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 (4-tert-OPnEO)

Use as a lysing agent for red blood cells in blood analysis diagnostic device

Submitting applicant

Instrumentation Laboratory SpA

ECHA/RAC/SEAC: AFA-O-0000006870-71-01/F

Consolidated version

Date: 12/11/2020

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:

Applicant	**Instrumentation Laboratory SpA** (position in supply chain: upstream)
Substance ID EC No CAS No	**4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)** 618-541-1 9036-19-5
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 - effects to the environment
Use title	**Use as a lysing agent for red blood cells in blood analysis diagnostic device**
	Other connected uses: Not applicable
	Same uses applied for: Not applicable
Use performed by	☐ Applicant ☒ Downstream Users of the applicant
Use ID (ECHA website)	0194-01
Reference number	11-2120833523-59-0001
RAC Rapporteur	BARAŃSKI Bogusław

SEAC Rapporteur SEAC Co-rapporteur	ROUW Aart MÅGE Marit
ECHA Secretariat	MARQUEZ-CAMACHO Mercedes VÄÄNÄNEN Virpi PENNESE Daniele

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	28/06/2019
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	28/01/2020
Application has been submitted by the Latest Application Date for the substance and applicant 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	12/02/2020 - 08/04/2020
Comments received	☐Yes ☒No Link:
Request for additional information in accordance with Article 64(3)	On 15/11/2019, 18/03/2020, 03/06/2020, and 10/06/2020 Link: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/25103/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Trialogue meeting	Not held – 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 opinion to the applicant	☐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	RAC: 17/09/2020, 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 applicant	09/11/2020
Date of decision of the applicant not to comment on the draft opinion, in accordance with Article 64(5)	12/11/2020
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: 12/11/2020, adopted by consensus.
	SEAC: 12/11/2020, 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,
- other available information.

In this application, the applicants did not derive PNEC(s). 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 for the endocrine disrupting properties of the 4-tert-OPnEO for the environmental organisms.

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicant 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 recommendations for the review report are expected to allow RAC to evaluate the review report efficiently

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, and
- 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 of the substance in accordance with Annex I of the REACH Regulation.

The following alternatives have been assessed (see Section 4 of the Justifications):

- Alternative surfactant 1 (confidential)
- Alternative surfactant 2 (confidential)

In addition, a comparative analysis was made between the equipment of IL and three competitors (which do not use 4-tert-OPnEO), regarding their analysis methods and performance.

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 applicant.
- 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 €50 million over 12 years. Additional important human health benefits to society (not monetised) include the avoided shortage of testing capacity in the EEA. Around 34 millions of blood samples can be tested annually with the applicant's equipment.
- Risks to the environment of shortlisted alternatives have not been quantified. There may therefore be a risk arising due to the use of an alternative should the authorisation not be granted.

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.

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

- cease altogether
- be taken up by market actors using the same substance (having an authorisation) operating inside the EU
- be substituted by market actors operating inside 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[1] at least 100-1 000 jobs would be lost.

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

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

Recommendations for the review report are made. These are listed in section 9 of the justification to the opinion.

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicant and the comments received on the broad information on use, a **12-year** review period is recommended for this use.

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

SUMMARY OF THE USE APPLIED FOR

Role of the applicant in the supply chain	Upstream ☐ [group of] manufacturer[s] ☒ importer ☐ [group of] only representative[s] ☐ group of formulators Downstream ☐ [group of] downstream user[s]
Number and location of sites covered	2 000-20 000 sites in the EU countries (hospitals, medical laboratories)
Total tonnage of Annex XIV substance used for all sites	2 223 kg in 2018. Expected to be 6 000 kg per year in 2032. Per individual user site: 1-100 kg per year at large sites; 1-50 kg per year at small sites.
Function(s) of the Annex XIV substance.	Lysing agent: required for the disruption of the cell membranes of red blood cells in a blood sample.
Type of products (e.g. articles or mixtures) made with Annex XIV substance and their market sectors	Lysing bags contained in disposable cartridges (PAK cartridges) used in two types of blood analysers: GEM®Premier™ 4000 and GEM®Premier™ 5000.
Shortlisted alternatives discussed in the application	Alternative substances considered: • Alternative surfactant 1 (confidential) • Alternative surfactant 1 (confidential) Alternative technologies considered: • Ultrasonic lysis • Whole blood analysis (without lysis) Others: n/a
Annex XIV substance present in concentrations above 0.1 % in the products (e.g. articles) made	☐Yes ☐No ☐Unclear ☒Not relevant
Releases to the environmental compartments	☐Air ☐Water ☐Soil ☒None
The applicant has used the PNEC recommended by RAC	☐Yes – [link to the relevant document]

	☐No – [alternative values used] ☒Not relevant
All endpoints listed in Annex XIV were addressed in the assessment	☒Yes ☐No if 'No' – which endpoints are not addressed
All relevant routes of exposure were considered	☒Yes ☐No if 'No' – which routes are missing and what was the reason given
Adequate control demonstrated by applicant for the relevant endpoint	☐Yes ☐No ☒Not Applicable – non-threshold substance
Level of release used by applicant for risk characterisation	Release of 4-tert-OPnEO to the environment: Air: 0 kg/year Water: 0 kg/year Soil: 0 kg/year
Risk Characterisation	Environmental compartments: The applicant did not attempt to derive PNECs or RCRs. The CSR describes how the operational conditions (OCs) and risk management measures (RMMs) in the exposure scenario (ES) prevent or minimise releases to the environment as far as technically and practically possible (with the view to minimising the likelihood of adverse effects).
Applicant is seeking authorisation for the period of time needed to finalise substitution ('*bridging application*')	☐Yes ☒No ☐Unclear
Review period argued for by the applicant (length)	12 years
Most likely Non-Use scenario	Interruption in supply of disposable cartridges for the GEM Premier analysers resulting in a shortage in blood gas measurement systems in the EEA.
Applicant concludes that benefits of continued use outweigh the risks of	☒Yes ☐No

continued use	☐Not Applicable – threshold substance with adequate control
Applicant's benefits of continued use	The applicant claims a profit loss between €10-100 million over the review period
Society's benefits of continued use	The applicant claims that the society's benefits are related to employment and the health sector and patients access to tests. The applicant has estimated the impacts for suppliers to the applicant to be €1-10 million and the impacts for the users of the applicants products to be €10-100 million over the review period.
Monetised health impact on workers	Not applicable
Distributional impacts if authorisation is not granted	Not available
Job loss impacts if authorisation is not granted	The applicant has estimated that 100-1 000 full time jobs will be lost.

SUMMARY OF RAC AND SEAC CONCLUSIONS[2]

1. Operational Conditions and Risk Management Measures

Since all relevant waste (used cartridges) is collected and disposed of for incineration, no relevant shortcomings to the operational conditions (OCs) and risk management measures (RMMs) have been identified by RAC.

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: 0 kg/year

Water: 0 kg/year

Soil: 0 kg/year

Conclusions of RAC

RAC considers that the estimates for releases of 4-tert-OPnEO provided by the applicants are appropriate.

RAC notes that some shortcomings remain in the assessment related to the small number of downstream users interviewed on how the PAK cartridges containing 4-tert-OPnEO are handled and disposed of.

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

Does RAC propose additional conditions[3] related to exposure assessment for the authorisation?

☐Yes ☒No

Does RAC propose monitoring arrangements[4] 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 applicant has considered 4-tert-OPnEO as a non-threshold substance and did not attempt to derive PNECs or RCRs. This approach is in line with RAC's paper *"Risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO"*, adopted at RAC-43[5] and RAC's conclusion on this issue at RAC-50.

Based on the OCs & RMMs described in the ES, notably the use of 4-tert-OPnEO in closed systems and the collection and adequate treatment of the relevant waste potentially contaminated with 4-tert-OPnEO, RAC is of the view that the applicant has demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible (with the view to minimising the likelihood of adverse effects).

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

[3] 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.

[4] 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.

[5] https://echa.europa.eu/documents/10162/13637/npneo_and_opneo_for_agreement_final_en.pdf/026cbafc-6580-1726-27f3-476d05fbeef0

4. Analysis of alternatives and substitution plan[6]

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

6 000 kg

Note: The volume in use was 2 223 kg in 2018 , but it is expected to grow to the indicated level over the course of the 12 year review period.

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

☐Yes ☒No

Has the applicant submitted a substitution plan?

☒Yes ☐No

Note that there is no separate substitution plan. However, all activities regarding the ongoing substitution are contained in the AoA (page 35ff). SEAC will consider this information as "the substitution plan".

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

☒Yes ☐No

SEAC concludes that the substitution activities as reported in the relevant sections of the application for authorisation are credible and consistent with the AoA and the SEA in this application.

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 applicant.

[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 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 applicant related to the content of the potential review report?

☐Yes ☒No

5. Benefits and risks of continued use

Has the applicant adequately assessed the benefits and risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

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,
- SEAC's assessment of the comments received in the public consultation,
- Any additional information provided by the applicant or its downstream users,
- RAC's assessment of the risks to the environment

6. Proposed review period for the use

☐ 4 years

☐ 7 years

☒ 12 years

☐ Other – … year

7. Proposed additional conditions for the authorisation

RAC

Additional conditions:

For the environment ☐Yes ☒No

SEAC

Monitoring arrangements ☐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. Applicant comments on the draft opinion

Has the applicant commented the draft opinion?

☐Yes ☒No

JUSTIFICATIONS

0. Short description of use

4-tert-OPnEO is imported by the applicant into the EU in closed containers (lysing bags) as an integral part of disposable cartridges (PAK). The lysing bags contain 4-tert-OPnEO as a solution with a concentration of 8 % to 13 % weight by weight. The cartridges are produced, assembled and sealed at the Intrumentation Laboratories production facility in the US and shipped to the applicant's distribution centre in Italy. Bags containing the solutions needed for analyses, including 4-tert-OPnEO, are filled, sealed and inserted into the PAK cartridge at the production facility. The cartridge contains a waste-bag collecting the mixture of blood sample, 4-tert-OP-nEO and other reagents after the analyses. The waste bag has a ventilation system with a membrane that allows exchange of gases with the outside air. This is to prevent gases from the waste to build up pressure in the waste bag. Note that both at the applicant's site and at the Downstream Users no handling of liquid 4-tert-OPnEO takes place, other than by using the closed lysing bags.

The PAK cartridges are used in two types of portable analysers (GEM®Premier™ 4000 and GEM® Premier™ 5000) for rapid analysis of whole blood samples. The GEM series instruments for blood-gas analyses are stand-alone equipment that are operated via a touch screen by specifically trained laboratory technicians. Once the type of analysis is selected in the touch screen, the GEM instrument conducts the analysis automatically without manual interference from the technician. The actual analysis is performed by recording an optical spectrum. The absorption curve is then computationally analysed using sophisticated algorithms to obtain the quantitative results for the various blood parameters.

These analysers serve as a critical analytical instruments in hospital laboratories, operating rooms, health emergency rooms and other point-of-health care within hospitals and commercial medical laboratories.

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

Table 1: Contributing Scenarios presented in the Use

Contributing scenario	ERC / PROC	Name of the contributing scenario
ECS1	ERC 9a: Widespread use of functional fluid (indoor)	Use of a 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a lysing agent for red blood cells in blood analysis diagnostic device
Contributing scenario (CS) 1	PROC 0	The receipt and storage of the disposable cartridges (PAK) containing 4-tert-OPnEO in the storage room of the medcal diagnostics laboratory
Contributing scenario (CS) 2	PROC 15	The use of the the disposable cartridges (PAK) containing 4-tert-OPnEO during blood analysis.
Contributing scenario (CS) 3	PROC 0	The disposal of cartridges (PAK) containing 4-tert-OPnEO after all blood analyses are completed (the end of PAK cartridge servce life.

CS 1. This scenario covers the receipt and storage of the disposable cartridges (PAK) containing 4-tert-OPnEO in the storage room of the medical diagnostics laboratory. The disposable cartridge (PAK) to be used in the GEM blood analyzer is a closed system made of hard plastic material, which is not intended to be opened. No release of the 4-tert-OPnEO into the environment is possible during this scenario.

CS 2. During this scenario the cartridge containing 4-tert-OPnEO is inserted into the GEM analyser without being opened, and used for blood analyses. No solutions or chemicals are added during service life. After every analysis, the mixture of blood sample and reagents is automatically collected in a sealed waste bag integrated in the cartridge. The waste bag stays in the cartridge during its whole service life and is not emptied at any time. No release of the 4-tert-OPnEO into the environment is possible during this scenario.

CS 3. After end of service life, i.e. after up to 600 analyses or approximately 1 month, the cartridge is removed by the professional health care worker and handled as infectious waste. At the hospitals and medical laboratories the infectious waste is separated from other types of waste and stored and handled separately. The containers are labelled with pictograms for infectious waste and will often have a specific color indicating it contains infectious waste. The individual waste containers are labelled according to the EU waste regulation. The containers are collected by authorized waste companies. The end treatment is by incineration. No release of the 4-tert-OPnEO into the environment is possible during this scenario.

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

4-tert-OPnEO is used as a lysing agent to rapidly rupture the cell membranes of the red blood cells in the whole blood sample allowing to report results of measurement in 45 seconds, which is essential to diagnose and treat critically ill patients.

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

Cartridge systems for the GEM Premier series analysers (GEM®Premier™ 4000 and GEM® Premier™ 5000) used for rapid analysis of whole blood samples. The following parameters can be measured: pH, pCO_2, pO_2, sodium, potassium, ionized calcium, chloride, glucose, lactate, hematocrit, total bilirubin (tBili), total hemoglobin (tHb), oxygen saturation (sO_2), and hemoglobin fractions including oxyhemoglobin (O_2Hb), deoxyhemoglobin (HHb), carboxyhemoglobin (COHb) and methemoglobin (MetHb). The analysis aids in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.

The GEM Premier series analysers are used in hospital laboratories, operating rooms, health emergency rooms and other point-of-health care within hospitals and in commercial medical laboratories in 2 000 to 20 000 sites in the EU.

0.4. Downstream user survey

Three different European hospitals (one in The Netherlands, one in France and one in Poland), using from 30 to 500 disposable cartridges (PAK) per year (exact number is claimed confidential), were visited with the aim to verify that the supplied PAK's are handled only by professionals and that there is no release to the environment during use and waste phase.

The site visits included interviews of the personnel responsible for the laboratories and the technical staff responsible for the handling of waste. Similar observations were made at all three hospitals:

1) After reception, the PAKs were stored in a separate room by, or near, the hospital laboratory facility. Only professionals (laboratory or technical staff) have access to the storage room.

2) The PAK has a shelf life which is indicated on the package. None of the hospitals have had cases where the shelf life of a PAK had been exceeded.

3) The use of the GEM4000 and GEM5000 analyzers, including the handling of cartridges, is done only by specifically trained laboratory staff.

4) After use the PAKs are collected in containers labelled with the pictogram for infectious waste according transport regulation on hazardous waste.

5) The infectious waste is held only in containers labelled 'infectious'. The storage of infectious waste is in separate containers or rooms in the hospitals.

6) The infectious waste, as well as other waste types, is collected by a professional waste company. The individual infectious waste containers are labelled/ numbered and they are traceable back to the individual departments at the hospital.

7) The end disposal for the infectious waste was in all cases by incineration.

According to the site visits and interviews performed at three EU hospitals the PAK cartridges are handled and used in a controlled way and only by specifically trained staff. After the end of service, the cartridges are labelled according to the EU rules for transport of infectious waste and handled separately from other hospital waste. Infectious waste is incinerated by authorised companies.

1. Operational Conditions and Risk Management Measures

1.1. Environment

4-tert-OPnEO is contained in a closed cartridge which is not opened during use or disposal.

The use is in a controlled laboratory environment. Only trained professionals have access to the cartridges, from their reception at the hospitals to their collection as infectious waste by an authorised waste management company. The end disposal of the used cartridges is by incineration. A summary of the OCs & RMMs in the environmental exposure scenarios is provided in table 2 below.

The applicant concludes that there is no release of 4-tert-OPnEO to the environment from the use.

Operational Conditions and Risk Management Measures in place for control of emissions to:

Air

During use of the cartridges, exchange of gases occurs through the ventilation membrane, therefore release of gases from the waste container in the cartridge is theoretically possible. However, due to the low vapor pressure of 4-tert-OPnEO and the room temperature at which the test takes place, releases of 4-tert-OPnEO to the air are considered negligible.

Water

Release of the liquid phase from the cartridge is not possible, since the cartridge is closed, and

liquids cannot pass the ventilation membrane in the waste bag.

Soil

Direct releases to the soil compartment are not possible.

Waste

The used cartridges containing 4-tert-OPnEO are disposed of as infectious waste by incineration. Therefore, no release of 4-tert-OPnEO to the environment through waste is expected.

Table 2: Environmental RMMs - summary

Compartment	RMM	Stated Effectiveness
Air	Controlled processes	Considering the absence of elevated temperatures during the process and low vapour pressure of 4-tert-OPnEO, emissions to air are considered negligible.
Water	Incineration of solid and liquid waste	No releases are assumed from the discarded cartridges (PAK) containing 4-tert-OPnEO segregated in hospitals and medical laboratories as infectious wastes, and therefore disposed of by incineration.
Soil	Controlled environment in the facility	Direct releases to soil are not possible.

1.2. Discussion on Operational Conditions and Risk Management Measures and relevant shortcomings or uncertainties

The description of the OCs and RMMs is sufficiently clear. All used cartridges which contain 4-tert-OPnEO are collected and disposed of for incineration.

Therefore, RAC is of the opinion, that OCs and RMMs in the ES are appropriate and effective in limiting the risk.

However, RAC notes that the applicant does not inform downstream users of the endocrine disrupting properties of 4-tert-OPnEO and does not provide instructions on how unused cartridges should be disposed of if discarded (e.g. expired sell by date). Upon request of further information by RAC, the applicant stated that according to the survey performed it is unlikely that there are out-dated cartridges and if there are, they are disposed of as chemical waste. Defective cartridges are returned to the supplier. RAC agrees with the applicant and considers that the emissions resulting from this source will be unlikely.

Nevertheless, RAC recommends the applicant to provide all downstream users of cartridges containing 4-tert-OPnEO with instructions on how unused cartridges should be disposed of due to the endocrine disrupting properties of 4-tert-OPnEO and to assess in any review report whether this recommendation on waste treatment has been followed.

1.3. Conclusions on OCs and RMMs

Are the operational conditions and risk management measures appropriate[7] and effective[8] in limiting the risk for workers, consumers, humans via environment and / or environment?

Environment ☒Yes ☐No ☐Not relevant

Overall conclusion: Since all the relevant waste is collected and disposed of for incineration, no relevant shortcomings to the operational conditions (OCs) and risk management measures (RMMs) have been identified by RAC.

Minor shortcoming in the RMMs lead to recommendations for the review report presented in section 9.

2. Exposure assessment

The applicant did not attempt to estimate the predicted environmental concentrations (PECs), since 4-tert-OPnEO has been treated as a non-threshold substance with regard to its endocrine disrupting properties for the environment and no release of 4-tert-OPnEO to the environmental media was demonstrated as a result of incineration of all solid and liquid wastes produced during the use, for which application for authorisation has been submitted.

2.1. Environmental emissions

Water

No release to water is assumed, since all solid and liquid wastes which contain 4-tert-OPnEO are disposed of as an infectious waste and incinerated.

Air

No release to air is assumed, since 4-tert-OPnEO is not volatile and the formation of aerosols during use can be excluded.

Soil

The disposable cartridges (PAK) containing 4-tert-OPnEO are handled indoor in well controlled environment, thus direct releases to soil are not possible.

[7] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[8] '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.

Table 3: Summary of environmental emissions

Release route	Release factor	Release per year (tonnes or kilograms)	Release estimation method and details
Water	0 %	0	4-tert-OPnEO is applied in a closed disposable cartridge.
Air	0 %	0	4-tert-OPnEO is applied in a closed disposable cartridge.
Soil	0 %	0	Direct releases to soil are not possible.

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

Environment

RAC notes that the environmental release of 4-tert-OPnEO has been prevented as a result of incineration of all solid and liquid waste that are potentially contaminated with that substance. RAC considers that the methodology for assessing the environmental releases of 4-tert-OPnEO is appropriate and the data provided by the applicant can be considered to be representative and are not likely to underestimate exposure. Due to the use of 4-tert-OPnEO within closed, disposable cartridges in well controlled laboratory environment, RAC concludes that releases to air are expected to be negligible. Similarly, RAC agrees that direct releases to soil are not likely.

RAC notes that minor shortcomings remain in the assessment related to the small number of downstream users interviewed on how the cartridges containing 4-tert-OPnEO are handled and disposed of and recommends that the applicant conducts a representative survey of their downstream users about the collection and treatment methods that are applied (e.g. incineration) and report the results in any review report. It is noted, however, that, according to the instructions provided to the downstream users, all waste resulting from the use of the cartridges considered in this application should be classified, labelled and disposed of as infectious waste, according to EU legislation on hazardous waste.

2.3. Conclusions on exposure assessment

RAC considers that the estimates for releases provided by the applicant are appropriate.

Minor shortcomings lead to recommendations for the review report presented in section 9.

3. Risk characterisation

3.1. Environment

The applicant has treated 4-tert-OPnEO as a non-threshold substance and did not derive PNECs or RCRs. This approach is in line with RAC's paper "Risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO", adopted at RAC-43[9] and RAC's conclusion at the 50th meeting that is currently not possible to determine a threshold for the ED properties of this substance.

Based on the OCs & RMMs described in the ES, notably the use of 4-tert-OPnEO in closed systems and the collection and adequate treatment of all relevant wastes potentially contaminated with 4-tert-OPnEO, RAC is of the view that the applicant has demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible (with the view to minimising the likelihood of adverse effects).

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

3.2. Shortcomings or uncertainties in the risk characterisation

No shortcomings were identified in the risk characterisation.

3.3. Conclusions on risk characterisation

Based on the OCs & RMMs described in the ES, notably the use of 4-tert-OPnEO in closed systems and the collection and adequate treatment of all relevant wastes potentially contaminated with 4-tert-OPnEO, RAC is of the view that the applicant has demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible (with the view to minimising the likelihood of adverse effects).

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

4. Analysis of Alternatives and substitution plan[10]

The scope of the analysis is the use of 4-tert-OPnEO as a lysing agent in the cartridge system of the GEM Premier series of blood analysers.

For the applicant, it is important that an alternative will maintain the unique performance characteristics of the GEM Premier series blood analysers (fast analysis, automatic quality

[9] https://echa.europa.eu/documents/10162/13637/npneo_and_opneo_for_agreement_final_en.pdf/026cbafc-6580-1726-27f3-476d05fbeef0

[10] 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*".

checks, automatic calibration, automatic documentation) in comparison with other commercially available equipment for similar use.

For the downstream users, it is important that an alternative will allow the use of the existing equipment and will keep the features of the GEM Premier series blood analysers.

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

6 000 kg

Note that in 2018, the total amount was only 2 223 kg, but that over the length of the 12 year review period it is expected to grow until the amount indicated.

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

Currently the applicant is working on two alternative surfactants to replace 4-tert-OPnEO in their GEM Premier series blood analysers. According to additional information supplied by the applicant at the request of SEAC, these alternatives have been recommended by the supplier and have shown promising results in lysing tests and preliminary tests performed with the applicant's equipment. However, the applicant shows that the development work and the necessary optimisation of the chemical analysis process and algorithms necessary for the numerical analysis will still take considerable time. In addition, further regulatory approvals and also the adaptation of existing equipment to the new surfactant will be necessary and will need considerable time before the substitution of 4-tert-OPnEO-containing lysing solution can take place. In case the surfactants under testing do not perform satisfactorily, the applicant indicated that other surfactants which are structurally similar will be selected and tested.

Based on a publication from 2012[11], the applicant provides an overview of four competitive analysers on the European market and compares their main characteristics with those of the Premier series of analysers.

Three analysers use a non-chemical ultrasound lysis procedure (Two from Radiometer and one from Roche), one uses a method where no lysis takes place at all, but whole blood samples are analysed directly (Siemens). The applicant states that each type of analyser has its strength and weaknesses. However, the applicant also states that in particular the following aspects negatively distinguish the competitor equipment from the Premier equipment:

- Use of chemicals with human health risks and PBT/vPvB properties (Siemens)
- Use of multiple cartridges or sensors that need to be exchanged (All).
- In some cases, cartridges need to be refrigerated (Siemens, Radiometer)
- Maintenance and calibration procedures are more complicated and therefore less suited for point-of-care use (All)

Based on this analysis, the applicant states that although the competitor equipment may perform similar types of analysis, the Premier series has unique properties and therefore concludes that at present no substitutes with a similar level of performance are available on the market for the Premier series of analysers.

[11] http://www.captodayonline.com/Archives/0812/0812_in_vitro_blood_gas_analyzers_guide.pdf

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 applicant and its downstream users before the Sunset Date ?

☐Yes ☒No

The applicant has shown that by the Sunset Date no alternatives that meet the requirements of the applicant and its Downstream Users will be available.

Previous work by the applicant has identified two potential surfactants that seem suitable to replace 4-tert-OPnEO. The applicant expresses its confidence that one of these will prove successful as an alternative. Both surfactants are currently commercially available. The raw material price of these potential alternatives is not considered to be an issue in potential use.

A comparison with some competitive analysers is presented (see section 4.1), showing that the equipment from the applicant has unique features not present in other available equipment. Consequently, these are not considered feasible alternatives for the Downstream Users

No comments were received during the public consultation

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

SEAC considers that the applicant's approach to identifying and assessing alternatives allows for conclusions on the availability and suitability of alternatives. In SEAC's view, the applicant's assessment and focus on two alternative substances is justified because of their proven effectiveness in the lysis step, which is considered the most important property for an alternative surfactant.

In SEAC's opinion, the applicant convincingly demonstrates that technically feasible alternatives will not become available to the applicant before the sunset date because of the internal development work, the required regulatory steps that must be completed for this

substitution to take place and the updating of the equipment that is in use today.

SEAC also notes that the applicant has made an extensive effort to show in what aspects the IL analysers are different from competitor models. SEAC accepts the conclusion that a replacement of the GEM series of analysers with competitors' equipment would degrade the quality of measurements (apart from any economic impacts).

4.4. Substitution activities / plan

The applicant already started looking for alternatives early in 2019, but concludes that it will not be possible to implement the use of one or both of the two alternatives before or at the Sunset Date. However, the applicant claims that it is reasonable to expect that by the end of a 12 year Review Period substitution will be successfully concluded.

The applicant describes in great detail the various milestones and the steps required to successfully complete substitution.

Table 4 : Overview of steps for substitution

Nr Milestone	Description	Expected Completion	Nr Substeps	FTE involved (various departments)
1	Choice of alternate substance	Q4_2020	9	3.0
2	Complete design and development	Q4_2021	7	3.5
3	Design transfer to manufacturing	Q3_2022	2	1.25
4	Complete design verification and validation	Q3_2024	3	2.75
5	Regulatory submission and product launch	Q2_2025	2	2.25
6	Upgrade legacy equipment	Q4_2029	2	4.5

The accompanying representation of the time line looks as follows :

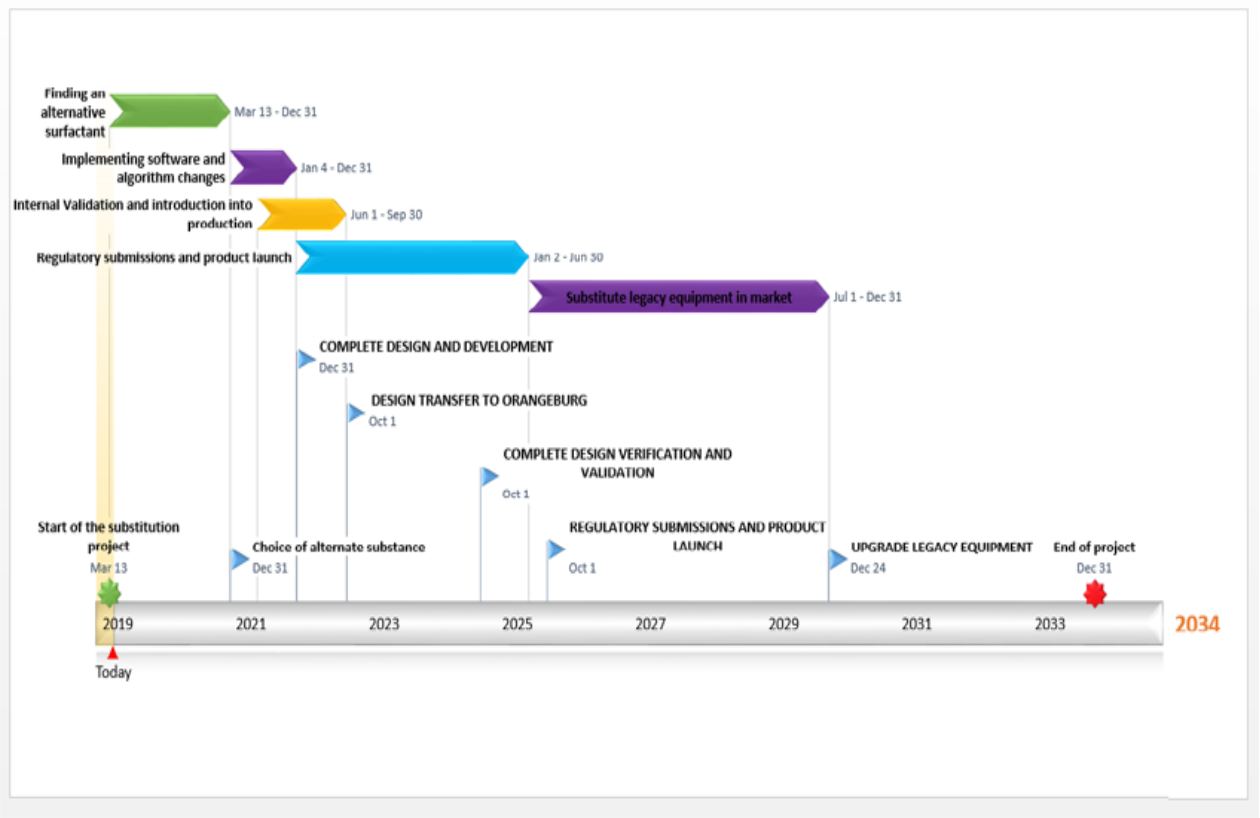

Figure 1 : Timeline for substitution project

Note that, as described by the applicant, the substitution process is supposed to be finished by the end of 2029 (i.e. Sunset Date + 9 years). In a reaction to an additional question from SEAC about the details of the time plan, the applicant expresses uncertainty on the duration of the stage for updating legacy equipment, because this is existing equipment that is in constant use and not under control of the applicant, so may not be directly accessible when the applicant asks for it. Moreover, the applicant prefers to already plan in 18 months to prepare a review report, in case the substitution efforts will not finish in time. The applicant requests 12 year review period, because they claim that the conditions set by ECHA for a long review period are fullfilled.

Has the applicant submitted a substitution plan?

☒Yes ☐No

Note that although the applicant has not submitted a separate substitution plan, the contents of such a plan, including monitoring activities, are present in the Analysis of Alternatives part of the application in sufficient detail.

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

☒Yes ☐No

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

SEAC notes the confidence of the applicant regarding the potential to replace 4-tert-OPnEO in their analysers. The sequence of steps and time needed for the various steps are clearly described in sufficient detail. Also the resources needed to complete this plan are well described. SEAC agrees with the applicant that some uncertainty in timing exists in the final stages of updating legacy equipment and it may require additional time than initially expected. As precautionary planning, time needed to prepare a review report has already been planned in, but it is not clear if this will be needed.

In SEAC's view the substitution plan presented by the applicant is sufficiently detailed and credible to allow a conclusion.

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

SEAC concludes 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 applicant. A credible substitution plan is contained in the Analysis of Alternatives.

Even though the applicant states that they are confident that the alternative(s) will prove to be suitable, it is difficult to predict exactly how much work will be involved before all equipment has been updated, leading to some inevitable uncertainties in the final part of the timeline.

5. Benefits and risks of continued use

Has the applicant adequately assessed the benefits and the risks of continued use?

☒ Yes

☐ No

5.1. Human health and environmental impacts of continued use

The applicant is applying for the authorisation to import 6 000 kg /year of 4-tert-OPnEO contained in the disposable cartridges to be used in the GEM® Premier™ 5000 and GEM® Premier™ 4000 blood analysers.

The applicant claims that there will be no (zero) emissions of 4-tert-OPnEO from the use of the disposable cartridges at hospitals and commercial laboratories in the EEA, since the substance is contained in a closed container, used by trained technicians under controlled conditions, and the closed cartridges containing 4-tert-OPnEO are collected and incinerated. Therefore, granting the authorisation will not cause any risk for the environment.

RAC concludes that the use applied for results in 0 kg per year emissions of 4-tert-OPnEO to the environment.

5.2. Benefits of continued use

Non-use scenario

The applicant describes the non-use scenario as a situation where they are not able to import

the cartridges containing 4-tert-OPnEO to the EEA area. The applicant does not have a suitable alternative to 4-tert-OPnEO before the sunset date, and asks for a review period of 12 years.

If an authorisation would not be granted, this would imply that many hospitals and laboratories in the EEA area will face shortages in blood gas systems, and this will effect the patients and the health care system.

The downstream users of these products can take different approaches in the non-use scenario. As a general outcome, different reactions can be expected across the multitude of customers (the downstream users). This will depend on which kind of contracts the downstream users had with the applicant, for example whether they are leasing the equipment or if they have bought the equipment.

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 using the same substance (having an authorisation) operating inside the EU
- the use would be substituted by market actors operating inside the EU
- the use would be taken up by market actors operating outside the EU

If an authorisation is not granted, it is likely that there will be a mix of reactions across the multitude of customers (downstream users). In the short run it is likely that the use could cease for a certain period of time, because changing supplier takes some time. In the longer run, the use will be taken over by competitors operating inside or outside the EU , either using the same substance or an alternative technology.

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

- Between 100-1 000 jobs would be lost in the European Union

Economic impacts of continued use

The applicant has divided the economic impacts into impacts for European suppliers to the applicant, the downstream users of the products applied for, the applicant itself and their competitors. The applicant has claimed the socio-economic data as confidential but has provided a public range for the different economic impacts upon request of SEAC.

<u>Impacts for the applicant</u>

The applicant claims that in case they are not granted an authorisation they will loose profits from the sale of these products in the EEA area. The applicant has used EBIT data to estimate the lost profits, and annualized, with an interest rate of 4 %. The applicant claims that the annualized losses are in the range of €10-100 million.

<u>Impacts for suppliers to the applicant in the EEA area</u>

The applicant claims that suppliers in the EEA area, that supply parts for the manufacturing of the IL equipment will have a profit loss. The applicant has estimated and annualized the loss, and claims that it is between €1-10 million.

Impacts for the downstream users

The applicant has estimated the loss for the downstream users based on an example from the BeNeLux area. In the estimation they have given estimates for the users that lease the equipment and the users that have bought the equipment. The applicant assumes that the customers that are leasing the equipment would continue to use a similar contract with competitors. And thus, that they are not facing capital costs in the same manner. The applicant claims that the customers who have bought the equipment will face capital costs, as the equipment will be useless. The avoided loss of residual value of capital is between €1-10 million.

The main costs of replacing the instruments are the capital cost of a competitive instrument, the costs to train the medical staff in the use of new instruments and the costs of tendering to get a new supplier. The applicant has estimated these costs and annualized the costs. The applicant claims that these costs could be between €10-100 million.

Impacts for competitors

The applicant also recognises that the non-use scenario will give new possibilities for competitors to increase their market shares. The applicant has estimated this effect to €2-20 million, annualized over the review period, as a benefit to the society in the non-use scenario.

Social impacts

The applicant has separated the social impacts into unemployment and the impacts for the patients and the health care system. The impacts on employment are monetized, but the impacts for the patients and the health care sector are neither quantified nor monetized but discussed in a qualitative manner.

Unemployment

The applicant claims that between 100-1 000 full time jobs will be lost in the European Union. The applicant states that the SEAC note on valuing unemployment and the Dubourg paper has been used to estimate the impacts on unemployment. The applicant claims that the social cost of unemployment is between €10-100 million over the review period.

Impact on patients and the health care system

The applicant explains that there will be a shortage of test capacity in the EEA area if they are not granted an authorisation. The average annual testing capacity provided by the applicant's equipment is estimated to be around 34 millions of tested samples of blood.

Table 5: Socio-economic benefits of continued use

Description of major impacts	Quantification of impacts over the review period (€)
1. Benefits to the applicant and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	10-100 million
1.2 Avoided profit loss due to ceasing the use applied for	11-110 million
1.3 Avoided relocation or closure cost	n/a
1.4 Avoided loss of residual value of capital	1-10 million
1.5 Avoided additional cost for transportation, quality testing, etc.	n/a
Sum of benefits to the applicant and / or their supply chain	-
2. Quantified impacts of the continuation of the SVHC use applied for on other actors	
2.1 Avoided net job loss in the affected industry[12]	10-100 million
2.2 Foregone spill-over impact on surplus of alternative producers	-
2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	++
2.4 Avoided other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	n/a
Sum of impacts of continuation of the use applied for	-
3. Aggregated socio-economic benefits (1+2)	50-200 million*

* The confidential ranges are the ones given by the applicant. They are not derived by summing up the different economic impacts

5.3. Combined assessment of impacts

The applicant argues that the quantified economic and social benefits together with the non-quantifiable benefits of use to the health care system in the EEA can justify the granting of an authorisation.

As demonstrated in the qualitative description of benefits, the non-granting of use will not only put customers under severe economic pressure to find new suppliers of tests, but also any disruption of service provision can lead to delays in the diagnosis of critical conditions and therefore increase mortality in the affected disease groups.

SEAC considers that the applicant's main argument is that when the emissions are zero, the economic impacts from the non-use scenario and the impacts for the patients will justify the granting of an authorisation.

[12] Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation).

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

Socio-economic benefits of continued use		**Excess risks associated with continued use**	
Benefits [€ over the review period]	50-200 million	- Monetised excess risks to workers directly exposed in the use applied for [annualised to € million per year]	n/a
Quantified impacts of the continuation of the SVHC use applied for	100-1 000 full time jobs will be lost in the European Union	Monetised excess risks to the general population and indirectly exposed workers [annualised to € million per year]	n/a
Additional qualitatively assessed impacts	Avoided shortage in the annual testing capacity that the EEA hospitals and commercial laboratories would be able to provide to the EEA society. Around 34 millions of blood samples can be tested annually with the applicant's equipment.	Additional qualitatively assessed risks	Emissions of the substance of 0 kg/year
Summary of socio-economic benefits [€ over the review period]	**50-200 million**	**Summary of excess risk**	**Emissions of the substance of 0 kg/year**

Table 7: Cost of non-use per kg and year

	over the review period
Total cost (€)	50-200 million
Total emissions (kg)	0
Ratio (€/kg)	n/a

Notes:

1. "Total cost" (of non-authorisation) = Benefit of authorisation
2. "Total emissions" (if authorisation is granted) = Estimated emissions to the environment, kg per year, based on Table 5
3. "Ratio" = Total cost/Total emissions
4. Annualised to a typical year based on the time horizon that you used in the analysis

5.4. SEAC's view on Socio-economic analysis

SEAC concludes that the methodology used to calculate foregone profits seems appropriate and provides a reasonable indication of the scale of the potential impacts for non-authorisation.

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. However, changes in profits made by the applicant and its customers does not necessarily reflect net changes in

consumer surplus across the EU economy. Considering the profit losses of the applicant over a long time period does not take into account the possibility of mitigating actions that could reduce the economic impacts (e.g. resources being redeployed by the applicant or by other companies) and may overstate the long-term impacts. Therefore, SEAC does not consider it appropriate to use the profit loss incurred by the applicant over 12 years and uses the single year of lost profits (€10-100 million) to account for the net changes in the producer surplus.

The approach used by the applicant to monetise the welfare loss associated with the unemployment of some of their workers follows the SEAC note on social cost of unemployment. SEAC considers that this impact would present a significant welfare loss and can be considered a significant benefit of continued use. SEAC further notes that additional jobs may be at risk for the companies that supply the applicant.

SEAC acknowledges that the impacts for the downstram users are complex, and vary according to how the downstream users have financed the equipment. SEAC finds it reasonable to differentiate between downstream users that are leasing the equipment and the downstream users that have bought the equipment. SEAC also finds it reasonable to base the estimations on an example from the BeNeLux area presented by the applicant. The applicant assumes that the customers that are leasing the equipment would continue to use a similar contract with competitors and thus they do not not face capital costs in the same manner. On the other hand, the customers who have bought the equipment will face capital costs, as the equipment will be useless. The main costs of replacing the instruments will therefore be the capital cost of a competitive instrument (for customers who own the equipment) , the costs to train the medical staff in the use of new instruments and the costs of tendering to get a new supplier. SEAC finds this approach to estimate the loss for the downstream users reasonable.

The applicant considers the main impacts of non-authorisation are on patients and the health care system, and SEAC concurs with that conclusion. The applicant states that their products represent more than 34 million tests of blood samples on an annual basis. A shortage of test capacity, even in the short run, will have a negative effect on the test capacity in the health sector. SEAC acknowledges the difficulties involved in quantifying that impact and considers the qualitative description made by the applicant as sufficient.

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 with the continued use of the substance. This conclusion is made on the basis of:

- The application for authorisation
- SEAC's assessments of benefits of continued use,
- SEAC's assessment of the availability, technical feasibility and economic viability of alternatives,
- Additional information provided by the applicant in response to questions from SEAC and RAC,
- RAC's assessment of the risks to the environment

6. Proposed review period

☐ Normal (7 years)

☒ Long (12 years)

☐ Short (…. years)

☐ Other: _____ years}

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

6.1. RAC's advice

RAC does not give any advice on the length of the review period.

6.2. Substitution and socio-economic considerations

SEAC agrees with the applicant that suitable alternatives will not be available by the Sunset Date. Regarding the presented timeline for substitution, SEAC notes that although the substitution process is expected to last for 9 years, the applicant expressed uncertainty about the length of the period for updating of legacy equipment. As explained in Section 4.4, it is possible this may take longer. Moreover, in their planning they added an extra 18 months to allow for the preparation of an review report in case the substitution effort will prove to be unfinished after 9 years. In order to accommodate these extras, this leads to a request for a 12 year review period. SEAC does not consider the reasoning to extend the requested Review Period beyond 10.5 years completely convincing. However, in view of the uncertainties of the time needed to upgrade the equipment and because of the relatively small difference between 10.5 and 12 years, SEAC will still recommend a 12 year review period. Moreover, it should be noted no emissions will take place during the use.

7. Proposed additional conditions for the authorisation

Were additional conditions[13] proposed for the authorisation?

☐ Yes

☒ No

7.1. Description

RAC

Proposed additional conditions

None

[13] 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.

SEAC

Proposed additional conditions

None

7.2. Justification

RAC is of view that:

- the applicant has demonstrated that releases to environmental compartments have been prevented or minimised as far as technically and practically possible based on the OCs and RMMs in the exposure scenarios.

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[14] proposed for the authorisation?

☐ Yes

☒ No

8.1. Description

No monitoring arrangements were proposed.

8.2. Justification

No release of 4-tert OPnEO is expected during the use.

9. Recommendations for the review report

Were recommendations for the review report made?

☒ Yes

☐ No

9.1. Description

RAC recommends the applicant to provide all downstream users of cartridges containing 4-tert-OPnEO with instructions on how unused cartridges should be disposed of due to the endocrine disrupting properties of 4-tert-OPnEO and to assess in any review report whether this recommendation on waste handling and treatment has been followed. In case a review report is submitted, the applicant shall report on a representative survey of their downstream users about the collection and treatment methods that are applied (e.g. incineration) to all waste.

[14] 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.

9.2. Justifications

A representative downstream user survey will allow to overcome the shortcomings related to the low number of respondents and demonstrate that all waste are handled and treated adequately at the downstream user facilities.

10. Comments on the draft final opinion

Did the applicant provide comments on the draft final opinion?

☐ Yes

☒ No

10.1. Comments of the applicant

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

☐ Yes

☐ No

☒ Not applicable – the applicant did not comment