Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

4-Nonylphenol, branched and linear, ethoxylated use:

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

Submitting applicant

Chemetall GmbH

ECHA/RAC/SEAC: AFA-O-0000006905-66-02/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	**Chemetall GmbH** (position in supply chain: downstream) **Chemetall PLC** (position in supply chain: downstream)
Substance ID EC No CAS No	**4-Nonylphenol, branched and linear, ethoxylated** - -
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
Use title	**Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1 % w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a).**
	Other connected uses: Use 1 of this application “The formulation of a hardener component containing NPE in Aerospace and Defence (A&D) two-part polysulphide sealants”.
	Same uses applied for: not applicable
Use performed by	☒ Applicants ☒ Downstream User(s) of the applicants

Use ID (ECHA website)	0207-02
Reference number	11-2120843376-50-0003 11-2120843376-50-0004
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 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/25627/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/25627/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, by [date] Reason: e.g. due to the need to ensure the efficient use of resources, and in order to synchronise the consultation with the plenary meetings of the Committees. ☒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 accordance with Article 64(4)(a) and (b)	RAC: 10/12/2020, agreed by consensus.
	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 up to 1.75 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 not 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 alternatives have been assessed:

1. Polyglycol ethers
2. Polyether phosphate
3. Alkylammonium salt of a copolymer with acidic groups
4. Anionic aliphatic ester.

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 its 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 €1.3 billion[1] per year and additional important benefits to society have been assessed qualitatively but have not been monetized, such as avoided negative impacts associated with unavailability of 4-NPnEO-sealants on maintenance repair and overhaul (MRO) shops, aircraft operators, flight passengers and companies relying on air cargo.
- Risks to the environment of shortlisted alternative have not been quantified. 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:[2]

- 40-100 jobs would be lost in the most likely non-use scenario (NUS 1) and approximately 5 540-7 600 in NUS 2.

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

No additional 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.

[1] Under the most conservative assumption, when only 1-year profit loss of 5.1 billion euro is considered.
[2] 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]
Indicative number and location of sites covered	Approximately 200 in the EU
Annual tonnage of Annex XIV substance used per site (or total for all sites)	50-350 kg/year
Function(s) of the Annex XIV substance.	4-NPnEO 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 and maintenance, repair and overhaul (MRO), of aerospace products
Shortlisted alternatives discussed in the application	Alternatives considered: • Polyglycol ethers • Polyether phosphate • Alkylammonium salt of a copolymer with acidic groups • Anionic aliphatic ester.
Annex XIV substance present in concentrations above 0.1 % in the products (e.g. articles) made	☐Yes ☒No (after the mixing of the hardener and the base) ☐Unclear ☐Not relevant
Releases to the environmental compartments	☐Air ☒Water (during service life)

	☐Soil ☒None (during mixing and application)
The applicants have used the PNEC 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>Release to the environment during mixing of the hardener with the base</u> Air: 0 kg/year. 4-NPnEO is not considered to be volatile and is unlikely to pose a risk to the air compartment. Water: 0 kg/year. There is no release to any wastewater on site. RMMs and OCs in place on site to prevent any release to the environment of 4-NPnEO containing hardener or sealant. Soil: 0 kg/year. There is no direct release to soil, no sludge from STP. <u>Release to the environment during application</u> Air: 0 kg/year. 4-NPnEO is not considered to be volatile and is unlikely to pose a risk to the air compartment. Water: 0 kg/year. There is no release to any wastewater on site. RMMs and OCs in place on site to prevent any release to the environment of 4-NPnEO. Soil: 0 kg/year. There is no direct release to soil, no sludge from STP. <u>Release to the environment during service life</u> Based on the conservative assumptions that 5 % of the sealant used in application is in contact with water and that that 10 % of this material is released to the environment during the first year of service life (release factor 0.5 %), the applicants estimated

	a release to the environment of 4-NPnEO of 1.75 kg/year, EU-wide.
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. Regarding the service life, the applicants stated that, considering the wide dispersive nature of the release across the EU, the predicted concentration even under the conservative assumptions taken is negligible and below both background levels and currently available analytical detection levels.
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-NPnEO 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 5 to 20 billion euros over the requested 4-year review period.
Society’s benefits of continued use	Some of the indirect benefits to the society in the continued use scenario are: • Avoided temporary gap in the manufacturing of aerospace 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 sections 5.2 and 5.4.
Job loss impacts if authorisation is not granted	40-100 job losses are expected in the most likely non-use scenario (NUS 1) and approximately 5 540-7 600 job losses in NUS 2.

SUMMARY OF RAC AND SEAC CONCLUSIONS[3]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for environment

Since no water is involved in the mixing of the base and hardener or in the application of sealant, no wastewater is produced, and since all solid waste which had been in contact with 4-NPnEO 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

Conclusions of RAC

RAC has not identified shortcomings or uncertainties in the exposure assessment provided by the applicants for mixing and application of the sealant and considers the potential for release to the environment very low as a result of the waterless process and the waste handling.

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

Regarding the release of 4-NPnEO during the service life of the equipment RAC notes that in addition to migration from intact sealant also some release could occur from abrasion, especially during maintenance using an abrasive pad. The applicants estimated (based on migration of the sealant) an annual release (EU-wide) of 1.75 kg/year 4-NPnEO from the service life of the sealant.

RAC considers that the applicants have provided sufficient information to demonstrate that release to environment compartments is prevented or minimised to the extent technically and practically possible.

RAC considers the emission estimate of 1.75 kg/year EU-wide (and the associated release factor of 0.5 %) as a worst-case release of 4-NPnEO from the service life of the sealant.

Does RAC propose additional conditions[4] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements[5] 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

Conclusions of RAC

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.

Regarding the service life, the applicants stated that, considering the wide dispersive nature of the release across the EU, the predicted concentration even under the conservative assumptions taken is negligible and below both background levels and currently available analytical detection levels.

RAC concludes that the current state of knowledge of the endocrine disrupting properties, mode(s) of action and effects of 4-NPnEO 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-NPnEO, RAC is of the

[4] 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.
[5] 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.

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 up to 1.75 kg per year emissions (EU-wide) of 4-NPnEO to the environment (including from the service life). RAC considers the emission estimate as a worst-case release of the use applied for.

4. Analysis of alternatives and substitution plan[6]

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

50-350 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 its 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 applicants will replace 4-NPnEO in all the 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

[6] 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*".

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

☐Yes ☒No

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 alternatives 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

Has action been taken resulting from the analysis of the applicants' comments?

☐Yes ☒No

JUSTIFICATIONS

0. Short description of use

This application for authorisation covers the mixing of the hardener (maximum 0.6 % 4-NPnEO) with the base of the polysulfide sealants. The resulting sealant contains < 0.1 % w/w of 4-NPnEO. The operations are carried out at production facilities and during MRO operations serving the aerospace industries across the EU[7], in approximately 200 sites. These sites use a total of 50-350 kg/year 4-NPnEO used in manufacture of polysulfide sealant.

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

The mixing of the base polysulfide sealant components with 4-NPnEO containing hardener can be completed in three ways: mixing of two compartment kits (either mechanically or manually), mixing in small scale batches by hand from can kits, as well as bulk mixing by machine from drum kits. These are covered by three separate environmental contributing scenario (ECSs) presented in Table 1 and as described underneath the table.

Following mixing, the concentration of 4-NPnEO in the sealant is below 0.1 % w/w. The applicants described the application of the sealant (e.g. by extrusion; brush or roller application or pouring) and the service life of the sealant and discusses the potential for release from these life stages. However, no contributing scenarios are provided for the application of the sealant or for the service life of the sealant.

Table 1: Contributing Scenarios presented in the Use

Contributing scenario	ERC	Name of the contributing scenario
ECS1	ERC6b[8]	Use and handling of the hardener component within two compartment kits
	ERC6b	Use and handling of the hardener component during small scale hand mixing
	ERC6b	Use and handling of the hardener component during bulk scale mixing

Environmental contributing scenario: Use and handling of the hardener component within two compartment kits (ERC 6b)

In this use, the hardener component is completely contained within the two-compartment sealant kit. The use of the two-compartment kit for mixing is a three-stage process. First, a piston rod breaks the seal between the hardener and base allowing them to be mixed within the cartridge body.

The process of mixing within the cartridge can be carried out by manual methods or by machine. The hardener, base, and resulting sealant are completely contained during this mixing process so there is no release of the hardener component to the environment during

[7] Including component manufacturers, Original equipment manufacturers (OEMs) production facilities, supplier production facilities, Maintenance repair and overhaul (MRO) shops, airport and airfields, military airfields and repair depots.

[8] ERC 6b: Use of reactive processing aid at industrial site (no inclusion into or onto article). In line with the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12, the applicants defined the activity as “Use at an industrial site”.

this process. The sealant will be applied via cartridge tubes.

Operators wear the relevant PPE also during application operations. After mixing or application, any disposable PPE are disposed of as hazardous solid waste in a bin on site. All 4-NPnEO contaminated waste is collected and processed and incinerated by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. The process does not involve the use of water.

Environmental contributing scenario: Use and handling of the hardener component during small scale hand mixing (ERC 6b)

In this use, the product is delivered to site in two separate containers, holding the base and the hardener component. In this case, the worker weighs out the amounts of each component in the correct ratios in a disposable vessel which is used to weigh and mix the materials using a disposable spatula. Then the mixture is applied to the relevant surface by brush, roller, spatula, etc.

The process does not include water. Workers use PPE and all 4-NPnEO contaminated waste is collected and processed by licensed third party waste management contractors as hazardous waste and incinerated.

Environmental contributing scenario: Use and handling of the hardener component during bulk scale mixing (ERC 6b)

This is an automated process where two drums contain the hardener component and the base component. In order to combine the two components, a pump system, is used to pump the material from the drums into a bulk mixing machine. The final mixed sealant is then pumped into the relevant containers – usually single compartment cartridges. Occasionally, it might be delivered to a pot for application by hand using a disposable spatula or similar disposable tool or a disposable syringe for small applications. Once mixed the sealant is applied by brush, spraying, spatula, etc.

Mixing and application locations operate without water sources and there is no release of hardener or sealant, to wastewater. Workers using the sealant are trained and wear PPE. All 4-NPnEO contaminated waste is collected by a license third party and incinerated.

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

Use 2 covers the mixing of base polysulfide sealant components with 4-NPnEO-containing hardener.

4-NPnEO has no known independent function during Use 2. During Use 1 it is used as a surfactant (dispersant) in the formulation of the hardener component.

The base is composed primarily of polymers and other ingredients. The hardener component is composed of the curing agent – manganese dioxide (MnO_2) – and other constituents. An adequate dispersion of the curing agent is important for achieving the desired cure and properties of the final sealants.

In particular, without the use of a surfactant the concentration of the curing agent in the hardener component would not be sufficient and the proportion of the hardener in the uncured sealant mix would need to be increased to be able to keep the curing time the same. However, this would lead to the alterations of some of the sealant's key properties, because when increasing the hardener component to adjust for the curing agent, the use of another component (plasticiser) needs to be increased. As a result, the cured sealant will be softer than the required technical specifications.

In addition to hardness, the following are the key technical criteria for the selection and use of the sealants:

- Viscosity
- Density
- Tear strength
- Bond shear strength
- Electrical insulation
- Galvanic isolation
- Adhesion of coatings
- Chemical and water resistance
- Corrosion resistance
- Thermal cycling resistance
- Compatibility with substrates/other coatings
- Erosion resistance and slump resistance
- Pot life/working life
- Cure time and temperature
- Tack-free time
- Shelf-life.

For each of these properties, specific performance criteria are set and need to be demonstrated trough repeatable testing.

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-NPnEO is the hardener, which is a component of two-part polysulfide sealants used in various aerospace applications. The concentration of 4-NPnEO is less than 0.6 % w/w in the hardener component and less than 0.1 % in the final polysulfide sealant (after the mixing the hardener and the base).

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 aerospace 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, or to keep fluids (e.g. fuel, hydraulic fluids, etc.).

Aviation components containing polysulfide sealants need to be able to perform in different environments and challenging operating conditions. Therefore, they need to be:

- resistant to degradation by fuel and other chemicals
- flexible over a wide range of temperatures (extremely high and low temperatures and humidity)
- able to stress-relax and so maintain adhesion when substrates expand and contract.

The sealant formulations[9] affected by the authorisation include the following product

[9] Please note that the above is a non-exhaustive list of the affected formulations. The total number of the sealant formulations affected by this authorisation has been provided in the confidential version of the response to one the SEAC questions.

categories:

- fuel tank and fuselage sealants (9 formulations)
- access door sealants (2 formulations) and
- fuel tank sealant also used for aerodynamic smoothing and protection of landing gears (1 formulation).

0.4. For upstream applications: Downstream User survey

The applicants, members of the Ethoxylates in Aerospace Authorisation Consortium (EAAC), has engaged with supply chain members through the use of webinars, surveys, email exchange and one-to-one meetings for the purpose of collecting information in support of the authorisation application. In particular, information on the uses of the sealants and on their specification criteria and parameters, was provided by the Airbus Division, which is also part of the EAAC.

1. Operational Conditions and Risk Management Measures

1.1. Environment

The polysulfide sealants are used by the A&D industries. Considering the wide variety of sites, the working environment is roughly divided into “Internal facilities” (workshops for production, assembly and Maintenance, Repair, and Overhaul - MRO) and “Flight line environment” (hangars and at the gate).

The applicants presented one exposure scenario and three environmental contributing scenarios for the three different mixing processes:

- Use and handling of the hardener component within two compartment kits
- Use and handling of the hardener component during small scale hand mixing
- Use and handling of the hardener component during bulk scale mixing

The detailed conditions of use are available from section 9.2.1.1, 9.2.2.1, 9.2.3.1 of the CSR. A summary of the OCs & RMMs in the environmental contributing scenarios is provided in what follows. Table 2 provides the operational conditions that are common to the three ECSs.

Table 2: Summary of Operational conditions

Daily use at site	Up to 24 hours per day
Annual use at site	Up to 365 days per year
Tonnage used per year at regional scale	350 kg/year
Total Releases of 4-NPnEO per year	0
Concentration of 4-NPnEO in the hardener component	0.6 %
Concentration of 4-NPnEO in the final mixture	< 0.1 %

According to the applicants the following Risk Management Measures (RMMs) are implemented in all three ECSs as described in the following.

Technical and organisational conditions and measures:

- No release of hardener or sealant, in uncured or cured form, in process or wash water to wastewater. There is no water in the process of mixing. Workers are trained to never release hardener or sealant to the wastewater system.
- Workers are trained in handling of the sealant, including waste management processes, and provided with appropriate disposable and re-usable PPE (aprons, goggles, gloves) and instruction in the use of PPE.
- Reusable PPE would, if contaminated with either 4-NPnEO 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.
- Signs to remind access limitations and waste management practices are provided at appropriate points in the workplace.
- In the unlikely case of any spillage to the flooring during use, a solvent impregnated rag or paper towel would be used to wipe up the material, and this is subsequently disposed of into the waste bins marked for hazardous waste, with the waste subsequently incinerated. Given the viscous nature of the 4-NPnEO-containing sealant hardener prior to mixing, a widespread spillage is not anticipated.
- Cleaning process are done with a rag or wipe pre-impregnated with solvent that are treated as hazardous waste.

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

- All 4-NPnEO contaminated waste (i.e. disposable equipment, wipes for cleaning impregnated with solvent, waste containers, etc.) is collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. Waste is incinerated.

Table 3: Environmental RMMs - summary

Compartment	RMM	Stated Effectiveness
Air	No risk management measures in indicated. The substance has low volatility.	No releases to air
Water	Mixing and application locations operate without water sources. All 4-NPnEO contaminated waste is collected and incinerated. Workers are trained in handling the hardener and provided with PPE.	No releases to water Emissions, although very unlikely, may occur during service life of equipment. No RMM are in place in this case.
Soil	There is no direct or indirect release to soil.	No releases to soil are expected

Application of sealant

Following mixing, the concentration of 4-NPnEO in the sealant is below 0.1 % w/w. Activities after mixing are not subject to authorisation in accordance with Article 56(6)(a) of REACH and no contributing scenarios are provided for these activities. Yet, OCs and RMM in place during application of sealant are presented by the applicants and can be summarised as follows:

- The application of the sealant does not involve the use of water and there is no generation of any liquid waste, either as water or as solvent. There is no release to

wastewater during production, maintenance, repairs or overhaul involving polysulfide sealant.

- Due to the viscous nature of the sealant, spillages are not anticipated to occur but in case a small amount of sealant was released to the floor during use it would be picked up or wiped up with a solvent impregnated rag/paper towel, which would then be disposed to waste bins marked for hazardous waste.
- In a flight line environment, where sealant repair or maintenance may be conducted in either a large hangar or the open air, only small spot repairs with small amounts of sealant are done. For major repairs, where sealants are part of the material being removed, sand or glass bead blasting may be used in a booth with a dust collection system. Big repairs are done in a dedicated internal workshop.
- Following application, the surface of the sealant may be abraded or trimmed to shape. Offcuts or dust from the process is recovered with a wipe, which is subsequently disposed of as hazardous waste.
- Workers wear the same PPE as for mixing. After mixing, any disposable PPE are disposed of as hazardous waste in a bin on site whether contaminated or not.
- All 4-NPnEO contaminated waste (tools, rags, towels, gloves, cartridges, etc.) used during the application process is collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. Waste is incinerated.

Service life

In principle, the sealant is designed to remain in place until maintenance is due or over the lifetime of the equipment. In case of reparation of the equipment is needed the old sealant is removed by cutting it away with a sharp tool. The removed sealant is collected by sweeping and disposed as hazardous waste. Smaller pieces are collected by vacuum cleaner fitted with an appropriate filter. The contents of the vacuum after use will be disposed of as hazardous waste.

In some cases, the surface may subsequently be abraded with an abrasive pad to remove any remnants not removed by use of the tool. The surface of the equipment from which the sealant was removed is then cleaned with a wipe to remove any residual small pieces of sealant, or dust. The removed sealant, abrasive pad, and wipe are consigned as hazardous waste.

According to the applicants, migration of 4-NPnEO from the article over the service life of sealants in A&D products will be limited, if it occurs at all. 4-NPnEO is expected to be encapsulated in the article. Interaction of the ethoxylate with the cross-linked matrix and any other residual (non-reacted) components would be expected to significantly retard migration of ethoxylate from the matrix.

Sealants within the fuel tank will be exposed to fuel, and potentially water. In case any 4-NPnEO was to migrate from the sealant to the fuel, it would be completely combusted in the aircraft engine. Sealants on exterior locations that are accessible and visible are mainly cover with paint and/or primer. Sealants on the interior locations by their nature are not exposed to the environment. Yet, some release from the sealant could be possible when the surface of the sealant is exposed to water (e.g. rain, wash water).

At end of life, all A&D products must, as part of aviation requirement to avoid being used as suspect unapproved parts, be destroyed to avoid reuse as counterfeit parts. At the end of life,

parts are collected in designated, secure boxes and sent to a licensed scrap dealer who treats the metals according to EU and national requirements.

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

The mixing of the base and hardener does not involve the use of water and no liquid waste is generated. All 4-NPnEO contaminated waste is required to be collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. Waste is being incinerated. Workers receive training on the correct handling of the sealing, including waste management processes.

These main OCs and RMMs are also applicable to the application of sealant. Application of sealant happens at the same type of sites with the same type of regulatory requirements and management systems.

Regarding the service life, the sealant is in principle designed to remain in place until maintenance is due or over the lifetime of the equipment. Migration of 4-NPnEO from the article over the service life of sealants in A&D products will only rarely be exposed to water and where such opportunity arises it will typically be covered with paint and/or primer.

Hence, RAC has not identified relevant shortcomings to the OCs and RMMs.

1.3. Conclusions on OCs and RMMs

Overall conclusion

RAC concluded that the OCs and RMMs 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[10] and effective[11] 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
Environment	☒Yes	☐No	☐Not relevant

2. Exposure assessment

2.1. Environmental emissions

The hardener component of the polysulfide sealant contains a maximum of 0.6 % w/w 4-

[10] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[11] '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.

NPnEO. The applicants qualitatively assessed the release from the mixing of two compartment kits, mixing in small scale batches by hand from can kits, as well as bulk mixing by machine from drum kits.

In addition, the applicants described the application of the sealant and the service life of the sealant and discusses the potential for release from these life stages.

Mixing

Water

During the process of handling and mixing of the base and hardener there is no use of water and not liquid waste is generated either as water or as a solvent. Mixing locations typically operate without water sources, serving further to prevent release of the material to wastewater during handling and use. Further, cleaning process are done with a wipe impregnated with solvent. In addition, all waste contaminated with 4-NPnEO is incinerated and workers are trained and warn not to release any contaminated material to water. Hence, there is no release to wastewater or water on site.

Air

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

Soil

Since waste that could be contaminated with 4-NPnEO is collected for incineration, as well as there are no releases to STP, direct or indirect releases to soil are not expected.

The applicants qualitatively estimated the emissions from the mixing as indicated in Table 4.

Table 4: 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-NPnEO during the process of mixing. A range of RMMs and OCs are in place which effectively prevents any release of 4-NPnEO to the environment during mixing.
Air	0	0	
Soil	0	0	

Application of the sealant

The applicants stated that during application of the sealant (e.g. by extrusion; brush or roller application or pouring) there are no emissions to water. The application of the sealant does not involve the use of water and there is no generation of any liquid waste, either as water or as solvent. The applicants stated that exposure of the sealant to water during mixing or curing would lead to quality issues. In addition, all waste contaminated with the sealant is stated to be incinerated.

Service life of the sealant

The applicants have semi-quantitatively evaluated possible emissions to water during equipment service life. In the cure sealant 4-NPnEO is present in very low concentrations (below 0.1 % w/w)

The applicants consider the assessment a conservative estimate where some release from the sealant is possible when its surface is exposed to water (e.g. rain, wash water). In reality, most of the sealant will be encapsulated in the article and migration will be difficult. The model for release considers the fraction of sealant that might be exposed at the outer surface of the A&D product (i.e. located on the exterior surface and not protected by paint or primer). It also considers that a fraction of the 4-NPnEO at the surface of the sealant may be released to the environment. The fractions are purposely set to be very high.

As shown in the table below the amount of 4-NPnEO released to the environment annually would be up to 1.75 kg/year, EU-wide, based on the semi-quantitative assessment.

	Worst hypothetical case	Comment
Use of 4-NPnEO in production of hardener in EU	350 kg/year	
Concentration of 4-NPnEO in sealant	< 0.1 %	
Volume sealant used in A&D industry in EU per year	350 t/a	
Tonnage of 4-NPnEO in sealant on aerospace equipment	350 kg/y	
% of Sealant used in applications that have contact to surface water	5 %	Assumes 95 % applications are internal or coated with primer so no release to surface water possible.
Tonnage of 4-NPnEO in sealant in applications that could be exposed to surface water	17.5 kg	EU wide
% of total 4-NPnEO in sealant that could be released to surface water considering e.g. contact of sealant with water at surface, K_{ow} (i.e. partitioning to water rather than sealant), etc.	10 %	Approximation total exposed surface area. Assumes e.g. only 10 % ethoxylate in surface facing edge of sealant available for release to the environment and all of that released in first year. 90 % remains in sealant at end of life.
Tonnage of 4-NPnEO in sealant in scope of this AfA released to surface water EU-wide	1.75 kg	Released globally across all flight paths. Assumes all exposed 4-NPnEO is released to water. However, the major fraction of any material released would be retained in soil, where it would eventually degrade.
EU area	> 4.5 million km^2	
Usage of 4-NPnEO in sealant in scope of this AfA released to surface water	~1 ng/m^2/year	Assumes all material released in the EU, which is an over-estimate.

EU-wide		Furthermore, the major fraction of any material released would be retained in soil, where it would eventually degrade.

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

Environment

No shortcomings or uncertainties were identified for mixing and application of the sealant. The potential for release to the environment is very low as a result of the waterless process and the waste handling.

Regarding the release of 4-NPnEO during the service life of the equipment RAC notes that in addition to migration from intact sealant also some release will occur from abrasion, especially during maintenance using an abrasive pad. The applicants stated that the activities after mixing are not subject to authorisation in accordance with Article 56(6)(a) of REACH and that they therefore do not require a formal risk assessment. RAC has considered in its assessment the potential for release from the application of the sealant and from the service life of the cured sealant.

RAC considers the emission estimate of 1.75 kg/year EU-wide (and the associated release factor of 0.5 %) as a worst-case release of 4-NPnEO from the service life of the cured sealant.

2.3. Conclusions on exposure assessment

RAC considers that the applicants have provided sufficient information to demonstrate that release to environment compartments is prevented or minimised to the extent technically and practically possible.

Overall, RAC considers the emission estimate of 1.75 kg/year EU-wide (and the associated release factor of 0.5 %) as a worst-case release of the use applied for (including from the service life).

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 and did not use them for risk assessment. Instead, the applicants stated that due to the RMMs and OCs, release to the environment is precluded and only performed a qualitative risk assessment. The applicants consider that the use poses no risk to the environment.

Regarding the service life, the applicants stated that, considering the wide dispersive nature of the release across the EU, the predicted concentration even under the conservative assumptions taken is negligible and below both background levels and currently available analytical detection levels.

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[12] and Brown et al (2017)[13]. 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[14].

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[15].

Species sensitivity distributions (SSDs) were used to calculate the $PNECs_{aquatic}$. The applicants applied assessment factors to the HC5 values[16] from the SSDs to cover apical and endocrine endpoints (instead of the default factor of 1-5, an assessment factor of 50 and 10 for freshwater and marine compartment was applied, respectively).

RAC assessed the SSD 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 has appropriate confidence intervals. However, there are reliability concerns related to the studies included in the freshwater and marine SSDs[17].

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 (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. This is the case of gastropods, which may be particularly sensitive to the substance.

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. Further, limited data for gastropods, covering a part of the life-cycle, are

[12] 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

[13] 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

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

[15] 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.

[16] 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).

[17] 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. In fact, several of the studies used in the SSD were considered not reliable in the Background Document to the restriction on Nonylphenol and Nonylphenol ethoxylates and include relevant taxonomic groups such as the mollusc study.

available as well. Hence, RAC considers that the dataset and analysis provided by the applicants are not sufficiently representative of sensitive taxonomic groups to reliably derive the PNECsaquatic for endocrine disrupting properties of 4-NPnEO for the environment.

Furthermore, the applicants derived $PNECs_{sediment}$ freshwater and marine based on four partial lifecycle long-term tests 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 not representative enough to derive a reliable $PNEC_{sediment}$ for the endocrine disrupting properties of the substance and questions whether the AF chosen are appropriate.

$PNEC_{soil}$ 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). According to the applicants, there is no evidence of endocrine effects in soil organisms. However, the data available 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-NPnEO 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 shortcomings or discrepancies with Guidelines requirements such as lack of statistical robustness, inadequate exposure period and life-stage, control variability, etc. These deviations undermine the adequacy and protectiveness of the estimated PNECs.

RAC concludes that the current state of knowledge of the endocrine disrupting properties, mode(s) of action and effects of 4-NPnEO 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-NPnEO, RAC is of the view that the applicants has 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 **up to 1.75 kg per year** emissions (EU-wide) of 4-NPnEO to the environment (including from the service life). RAC considers the emission estimate as a worst-case release for the use applied for.

4. Analysis of Alternatives and substitution plan[18]

The sealants are made in two steps:

1) Formulation of the hardener where 4-NPnEO 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-NPnEO 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?

50 and 350 kilograms.

4.1. Summary of the Analysis of Alternatives and substitution plan by the applicants and of the comments received during the consultation and other information available

The applicants' substitution efforts are focused on developing a formulation with an alternative surfactant, which needs to ensure that the reformulated sealants meet the technical requirements of 4-NPnEO-based sealants.

The applicants have screened more than 100 different surfactants and – during preliminary reformulation activities – concluded that many surfactants were suitable only for aqueous solutions and unable to disperse the curing agent particles into the rest of the liquid hardener mix.

The applicants have however identified 4 potential alternatives:

- Polyglycol ethers
- Polyether phosphate
- Alkylammonium salt of a copolymer with acidic groups
- Anionic aliphatic ester.

[18] 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*".

The applicants have assessed each of the four alternatives against the following key parameters:

1. Viscosity of the hardener
2. Stability of the hardener
3. Suitability for all sealant hardeners
4. Impacts on mechanical properties of the mixed sealant
5. Impacts on mechanical properties of the mixed sealant after adjustment of the base/hardener formulation
6. Impacts on the curing behaviour of the mixed sealant
7. Impacts on the viscosity of the mixed sealant
8. Impacts on the adhesion of the mixed sealant and
9. Impacts on the adhesion of the mixed sealant after adjustment of the base/hardener formulation.

On the basis of the results from the above assessment, the applicants consider polyether phosphate as the most promising alternative.

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

As seen in section 4.1, the applicants have identified several potential alternatives and conducted initial testing, which demonstrated that the most promising alternative is polyether phosphate. However, the applicants state that the technical suitability of this potential alternative can only be confirmed once OEMs (Original Equipment Manufacturers) have completed their qualification process and demonstrated that the 4-NPnEO free sealants are interchangeable with 4-NPnEO-based ones. Since the qualification process by OEMs cannot be completed before the end of 2024, the applicants have concluded that there are no technically feasible alternatives before Sunset Date.

Regarding economic feasibility, according to the applicants, the costs for replacing 4-NPnEO in the hardener component are expected to be minor because the surfactants are used in low concentration and have similar prices. Moreover, the applicants explain that no additional investments in equipment will be required for implementing the identified alternative.

The main cost burden associated with the substitution is the requirement for testing at both formulator (applicants) and downstream users' level. These costs are expected to be more than 3 million euro. The applicants did not claim that these costs make substitution economically infeasible.

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

The applicants have described the technical requirements that make the short-listed alternatives as the most promising ones from both technical and economic perspectives.

SEAC has reviewed the information provided by the applicants on the examined alternatives 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 alternatives needs to be confirmed by downstream users and SEAC concurs with the applicants that this process cannot be completed before the second quarter of 2024.

Regarding economic feasibility, SEAC notes that the applicants do not claim the costs make substitution economically infeasible.

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

SEAC does not have any reservation on applicants' conclusions from the analysis of alternatives.

4.4. Substitution activities / plan

Has 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 most promising alternative - polyether phosphate - is expected to successfully complete the development testing phase by the 2nd quarter of 2021. During this step, initial laboratory testing is followed by small (bench) scale testing and by full scale batch production testing to identify any potential 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 sealant specifications (such as water immersion and fuel immersion tests).

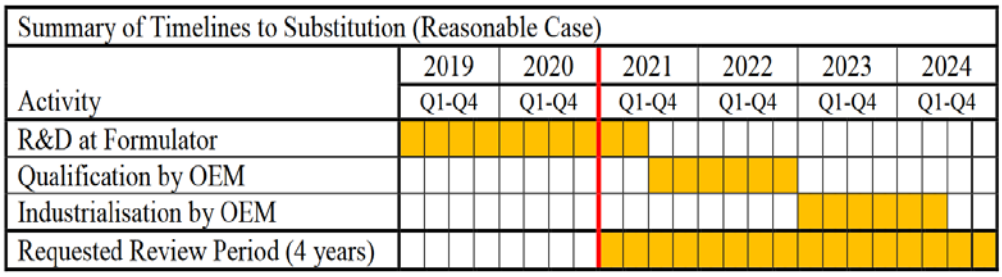
Once the R&D activities at formulator level are completed, the representative samples of the reformulated sealants will be sent to OEMs (Original Equipment Manufacturers)[19] for testing

[19] Organization that designs, integrates, and is responsible for certification of new top-level systems (e.g. aircraft, radars systems, missiles).

by the end of the 2nd quarter of 2021. OEMs need to verify, through their specific testing procedures, that the reformulated sealants are interchangeable with 4-NPnEO-based ones and so able to meet their own technical specifications. OEMs will conduct the qualification process from the 3rd quarter of 2021 until the end of 2022.

The final step - which requires the industrialisation of the 4-NPnEO free sealants by OEMs - is expected to take place from the 1st quarter of 2023 until 2nd quarter (included) of 2024. During this step the use of the sealants in the actual production and maintenance operations needs to be defined and implemented. This is because – even in case the interchangeability can be demonstrated – all actors within the manufacturing process, repair operation and supply chain need to switch over to the correct formulation.

The following table provides information on the time expected for completing each step of the substitution plan.



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 different steps, in the sequence described by the applicants, need to occur before concluding on the suitability of the alternative formulations. In particular, SEAC concurs with the applicants that the qualification by OEMs is required, given that the formulator is able to test the sealants only against a limited number of technical parameters and that only OEMs can conduct the necessary additional testing to confirm the interchangeability of the alternative formulations.

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

Conclusions of SEAC

SEAC concurs with the applicants that no technically suitable alternative will be available before the sunset date. SEAC finds it credible that the applicants will replace 4-NPnEO in all the formulations by the second quarter of 2024.

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.

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

The applicants consider that on the basis of the currently applied RMMs and operating conditions in place, there is no potential for releases to the environment of the 4-NPnEO-containing hardener component of the two-part sealant during formulation or when mixing within the two-compartment kit, in small scale batches by hand or bulk mixing by machine. Accordingly, applicants state that there is no risk to the environment from the uses targeted in this application for authorisation.

SEAC notes that the applicants have provided an uncertainty analysis where it has examined a worst-case scenario that considers emissions throughout the life-cycle of an aerospace product. In this scenario 1.75 kg of 4-NPnEO are emitted to the environment per annum.

This release estimate is exclusively from the service life of an aerospace product and thus the applicants assumed no release to the environment during formulation (Use 1), the mixing by DU (Use 2), nor during the application of sealant by downstream users.

Assuming a constant release per annum for the entire review period of 4 years, the applicants estimated the total emissions of 7 kg of 4-NPnEO from the service life cycle of the aerospace products.

5.2. Benefits of continued use

Applicants' assessment of the benefits in continued use has considered the following actors in the aerospace supply chain:

- Chemetall GmbH (formulator) and
- Downstream users, including Airbus Group companies (as OEMs).

Non-use scenario

On the basis of the information gathered from internal consultation (within aerospace industry sector) which was supported by independent consultants, two possible non-use scenarios have been identified by the applicants, should an authorisation not be granted.

NUS 1 refers to a situation where all processes of all aerospace operations in the EEA would be changed to the exclusive use of 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 the EEA via refrigerated airfreight. Given that 4-NPnEO concentration in the final sealants is less than 0.1 %, their use is exempted from the authorisation. This NUS would entail a period of 1 to 2 years where no manufacturing or MRO of aerospace equipment would be possible in the EEA, due to unavailability of 4-NPnEO-containing sealants.

NUS 2 refers to a situation where manufacturing and Maintenance, Repair and Overhaul (MRO) of aerospace equipment would need to be stopped until a 4-NPnEO-free alternative is developed by the applicants and fully qualified and industrialised at all aerospace 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 it would be possible to establish a production facility outside the EEA capable of delivering the needed amounts of sealants as PMF product for Airbus companies and its EEA suppliers as soon as needed. Moreover, the downstream users would not be able to import alternative sealants, because for the specific aerospace applications concerned by this application, no alternative SVHC-free sealants have been qualified by them.

Moreover, applicants note that the delivery of sealants (as PMF) 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 a significant 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 does not represent an improvement from an environmental perspective. 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.

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

According to the applicants these NUSs will have, at the minimum, the following consequences:

• Temporary loss of ‘value added’, not only from sealants’ formulation 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 aerospace 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-NPnEO-containing sealants would 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 in the EU
- 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 and 40 and 100 jobs could be lost in the European Union. The number represents the expected job losses at the formulator's site in NUS 1. No job losses are expected at downstream users' sites in NUS 1.
- In NUS 2, 40 and 100 jobs could be lost at applicants' site and 5 500-7 500 at Airbus's sites.

Economic impacts of continued use

The applicants have estimated the following costs in NUS 1:

At formulator site:

Relocation Costs

To supply only PMF sealants for all relevant DU applications in the EEA, the production will need to be relocated outside the EEA and adapted to the exclusive production of PMF sealants. The applicants provided an estimate of the expected relocation costs in the range of 6-24 million euro. These numbers include 1-9 million euro for transferring the existing equipment and installation to a non-EEA site in 2021 and 5-15 million euro for the extension of production capacity in non-EEA. The applicants also expect additional costs associated with the longer lead-time in NUS 1, given that the delivery of the sealants to the EEA sites would require more time, when compared to the current situation.

Foregone profit

According to the applicants 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 applicants have not disclosed to SEAC[20] the profit losses for confidentiality reasons, nor has included any range in the submitted application.

Social cost of unemployment

Between 40 and 100 job losses are expected at the formulator's site and the related social costs have been estimated by the applicants between 4 and 10 million euro.

At downstream user's level:

To assess the impact on downstream users, the applicants have considered the:

- Foregone profits associated with production interruption
- The investment costs
- Social cost due to the expected job losses.
- Logistics costs
- Energy costs
- Environmental costs due to CO_2 emissions.

SEAC notes that in its assessment, the applicants have considered the impacts on Airbus Division only, with the exception of the quantification of logistics costs and external environmental costs, where the costs have been calculated based on the total tonnage of 4-NPnEO -containing sealants used in the EEA by all relevant downstream users.

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

Foregone profit for Airbus

Based on the information provided by the applicants, 4-NPnEO polysulfide sealants are the only sealants which are qualified by Airbus for the specific applications in the scope. And so no alternative SVHC free sealants would be available to the them in the NUS. Any alternative sealant would need to go through the full qualification process by Airbus and this would require several years.

For the period of supply interruption, in case of a non-granted authorisation, the applicants estimated the foregone profits, based on the Airbus revenue figures. Considering a discount rate of 4 % and the base year 2020, the applicants provided a range of values for the expected foregone profit under NUS 1 at approximately 5 100-10 000 million euro (assuming a loss over 1 or 2 years respectively).

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. The total investment costs to be borne by the downstream users have been estimated by the applicants in the range of 1-9 million euro. The overall process is expected to take up to 2 years.

Operating costs

According to the applicants, the downstream users will also incur an increase in the following operating costs. These are considered only for the last 2 years (2022-2024) of the requested period, once the supply of the sealants recommences, after the relocation process has been completed:

- Energy costs, for running cold storage freezers to store PMF sealants that will be imported to the EEA to preserve quality standards, in the range of 0.3-3 million euro.
- Logistic costs, 1-9 million (based on the total tonnage of 250-1 750 tonnes expected to be delivered over 2022-2024).

The applicants have also monetised the CO_2 emissions that would result from the expected imports of PMF sealants (250-1 750 tonnes) at 0.02-0.16 million euro. These values correspond to the values calculated with the DHL emission calculator for the transport of products from a non-EU region and the CO_2 price from the Emission Trading System. SEAC took note of these estimations but has concern related to the relevance and quality of the data used by the applicants. Therefore, these monetised emissions have not been considered in the quantification of the total benefits in continued use scenario.

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, especially for the line maintenance activities or unscheduled repairs, where the amount of sealant required cannot be forecasted. 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.

The total economic impacts in NUS 1

The applicants estimated the total economic impact of this NUS at more than 5 000-10 000 million euro.

In NUS 2, the applicants have quantified the following impacts:

- 40 and 100 job losses at formulator level.

- Foregone profit for the Airbus companies at 5 100-19 300 million euro (over 1 and 4 years respectively).
- 5 500-7 500 employees job losses at Airbus companies with the related social costs in the range of 500-700 million euro.

Table 5: Socio-economic benefits of continued use

Description of major impacts	**Quantification of impacts [€ million] NUS 1**	**Quantification of impacts [€ million] NUS 2**
1. Benefits to the applicant		
1.1 Avoided profit loss due to ceasing the use applied for	Not provided due to confidential reason	Not provided due to confidential reason
1.2 Avoided relocation or closure cost	6-24	n/a
1.3 Avoided net job losses	4-10	4-10
Sum of benefits to the applicant	***10-34***	***4-10***
2.Quantified impacts of the continuation of the SVHC use applied for Airbus		
2.1. Avoided profit loss due to ceasing the production process 2 year	5 100-10 000	5 100-19 300
2.2 Avoided additional cost for quality testing additional asset acquisition cost	1-9	n/a
2.3 Avoided net job losses	n/a	500-700
2.4 Avoided additional energy costs	0.3-3	n/a
2.5 Avoided additional logistics costs	1-9	n/a
Sum of impacts of continuation of the use applied for	**5 100-10 000**	**5 600-20 000**
3. Aggregated socio-economic benefits	**5 100-10 000**	**5 600-20 000**

5.3. Combined assessment of impacts

Based on the information presented by the applicants on potential impacts expected in the discussed NUSs, SEAC has calculated that socio-economic benefits of continued use would be approximately between 5 and 20 billion euro over the review period.

SEAC acknowledges that the value of socio-economic benefits of continued use might still be underestimated due to the fact that the applicants did not quantify in monetary terms all the foreseen impacts and therefore these additional costs were not considered when calculating the cost per kg of prevented emissions of 4-NPnEO.

Furthermore, the applicants have adopted a conservative approach, by assuming under a worst-case scenario, that 7 kg of 4-NPnEO would be emitted over the requested period.

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-NPnEO in the environment is €0.7-2.90 billion.

Table 6: Socio-economic benefits and risks of continued use

Socio-economic benefits of continued use (NUS 1)		**Socio-economic benefits of continued use (NUS 2)**	**Excess risks associated with continued use**	
Benefits [€ million]	Avoided loses for the applicants (formulator): 10-34 million Avoided profit losses for the downstream users: 5 100-10 000 million euro + avoided requalification cost 1-9 million + avoided operating cost 0.3-3 million euro for energy and 1-9 million euro for logistics	Avoided losses for the applicants (formulator) 4-10 million euro + avoided profit losses for downstream users 5 100-19 300 + avoided job losses for downstream users: 500-700 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	Potential benefits in terms of avoided CO_2 emission costs associated with logistics		Monetised excess risks to the general population and indirectly exposed workers	Not applicable.
Additional qualitatively assessed impacts	Avoided negative impacts on MRO activities	Avoided negative impacts on MRO activities	Additional qualitatively assessed risks	1.75 kg of 4-NPnEO per year in the worst-case scenario
Summary of socio-economic benefits	**5 100-10 000 million euro**	**5 600-20 000 million euro**	**Summary of excess risk**	7 kg of 4-NPnEO over the requested period of 4 years

Table 7: Cost of non-use per kg

	NUS 1	NUS 2
Total cost over 4 years (€)	5 100-10 000 million	5 600-20 0000 million
Total emissions over 4 years (kg)	7 kg	7 kg
Ratio (€/kg)	0.7-1.4 billion	0.8-2.9 billion

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 the selection and justification of the NUSs 1 and 2. Section 5.2 provides details on possible consequences in the selected NUSs and this information is supportive of the applicants' claim that a refused authorisation would lead to substantial welfare losses to the aerospace industry as well as to the whole society.

SEAC considers that the methodology used by the applicants to calculate the foregone profits was appropriate and provides a good indication of the scale of the potential impacts of an

authorisation not being granted.

SEAC considers that changes in profits are a relevant measure of changes in producer surplus and appropriate to monetising the welfare implications of continued use. SEAC concurs that the methodology used by the applicants 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-NPnEO 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-NPnEO 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 applicants. As seen in section 5.2, a temporary unavailability of the 4-NPnEO 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, etc. Due to data limitation, a quantitative assessment of these impacts was not possible according to the applicants.

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

Moreover, SEAC agrees with the applicants that the NUSs would likely result in job losses at the applicants' and downstream users' facilities. SEAC notes that this impact would present a significant welfare loss and so can be an important component of the benefits of continued

use. SEAC also notes that in case of a refused authorisation, substantial additional operating costs (energy and logistics) will be borne by the downstream users.

SEAC also agree that in case of a refused authorisation, an increase of CO_2 emissions will likely result from the expanded logistics due to import of sealants from outside the EEA. However, SEAC has concern related to the quality of the data used by the applicants to calculate the monetized value of the expected CO_2 emissions and did not included it in the quantitative assessment. In conclusion, due to the exclusion of several impacts from the cost-effectiveness calculation, including some that could be substantial, like foregone profit for the formulator and other downstream users (in the addition to the Airbus Division), SEAC considers that the final benefits in the continued use are likely to be close to the upper bound estimates.

5.5. Conclusion on the socio-economic analysis

SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's 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 its 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 new 4-NPnEO-free formulations, given the long testing process required at both applicants and downstream users' level and takes note 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-NPnEO-free polysulfide sealants.
- 4-NPnEO 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[21] 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 technically and practically possible.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[22] proposed for the authorisation?

☐ Yes

☒ No

[21] 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.
[22] 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.

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

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.