Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for use:

The formulation of a hardener component containing OPE in Aerospace and Defence (A&D) two-part polysulphide sealants

Submitting applicant

PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc. – OR5

ECHA/RAC/SEAC: AFA-O-0000006902-72-01/F

Consolidated version

Date: 24/12/2020

Consolidated version of the
Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis
on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to the following application for authorisation:

Applicants	**PPG Europe B.V. in its legal capacity as Only Representative of PRC DeSoto International Inc. – OR5** (position in supply chain: upstream) **Sealants Europe SAS** (position in supply chain: downstream) **PPG Industries (UK) Ltd.** (position in supply chain: downstream) **Boeing Distribution, Inc.**[1] (position in supply chain: downstream) **Aviall UK Inc.** (position in supply chain: downstream) **Wesco Aircraft EMEA Ltd (Poland)** (position in supply chain: downstream) **Wesco Aircraft EMEA, LTD (UK)** (position in supply chain: downstream)
Substance ID EC No CAS No	**4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (referred to as 4-tert-OPnEO)** - -
Intrinsic properties referred to in Annex XIV	☐Carcinogenic (Article 57(a)) ☐Mutagenic (Article 57(b)) ☐Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☒Other properties in accordance with Article 57(f) - Endocrine disrupting properties – environment

[1] Following submission of the application Aviall Services, Inc. notified ECHA of the change of the corporate name change to Boeing Distribution, Inc.

Use title	**The formulation of a hardener component containing OPE in Aerospace and Defence (A&D) two-part polysulphide sealants.**
	Other connected uses: Use 2 of this application "Mixing, by Aerospace and Defence Companies, and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1 % w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a).".
	Same uses applied for: not applicable.
Use performed by	☒ Applicants ☐ Downstream User(s) of the applicants
Use ID (ECHA website)	0203-01
Reference number	11-2120843377-48-0001 11-2120843377-48-0002 11-2120843377-48-0003 11-2120843377-48-0004 11-2120843377-48-0005 11-2120843377-48-0006 11-2120843377-48-0007
RAC Rapporteur RAC Co-rapporteur	BRANISTEANU Radu DE LA FLOR TEJERO Ignacio
SEAC Rapporteur SEAC Co-rapporteur	SHAKHRAMANYAN Nikolinka
ECHA Secretariat	ROGGEMAN Maarten LAZIC Nina LIOPA Elīna

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	02/07/2019
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	08/05/2020
Application has been submitted by the Latest Application Date for the substance and applicants and their DUs can benefit from the transitional arrangements described in Article 58(1)(c)(ii).	☒Yes ☐No
Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	13/05/2020 - 08/07/2020
Comments received	☒Yes ☐No Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25618/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Request for additional information in accordance with Article 64(3)	On 09/06/2020 and 18/06/2020 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25618/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Trialogue meeting	Not held – no new information submitted in consultation and no need for additional information/discussion on any technical or scientific issues related to the application from the rapporteurs.
Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the applicants	☐Yes ☒No
The application included all the necessary information specified in Article 62 that is relevant to the Committees' remit.	☒Yes ☐No Comment:
Date of agreement of the draft opinion in	RAC: 10/12/2020, agreed by consensus.

accordance with Article 64(4)(a) and (b)	SEAC: 17/09/2020, agreed by consensus.
Date of sending of the draft opinion to applicants	17/12/2020
Date of decision of the applicants not to comment on the draft opinion, in accordance with Article 64(5)	24/12/2020
Date of receipt of comments in accordance with Article 64(5)	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 24/12/2020, adopted by consensus.
	SEAC: 24/12/2020, adopted by consensus.
Minority positions	RAC: ☒N/A
	SEAC: ☒N/A

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the risk management measures described, as well as
- other available information.

In this application, the applicants derived PNEC(s). However, RAC concluded that the applicants have not demonstrated a threshold level for the endocrine disrupting properties for the environment of the substance. Therefore, RAC concluded, in accordance with Annex I of the REACH Regulation, that for the purposes of the assessment of this application it was not possible to determine PNEC(s) for the endocrine disrupting properties for the environment of the substance.

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicants or their downstream users with the same function and similar level of performance. Therefore, RAC did not evaluate the potential risk of alternatives.

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.

The use applied for may result in 0 kg per year emissions of the substance to the environment.

THE OPINION OF SEAC

SEAC has formulated its opinion on:

- the socio-economic factors,
- the suitability and availability of alternatives associated with the use of the substance as documented in the application, as well as
- other available information.

SEAC took note of RAC's conclusion that it is <u>not</u> possible to determine a PNEC for the endocrine disrupting properties for the environment of the substance in accordance with Annex I of the REACH Regulation.

The following alternative has been assessed: removal of 4-tert-OPnEO from the hardener formulation (see section 4 of the Justifications).

SEAC concluded on the analysis of alternatives and the substitution plan that:

- By the sunset date there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicants and their downstream users.
- The substitution plan was credible and consistent with the analysis of alternatives and the socio-economic analysis.

SEAC concluded on the socio-economic analysis that:

- The expected socio-economic benefits of continued use are at least €1.1[2] billion per year and additional important benefits to society have been assessed qualitatively but have not been monetised, such as avoided negative impacts associated with unavailability of 4-tert-OPnEO sealants on maintenance repair and overhaul (MRO)

[2] Under the most conservative scenario, by considering 1-year profit loss of € 4.5 billion.

shops, aircraft operators, Ministries of defence, flight passengers and companies relying on air cargo .

- Risks to the environment of shortlisted alternative have not been quantified, on the basis that the alternative implies the removal of 4-tert-OPnEO from the hardener formulation. Therefore, any risk from this alternative is precluded.

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the risks to the environment associated with the continued use of the substance.

SEAC considered that if an authorisation was refused, the use of the substance could:

- cease altogether in the EU
- be taken up by market actors operating outside the EU.

SEAC considered that, if an authorisation was refused, it was likely that in the European Union:[3]

- 70-120 jobs would be lost in the NUS 1 and
- 7 570-9 620 jobs would be lost in the in NUS 2.

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

No conditions for the authorisation or monitoring arrangements for the authorisation are proposed.

No recommendations for the review report are made.

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicants and the comments received on the broad information on use, a **4-year** review period is recommended for this use.

[3] Wherever reference is made to the European Union, this shall apply also to EEA countries.

SUMMARY OF THE USE APPLIED FOR

Role of the applicants in the supply chain	Upstream ☐ manufacturer[s] ☒ importer[s] ☒ only representative[s] ☒ formulator[s] Downstream ☒ downstream user[s]
Number and location of sites covered	2 sites: PPG UK in Shildon (United Kingdom) and Sealants Europe SAS[4] in Bezons (France)
Annual tonnage of Annex XIV substance used per site (or total for all sites)	Across the two sites, between 50 and 250 kg of 4-tert-OPnEO is used during formulation of the hardener per annum.[5]
Function(s) of the Annex XIV substance.	4-tert-OPnEO acts as surfactant to assist in evenly dispersing the curing agent (manganese dioxide) in the hardener component of the two-part polysulfide sealants. Some of the key technical criteria for the selection of sealants are: viscosity, density, working life, cure time, shelf life. Moreover, the sealants also need to meet a number of performance parameters, such as: hardness, adhesion, chemical and water resistance, corrosion resistance, thermal cycling resistance compatibility with substrates, etc.
Type of products (e.g. articles or mixtures) made with Annex XIV substance and their market sectors	Product: Hardener part of two-part polysulfide sealants. Market sector: Production, maintenance, repair, and overhaul (MRO) of Aerospace and defence industry.
Shortlisted alternatives discussed in the application	Alternatives considered: -removal of 4-tert-OPnEO from the hardener formulation and application of mechanical means to ensure adequate dispersion of the curing agent. -4-tert-OPnEO-free polysulfide formulations already existing on the market and -sealants based on alternative chemistries (polythioether sealants, epoxy-based sealants, silicone sealants and polyurethane sealants).

[4] http://www.ppgaerospace.com/Products/Sealants/SealantsEurope.aspx
[5] The total per annum usage of 4-tert-OPnEO covered by the authorisation is 100-500 kg: 50-250 kg/year is used in the formulation of polysulfide sealant and 50-250 kg/year is present in imported polysulfide sealant formulated at non-EU sites.

Annex XIV substance present in concentrations above 0.1 % in the products (e.g. articles) made	☒Yes (in the hardener component) ☐No ☐Unclear ☐Not relevant
Releases to the environmental compartments	☐Air ☐Water ☐Soil ☒None
The applicants have used the PNECs or dose response relationship recommended by RAC	☐Yes ☐No ☒Not relevant
All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No
All relevant routes of exposure were considered	☒Yes ☐No
Adequate control demonstrated by applicants for the relevant endpoint	☐Yes ☐No ☒Not Applicable – non-threshold substance
Level of release used by applicants for risk characterisation	<u>Environment</u> Air: 0 kg/year. The substance is not considered to be volatile and is unlikely to pose a risk to the air compartment. Water: 0 kg/year. The formulation of the polysulfide sealant hardener does not involve the use of water at any point. Cleaning and maintenance of equipment also excludes use of water. In addition, all contaminated waste is incinerated. Therefore, there is no possibility that 4-tert-OPnEO can come into contact with water or be released to wastewater Soil: 0 kg/year. The substance is handled indoor, there is no direct release to soil and no sludge from Sewage Treatment Plant (STP).
Risk Characterisation	Environmental compartments: The applicants did derive PNECs for the endocrine disrupting properties for the environment of the substance but did not compare these with PECs. The applicants stated that due to the RMMs and OCs, release to the

	environment is precluded. Therefore, only a qualitative risk assessment is conducted. The applicants consider that the use poses no risk to the environment.
Applicants are seeking authorisation for the period of time needed to finalise substitution ('*bridging application*')	☒Yes ☐No ☐Unclear
Review period argued for by the applicants (length)	4 years
Most likely Non-Use scenario	Relocation to a non-EU site and imports of pre-mixed frozen (PMF) sealants, where 4-tert-OPnEO concentration is less than 0.1 %.
Applicants conclude that benefits of continued use outweigh the risks of continued use	☒Yes ☐No ☐Not Applicable – threshold substance with adequate control
Applicants' benefits of continued use	From 4.5 to 19 billion euros over the 4-year review period.
Society's benefits of continued use	Some of the indirect benefits to society in the continued use scenario are: • Avoided temporary gap in the manufacturing of A&D applications. • Avoided delays in Maintenance, repair and overhaul (MRO) activities. • Avoided delays in flights. Avoided negative impacts to the air cargo transportation and so to the trade.
Distributional impacts if authorisation is not granted	Described in section 5.2 and 5.4.
Job loss impacts if authorisation is not granted	70-120 job losses are expected in the most likely non-use scenario (NUS 1) and 7 570-9 620 job losses in NUS 2.

SUMMARY OF RAC AND SEAC CONCLUSIONS[6]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for environment

Since no water is involved in the formulation process, no wastewater is produced, and since all solid waste which had been in contact with 4-tert-OPnEO is collected and disposed of as waste for incineration, RAC concluded that operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.

Are the OCs/RMMs in the Exposure Scenario appropriate and effective in limiting the risk?

☒Yes ☐No

Does RAC propose additional conditions related to the operational conditions and risk management measures for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements related to the operational conditions and risk management measures for the authorisation?

☐Yes ☒No

Does RAC make recommendations related to the operational conditions and risk management measures for the review report?

☐Yes ☒No

2. Exposure Assessment

Releases to the environmental compartments

Air: No emissions
Water: No emissions
Soil: No emissions.

All wastes that could be contaminated with 4-tert-OPnEO are collected for incineration. No water is involved in the formulation process and no emissions to waste water occurs. Further, the amount of water used for floor regular cleaning is treated as hazardous waste and incinerated. The emissions to air are expected to be approximately zero, considering the

[6] The numbering of the sections below corresponds to the numbers of the relevant sections in the Justifications.

relatively low vapour pressure of 4-tert-OPnEO. There is no direct release to soil.

Conclusions of RAC

RAC considers that the applicants have provided enough information to demonstrate that release to environment compartments is prevented as far as technically and practically possible. The release of 4-tert-OPnEO to the environment from the formulation is zero.

Does RAC propose additional conditions[7] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements[8] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC make recommendations related to exposure assessment for the review report?

☐Yes ☒No

3. Risk Characterisation

The applicants derived PNECs for the endocrine disrupting properties for the environment of the substance but did not compare these with PECs. The applicants stated that due to the RMMs and OCs, release to the environment is precluded. Therefore, only a qualitative risk assessment is conducted. The applicants consider that the use poses no risk to the environment.

RAC concludes that the current state of knowledge of the endocrine disrupting properties, mode(s) of action and effects of 4-tert-OPnEO in the environment as presented by the applicants is insufficient to determine a threshold.

Based on the OCs & RMMs described in the exposure scenario, notably the waterless process and the collection for incineration of all waste contaminated with 4-tert-OPnEO, RAC is of the view that the applicants have demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible.

The use applied for may result in 0 kg per year emissions of 4-tert-OPnEO to the environment.

[7] Conditions can be proposed where RCR is > 1, OCs and RMMs are not appropriate and effective, risk is not adequately controlled, minimisation of emissions is not demonstrated.

[8] Monitoring arrangements can be recommended where RCR is < 1, OCs and RMMs are appropriate and effective, risk is adequately controlled, minimisation of emissions is demonstrated – but minor concerns were identified.

4. Analysis of alternatives and substitution plan[9]

What is the amount of substance that the applicants use per year for the use applied for?

100-500 kilograms per year.

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicants and their downstream users before the Sunset Date?

☐Yes ☒No

Have the applicants submitted a substitution plan?

☒Yes ☐No

If yes, is the substitution plan credible and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

Conclusions of SEAC

By the sunset date there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicants. A substitution plan was submitted and SEAC finds it credible that the formulator will replace 4-tert-OPnEO in all the 25 formulations by the end of 2024.

Does SEAC propose any additional conditions or monitoring arrangements related to the assessment of alternatives for the authorisation?

☐Yes ☒No

Does SEAC make any recommendations to the applicants related to the content of the potential review report?

☐Yes ☒No

[9] The judgment of the ECJ Case T-837/16 Sweden v Commission stated that the applicant has to submit a substitution plan if alternatives are available in general. The Commission is currently preparing the criteria, derived from the judgment for establishing when an alternative is available in general. Once these are prepared this opinion format will be amended accordingly. The European Commission informed the REACH Committee in 9-10 July 2019 of its preliminary views on the criteria. In that note that Commission considered that the criteria defining a 'suitable alternative' would imply that it was i) *safer* and ii) *suitable*. Suitability would not mean it to be *"in abstracto"* or "*in laboratory or exceptional conditions*" but it should be "*technically and economically feasible in the EU*" and "*available, from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market*".

5. Benefits and risks of continued use

Have the applicants adequately assessed the benefits and the risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the risks to the environment, associated with the continued use of the substance.

This conclusion is based on the following:

- the analysis of impacts provided in the application for authorisation.
- SEAC's assessment of the benefits to the applicants and the society of the continued use.
- SEAC's assessment of the suitability of the alternative identified by the applicants.
- SEAC's assessment of the credibility and transparency of the substitution plan.
- RAC's assessment of the risk to the environment.

Any additional information provided by the applicants.

6. Proposed review period for the use

☒ 4 years

☐ 7 years

☐ 12 years

☐ Other – ... years

7. Proposed additional conditions for the authorisation

RAC

Additional conditions:

For the environment ☐Yes ☒No

SEAC

Additional conditions: ☐Yes ☒No

8. Proposed monitoring arrangements for the authorisation

RAC

Monitoring arrangements:

For the environment ☐Yes ☒No

SEAC

Monitoring arrangements ☐Yes ☒No

9. Recommendations for the review report

RAC

For the environment	☐Yes	☒No

SEAC

AoA	☐Yes	☒No
SP	☐Yes	☒No
SEA	☐Yes	☒No

10. Applicants' comments on the draft opinion

Have the applicants commented the draft opinion?

☐Yes ☒No

Have actions been taken resulting from the analysis of the applicants' comments?

☐Yes ☒No

JUSTIFICATIONS

0. Short description of use

This application for authorisation covers the use of 4-tert-OPnEO as a dispersant in the formulation of a hardener of a range of two-part specialty polysulfide sealants for use in the aerospace and defence (A&D) industry sector.

The formulation takes place at two sites, Shildon (UK) and Bezons (France) and is performed by PPG UK and Sealants Europe SAS[10], respectively.

The amount of substance used is in Use 1 is 100-500 kg/year. The hardener component contains concentrations of 4-tert-OPnEO below 0.5 %.

0.1. Description of the process in which Annex XIV substance is used

The applicants presented one exposure scenario with one environmental contributing scenario (ECS):

- ECS 1 Formulation of hardener component (ERC 2)

The steps in the formulation process are described as follows:

Incoming of goods and storage

The 4-tert-OPnEO surfactant is brought onto site on pallets in a drum. Upon delivery, the drum is transferred to the raw material warehouse.

Formulation/Production

Formulation is undertaken within a dedicated sealant production room. When needed, the drum containing the 4-tert-OPnEO surfactant is transferred on a trolley to the weighing area in the production area. The drum is fitted with a manually operated tap by which the surfactant can be dispensed into the mixing cylinder via an inlet. A plastic sheet is placed on the floor below the mixing equipment to ensure any residual material is captured. The plastic sheet is disposed of as hazardous waste.

Later, the mixing cylinder is wheeled to a triple roller that breaks down any lumps of raw materials to ensure a homogeneous hardener component.

After, the material is transferred by funnel to a second mixing cylinder to ensure homogeneity within the mixture. The final hardener is a viscous liquid.

After use, the roller and funnel are scraped down to remove residual hardener, then cleaned using rags soaked in solvent. These small quantities of hardener and the used rags are disposed of as hazardous waste. This cleaning process is carried out by trained operators.

The whole formulation process is waterless.

Filling

After formulation, the hardener is transferred to a drum via an outlet in the bottom of the mixing cylinder. When filled, the drums are sealed.

The hardener may also be further packaged in two compartment kits or smaller containers on site in two different dedicated rooms. Filling of the two-compartment kits is conducted via

[10] PPG UK and Sealants Europe SAS are referred to as “the formulator” in what follows.

dedicated lines. Alternatively, and in a similar way, the formulated hardener component may be filled into smaller containers for shipment with its relevant base component as a two-tin kit.

The dedicated line in place to pump the hardener from the drum to the worker station is contained and prevents any release; there is no access to the hardener during transfer. Filling equipment is wiped down after use with a disposable rag with solvent. The rag is subsequently disposed of as hazardous waste.

0.2. Key functions and properties provided by the Annex XIV substance

4-tert-OPnEO is used as a surfactant (dispersant) in the formulation of the hardener component of the two-part polysulfide sealants (base and hardener). Base is composed primarily of sulphide polymers and other ingredients (present at < 10 %). The hardener component is composed of manganese dioxide (MnO_2) and other constituents. 4-tert-OPnEO ensures adequate dispersion of MnO_2 within the hardener and this is key for achieving the desired cure and properties of the final sealants.

The key technical criteria for the selection and use of the sealants are:

- Viscosity
- Density
- Working life
- Cure time and temperature
- Tack-free time
- Shelf life.

Aerospace & Defence (A&D) components containing polysulfide sealants need to be able to perform in different environments and challenging operating conditions, such as:

- Mechanical shocks
- Exposures to extremely high and low temperatures
- Exposures to high and low humidity
- Exposures to different types of fluids (jet fuel, hydraulic fluid, coolants, cleaning agents)
- Exposure to sunlight and weathering.

4-tert-OPnEO is used as a dispersant because an inadequate dispersion of the curing agent can severely impact sealants' final properties (such as cure time, adhesion and resistance to corrosion) and as result this could lead to an inadequate functioning of the sealants in the different conditions where they need to perform.

0.3. Type(s) of product(s) made with Annex XIV substance and market sector(s) likely to be affected by the authorisation

The product made with 4-tert-OPnEO is the hardener, which is a component of the two-part polysulfide sealants, used in a wide range of A&D applications and in particular 25 sealant formulations are affected by the authorisation.

The base and hardener are packaged together and distributed:

- as two-part kits (for example in cans or in drums),
- in pre-metered cartridges or
- pre-mixed and frozen (PMF).

The sealants can be applied in a wide range of locations of A&D systems to provide different

functions. For example, they are used to bond structures requiring flexibility (adhesive applications), to fill gaps, to separate dissimilar surfaces to prevent corrosion, to seal defence systems against chemical agents, to keep fluids (e.g. fuel, hydraulic fluids, etc.)

On the basis that 4-tert-OPnEO's concentration in the final sealants is less than 0.1 % their use is exempt from authorisation requirements.

Some of the hardware components, requiring the use of polysulfide sealants are:

Sector	Example of hardware components
Aerospace	• Fuel tanks • Actuators, which are components responsible for moving and controlling a mechanism or system • Engines • Nacelles, which hold engines, equipment or fuel on an aircraft • Windows and doors • Electronic controls • Propeller blades
Defence	• Missiles • Missile launchers • Satellite launchers • Naval vessels • Radar systems • Communication systems
Space	• Gyros • Rockets • Space vehicles • Satellite launchers

0.4. For upstream applications: Downstream User survey

The formulator and OEM companies engaged with relevant members of the A&D supply chain between 2017 and 2018, via online surveys, email exchange, webinars and face to face meetings as well as with the members of Ethoxylates in Aerospace Authorisation Consortium (EAAC), which was formed in mid-2018[11]. This consultation allowed the identification of the products which are relevant for this authorisation and collection of data and information, which supported the preparation of the authorisation application.

1. Operational Conditions and Risk Management Measures

1.1. Environment

The applicants presented one exposure scenario/exposure contributing scenario: The formulation of a hardener component containing 4-tert-OPnEO within Aerospace and Defence (A&D) two-part polysulfide sealants.

The entire formulation process takes place over a single shift and is fulfilled by a single worker. This worker also undertakes the cleaning and maintenance tasks. In each site, the batches are prepared twice per month. Since a formal worker risk assessment is not required, the applicants provided explanations of OC and RMMs only to the extent necessary to demonstrate

[11] PPG is also a member of EAAC.

the absence of incidental environmental exposure from contaminated worker clothing.

A summary of the OCs and RMMs in the environmental contributing scenarios is provided in Table 1. The detailed conditions of use are available in section 9.1 of the CSR.

Table 1: Summary of Operational conditions

Volume of 4-tert-OPnEO used per annum (total covering both sites)	50-250 kg
Volume of 4-tert-OPnEO used per working day	~2-10 kg
Releases of 4-tert-OPnEO per year	0
Concentration of 4-tert-OPnEO in the hardener component	0.5 %
Daily use at site	Up to 8 hours per day
Production days of the hardener component per year	24 days

According to the applicants the following Risk Management Measures (RMMs) are implemented across the two sites:

Technical and organisational conditions and measures

- The hardener is prepared in accordance with a Standard Operating Procedure (SOP) that sets out the equipment to be used and process to be followed, including procedures to be observed in relation to environmental protection and waste management.
- All contaminated equipment is cleaned by wiping with a rag with solvent. For maintenance purposes, pipework and tanks are flushed with solvent.
- All waste hardener and other waste (e.g. rags, containers, PPE) contaminated with hardener and/or 4-tert-OPnEO is collected and clearly labelled as hazardous waste in designated bins according to company procedures.
- The process is waterless. There is no water supply to and no wastewater discharge point from the production room. Workers' training includes prohibition on the release of raw materials or sealant to the wastewater system.
- Reusable PPE, such as overalls, safety boots, and eye protection, are worn on site and must be put on by workers prior to entering the production area.
- RMMs and OCs including worker training are in place to avoid contamination of overalls. A licensed industrial laundry facility cleans contaminated clothing.
- Workers are trained to manage spillages. In the event of a release during formulation or filling, workers use disposable rags to contain and clean up the spill. After removal of the bulk of the spill, the area may be wiped down with rags soaked in solvent. All the contaminated rags generated from such a process would be consigned as hazardous waste.
- The floor in the production and filling area is coated with a chemically resistant floor.
- The flooring is regularly cleaned with a solvent impregnated rag. Following this, the floor is cleaned with a damp mop, using minimal water. Wastewater generated in this process is stated to be disposed of as hazardous waste and subsequently incinerated.

Conditions and measures related to treatment of waste (including article waste)

- All waste hardener and other waste (e.g. rags, containers, PPE) contaminated with hardener and/or 4-tert-OPnEO is collected and clearly labelled as hazardous waste in designated bins according to company procedures. The waste material is consigned as hazardous waste and collected and processed by licensed third party contractors as hazardous waste in line with applicable local, regional, and national regulations. According to the conditions of use, compliance with these regulations precludes release to the environment and generally involves incineration. Following RAC's request to clarify the statement, the applicants declared that all hazardous waste generated is incinerated.
- The waste code relevant for the consignment of 4-tert-OPnEO contaminated materials is 08 04 09* (Waste adhesives and sealants containing organic solvents or other hazardous substances).

1.2. Discussion on OCs and RMMs and relevant shortcomings or uncertainties

The applicants described the process as "automated and fully contained". It is noted however, that the mixing cylinders are open throughout the process to allow access of the mixing tool and addition of supplementary material. In addition, operations such as dosage of 4-tert-OPnEO, moving of the first mixing cylinder, moving of cylinder to the roller, material transfer to the second cylinder and filling of containers of different sizes with the hardener are essentially performed manually. Manual operations can lead to spills but RAC notes that the applicants have implemented an appropriate spill management system.

Since no water is involved in the formulation process, no wastewater is produced, and since all solid waste which had been in contact with 4-tert-OPnEO is collected and disposed of as waste for incineration, no relevant shortcomings to the OCs and RMMs have been identified.

1.3. Conclusions on OCs and RMMs

Overall conclusion

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.

Are the operational conditions and risk management measures appropriate[12] and effective[13] in limiting the risk for workers, consumers, humans via environment and / or environment?

Workers	☐Yes	☐No	☒Not relevant
Consumers	☐Yes	☐No	☒Not relevant
Humans via Environment	☐Yes	☐No	☒Not relevant

[12] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[13] 'Effectiveness' – evaluation of the degree to which the RMM is successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

Environment ☒Yes ☐No ☐Not relevant

2. Exposure assessment

2.1. Environmental emissions

Water

There are not releases to water since the process is waterless and all waste that could be contaminated with 4-tert-OPnEO are collected for incineration. Possible water used during regular cleaning activities of the floor is stated to be collected and incinerated.

Air

Releases to air are not expected taking into account the activities performed and the low vapour pressure of the substance.

Soil

Direct or indirect releases to soil are not expected since all solid and liquid waste that could be contaminated with 4-tert-OPnEO is collected for incineration, and there are no releases to an STP.

Table 2: Summary of environmental emissions

Release route	**Release factor**	**Release per year** (tonnes or kilograms)	**Release estimation method and details**
Water	0	0	There are no releases to the environment of 4-tert-OPnEO or the hardener component during formulation and filling of the polysulfide sealant. A range of RMMs and OCs are in place which effectively prevents any release of 4-tert-OPnEO to the environment during formulation, mixing, filling and packaging.
Air	0	0	
Soil	0	0	

2.2. Discussion of the information provided and any relevant shortcomings or uncertainties related to exposure assessment

The applicants provided a qualitative exposure assessment that focussed on the points in the process at which release of 4-tert-OPnEO to the environment could occur. Based on the description of the process and the OCs & RMMs in place, RAC concurs that release of 4-tert-OPnEO to the environment from the formulation is zero.

2.3. Conclusions on exposure assessment

RAC considers that the applicants have provided enough information to demonstrate that release to environment compartments is prevented as far as technically and practically possible. The release of 4-tert-OPnEO to the environment from the formulation is zero.

3. Risk characterisation

The applicants did derive PNECs for the endocrine disrupting properties for the environment of the substance but did not compare these with PECs. The applicants stated that due to the RMMs and OCs, release to the environment is precluded from the formulation use. Therefore, only a qualitative risk assessment is conducted. The applicants consider that the use poses no risk to the environment.

The applicants derived PNECs for six compartments, i.e. water, marine water, STP, soil, and sediment and marine sediment, as well as for secondary poisoning. The applicants provided a review of the evidence pertaining to Adverse Outcome Pathways (AOP) for endocrine effects in aquatic organisms relating to 4-tert-OP and 4-NP exposure in a separate report, primarily using the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) guidance on adverse outcome pathways[14] and Brown et al (2017)[15]. The oestrogenic-mediated pathway from molecular to population levels of biological organisation was assessed. The assessment considered also RAC's document "Risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO", adopted at RAC-43[16].

The evidence gathered by the applicants has not confirmed a complete pathway and adverse outcome for either octyl- or nonylphenol. The applicants did not address the presence or absence of a threshold based on androgen signalling, despite some indications of effects from that mode of action[17].

A read-across approach from 4-tert-NP was used to meet minimum data requirements to calculate $PNECs_{aquatic}$ using species sensitivity distributions (SSDs). The applicants applied an assessment factor of 10 instead of the default factor of 1-5 to the HC5 values[18] from the freshwater and marine SSDs to cover apical and endocrine endpoints.

RAC assessed the SSDs performed by the applicants against the principles established in the "Guidance on information requirements and chemical safety assessment; Chapter R.10: Characterisation of dose (concentration)-response for the environment".

The data fit well to the distribution and the calculated HC5 values have appropriate confidence intervals. However, there are reliability concerns related to the studies included in the freshwater and marine SSDs[19].

Further, several endpoints from the same species and study were used for deriving the freshwater and marine SSDs whereas R.10 Guidance indicates that only one value per species

[14] ECETOC (2016). European Centre for Ecotoxicology and Toxicology of Chemicals. Guidance on Assessment and Application of Adverse Outcome Pathways relevant for the endocrine system. Technical Report 128

[15] Browne P, Noyes P D, Casey W M, Dix D J (2017). Application of Adverse Outcome Pathways to U.S. EPA's Endocrine Disruptor Screening Program. Environmental Health Perspectives

[16] https://echa.europa.eu/documents/10162/13637/npneo_and_opneo_for_agreement_final_en.pdf

[17] Member State Committee Support Document for identification of 4-nonylphenol, branched and linear as substances of very high concern because due to their endocrine disrupting properties they cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMRs and PNTs/vPvBs. Adopted on 13 December 2012.

[18] The HC5 value is the hazardous concentration corresponding with the point in the species sensitivity distribution below which 5 % of the species occur (i.e. the fifth percentile).

[19] The concerns related to the reliability are: the use of nominal concentrations without confirmation that they were maintained within 80 % of nominal throughout the test, duration of the studies, statistical robustness and number of replicates, etc. Some of these deficiencies were found in relevant taxonomic groups and species such as *Potamopyrgus antipodarum*, which may be particularly sensitive to the substance and for which no reliable data is available or *Dreissena polmorpha.*

(lowest or geomean) should be used for SSD.

In addition, *C. elegans and C. tentans* are considered sediment or soil organism according to Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7b: Endpoint specific guidance Version 3.0 February 2016. This, together with reliability issues, casts uncertainty on the representativeness and diversity of the data with some taxonomic groups poorly or not represented, compromising the minimum requirement of at least 8 taxonomic groups.

Overall, RAC does not support the applicants' approach to derive $PNECs_{water}$ using SSD.

RAC also notes that the ED assessment contains a limited number of level 4 and 5 (multi-generation) studies done according to relevant guidelines for Endocrine Disruption, as specified in OECD GD 150. In addition, available ecotoxicological data on 4-t-OP suggests that gastropods may be the most sensitive group of species. Limited data, covering only a part of the life-cycle, is available for gastropods. Hence, RAC considers that the dataset and analysis provided by the applicants are not sufficiently representative of sensitive taxonomic groups to reliably derive a $PNEC_{water}$ for endocrine disrupting properties of 4-tert-OPnEO for the environment.

Furthermore, the applicants used read-across from 4-tert-NP to derive $PNECs_{sediment}$ for freshwater and marine using an assessment factor (AF) approach (AF of 50 for apical endpoints and an additional AF of 10 or 2, respectively, for endocrine effects). RAC considers the data set (4 partial life cycle studies) is not representative enough to derive reliable $PNECs_{sediment}$ for the endocrine disrupting properties of the substance and questions whether the AFs chosen are appropriate to cover the uncertainties and the endocrine properties of 4-tert-OP.

For soil, the PNEC was derived using the assessment factor approach, based on most sensitive of three reliable long-term studies, representing organisms from three trophic levels (invertebrates + plants + microbes). A read-across approach from 4-tert-NP was applied. According to the applicants, there is no evidence of endocrine effects in soil organisms. However, available data involve apical endpoints sensitive to, but not diagnostic of endocrine activity. Thus, RAC considers the analysis provided by the applicants not sufficient to reliably derive a PNEC for soil for endocrine disrupting properties of 4-tert-OPnEO for the environment.

Based on the information available, RAC cannot fully check the reliability of the available data. Nevertheless, RAC notes that several of the studies presented have relevant shortcomings (i.e. lack of statistical robustness, inadequate exposure period and life-stage, control variability, etc). These deviations, found across different studies, undermine the adequacy of the estimated PNECs.

Therefore, RAC concludes that the current state of knowledge of the endocrine disrupting properties, mode(s) of action and effects of 4-tert-OP in the environment as presented by the applicants is insufficient to determine a threshold.

Based on the OCs & RMMs described in the exposure scenario, notably the waterless process and the collection for incineration of all waste contaminated with 4-tert-OPnEO, RAC is of the view that the applicants have demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible.

The use applied for may result in 0 kg per year emissions of 4-tert-OPnEO to the environment.

4. Analysis of Alternatives and substitution plan[20]

The sealants are made in two steps:

1) Formulation of the hardener where 4-tert-OPnEO acts as surfactant (dispersant) for manganese dioxide (Use 1); and
2) Mixing hardener and base (second component) to obtain the final sealant (Use 2).

The substance does not have any known function in Use 2. The application for Use 2 is required because 4-tert-OPnEO concentration in the hardener component is above 0.1 % w/w.

Two separate AoAs for Use 1 and 2 and two separate SPs would not have been meaningful because the substance has a known function only in Use 1. Moreover, it is not meaningful to discuss the non-use scenario for Use 2 without discussing the non-use scenario(s) for Use 1. The two uses are interlinked and any choice of the NUS for Use 2 strictly depends on the NUS for Use 1. It follows that a unique SEA, AoA and SP were submitted for both uses.

Based on the above, the SEAC opinion for Use 1 reflects the content of the SEAC opinion for Use 2.

What is the amount of substance that the applicants use per year for the use applied for?

100-500 kg per year.

4.1. Summary of the Analysis of Alternatives and substitution plan by the applicants and other information available

The formulator's substitution efforts are focused on developing an 4-tert-OPnEO-free formulation on the basis that thanks to the process evolution, the function provided by 4-tert-OPnEO – as a dispersant - might not be required any longer. This is because the formulator is confident that an adequate dispersion of the curing agent might also be achieved by mechanical means and so the testing activities – described in the substitution plan – will be able to confirm 4-tert-OPnEO-free formulations' interchangeability with 4-tert-OPnEO-based ones.

The suitability of the 4-tert-OPnEO-free formulations has to be assessed from both the formulator's and Original Equipment Manufacturers (OEMs) perspectives. This is explained by the fact that the formulator can only test the reformulated sealants against some key parameters, while each OEM needs also to perform additional assessments to verify that the reformulated sealants comply with their own technical specifications.

The formulator has undertaken extensive research and development (R&D) activities to identify the most promising alternative. As indicated by the formulator, any suitable alternative needs to ensure:

[20] The judgment of the ECJ Case T-837/16 Sweden v Commission stated that the applicant has to submit a substitution plan if alternatives are available in general. The Commission is currently preparing the criteria, derived from the judgment for establishing when an alternative is available in general. Once these are prepared this opinion format will be amended accordingly. The European Commission informed the REACH Committee in 9-10 July 2019 of its preliminary views on the criteria. In that note that Commission considered that the criteria defining a 'suitable alternative' would imply that it was i) *safer* and ii) *suitable*. Suitability would not mean it to be *"in abstracto"* or "*in laboratory or exceptional conditions*" but it should be "*technically and economically feasible in the EU*" and "*available, from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market*".

- an adequate dispersion of the curing agent in the hardener and
- that the final polysulfide sealants meet the industry and OEM's specific technical and performance specifications.

The key technical requirements of the A&D sealants are: viscosity, density, working life, cure time, tack free time and shelf life, while some of performance requirements are: hardness, electrical isolation, adhesion, chemical resistance, corrosion resistance etc. For each requirement one or more parameters are used to assess whether 4-tert-OPnEO-free sealants are comparable to 4-tert-OPnEO containing ones. For example, a viscosity in the range of 9 000-16 000 P (poise) is one of the key parameters against which the performance of the 4-tert-OPnEO-free formulation has been assessed and the results have demonstrated the initial viability of the candidate alternative.

The formulator has already started implementing the substitution plan to remove 4-tert-OPnEO from 25 formulations, which are affected by the authorisation. R&D activities at formulator level were concluded in the first quarter of 2019 and during this step the formulator performed the initial testing of the 4-tert-OPnEO-free formulations to verify adequate dispersion of the curing agent and sealants' compliance with key industry specifications.

4.2. Risk reduction capacity of the alternatives

Would the implementation of the short-listed alternative(s) lead to an overall reduction of risks?

☐Yes

☐No

☒Not applicable

Not applicable as no technically and economically feasible alternatives are available before the sunset date.

4.3. Availability and technical and economic feasibility of alternatives for the applicant

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicants and its downstream users before the Sunset Date?

☐Yes ☒No

The formulator has considered several potential alternatives, before identifying the removal of 4-tert-OPnEO as the most promising one. In its assessment the formulator analysed:

- 4-tert-OPnEO-free polysulfide formulations already existing on the market and
- sealants based on alternative chemistries (polythioether sealants, epoxy based sealants, silicone sealants and polyurethane sealants).

4-tert-OPnEO-free polysulfide formulations are already available on the market. However, according to the applicants (formulator), these formulations have not been qualified by the OEMs for the A&D applications where currently 4-tert-OPnEO-based polysulfide sealants are used and so will have to go through the full qualification and validation process within the OEMs. The assessment also showed that these alternatives might differ from 4-tert-OPnEO

free formulations in respect to some key technical parameters (such as density). Finally, according to the formulator, 4-tert-OPnEO-free polysulfide sealants still contain other SVHCs and therefore, this alternative was not further considered by the formulator.

Sealants based on alternative chemistries have been assessed on paper by the OEMs and they were not considered technically suitable, due the fact that they were not able to meet some of the key A&D specification parameters. According to the information provided in the analysis of alternatives:

- polythioether sealants do not have corrosion inhibition properties and are not sufficiently resistant to temperatures,
- epoxy-based sealants are not able to provide sufficient protection against the ingress of moisture and are less flexible when compared to 4-tert-OPnEO polysulfide sealants,
- silicone-based sealants are not sufficiently resistant to the different conditions in which A&D applications need to work and
- polyurethane sealants may not be suitable for aero smoothing or fuel tank applications, which are key for the A&D industry.

The removal of 4-tert-OPnEO from the formulation and achievement of an adequate dispersion of the curing agent by mechanical means is therefore considered by the formulator as the most promising alternative.

So far R&D activities at formulator level have been performed and the results indicate that 4-tert-OPnEO free polysulfide sealants are comparable to the 4-tert-OPnEO containing counterparts. The alternative formulations have been tested against the key parameters, such as: viscosity, working life, tack free time, hardness, cure time and all the results were within the required ranges.

However, as described in section 4.4, qualification and industrialisation by OEMs would still be required before this alternative can be considered viable, and these activities would extend beyond the sunset date. The formulator therefore considers that the alternative is not technically feasible for the formulator and its downstream users before the sunset date

SEAC's evaluation / view on the availability and technical and economic feasibility of alternatives for the applicant

The formulator has described the technical requirements that make the short-listed alternative (removal of 4-tert-OPnEO from the hardener component) as the most promising one from both technical and economic perspectives.

SEAC has reviewed the information provided by the applicants on the examined alternative and the potential alternatives that were rejected and notes that the analysis is comprehensive and transparent. Therefore, SEAC agrees with the applicants that no technically suitable alternative will be available to the applicants by the sunset date. The interchangeability of the assessed alternative needs to be confirmed by downstream users of the 4-tert-OPnEO-based sealants, and SEAC concurs with the applicants that this process cannot be completed before the end of 2024.

Regarding economic feasibility, SEAC notes that the costs for removing 4-tert-OPnEO from the hardener component are expected to be negligible and that the main cost burden associated with the removal of 4-tert-OPnEO is the requirement for testing at both formulator and downstream users' levels.

Based on the above, SEAC considers credible the approach adopted by the applicants in the assessment of the alternatives, where the applicants have demonstrated that no suitable alternative will be available before the sunset date.

4.4. Substitution activities / plan

Have the applicants submitted a substitution plan?

☒Yes ☐No

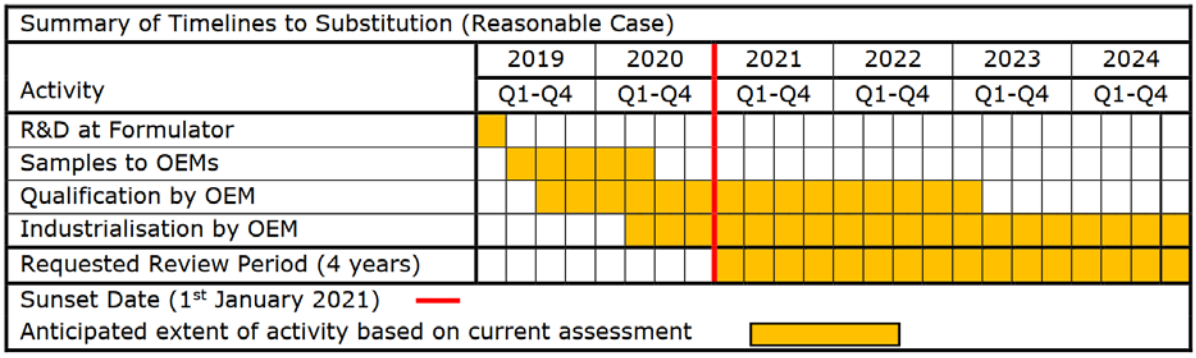
If yes, is the substitution plan credible and consistent with the analysis of alternatives and the socio-economic analysis?

☒Yes ☐No

The formulator indicated that the most promising alternative – 4-tert-OPnEO-free formulation - is expected to successfully complete the development testing phase before the sunset date. During this step, initial laboratory testing is followed by small (bench) scale testing and by full scale batch production testing, to identify any potential technical issue in the manufacturing of the reformulated hardener component. Once the new formulation successfully passes the three steps, the reformulated hardener and mixed sealants are tested against key industry sealant specifications.

Testing by the formulator is followed by the OEMs' specific testing procedures. And each OEM has to qualify and validate the alternative formulations before being able to confirm the interchangeability of the 4-tert-OPnEO-free formulations for their specific A&D applications. This is because each OEM might have its own specifications, against which it has to assess the samples of the alternative formulations. In the final step each OEM needs to industrialise the qualified 4-tert-OPnEO-free formulations and so adapt all the processes and related documentations to reflect the relative change.

The full implementation of the substitution plan – reported below - is expected by the end of 2024, based on the assumption that the OEMs will confirm the interchangeability of 4-tert-OPnEO-free formulations**.**



SEAC's evaluation / view on the substitution activities / plan

It is in SEAC's view that the substitution plan submitted by the applicants is credible and the related timeline justified.

The applicants have described the steps in the substitution plan in a detailed and transparent way. SEAC agrees with the applicants that the steps included in the substitution plan, in the

sequence described, need to occur before concluding on the suitability of the 4-tert-OPnEO-free formulation. In particular, SEAC concurs with the applicants that the qualification by OEMs is required, given that the formulator is able to test the reformulated sealants only against a limited number of technical parameters and that OEMs need to perform additional testing to confirm that the alternative formulations meet their own specifications.

Finally, SEAC also concurs with the timeframe of each step and finds the applicants' justification credible.

4.5. Conclusions on the analysis of alternatives and the substitution plan

By the sunset date there are no alternatives available with the same function and similar level of performance that are safer and technically and/or economically feasible for the applicants. A substitution plan was submitted and SEAC finds it credible that the formulator will replace 4-tert-OPnEO in all the 25 formulations by the end of 2024.

5. Benefits and risks of continued use

Have the applicants adequately assessed the benefits and the risks of continued use?

☒ Yes

☐ No

5.1. Human health and environmental impacts of continued use

Based on the existing RMMs and operating conditions in place, the applicants consider that the releases to the environment of 4-tert-OPnEO during formulation or when mixing the two-compartment kit are negligible. So, the applicants have concluded that there is no risk to the environment from Use 1 and Use 2. In line with this conclusion, the applicants did not provide qualitative or quantitative assessment of the environmental impacts of continued use.

However, in the analysis of uncertainties, the applicants have adopted a conservative mass-balance approach to evaluate absolute worst-case releases of 4-tert-OPnEO to the environment from the sealants' life cycle, under highly conservative conditions.

As a result of the service life of the equipment treated with the sealant, which is not subject to Authorisation in accordance with Article 56(6)(a) of REACH, 2.5kg of 4-tert-OPnEO could be emitted to the environment per year and so 10 kg over 4 years[21].

This release estimate of 10 kg over the requested review period is therefore exclusively from the service life (migration to water of 4-tert-OPnEO from hardened sealant) and thus the applicants assumed no release to the environment during formulation (Use 1), the mixing by downstream users (Use 2), nor during the application of sealant by downstream users.

5.2. Benefits of continued use

The applicants' assessment of the benefits under the continued use scenario has considered the following actors in the A&D supply chain:

- The formulator[22] and

[21] Please see also RAC's assessment in the opinion for Use 2.
[22] Is also part of EAAC.

- Downstream users (OEMs members of Ethylates in Aerospace Authorisation Consortium (EAAC)).

Non-use scenario

On the basis of information gathered from internal consultation (within A&D EAAC members) which was supported by independent consultants, two most likely NUSs have been identified in the authorisation application:

NUS 1 refers to a situation where all processes of all A&D operations in the EEA would be changed to the exclusive use of Pre-Mixed and Frozen (PMF) sealants. In this scenario, the total volume of sealants needed within the EEA would be pre-mixed and frozen in a non-EEA country and imported to EEA via refrigerated air cargo. Given that 4-tert-OPnEO concentration in the final sealant is below 0.1 %, its use is exempted from authorisation requirement. This NUS would entail a period of approximately 1-2 years where no manufacturing or Maintenance, Repair and Overhaul (MRO) of A&D equipment would be possible in the EEA, due to unavailability of 4-tert-OPnEO-containing sealants. This NUS would also involve substantial additional costs relating to acquisition, installation and operation of new process and storage equipment and to transportation requirements. This scenario is considered as the most likely one by the applicant[23].

NUS 2 refers to a situation where manufacturing and MRO of A&D equipment would need to be stopped until a 4-tert-OPnEO-free alternative is developed by the formulator and fully qualified and industrialised by all A&D companies in the EEA.

The applicants have stressed that there are substantial doubts about the technical feasibility of NUS 1. For example, the applicants have stated that it is uncertain whether they would be able to establish a production facility outside the EEA capable of delivering the needed amounts of sealants as PMF product for A&D companies and its EEA suppliers as soon as needed. In addition to that, A&D companies could not switch to alternative sealants because, for the specific A&D applications here discussed, no alternative SVHC-free sealants have been already qualified by them.

Moreover, the applicants note that NUS 1 is theoretically possible only for the categories of sealants with a work-life higher than 30 minutes. These sealants can be pre-mixed, frozen and stored at -40 °C for a maximum of 35 days for later use.

Fast-cure sealants have instead a working life of only several minutes and can therefore not be supplied as a PMF sealant because the sealant would cure during packaging, freezing and thawing, making it unusable. The possibility to switch from fast cure sealants to sealants with a longer cure time to support the use of PMF sealants will depend on each application on a case-by-case basis and the curing time may limit production rate and maintenance turnaround times.

Moving to longer cure times could have an important adverse effect on the process flow in the assembly and maintenance and repair operations and would be particularly disruptive for those last-minute, unscheduled repairs performed at the gate or airport.

Finally, according to the applicants, NUS 1 might not represent an improvement from an environmental perspective, due to an increase in CO_2 emissions that would result from the transport of sealants from the non-EEA site to all the EEA customers.

[23] To note that while the application has been submitted by the formulator, the impacts reported in the submitted SEA are based on information provided by the both the formulator and all other applicants and downstream users.

On the basis of the above uncertainties and challenges associated with NUS 1, the applicants have also discussed NUS 2 and described the related impacts.

The applicants consider that 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 event of authorisation being refused.

According to the applicants both these NUSs will, at the minimum 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).
- Significant impacts across all the supply chain because the absence of one single part can severely disrupt or even prevent the delivery of many A&D products (including aircrafts). Hundreds of suppliers deliver parts from around the world, which are ultimately connected in assembly lines. Therefore, loss of even a limited number of parts treated with 4-tert-OPnEO-containing sealants could have substantial economic effects.

What is likely to happen to the use of the substance if an authorisation was not granted?

- The use would cease altogether
- The use would be taken up by market actors operating outside the EU.

What is likely to happen to jobs in the European Union if an authorisation was refused?

- Between 70 and 120 jobs could be lost in the European Union. The number represents the expected job losses at the formulator sites in NUS 1. No job losses are expected at downstream users' sites in NUS 1.
- In NUS 2 between 70 and 120 job losses at formulator's site are expected and 7 500–9 500 employees will have to be dismissed by downstream users.

In response to a SEAC question asking for clarification on how the number of job losses was estimated, it has been clarified that the estimation is based on confidential inputs provided by the formulator and downstream users, which were then presented as non-confidential ranges in the submitted Socio-Economic Analysis.

Economic impacts of continued use

The applicants have provided the following costs in NUS 1:

<u>Impacts on the formulator:</u>

<u>Relocation Costs</u>

To supply only PMF sealants to all relevant downstream users in the EEA, the formulator will have to relocate the production outside the EEA and adapt the production process, based on OEMs' specific material and process specifications. For the time being, exact relocation costs for the formulator cannot be estimated by the applicants. They are, however, expected to be in the range of several million euros.

Foregone profit

According to the formulator, for the period of supply interruption due to relocation and adaptation of processes, impacts in the form of foregone profits with a lower bound of one year (i.e., 2021) and an upper bound of two years (i.e., 2021-2022) are expected. However, the formulator has not disclosed to SEAC[24] the profit losses for confidentiality reasons, nor has included any range in the submitted application.

Social costs of unemployment

Between 70 and 120 job losses at the formulator's site are expected and the related societal welfare loss was estimated by the applicants at 7 and 12 million euro, by applying the ECHA methodology on the social cost of unemployment[25].

Impacts on downstream users:

Foregone profit

EAAC member companies would incur a profit loss for the period of sealants' supply interruption, during which no manufacturing of A&D applications would take place. According to the applicants,4-tert-OPnEO polysulfide sealants are the only sealants which are qualified by the A&D downstream users for the specific applications in the scope, so no alternative SVHC-free sealants would be available to the downstream users in the relocation scenario. Any alternative sealant – based on different chemistry – which is available on the market would need to go through the full qualification process by downstream users, which would require several years.

The downstream users' profit losses have been estimated by the applicants at 4 500-6 500 million euro over one year (lower bound) and 8 500-11 500 million euro over two years (upper bound), considering a discount rate of 4 % and the base year 2020.

Requalification costs:

Downstream users will also have to qualify the PMF materials. This means that these downstream users' sites cannot use PMF sealants until all relevant materials specifications have been updated to include the use of PMF sealants for all relevant applications.

According to the downstream users, qualification is required each time that the source of sealants or the supplier's site is changed. This step is needed to confirm that the formulation coming from a new source or from a new site meets all the necessary technical and performance requirements.

The downstream users have estimated the related investment costs in the range of 1-9 million euro. This estimate does not include investment in other important equipment, including back-up generators and temperature recorders during transportation.

Impacts on MROs (civil and military), Airlines Operations

According to the applicants , NUS 1 is also expected to have significant negative impacts on MRO activities, as a temporary unavailability of the 4-tert-OPnEO hardener would not only lead to a temporary production halt of the A&D applications, but will also make not possible the

[24] In one of the questions sent to the applicant, SEAC asked whether ranges of profit losses could be provided by the applicant.

[25] https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554

MRO activities on these specific applications with additional significant impacts across the whole A&D supply chain. Moreover, 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 in situations where sealants with short cure time are essential to avoid prolonged "aircraft on ground" time. These impacts have been only described qualitatively by the applicants.

Impact on CO_2 emission

The applicants state that, considering the CO_2 emissions resulting from the import of sealants from outside the EEA, NUS 1 could be worse from an environmental perspective when compared to continued use scenario. The applicants did not provide quantitative estimates of the expected CO_2 emissions.

In NUS 2 the following impacts are expected:

- Foregone profit at formulator level which has not been disclosed for confidentiality reason.
- Between 70 and 120 job losses at formulator's sites, associated with welfare loss in the range of 7-12 million euro.
- Foregone profit for the EAAC member companies due to sealant's supply interruption in the range of approximately 4 500-18 000 million euro (over 1 and 4 years respectively).
- Job losses at EAAC member companies in the range of 7 500-9 500. The applicants have estimated the related social costs at 740-940 million euro.

Table 32: Socio-economic benefits of continued use

Description of major impacts	Magnitude of impacts (NUS 1) – million euro	Magnitude of impacts (NUS 2) – million euro
1. Benefits to the applicants (formulator)		
1.1 Avoided profit loss	Not available for confidentiality reasons.	Not available for confidentiality reasons.
1.2 Avoided job losses at applicant's site	7-12	7-12
1.3 Avoided relocation or closure cost	In the range of several million euros.	Not applicable
Sum of benefits to the applicants (formulator)	7-12	7-12
2. **Benefits to the downstream users A&D EAAC members**		
2.1 Avoided profit loss	4 500-11 500	4 500-18 000
2.2 Avoided investment costs	1-9	Not applicable.
2.3 Avoided job losses	No job losses are expected.	740-940
Sum of benefits to the downstream users	4 500-11 500	5 200-18 900
3. Aggregated socio-economic benefits (1+2)	4 500-11 500[26]	5 200-19 000[27]

[26] The values are rounded up.
[27] Value rounded up.

Table 4: Socio-economic benefits and risks of continued use

Socio-economic benefits of continued use (NUS 1 if 2 years profit loss considered)		Socio-economic benefits of continued use (NUS 2)	Excess risks associated with continued use	
Benefits [€ million]	Avoided social cost of job losses at formulator's facilities: 7-12 million euro Avoided total cost for downstream users: 4 500-11 500 million euro	Avoided social cost of job losses at formulator's facilities: 7-12 million euro Avoided cost for downstream users: 5 200-19 000 million euro	Monetised excess risks to workers directly exposed in the use applied for	Not applicable
Quantified impacts of the continuation of the SVHC use applied for	Avoided CO_2 emission costs associated with logistics	Not applicable.	Monetised excess risks to the general population and indirectly exposed workers	Not applicable.
Additional qualitatively assessed impacts	Avoided negative impacts on MRO activities		Additional qualitatively assessed risks	10 kg of 4-tert-OPnEO over the review period in the worst-case scenario
Summary of socio-economic benefits	**€ 4 500-11 500 million**	**€ 5 200-19 000 million**	**Summary of excess risk**	10 kg of 4-tert-OPnEO over the requested period of 4 years

5.3. Combined assessment of impacts

According to the applicants, emissions to the environment are precluded, given the RMMs and operating conditions in place. However, the applicants have estimated that in the worst-case scenario the service life emissions of 4-tert-OPnEO would be 2.5 kg per year and so 10 kg over 4-year review period. Based on the information presented by the applicants and when considering the most likely NUS, SEAC has quantified the socio-economic benefits of continued use at approximately 4 500-11 500 million euro. SEAC acknowledges that this value might underestimate the socio-economic benefits of continued use considering that it does not include the relocation costs and the profit loss that the formulator will incur and all the necessary investments that the downstream users will have to make (such as investments in back-up generators and temperature recorders).

When NUS 2 is considered, the socio-economic benefits of continued use have been estimated at € 5 200-19 000 million.

By using the service life emissions provided by the applicants in the analysis of uncertainties, SEAC calculated that the cost per kg of prevented emissions of 4-tert-OPnEO in the environment is € 450-1 900 million.

Table 5: Cost of non-use per kg

	NUS 1	NUS 2
Total cost over 4 years (€)	4 500-11 500 million	5 200-19 000 million
Total emissions over 4 years (kg)	10 kg	10 kg
Ratio (€/kg)	450-1 150 million	520-1 900 million

5.4. SEAC's view on Socio-economic analysis

Based on the information provided by the applicants SEAC concurs with the potential NUSs and has no reservation on selection and justification of the two NUSs 1 and 2. The applicants have described in a transparent way the complexity of the production processes and importance of each A&D component in the assembling process of the products. Section 5.2 provides details on possible consequences in the selected NUSs. This information is supportive of the applicants' claim that a refused authorisation would lead to substantial welfare loses to the whole industry as well as to society.

SEAC also notes that the applicants have underestimated the monetised impacts at formulator level, by excluding relocation costs and profit losses that it would incur. The applicants have clarified that due to the confidentiality reasons, the profit losses at formulator level could not be provided. SEAC took note of the applicants' clarification and acknowledges that the monetised costs in NUS 1 might be underestimated.

SEAC concurs that the methodology used to calculate foregone profits for the downstream users was appropriate and provides a good indication of the scale of the potential impacts of an authorisation not being granted.

Typically, 1-year loss of profit is a more relevant measure of changes in producer surplus than the total profit loss over the assessment period, and the appropriate measure to monetise the welfare implications of a non-use scenario. This is because considering the economic losses over a long time period does not take into account the possibility of mitigating actions that could reduce the socio-economic impacts (e.g. resources being redeployed by the applicants or by other companies) and could then overestimate the long-term impacts.

However, in this particular case SEAC notes that consideration of only 1-year profit loss might underestimate the overall welfare losses expected in the possible NUSs. This conclusion is based on the following considerations:

- A&D is a sector with very few players and the applicants using 4-tert-OPnEO in the manufacturing of A&D applications have a very large global market share. No other SVHC free sealants have been qualified by these companies and therefore in the NUSs, where the unavailability of 4-tert-OPnEO sealants is expected, these companies would not be in position to simply switch to alternative types of sealants, which are already available on the market. These companies would have to requalify any alternative sealants before using them in their A&D applications and, as seen in previous sections, this type of process requires several years.
- During the period of production interruption, the A&D companies will not be able to manufacture A&D products and it is very unlikely that they would be able to allocate their resources to other productive activities, given the complexity and specificities of the equipment used in the manufacture of A&D products as well as the complex regulatory framework of this sector.

- Given high economic barriers of this sector, it is very improbable that the production of A&D applications could be taken over by new market actors in short term. As a result, it is very unlikely that other market players would be able to benefit in short-term in the examined NUSs.
- Moreover, an important number of impacts have been only described in qualitative terms by the applicant. As seen in section 5.2, a temporary unavailability of the 4-tert-OPnEO hardener would not only cause a production halt of the A&D applications, but will also make impossible the MRO activities on these specific applications with additional significant impacts across the whole A&D supply chain.
- Finally, additional negative impacts can be expected on other actors, such as, distributors, processors, component manufacturers, as well as airlines, Ministries of Defence, etc. Due to data limitation, a quantitative assessment of these impacts was not possible according to the applicants (formulator).

SEAC will therefore consider profit losses for more than one year as the upper bound, as described above.

SEAC also agrees that NUSs would likely result in job losses at the formulator's and other downstream users' facilities. The approach to monetise the related impacts follows the SEAC note on the social cost of unemployment. SEAC notes that this impact would present an important welfare loss and so can be considered as a significant benefit of continued use.

Finally, SEAC agrees with the applicants that NUS 1 might not represent an improvement from an environmental perspective because it would lead to an increase in CO_2 emissions resulting from the expanded logistics required to import sealants from outside the EEA but notes that this impact has been only described qualitatively by the applicants.

5.5. Conclusion on the socio-economic analysis

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicants' assessment of the benefits and the risks to the environment associated with the continued use of the substance. This conclusion is made on the basis of:

- the application for authorisation,
- SEAC's assessment of the benefits of continued use,
- SEAC's assessment of the availability, technical feasibility and economic viability of alternatives,
- Any additional information provided by the applicants or their downstream users,
- RAC's assessment of the risks to the environment.

6. Proposed review period

☐ Normal (7 years)

☐ Long (12 years)

☒ Short (4 years)

☐ Other: _____ years

When recommending the review period SEAC took note of the following considerations:

6.1. RAC's advice

RAC gave no advice on the length of the review period.

6.2. Substitution and socio-economic considerations

SEAC recognises the complexity of the process in developing 25 new 4-tert-OPnEO-free formulations, given the long testing process required at both formulator and downstream users' level. SEAC also notes that:

- significant welfare losses are expected in the examined NUSs,
- the applicants have requested a review period of 4 years for being able to complete the development of 4-tert-OPnEO-free polysulfide sealants.
- 4-tert-OPnEO is expected to be phased out by 2024

Taking into account these points SEAC recommends a 4-year review period as requested by the applicants.

7. Proposed additional conditions for the authorisation

Were additional conditions[28] proposed for the authorisation?

☐ Yes

☒ No

7.1. Description

RAC

Proposed additional conditions

None.

SEAC

Proposed additional conditions

None.

7.2. Justification

RAC is of the view that the applicants have provided sufficient information to demonstrate that releases to environmental compartments have been prevented or minimised as far as

[28] Conditions are to be proposed where RCR is > 1, OCs and RMMs are not appropriate and effective, risk is not adequately controlled, minimisation of emissions is not demonstrated.

technically and practically possible.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[29] proposed for the authorisation?

☐ Yes

☒ No

8.1. Description

None.

8.2. Justification

RAC is of the view that the applicants have provided sufficient information to demonstrate that releases to environmental compartments have been prevented or minimised as far as technically and practically possible.

9. Recommendations for the review report

Were recommendations for the review report made?

☐ Yes

☒ No

9.1. Description

None.

9.2. Justifications

RAC is of the view that the applicants have provided sufficient information to demonstrate that releases to environmental compartments have been prevented or minimised as far as technically and practically possible.

10. Comments on the draft final opinion

Did the applicants provide comments on the draft final opinion?

☐ Yes

☒ No

[29] Monitoring arrangements for the authorisation are to be proposed where RCR is < 1, OCs and RMMs are appropriate and effective, risk is adequately controlled, minimisation of emissions is demonstrated – but there are some moderate concerns.

10.1. Comments of the applicants

Was action taken resulting from the analysis of the comments of the applicants?

☐ Yes

☐ No

☒ Not applicable – the applicants did not comment

10.2. Reasons for introducing the changes and changes made to the opinion

Not applicable.

10.3. Reasons for not amending the opinion

Not applicable.