at considerable expense. Highly specialised component manufacturer SMEs that do not have the financial capabilities will cease production and be forced from the market.

Limitations of NUS 2

NUS 2 will have important implications for aerospace product life, quality, cost, schedule, and security of supply. The loss of spare production capability may decrease the life of more complex sub-assemblies and/or durable articles, thus increasing the likelihood that the article will be disposed of. The NUS will result in a temporary but complete shutdown of all activities and result in the loss of production and supply. Losses in industrial capacity, jobs, market revenue and cancelations of contracts are a distinct possibility.

The reactions of the different actors in the aerospace industry supply chain as a result of a refused authorisation point to considerable losses for the UK and jeopardising UK competitiveness and workplaces. Furthermore, environmental emissions will not be reduced. In fact, they are likely to increase, due to less stringent regulations in many countries that may be the recipients of relocated production or maintenance and repair activities. This is true for all industry sectors.

As a conclusion, the NUS can be summarised as follows:

- Stop of production processes related to NPE containing sealants in the UK.
- Where feasible, relocation of all affected processes outside the UK to maintain production and/ or maintenance and repair activities.

This NUS will have the following consequences:

- Temporary loss of 'value added', not only from sealant activities, but also from further and final steps in the value chain (parts manufacturing and final assembly).

- Absence of one single part can severely disrupt, or even prevent, the delivery of many aerospace products (including aircraft). Hundreds of suppliers deliver parts from around the world which are ultimately connected in assembly lines. For example, the fuselage consists of several single sections (e.g., forward and centre fuselage, centre wing box, tail cone, etc.) which need to be joined. Assembling is a mechanical process and tolerances of the parts need to be corrected by machining. During this process, e.g., docking of wings or engines, the surface can suffer damage. Therefore, loss of even a limited number of parts treated with NPE containing sealants will have substantial effects. Using these sealants is mandatory and is essential to the safety of the aircraft. When these processes are no longer available, the entire process must stop or be relocated. From an operational perspective, these sealants are a small element of the overall process flow in most mixed facilities, with the combination of machining, finishing, assembling, testing and inspection dominating. However, as noted above, they cannot be separated from one another. The impacted operations, and therefore socio-economic impacts to industry in the non-use scenario, go far beyond the specific processes directly using these sealants and have substantial implications for processes that are indirectly affected to be performed one after the other. Hence, individual parts of this process cannot be moved – only the whole process.

Moreover, this situation is the same even if – hypothetically again – an NPE-free alternative was successfully qualified for one or two components. This would not change the overall impacts, since, as stated at many points in this report, the whole supply chain must be available to produce an aircraft – an aircraft cannot operate with even one missing component. If only one part requiring these sealants is not available/usable, production or repair/maintenance of the affected component would simply stop, with knock-on consequences down the supply chain, ultimately impacting operational activities. The following illustrations demonstrate the interdependency of every single part used, and the effect of only one part missing, for the overall assembly process of the aircraft. It should be noted that this represents only a highly simplified supply chain of parts needed for the final assembly of an aircraft. If only one part cannot be produced according to type certification, the manufacture of the entire aircraft is jeopardised (see Figure 23).

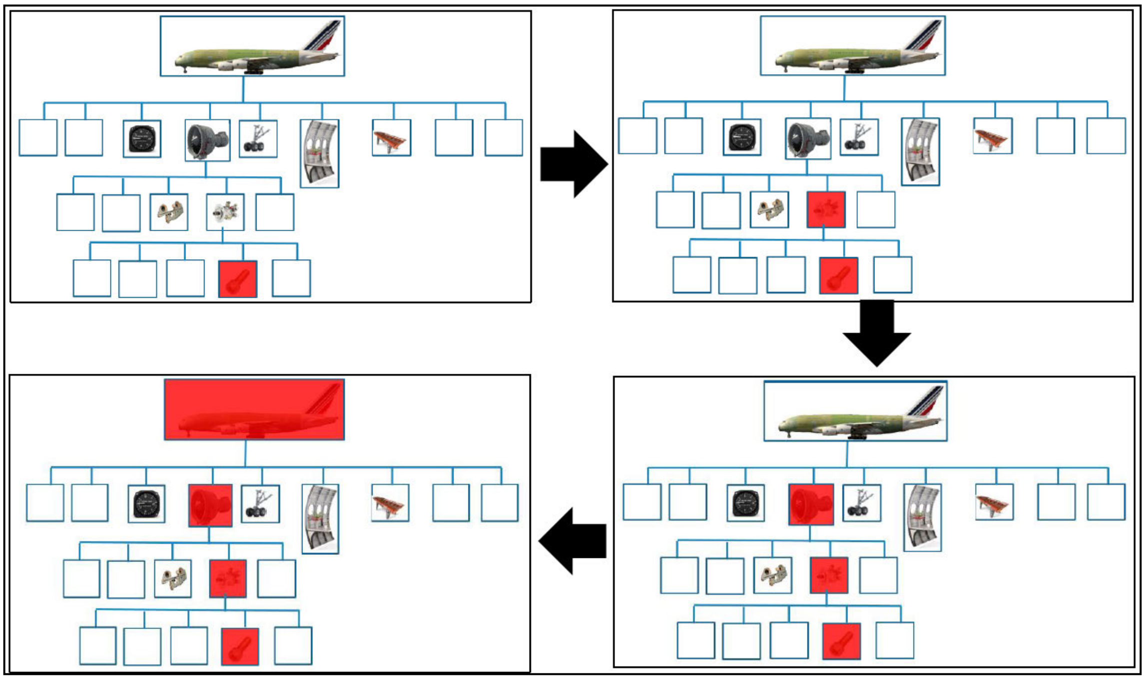


FIGURE 23: DEMONSTRATION OF INDIVIDUAL COMPONENT INTERDEPENDENCY

In conclusion, it is not possible to relocate single NPE based sealant activities. These processes mostly are an integral part in the production chain and cannot be separated from previous or following process steps. As a further illustration, consider sealing during the assembly process of the fuselage. In this case, it is simply impossible to ship the entire fuselage to outside the UK, ship it back into the UK for continued assembly, and so on. Therefore, delivery of the final product in the aerospace value chain – Aircraft and other aerospace products - is not possible anymore!

There are several other cases to consider:

- ***Small Parts***: Currently, some small parts may be able to be removed and then repaired on-site or replaced with a new part from stock (from inside or outside Europe). In the case of a denied authorisation, no on-site repair would be possible. The part either must be sent outside of UK for repair, or a new part from stock would ultimately have to originate from outside the UK. However, since NPE-containing sealants are needed in many final assembly processes, even if those parts could be repaired outside the UK, they could not be re-assembled to the aircraft, rendering such maintenance in the UK unfeasible.

- ***Assemblies***: Sometimes a small part can be removed from a larger assembly, or from the airframe itself, but cannot be treated as above for small parts because a sealant-based treatment is required to be applied at the assembly level (e.g., to bridge across joints of different parts in the assembly to prevent corrosion). Outsourcing of this process would require the entire assembly/airframe to be repaired outside the UK.

- ***Large Parts***: Some large parts, like wing or fuselage skins, are rarely or never removed, so processing *in situ* is the primary method for repairs. Without moving the entire aircraft outside the UK, the repair is not possible.

In the base case, the repairs that require *in situ* use of NPE-containing sealants can be planned to be performed outside UK. This may entail the added cost of longer, non-revenue flights to the non-UK repair centre. In the worst case, unplanned damage needs to be repaired before the aircraft can be moved. If this is in the UK, this creates an unworkable situation. From these examples, it is therefore crystal clear that relocation of single activities is in most cases not an option. Consequently, in the non-use scenarios of the companies affected by authorisation, more and more parts of the supply chain, and alongside jobs, know-how and R&D investments, will move out of the UK. For the majority of the parts that require NPE containing sealants, the substance is applied at key stages in the production and assembly process, and timing of the application is essential. Related processing steps are typically done at a single location.

Consequently, a significant portion (if not 100%) of the total turnover of EUR 22.4 billion (2020) delivered by the European aerospace industry will be impacted (ASD, 2022 - Facts & Figures, 2022).

For the avoidance of doubt, this does not account for the impact on airlines and other users of aerospace products that do not receive them and cannot maintain operations because of missing spare-parts and maintenance operations that rely on NPE containing sealants. Furthermore, industry expects adverse impacts on contract commitments, damage to business relationships, loss of future contracts, impacts on future competitiveness, etc. As exact monetary values connected to the impacts stated above are very hard to quantify, the aim is to assess the minimum socio-economic impacts connected to a non-authorisation.

However, it must be clear that the impacts assessed in Section 0 represent a massive underestimation of the real impacts to be expected. The overall scale of the known impacts to the aerospace industry alone are expected to be of the order of several billion GBP. The scale of the impact to industries that rely on the smooth operation of the aerospace industry (e.g., air travel, cargo, commerce, tourism, telecommunication, navigation, weather forecasts, etc.) will be many-fold higher. Further non-quantifiable impacts on national defence, military, humanitarian relief missions, safety of armed forces and rescue operations must be considered.

For a case-by-case analysis of impacts on the industries mentioned above, please refer to the case studies provided in Annex A.

4.3.3. Summary of the consequences of non-use

4.3.3.1. NUS 1 – Exclusive use of PMF sealants

NUS 1 would yield the following direct costs/consequences for Airbus, some of which are detailed and quantified in the following sections:

Economic impact

- Costs associated with Process Planning and Adaptation
  - Costs associated with production interruption
  - Technical and procedural adaptations
  - Requalification costs
  - Reduction in output efficiency
  - Costs of unmet contractual obligations
- Costs associated with Installation of additional Equipment

  - Cost of freezing equipment
  - Cost of cold storage capacity
  - Cost of back-up generators
  - Cost of de-frost equipment
- Additional operating costs
  - Electricity costs associated with increased energy consumption
  - Increased storage costs
  - Increased costs for quality control
  - Increased scrapping costs for products at the end of shelf life
  - Increased sealant costs (PMF Cartridges vs. Bulk Sealants)
- Costs associated with Logistics
- Impacts on MROs, Airlines and Military Operations
  - Process delays and additional AOG times

Social impact

- Costs of unemployment due to relocation of formulator activities related to production of PMF sealants for the UK market.

Environmental impact

- Costs associated with increased CO_2 emissions from transportation
- Costs associated with increased packaging-related waste generation
- Costs associated with scrapping of PMF sealants due to their short shelf life

4.3.3.2. NUS 2 – Shutdown/Relocation/Subcontracting to outside the UK

NUS 1 would yield the following direct costs/consequences for the formulators and/or Airbus:

Economic impact

- Producer surplus losses at applicant and DU sites

Social impact

- Costs of unemployment at applicant and DU sites

5. Societal costs associated with non-use

The following section describes the socio-economic impacts of a refused authorisation for the use of NPE over the requested review period based on the most-likely non-use scenarios (NUS 1 and NUS 2) for the stakeholders involved. The aim of this analysis is to support the findings of the qualitative description, where it has been concluded that the benefits of continued use of NPE would be substantial, while the remaining risks to the environment are negligible.

The evaluation of impacts in this Review Report will be carried out for a review period of 6 years using 2025 as a base year for all calculations. As the authorisation decision issued for the applicant expires on 4th January 2025, the impact triggering period is assumed to commence from January 2025 for the sake of simplification and clarity in the assessment. Finally, as a general approach for the entire assessment, all monetized impacts were adjusted to the base year 2025 by applying a social discounting rate of 4%. To further annualize the net present value (NPV) of monetized impacts over the period considered for this impact assessment (6 years), the same rate of 4% was applied.

The socio-economic impacts are evaluated based on NUS 1 and NUS 2, relating to a lower and upper bound of impacts, respectively.

5.1. NUS 1 – Exclusive Use of PMF Sealants

Section 4.3.2.1 lists the direct costs/consequences for the formulators and/or Airbus and its supply chain in NUS 1, some of which are quantified in the following sections.

5.1.1. Economic impacts on the supply chain (USE 1)

The following impact assessment focuses on effects at Airbus only. An exception exists for the assessment of logistics costs and external environmental costs, where the costs have been calculated based on the total tonnage of NPE containing sealant used in the UK. Additional information from the DU's supply chain including airlines and MRO shops remained unavailable. That means, impacts on upstream or downstream supply chains have not been quantified.

The following sections aim to quantify the impacts related to process planning and adaptation, and the costs associated with installation and operation of cold storage freezers at all affected sites of Airbus. Given the nature of these impacts, different impacts will occur at different times in the future and have been discounted accordingly. Additionally, only a fraction of these real impacts was monetized in the following. Examples of impacts that have not been quantified include:

- Reduced output at Airbus, due to inability to use fast-cure sealant products for some applications
- Impacts on MRO operations and related impacts on air transport, air travel and military operations.
- Impacts on Airbus suppliers

These impacts have not been quantified, due to the lack of information and the related uncertainties. However, as it is shown in the following, the fraction of impacts that was quantified for Airbus companies only gives an impression of the order of magnitude of impacts in this scenario.

5.1.1.1. Additional one-off investment costs

5.1.1.1.1. Requalification costs

The following steps are necessary before production could commence:

- Re-qualification of all Chemetall sealants after technical qualification: 18 months

To use only PMF sealants, all DU sites will have to update their material and process specifications. This implies that these sites cannot use PMF sealants until all the process specifications have been updated to adapt the use of PMF sealants for all former sealant applications.

Assuming that the costs of requalification are equally distributed during the period of process planning and adaptation, it is discounted as follows:

In addition to that, Airbus internal manufacturing processes would need to be adapted, e.g.:

- New line balancing: e.g., if current processes are not feasible with longer cure sealants, a completely new assembly concept/line would be needed. This could involve purchasing of new equipment and reworking the assembly layout with the new equipment
- Validation of new equipment

One example for an Airbus internal process adaptation that would be needed in case only PMF sealants could be used is the following.

[redacted]

CBI 2

[redacted]

Adaptations of such processes potentially requires significant resources, that have not been accounted for in this SEA.

5.1.1.1.2. Asset acquisition costs

As mentioned previously, in case an authorisation is not granted, the base and hardener mixing will need to be performed outside the UK. Consequently, only PMF sealants will be imported and used by DU sites in the UK, because their NPE concentration will be <0.1%).

The costs incurred by Airbus in this scenario are highly dependent on the existing infrastructure of every DU site in the UK. It is anticipated that all sites will have to procure equipment, such as cold storage freezers. The number of cold storage freezers has been provided by Airbus based on freezer capacity and the amount of sealant consumed at each industrial site in the UK. Additional investment in other important equipment, including back-up generators and temperature recorders during transportation, have not been taken into account.

As a result of process adaptations explained in section 5.1.1.1.1, all Airbus activities will incur a production interruption of 1 to 2 years, leading to profit losses and additional costs or penalties related to delayed or no product delivery during this time.

5.1.1.2. Producer surplus losses

For this period of supply interruption, in case of a non-granted authorisation, impacts are estimated in the form of foregone profits. Consequently, the following assumptions were made to monetize producer surplus losses within the UK due to foregone profits incurred by Airbus:

- A lower bound of profit losses was considered for one year (2025)
- An upper bound of profit losses was considered for two years (2025 – 2026) assuming production could commence after relocation is completed and PMF sealants are available for DU sites.
- EBITs (Earnings before interest and taxes) have been used as a proxy to estimate foregone profits. The EBIT estimate of EUR 5 325 million has been obtained from the Airbus SE financial statements 2022. For this assessment constant EBITs until 2030 are assumed.
- EBITs for Airbus due to non-use scenario 1 and 2 in the UK would not be expected to exceed a quarter of the foregone profits illustrated for the EU. Based on this assumption, an estimate of EUR 1 331.25 million has been used to monetise producer surplus losses. The estimate has been converted to GBP using an exchange rate of 1 EUR = 0.87 Pound sterling as of 06.04.2023.

TABLE 12: FOREGONE EBITS DUE TO PROCESS PLANNING AND ADAPTATION

Foregone EBITs due to process planning and adaptation (in GBP million)	
Lower bound	
2025	1 158.18
TOTAL NPV 2025	**1 113.64**
Upper bound	
2025	1 158.18
2026	1 158.18
TOTAL NPV 2025	**2 184.45**

As shown above, foregone EBITs in NUS 1 for Airbus amount to 1 114 – 2 185 million GBP in 2025.

Moreover, as a result of production interruption in 2025, no new Aerospace products would be manufactured and simultaneously no Aerospace products would be maintained or repaired. This would lead to cancellation of flights, resulting from non-usability of Aerospace products due to unavailability of sealants containing OPE, creating knock-on impacts. An upper limit of the costs that would be incurred due to such distributional impacts for Aerospace products can be referred to in Case study 1 in Annex.

For the remaining time of the review period, i.e., for the period after the processes have been adapted and implemented with the use of PMF sealants, a reduction in output efficiency is anticipated due to the inability to use fast cure sealants, as fast cure sealants cannot be frozen.

For the sake of the impact assessment from here on, a conservative approach has been taken assuming a supply interruption of only one year and resuming of all former processes with PMF sealants thereafter from 2026 - Jan 2031. However, for the remaining years of the review period (i.e., 2026 – Jan 2031) after the processes have been adapted and implemented with the use of PMF sealants, a reduction in output efficiency is anticipated due to the inability to use fast cure sealants, as fast cure sealants cannot be frozen.

5.1.1.3. Reduction in Output Efficiency

The inability to use fast cure sealants will reduce the output efficiency (as shown in Figure 24), i.e., increase the lead time of the processes that are achieved at specific efficiency rates and cannot be ensured anymore.

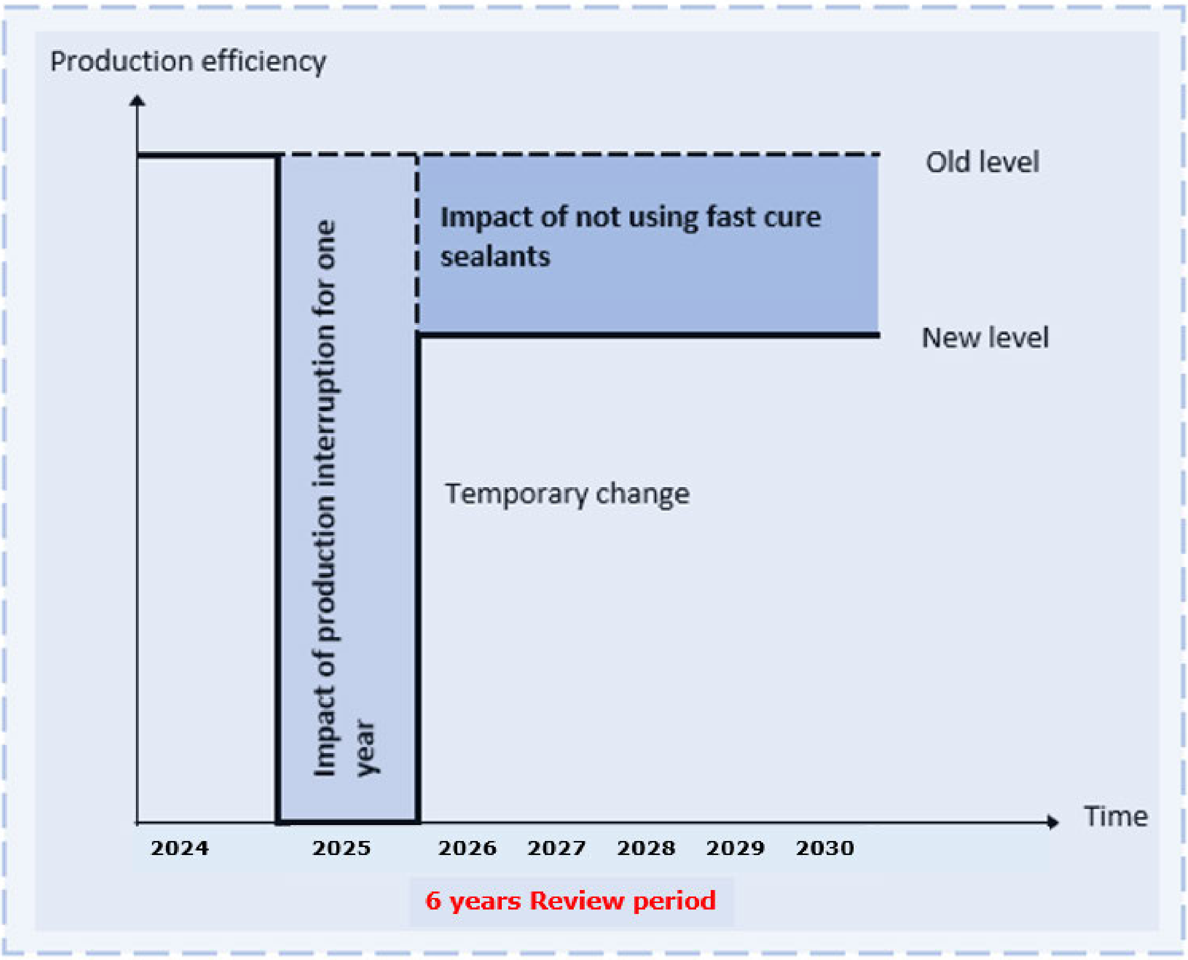


FIGURE 24: EXEMPLARY IMPACT OF PROCESS ADAPTATIONS ON PRODUCTION EFFICIENCY

[redacted]

CBI 1

[redacted]

CBI 1

Further, material and process specifications would need to be updated but the costs of such cannot be estimated at present.

5.1.1.4. Additional operating costs

5.1.1.4.1. Energy costs

Additional cold storage freezers will be required at all Airbus DU sites to store PMF sealants that will be imported to the UK to preserve quality standards. These costs only occur from 2026-2030, after process planning and adaptation of PMF sealants for all applications is complete. In addition to the costs associated with electricity consumption, increased costs associated with maintenance of the storage facility and quality control are also anticipated but not included in the assessment due to lack of estimates around such costs.

Another important cost element anticipated alongside the use of PMF sealants from 2026-2030, is the increased cost associated with scrapping of sealants due to shelf-life limitations. Assuming that a safe quantity of PMF sealants is ordered as compared to actual working units required per year, scrapping of unused PMF sealant due to expiry of use is foreseeable but difficult to quantify based on current practices.

5.1.1.4.2. Logistics costs

Additional logistics costs associated with air freight of PMF sealants as compared to road transport in the baseline scenario. These costs only occur from 2026 -2030, after process planning and adaptation of PMF sealants for all applications is complete. This impact is however only qualitatively described due to lack of quantitative information. .

5.1.1.5. Impact on MRO activities

The application of sealants for MROs is similar to its applications in the commercial production of aircraft. Sealants are especially used in structural repairs for sealing and delaying corrosion by MROs and airlines. Some MROs activities need to be carried out overnight.

For MRO activities, such a scenario would be difficult to implement, especially for the line maintenance activities or unscheduled repairs, where the amount of sealant required cannot be forecasted. Field repairs (e.g. on-wing or fuselage repairs) usually require the use of fast cure sealants with a short working life. An on-site repair requires the immediate use of these sealants wherever an aircraft lands, in case of a defect. While non-MRO operations could theoretically cope with longer cure times of PMF sealants (provided process adaptations are successful), such a scenario is deemed infeasible, especially for unscheduled MRO operations where a short cure time for sealants is essential to avoid prolonged AOG times and related costs and impacts. Please consider the case studies presented in Annex A for further details.

It is commonly accepted in the commercial aircraft industry that a majority of sealants used on the aircraft are in fuselage, electrical and electronic common installation, wings, doors and air conditioning and pressurization systems. Loss in the functionality and applicability of these sealants at any MRO site would result in delays or flight cancellations and the aircraft would have to be grounded. The PMF sealants have a short shelf life of 4-6 weeks. Storing large amounts of it, without knowing its forecasted need in the future, would only lead to an equivalent amount of NPE-containing sealant waste at these sites.

The exact dimensions of impacts on MRO operations remain difficult to estimate but can be reasonably expected to be in the same order of magnitude as the quantified impacts presented above, especially if cascading impacts on the "end-use applications" of aircraft, such as air transport, air travel, armed forces, are included in the assessment.

5.1.2. Wider socio-economic impacts

5.1.2.1. Social impacts due to job losses

No job losses at GB DU sites are expected in NUS 1.

5.1.2.2. External Environmental Costs

External costs due to environmental emissions can be anticipated in NUS 1 in terms of CO_2 emissions. These costs are not representative of the costs borne by either of the parties but the society as a whole and can, however, be seen as a result of pursuing this non-use scenario. These costs have not been monetised due to lack of data for the use of NPE sealants at the UK DU sites.

Additional environmental costs would include high volumes of plastic packaging waste generated due to high quantity of cartridges being produced and transported. Further costs associated with scrapped sealants will also be incurred.

Again, it is important to highlight that only the environmental costs related to CO_2 emissions from transport have been considered here. Costs arising from CO_2 emissions stemming from electricity production needed to run the freezing equipment have not been considered here.

5.1.3. Summary of socio-economic impacts in NUS 1

The total economic impact of this non-use scenario is calculated as follows.

TABLE 13: TOTAL COSTS OF NUS 1

Cost Item	Impact [GBP million]
Total economic costs incurred by DUs	**1 114 – 2 185**
Requalification Costs	Not monetised
Costs associated with Production Interruption	1 114 – 2 185
Costs Associated with Installation of additional Equipment	Not monetised
Additional Energy Costs	Not monetised
Costs associated with Logistics	Not monetised
External Environmental Costs	Not monetised
Social Impacts incurred by Formulators	**N/A**
Total costs across the review period (NPV 2020)	**1 114 – 2 185**

Thus, the total economic impact of this non-use scenario is far higher than **1 114 – 2 185 million GBP**. This figure represents the **lower limit** of the monetised **economic impact of a not granting an authorisation for the continued use of the substance.**

5.2. NUS 2 – Shutdown/Relocation/Subcontracting to outside the UK

5.2.1. Economic impact on the supply chain (USE 1)

The following impact assessment focuses on impacts on Airbus only.

For the evaluation of this scenario, it is assumed that polysulfide sealants are not available until an alternative has been fully industrialised by Q4 2030. This means that no Aerospace product can be produced in this timeframe at the affected DU sites.

5.2.1.1. Producer surplus losses

For this period of supply interruption, in case of a non-granted authorisation, impacts are estimated in the form of foregone profits, with a lower bound of one year (i.e., 2025) and an upper bound of 4 years. According to SEAC's guidance on evaluating losses in producer surplus in no-SAGA cases, these foregone profits are the result of premature retirement of productive capital assets and represent losses to the UK society (ECHA, 2021). Based on this methodology established by SEAC, these foregone profits can be accounted for as producer surplus losses for the remaining service lifetime of the affected entity's capital assets at the point of decision making. This remaining service lifetime is based on the period of time needed by competitors to take over the affected entity's market share for products dependent on the substance use (ECHA, SEAC's approach to assessing changes in producer surplus, 2021).

Assumptions

- EBITs (Earnings before interest and taxes) have been used as a proxy to estimate foregone profits. The EBIT estimate of EUR 5 325 million has been obtained from the Airbus SE financial statements 2022. For this assessment constant EBITs until 2030 are assumed.

- EBITs for Airbus due to non-use scenario 1 and 2 in Great Britain would not be expected to exceed a quarter of the foregone profits illustrated for the EU. Based on this assumption, an estimate of EUR 1 331.25 million has been used to monetise producer surplus losses. The estimate has been converted to GBP using an exchange rate of 1 EUR = 0.87 Pound sterling as of 06.04.2023.

TABLE 14: FOREGONE PROFITS FOR AIRBUS IN NUS 2

Foregone profits: Lower bound	
Cost item	million GBP
2025	1 158.18
NPV 2025	**1 113.64**
Foregone profits: Upper bound	
Cost item	million GBP
2025	1 158.18
2026	1 158.18
2027	1 158.18
2028	1 158.18
NPV 2025	**4 204.10**

As shown above, producer surplus losses estimated for Airbus in NUS 2 are estimated at 1 114 – 4 204 million GBP in 2025.

5.2.2. Wider economic impacts

5.2.2.1. Social impacts due to job losses

In NUS 2, job dismissals would be expected at UK DU sites. The number of FTEs to be dismissed remain difficult to estimate. This impact is therefore only qualitatively described.

5.2.3. Summary of socio-economic impacts in NUS 2

The total economic impact of this non-use scenario is calculated as follows.

TABLE 15: TOTAL COSTS OF NUS 2

Cost Item	**Impact [GBP million]**
Total economic costs incurred by DUs	1 114 – 4 204
Total social cost of unemployment at DU	Not monetised
Total costs across the review period	**1 114 – 4 204**

Thus, the total economic impact of this non-use scenario is EUR 1 114 – 4 204 million GBP million. This figure represents the **upper limit** of the monetised **economic impact of a not granting an authorisation for the continued use of the substance.**

5.3. Economic impact on competitors

The aerospace market in the UK is operated by more than 3,000 companies. Among those are domestic operators, like BAE Systems, Rolls-Royce and Cobham, as well as non-domestic companies with a major presence, such as Boeing and the Airbus (International Trade Administration, 2022). In 2020 the market was dominated by these two non-domestic companies and two Airbus models made up the majority of aircrafts in the UK (Statista Research Department, 2023). Given the historical facts, in case of a refused authorisation, it cannot be simply assumed that another operator would immediately have the capacity to fully compensate for Airbus market share, at least in the short term, if Airbus could no longer operate as usual.

5.4. Other wider economic impacts

5.4.1. Negative spillover effects

As shown in the SEA, the impacts attributed to the NUS described by Airbus are significant. This can be regarded as a reflection of the essential function that polysulfide sealants play in aerospace product manufacturing, operations and maintenance, and the technical and logistical challenges associated with replacing them in the foreseeable future.

The relationship between a country's connectivity between the global Aerospace industry and its productivity and economic growth is directly proportional. The case studies in section 0 provide a glimpse of the wider economic impacts due to a bottleneck in the production and repair of Aerospace products, because of not granting an authorisation for the continued use of the Annex XIV substance, NPE (>0.1%) in the formulation and mixing of sealants. This covers the impacts on airlines and passengers (in and outside the UK) due to delays in or inoperable Aerospace products, targeting direct, indirect and induced impacts on air cargo, tourism, other aviation-linked industries (for instance, aircraft interior and design, airline technology, on-board services and maintenance) and UK and allied military activities, respectively, accompanied by subsequent job losses. A decrease in these commercial activities would bring a proportional effect in the producer and consumer surplus, in general reducing the welfare of the society in the UK. A temporary disruption in the production of Aerospace products would culminate in prolonged impacts beyond the review period applied for.

Limited Aerospace connectivity would hamper existing trade within and outside the UK and may induce an impact on its foreign trade relations. **It must be noted that all Airbus wings are manufactured in GB and exported to the EU. A refused authorisation for this use whilst precluded environmental releases not only has drastic consequences for GB but also the EU**. This will entail economic restructuring, in part, because of increased prices and decreased accessibility due to limited aviation transport services, causing paradigm shifts in marginal costs of OEMs and demand for related goods and services, rippling through market mechanisms, affecting employment, output and income in the short run. Over time, dynamic development effects originating from the market mechanisms set in motion in pursuance of the non-use scenarios will activate a plethora of interconnected economy-wide processes and yield a range of sectoral, spatial and regional effects, plummeting overall productivity and GDP growth, as the increased price of overseas travelling would be passed on to the end user of the Aerospace products. This could materialise as increased air fare for passengers and increased import tariffs on foreign trade, for example, hindering unfettered trading arrangements, increasing the economic burden for the UK. Considerable losses for the UK will jeopardise European competitiveness on an international level in the Aerospace industry.

These impacts can only be theoretically anticipated but remain extremely difficult to monetise with accuracy. From the above-mentioned impacts and the provided case studies in the Annex, it can be reasonably argued that the wider economic impacts that would occur in the non-use scenario are much higher, when compared with the applied for use scenario, where the Aerospace industry is vested in maintaining the status quo with no OPE-related environmental risks, given the zero-emissions strategy pursued by the formulator and the downstream users in the supply chain.

5.4.2. Distributional impacts

The previous sections have focused on the impacts of granting an authorisation in terms of additional costs incurred by the formulator and Airbus. The impacts on other members of the supply chain, such as chemical manufacturers, importers, distributors, processors, component manufacturers, as well as airlines and MRO companies as final customers or end users, have not been assessed in this SEA due to limitations in availing the information.

However, these individual groups will be directly or indirectly impacted because of non-authorisation due to a temporary unavailability of sealants to produce aerospace products. The relevant impacts would be related to lower, or no utilisation of the production factors previously used to produce the substance or the formulations where the substance was a key component in the UK.

In the non-use scenarios, as compared to the applied for use scenario, the applicant, and the supply chain in the UK will experience negative socio-economic impacts along with wider subgroup of uses that aerospace products are used for, in and outside the UK (affected passengers and trade). These socio-economic impacts are listed in Table 16 below, separately, for the applicant and the downstream user, Airbus. Since, no NPE emissions are seen throughout the sealant life cycle of the aerospace products, no environmental impact during continued use of the substance for authorisation is estimated throughout the supply chain.

Since a technically and economically feasible alternative to the use of NPE for the DU sites has not been identified in the AoA, impacts on the suppliers of alternatives in and outside the UK are not applicable here. In addition, NPE-free polysulfide sealants in the UK market at present have not been qualified, validated, or industrialised for the applications in the scope of this review report and hence cannot replace the NPE containing sealants currently in use.

The public at large will be affected majorly due to aircraft delays and other wider economic impacts due to non-authorisation. As for the geographical span, the UK will be affected as a result of decreased GDP and lost jobs due to a non-authorisation, leading to incompliance of services related to the aerospace industry affected due to non-authorisation. The environmental benefits, seen as a result of the non-use scenario, are not significant, when compared to negligible NPE related environmental risks in the applied for use scenario, as per the results of the CSR.

Within the applicant's business, employee dismissals (permanent and temporary dismissals in NUS 1 and NUS 2 respectively) would be seen, negatively impacting the revenue gained by the employer.

Thus, as a result of non-authorisation, all the actors in the supply chain in the UK as well as the public at large would be economically worse off as compared to the applied for use scenario. The environmental impacts remain near zero, with or without authorisation. However, external environmental impacts, due to increased CO2 emissions because of increased logistics required to import sealants from outside the UK (NUS 1), would be experienced, theoretically making the non-use scenario worse-off than the applied for use scenario in terms of environmental benefits obtained.

5.5. Combined impact assessment

Finally, the socio-economic benefits of continued use are summarised in the following Table 16 below.

TABLE 16: SOCIETAL COSTS ASSOCIATED WITH NON-USE

Description of major impacts	**Monetised/quantitatively assessed/qualitatively assessed impacts**	
	Million GBP [per year] [Over 6 years]	
	NUS 1	**NUS 2**
1. Monetised impacts		
Producer surplus loss by Airbus due to production interruption by DU sites	[213 - 417] [1 114 – 2 185]	[213 - 802] [1 114 – 4 204]
2. Additional quantitatively assessed impacts		
N/A	N/A	N/A
3. Additional qualitatively assessed impacts		
	• One -off investment cost for requalification of PMF sealants by Airbus • Asset acquisition costs (cold storage freezers, back-up generators) by Airbus • Operating costs (energy costs, logistics costs) by Airbus • External environmental costs of CO_2 emissions • Social costs of unemployment at GB DU sites • MRO activities remain infeasible in this scenario. See section 5.1.1.5 for details.	N/A

5.5.1. Comparison of impacts

The non-use scenarios imply a lower and upper bound to the duration (and impacts) of a temporary supply disruption in the provision of sealants, typically used to manufacture, maintain, and repair aerospace products. Given the complexity of the Aerospace supply chain and the multitude of affected processes and applications, as well as the nature of impacts that would occur due to the non-use scenario, it was not possible to carry out a detailed impact assessment, quantifying all impacts at all actors in the supply chain. This, however, does not change the overall conclusion of the SEA, as the consequent risks of the applied for use scenario are precluded. The NPE concentration is >0.1% only prior to mixing of the base and the hardener components. For Use 1 and Use 2, release is controlled by following proper risk management measures and operational controls. NPE releases are precluded throughout the sealant lifecycle of an aerospace product.

Based on these results from the CSR, the monetised environmental risk arising from the applied for use scenario is near zero (zero-emissions strategy). Thus, even if the socio-economic aspects of the impact assessment are substantially under-estimated, it is still clear that the benefits of continued use outweigh the monetised risks associated with continued use of the substance for authorisation.

In other words, there are no environmental benefits associated with either non-use scenario, since there is no potential for NPE release into the environment (i.e., no potential to reduce emissions). However, NUS 1 entails additional CO2 emissions, due to import of sealants from outside the UK, and NUS 2 carries heavy socio-economic impacts for the entire UK society. The applied for use scenario carries a smooth transition of production processes from sealants containing NPE to NPE free sealants in 4 years. However, NUS 1 and NUS 2 (being the lower and upper bound of impacts respectively), entail financial losses for Airbus, its downstream users (airlines and MROs) and the society overall in the UK.

Economic impacts would be seen in terms of EBIT losses for Airbus, along with cascading effects on the UK economy and the society, leading to dismissal of FTEs at least in NUS 2. Even so, these job dismissals represent a minimum estimate at the Airbus only. No dismissals at companies upstream or downstream the supply chain have been considered here.

A quantitative comparison of the socio-economic benefits and risks of continued use can be seen in Table 17 below. It should be highlighted again that the impacts described as the difference between the "applied for use" and the "non-use" scenarios represent the absolute minimum impact on Airbus. Real impacts are, by far, much higher than the impacts anticipated in this SEA.

TABLE 17: COMPARISON OF SOCIO-ECONOMIC BENEFITS AND RISKS OF CONTINUED USE

	[Per year] [Over 6 years]
Total costs (million GBP)	[213 – 802] [1 114 – 4 204]
Total releases (kg)	No releases

The table above shows the net benefits of authorisation or continued use of the substance in the UK. As the applicant and the DUs, including Airbus, carry a zero-emissions strategy, potentially, no or near zero emissions can be assumed and thus estimation of a benefit/monetised risk and a cost effectiveness ratio is not applicable here.

Since NPE emissions are foreseen to be zero, or only in the range of several kgs over the entire review period if unrealistic worst-case assumptions are applied, there is no imaginable case where the net benefit of a granted authorisation could become negative.

5.6. Sensitivity analysis

The ECHA Guidance on SEA (ECHA, Guidance on the preparation of socio-economic analysis as part of an application for authorisation. Version 1, 2011) proposes an approach for conducting the uncertainty analysis. This approach provides three levels of assessment that should be applied if it corresponds:

- qualitative assessment of uncertainties
- deterministic assessment of uncertainties
- probabilistic assessment of uncertainties.

The ECHA Guidance further states: the level of detail and dedicated resources to the assessment of uncertainties should be in fair proportion to the scope of the SEA. Further assessment of uncertainties is only needed if the assessment of uncertainties is of crucial importance to the overall outcome of the SEA.

Hence, a deterministic assessment of uncertainties has been carried out. To monetise the environmental impacts related to these emissions, the methodology as outlined in Annex B has been used.

Since a probabilistic assessment of uncertainties would not be of significant importance for the overall outcome of the SEA, this assessment has not been carried out in this SEA.

5.6.1. Qualitative assessment of uncertainties

Table 18 illustrates the systematic identification of uncertainties related to environmental and socio-economic impacts.

TABLE 18: UNCERTAINTIES CONCERNING SOCIO-ECONOMIC IMPACTS

Identification of uncertainty (assumption)	Classification	Evaluation	Criteria and scaling (contribution to total uncertainty)
NPE emissions to the environment	Parameter uncertainty	Over/underestimation	Low
Foregone profits for Airbus	Parameter uncertainty	Underestimation	High
Estimation of investment costs	Parameter uncertainty	Based on past experiences and conservative estimation	Low
Estimation of electricity cost	Parameter uncertainty	Based on publicly available data and conservative estimation	Low
Estimation of logistics cost	Parameter uncertainty	Based on market data and conservative estimation	Low

5.6.2. Deterministic assessment of uncertainties

A conservative mass-balance approach in the CSR aims to evaluate absolute worst-case releases of NPE to the environment from the sealant life cycle, under highly unrealistic conditions. This deterministic assessment of uncertainties is based on the outcomes of this analysis and aims to provide an absolute worst-case estimate of environmental costs, considering these overestimated emissions over the sealant life cycle of aerospace product.

For this purpose, it is assumed that **0.175 kg of NPE** are emitted to the environment per annum.

TABLE 19: UNCERTAINTY ANALYSIS FOR ENVIRONMENTAL IMPACT

Uncertainty analysis for environmental impact		
	NUS 1	**NUS 2**
Assumed worst-case emissions across the review period of 6 years (kg NPE)	1.05	1.05
Socio-economic impacts (GBP million)	1 114 – 2 185	1 114 – 4 204
Cost-effectiveness ratio (Cost per kg of avoided NPE emissions) [GBP million / kg]	**1,061:1 – 2,081:1**	**1,061:1 – 4,0004:1**

This assessment has been provided to preclude any uncertainty regarding the releases from the NPE-containing hardener component of the sealant. As concluded in the CSR, there are no releases to the environment and the net cost of not granting an authorisation would be far more than 1 114 – 2 185 million GBP for NUS 1 and far more than 1 114 – 4 204 million GBP for NUS 2. Overall, this assessment shows that even an unrealistic worst-case scenario does not change the outcome of this SEA.

5.7. Information to support for the review period

The Applicant is applying for a 6-year review period, to finish at the beginning of 2031. The applicant is seeking this authorisation to enable them to transition to an alternative within the requested review period. The criteria for this review period are provided below:

- There is not a technically suitable alternative available (Sections 3.2, 3.3, and 3.4) at the time of submission of this Review Report to meet the technical requirements that must be achieved for sealants within the aerospace industry (Section 3.1.3.5).
- The Applicant is of the opinion that the substitution effort can be completed and that a technically and economically feasible alternative can be found within the requested review period (Section 4.1.3). This timeframe allows for:
    - The completion of the R&D effort by the Applicant (end in Q4 2026),
    - Qualification by Airbus (18 months; end in Q2 2028), and
    - The Industrialisation by Airbus and the Supply Chain (24 months; end in Q2 2030).
- There is no risk associated with the continued use of the substance (Section 4.2 and accompanying CSR).

6. CONCLUSION

No alternative identified in this AoA-SEA can be substituted prior to the end of the Review Period. The Applicant, as formulator, has undertaken significant research and development activities (Section 3.2.1). During early reformulation activities, it was identified that surfactants that are not derived from NPE substances are not as efficient at bonding the curing agent into the rest of the liquid hardener mix. It was also determined that, contrary to initial expectations, it is not a straight-forward process to find a suitable alternative surfactant that works to the same standard but does not contain NPE.

The Applicant has screened >100 different surfactants and has been investigating suitable alternatives for NPE surfactants in its polysulfide sealants. Of these four potential alternatives have been highlighted for further assessment (Section 3.3). Overall, the Applicant believes that it will most likely be able to introduce a fully working NPE-free reformulated alternative sealant product to Airbus, ready to commence technical qualification, by Q4 2026. Potential Alternative 2 (Polyether phosphate) is currently considered as the most mature candidate and will be focussed on as a priority. This alternative is the most likely to successfully complete the development testing phase, before reformulated sealant samples are made available to Airbus for testing. However, the other potential alternatives are undergoing similar development tests, and in the case of multiple viable potential alternatives, the Formulator may use multiple surfactants in sealant formulations going forward to avoid dependence on a single surfactant source. The R&D work with the formulator is still ongoing and is expected to end Q4 2026 for the last sealant reference.

As such it can be concluded that there are suitable alternatives in general to the Applicant, but these alternatives are not yet technically feasible. As required a substitution plan has been included within this AoA-SEA (see Section 4.1.3). Within the Substitution Plan the Applicant has provided a timetable of works associated with the substitution of NPE from the relevant sealants. The Applicant is of the opinion that the substitution effort can be completed and that a technically and economically feasible alternative can be found within the requested review period. Based on this timetable the Applicant has requested a Review Period of 6 years, running to beginning of 2031, in order to try completing the substitution effort. This timeframe allows for:

- The completion of the R&D effort by the Applicant (end in Q4 2026),
- Qualification by Airbus (18 months, end in Q2 2028), and
- The Industrialisation by Airbus and the Supply Chain (24 months, end in Q2 2030).

The continued applied for use is for the Applicant to continue using the substance under the conditions of the existing AfA and continue their substitution efforts, with support from Airbus.

There is no risk to the environment associated with the continued uses of the substance (Section 4.2 and accompanying CSR). There is no potential for releases to the environment of the NPE-containing hardener component of the two-part sealant during formulation or mixing within the two-compartment kit, in small scale batches by hand or bulk mixing by machine, in line with the RMMs and OCs mentioned in this report and the accompanying CSR.

If this Review Report and accompanying review period is not accepted the least disruptive NUS assumes logistics and processes for all aerospace operations in the UK can be adapted to allow use of pre-mixed and frozen (PMF) polysulfide sealants. Full details of the NUS are in Section 4.3. There are substantial doubts about the technical feasibility of this NUS and even if these can be overcome there would have to significant investment required (e.g., new low cold storage freezers, back-up generators and other relevant equipment needed at by DUs in the UK) and considerable logistical challenges (customs, refrigerated air freight etc.) to address. The energy requirements and increased CO_2 emissions associated with the NUS are also substantially greater than the current situation and as there is no potential for release of NPE to the environment under the authorised use, the NUS does not represent an improvement from an environmental perspective. **Considering the greater energy use required the NUS has a far more substantial negative environmental impact than the authorised use.**

The Applicant employed a conservative approach to the economic assessment based on the NUS above and accounting for only those impacts within that NUS that can be reliably quantified with available hard data. The assessment demonstrates the NUS would involve socio-economic costs in the range of 1,114 – 2,185 million GBP, while the volume of NPE-containing sealants would not decrease at all. In addition, environmental impacts associated with the NUS would be greater than the baseline, due to substantial additional energy costs associated with the need to refrigerate the PMF sealant, and to transport by air.

The economic impacts to customers of the aerospace industry and those that rely on these industries will also be substantial. Interruptions in aerospace product and service (maintenance and repair) availability during the expected period where no aircraft production takes place while production is moved outside the UK, will bring disruption to commercial and defence aerospace industries, with widespread implications.

Considering these downstream economic impacts during the quantitative assessment would greatly influence the ratio between economic benefits and safety and security impacts, further distinguishing the benefits of authorisation.

As indicated above, there are substantial doubts about the technical feasibility of this NUS. In this case, production of Airbus and Airbus related products and components (sealant is required for final assembly of aircraft) that require NPE-containing sealants in the UK would stop. Airbus products could not be assembled in the UK and MRO activities that require these sealants would also stop.

The SEA shows, in case it is not possible to establish use of imported PMF in the medium term, the impact of stopping operations is estimated to be more than 1 114 – 4 204 million GBP.

The Applicant is of the firm belief that the socio-economic benefit of the continued use far outweighs the risk to the environment. This is backed up by Section 5.6.2, where when the absolute worst-case scenario of emissions of NPE was used (note this is not a real-world figure and as concluded in the CSR, there are no releases to the environment) to calculate the cost effectiveness ratio (cost per kg of avoided NPE emissions). The calculated ratio using this absolute worst-case scenario is > 1,000 million GBP to 1 kg of

NPE emitted showing that even when using an unrealistic worst-case scenario the SEA benefits of continued use are exceptionally strong.

Based on the lack of a technically and economically feasible alternative at the time of submission, the significant R&D effort already completed and the substitution plan in place, the lack of any impact to the environment associated with the continued use (and the greater impact the NUS would have on the environment), and the significant socio-economic impact a rejection of this application would have on the aerospace industry in the UK, the Applicant believes a review period of 6 years (finishing beginning 2031) is justified.

The Applicant is of the opinion that the societal costs of discontinuing the use of the Annex XIV Substance **far outweigh** the imperceptible risks to the environment associated with the continued use. It is for this reason that the review period should be granted as requested to allow the Applicant to continue use as currently allowed under the existing AfA and for the substitution process to be completed.

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APPENDICES

Annex A: Case Studies

Case study 1: Examples for affected daily operations due to a non-granted authorisation

Impacts on airlines

In the case of non-granted authorisation, aircraft on ground (AOG) situations will become increasingly common. These AOG scenarios are highly expensive and disruptive for airlines. AOG occur, for example, when planes are not allowed and/or able to fly due to technical defects or any other issues which require repair activities. There are thousands of maintenance and repair tasks (e.g., [redacted]) that require polysulfide sealants. CBI 2

An inability to access sealants containing NPE makes MRO activities unfeasible and replacement of components[13] (if possible, in the integrated design and structure of an aircraft) mandatory. For replaceable components, aircraft operators have only one possibility to keep their aircraft flying – stocking parts at flight destinations to avoid running out of parts. Because it is not always predictable which part will need replacement/service, this stocking of parts is associated with tremendous costs. Adding to that, the proper disposal of parts that may have suffered only minor damage (as opposed to the repair of such a part), the increase in costs and waste would be huge. Already today, where the possibility to use sealants containing NPE exists, the costs of maintaining such replacement stocks (> € 100 million per airline) as well as managing AOG scenarios are substantial, e.g., one source estimates that each cancelled transatlantic flight results in costs of approximately US$ 200,000. This can be further explained by the obligation to provide accommodation, meals, and transport for passengers, to reschedule crew planning, cascade effects on the same day and the next day concerning the return flight as well as overtimes of mechanics to handle AOG (Aviation week network, 2015).

It should be clear that given 100 000 flights a day worldwide (International Air Transport Association, n.d.), such AOG scenarios due to non-granted authorisation quickly make aircraft use economically and operationally unfeasible. In the case of a non-granted authorisation, the frequency of AOG scenarios would increase and the costs needed to counter such scenarios would rocket.

A study about the disruption of 80 % of Europe's air traffic in 2010 due to the volcanic ash plume of Eyjafjallajokull demonstrates what happens 'when the system stops working' (Aviation Benefits). In the EU, usually 25,000 flights per day take place in Europe. In one week 10 million passengers were affected and US$ 5 billion in the global economy was lost. The EU suffered a GDP impact of US$ 2.6 billion, and US$ 867 million lost in sales.

A non-granted authorisation would heavily affect today's business as well as future growth. IATA recently published a study (IATA, n.d.) which demonstrates the current and predicted future economic activity supported by the aviation sector in the EU-28 (see summary in

[13] Components must be replaced with identical parts manufactured outside the EU

Table A-1). The study foresees substantial growth in revenue and employment over the next 20 years under normal circumstances.

TABLE A-1: ECONOMIC ACTIVITY SUPPORT BY THE AVIATION SECTOR IN EU-28

	2012		2035	
	Jobs, '000	GDP, € bn	Jobs, '000	GDP, € bn
Direct	2,031	121	2,727	170
Indirect and Induced	3,499	213	4,977	318
Tourism	3,749	178	4,856	235
Total	**9,279**	**512**	**12,561**	**722**

Furthermore, this study provides an analysis of delayed flights (about 31% of all flights were delayed in 2022) according to the United States Department of Transportation (Transtats, 2022) which are broken down as follows:

- delays of air carriers (9.33 %);
- national aviation system delays (5.98 %);
- cancelled flights (5.49 %)
- diverted flights (0.23 %);
- extreme weather (1.14 %);
- security delays (0.07 %);
- on-time (68.72 %).

In 2022 the average delay per flight mounted up to 17.3 minutes. This number is at a 5-year high and sharply increased compared to 2021, where the average flight delay was at 9.2 minutes per flight. This development was mostly driven by the aviation industry generally struggling to adjust to the higher passenger number and flights after the COVID-19 pandemic (CODA Digest, 2023).

Losing connection to global destinations will hamper Europe's productivity and economic growth. Statistical relationship between air connectivity and labour productivity yields an estimate that a 10 % rise in connectivity, relative to a country's GDP, will boost labour productivity levels by 0.07 % (IATA, n.d.). If now due to a non-granted authorisation further AOG scenarios are unavoidable this value will dramatically increase.

Cargo

Impacts due to a non-granted authorisation for air freight shall also be expected to be significant. In 2014, airlines transported globally 51.3 million metric tonnes of goods, representing more than 35 % of global trade by value but less than 1 % of world trade by volume. That is equivalent to US$ 6.8 trillion worth of goods annually, or US$ 18.6 billion worth of goods every day. An increase in the value of goods carried by air was estimated to be US$ 6.2 trillion in 2018. On average, cargo business generates 9 % of airline revenues, representing more than twice the revenues from the first-class passenger segment (Aviation week network, 2015). Concerning cargo carriers, all earnings might be lost in the case of delayed deliveries due to heavy penalties; such penalties must be avoided by providing significant numbers of spare aircraft and spare parts resulting in considerable additional costs compared to passenger airline (Aviation week network, 2015).

Tourism

The tourism industry will be negatively affected in the case of a non-granted authorisation of NPE. The connection of aviation and the tourism industry is strong, this is well understood by tourism management, and it is easy to find public strategy documents showing their vested interested in attracting and maintaining airline routes to their areas to promote tourism. Travelling by airplane is convenient and popular, contributing both to individual mobility and employment in the tourism sector. In fact, over 57 % of international tourists travel by air (ATAG, Aviation benefits beyond borders, 2018). The tourism industry relies heavily on the aerospace industry, for example a report by ATAG shows that in Africa '…an estimated 4.9 million people directly employed in tourism are supported by overseas visitors arriving by air, contributing US$ 36 billion to GDP in African economies in 2016 (ATAG, Aviation benefits beyond borders, 2018). Some economies significantly rely on tourism which in turn is heavily dependent on-air travel. According to the World Travel and Tourism Council (Council, 2017), Travel and Tourism in Malta directly contributed € 2,425,5 million to the GDP (26.7 % of Malta's total GDP) in 2017 and 27,500 direct employments (15.5 % of Malta's total employment) were correlated to Travel and Tourism in 2016.

Important global figures for the dependence of tourism on air transport taken directly from the ATAG website are as follows:

- direct: 15.6 million direct jobs in tourism globally are estimated to be supported by the spending of foreign visitors arriving by air. This includes jobs in industries such as hotels, restaurants, visitor attractions, local transport, and car rental, but it excludes air transport industry jobs.
- indirect: A further 14.1 million indirect jobs in industries supplying the tourism industry are supported by visitors arriving by air.
- induced: These direct and indirect tourism jobs supported by air transport generate a further 36.7 million jobs in other parts of the economy, through employees spending their earnings on other goods and services (ATAG, Aviation benefits beyond borders, 2018).

Thus, negative effects on the aviation industry due to non-granted authorisation will lead to consequences in the entire tourism industry, and even entire economies that are dependent on tourism and their related industries, creating a 'ripple effect' throughout these economies causing far reaching negative socio-economic impacts. The direct, indirect, and induced effects included, air transport globally supported 292 million jobs within tourism, contributing to over US$ 7.6 trillion a year in 2016 (ATAG, Aviation benefits beyond borders, 2018).

Impacts on aviation-linked industries

Several examples of linked industries are provided below. Regarding the linked industries, it is important to note:

- In general, a healthy aviation industry can have positive effects on a country´s economy since the attractiveness as business location is increased as integration in worldwide activities is enabled.
- The aviation industry significantly contributes to the development and maintenance of foreign trade relationships (import and export) of high-tech products, machine

and vehicle parts, sensitive goods etc., through the ability to provide quick, safe, and reliable transport over long distances.

Each of these linked industries represents large industries in themselves, and most are reliant on the aviation industry to even exist. The non-authorisation of NPE and the subsequent closure (even temporarily or partially) would result in massive negative socio-economic impacts not only for the aviation industry, but for the many linked industries, and for other industries supporting these linked industries. The following list gives an insight of possibly affected branches of aviation industry in case of non-authorisation (Airline Suppliers, n.d.):

- **Aircraft interior and design**
  - airline branding solutions (placards, aircraft paintings, technical stickers for aircraft interiors and exteriors etc.);
  - cabin interior designs (aircraft seats, LED reading lights, aircraft stowage, heat shielding and sound damping solutions etc.);
  - leather manufacturers for aircraft interior;
  - manufacturers of carpet and upholstery solutions (interior seats, aircraft flooring);
  - aircraft lifesaving and emergency equipment (safety relevant seat components, life jackets etc.);
  - airline consultancy and planning (design, fleet and financing solutions, aviation IT-specialists, technical services etc.);
  - manufacturers of airline clothing, uniforms, and cabin footwear.

- **Airline Technology**
  - airline communication solutions (voice communication systems for airlines and airports, tracking and tracing systems etc.);
  - airline check-in equipment (production of boarding passes, baggage tags, air waybills etc.);
  - passengers with reduced mobility (PRM) solutions (medical lifts, board transit chairs etc.);
  - inflight entertainment.

- **On-board services**
  - airline food and beverages (sweet and savoury snacks, hot snacks and sandwiches, ready snacks, on-board bottled wines, boxed cakes and desserts etc.);
  - aircraft cleaning and sanitation solutions (lavatory and water systems, dishwashing systems for aircraft kitchens, on-board waste-management, disposable tray sets etc.);
  - manufacturers of airline passenger service products (hot and cold towels, pillows, napkins catering service carts etc.);

- **Maintenance**
  - aircraft maintenance, repair, overhaul (MRO);
  - manufacturers of docking systems for aircraft movements;
  - manufacturers of airline cargo equipment (passenger ramps, luggage tow tractors, cargo high loaders etc.);

  - aircraft de-icing equipment and chemicals.

Further impacts

In the absence of any alternative to maintain, repair or overhaul aircraft, the ground readiness for all types of aircraft will be impaired, with expected essential consequences. For example, helicopters are especially vulnerable to being affected by the lack of MRO services (DHV). In this context, air rescue must be mentioned as an important field of application in difficult to access terrain, such as mountains or on sea. Control and maintenance of pipelines (oil, gas, water) and high-voltage systems is another sector where helicopters are essential and frequently applied. Moreover, helicopters help to build up and supply oil plants and offshore wind farms, support agriculture by crop spraying, report news and sport events from the air and operate photo and film flights for terrain exploration and cartography. Finally, people can be easily transported in difficult landscapes or less developed regions without airports or simply for touristic purposes. The highest technical demands and safety standards must be ensured in all these situations, remembering that these aircraft operate in harsh environments and often at the limit of their specifications.

Conclusions

Impacts relating to a change in air transportation availability will significantly impact direct, indirect, and induced employment, but have a much wider impact on the employment and income of services as economic activities that rely on the availability of air transportation services, such as tourism, trade, local investment and productivity improvement, are affected. Aggregate trend analysis shows that there is a correlation between air travel and GDP and that the cost of delays has an adverse effect on economic activity especially at the regional level as an air transportation system becomes saturated (Massachusetts Institute of Technology).

Case study 2: Military Aircraft– potential downstream user impacts of a non-authorisation

Military strength and readiness are key to maintain peace and prosperity in the EEA. Military aircraft would be impacted by a decision to not grant authorisation for the continued use of NPE. Some military aircraft in operation rely heavily upon well-known and time-tested processes that utilise NPE-containing sealants.

In the case of non-authorisation of NPE for use in military aircraft, availability and performance would be negatively affected. This would also have an adverse impact on European and allied military activities, especially in current and future conflict situations.

Interruption to the manufacture, repair, and overhaul of these components due to the non-availability of NPE would jeopardise the availability and combat readiness of military aircraft and therefore the safety of armed forces in case of a military emergency.

Practical examples of how a decision not to authorise the continued use of NPE in polysulfide sealants could impact military aircraft include:

- Availability of mission critical aircraft could be impaired due to drastically shortened maintenance and service intervals or failure of aerospace components.

- Turnaround times for maintenance and repair of equipment might also be longer due to additional transport times where MRO activities cannot be performed in the EEA anymore. Furthermore, it might not be possible to export components for MRO to other countries due to national security regulations.
- Production, maintenance and/or repair costs for, or associated with military aircraft will increase for the industry and its customers.
- Any of the examples described above could affect the ability to successfully accomplish a mission, which could potentially have dire consequences.

It can be concluded that despite the limited quantities of these sealants used for military aircraft, the availability of this substance is essential to the European armed forces.

Case study 3: Production of aerospace products in the EEA – potential impacts due to a non-granted authorisation

Since there are no alternative substances or production processes available for the aerospace sector, the unavailability of NPE containing sealants due to a non-granted authorisation would result in cessation of production stop for certain aerospace components. It would force the relocation of these production processes to non-EEA countries. In best cases, existing production sites outside the EEA can be used, assuming adequate capacity available or can be created. However, many of the small and much specialised companies that are suppliers to OEMs do not have the resources, facility or know-how to relocate their production; they would be forced to simply cease their business activities.

Consequently, in this scenario, OEMs would, in theory, need urgently to identify and qualify non-EEA suppliers to continue their production, subject to the condition that the aerospace components will be identical to those currently produced. In practice, the OEMs advise it will be impossible to find and qualify new suppliers, re-certify and start production without business interruption.

Assuming only half a year of interruption (although two to three years interruption is considered more realistic, noting that relocating final assembly lines will take up to nine years), the direct socio-economic impacts will be potentially devastating. Table A-2 sets out the estimated turnover and employment of the European aerospace industry.

TABLE A-2: ECONOMIC DATA OF THE EUROPEAN AEROSPACE INDUSTRY (ASD, 2022 - FACTS & FIGURES, 2022)

	Turnover billion € [2021]	Employment ('000) [2021]
Aeronautics (civil + military)	179	604

As discussed within the SEA in detail, relocation of production is expected to ultimately result in a shift of production activity and logistics around component manufacture, since it makes economic and technical sense to carry out many production activities (e.g. machining, treatment, sub-assembly) in close proximity. Over time, it is expected there would be a loss in technical know-how, design and research and development as well as associated infrastructure in the EU as the centres of technical activity associated with the aerospace industry move elsewhere.

The aerospace sector in the EU continues to invest significant resources into the aerospace industry, including for environmentally friendly aircraft. One example of this is the Clean Sky initiative which is a public-private partnership worth € 1.6 billion. To maintain competitiveness, the aerospace industry needs to make huge investments which can take years to become profitable. Aerospace leaders in the EU such as France and the UK have '… taken an initiative to make improvement in policies that adapts to the concern of investors.' (Invest in EU, kein Datum). France aerospace industry, one of the dominant in the EU is estimated to be worth US$ 15 billion, being involved in the production of essentially all major aerospace products and services. The turnover of the EU aeronautic industry, at well over € 140 billion will be impacted negatively on a huge scale.

Moreover, it must be noted that such a scenario results in distortion of an entire industry with severe distortion of global competition. Market forecasts state that 37,400 new passenger and freight aircraft will be required by 2037, approximately 19% of which will be required in Europe. This shows the steady growth of the industry and its contribution to healthy growth of other sectors (e.g. airlines and tourism, see case study 2). A decision not to grant an authorisation would therefore have dramatic impacts even on the global economy.

ANNEX B: JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

Blanked out item reference	Page number	Justification for confidentiality
CBI 1	16, 20, 22, 24, 107	**<u>Demonstration of Potential Harm</u>** Dissemination of this information could reveal the overall size of the Chemetall Market which is not publicly available information. This could lead to competitors to Chemetall engaging in predatory practices that could severely harm the commercial interests of Chemetall. This confidentiality claim will remain valid indefinitely
CBI 2	53, 56, 58-60, 64, 67, 69, 72, 105, 127	**<u>Demonstration of Potential Harm</u>** Dissemination of this information could reveal details of the substitution effort by Airbus and Chemetall, including details of manufacture, impacted products and operations carried out by each company with regards to substitution. This information is not publicly available. Disclosure of this information could lead to competitors to Chemetall engaging in predatory practices that could severely harm the commercial interests of Chemetall. This confidentiality claim will remain valid indefinitely