Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr(VI)) in the refrigerant solution)

Submitter: Ariston Thermo SpA.

ECHA/RAC/SEAC: AFA-O-0000006780-72-01/F

Consolidated version

Date: 11/06/2020

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(s)[1]	**Ariston Thermo SpA.** Downstream user
Substance ID EC No CAS No	**Sodium chromate** 231-889-5 7775-11-3
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	Use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr^{6+}) in the refrigerant solution
	Other connected uses: none
	Same uses applied for:
Use performed by	☒ Applicant(s) ☐ Downstream User(s) of the applicant(s)
Use ID (ECHA website)	0136-01
Reference number	11-2120808694-49-0001

[1] 'Applicant(s)' - includes also 'Authorisation Holder(s)' in case of the review report

RAC Rapporteur RAC Co-rapporteur	Elena R. CHIURTU Raili MOLDOV
SEAC Rapporteur SEAC Co-rapporteur	Jānis LOČS John JOYCE
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PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	20/02/2019
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	14/05/2019
Application has been submitted by the Latest Application Date for the substance and the applicant 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	22/05/2019 - 17/07/2019
Comments received	☐Yes ☒No Link:https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/23315/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Request for additional information in accordance with Article 64(3)	23/05/2019 and 26/07/2019 Link:https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/23315/del/200/col/synonymDynamicField_302/type/asc/pre/2/view
Trialogue meeting	06/08/2019

Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the applicant(s)	☐Yes, by [date] ☒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: 05/12/2019, agreed by consensus
	SEAC: 20/09/2019, agreed by consensus
Date of sending of the draft opinion to applicant(s)	07/02/2020
Date of decision of the applicant(s) to comment on the draft opinion, in accordance with Article 64(5)	16/03/2020
Date of receipt of comments in accordance with Article 64(5)	14/04/2020
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 11/06/2020, adopted by consensus.
	SEAC: 11/06/2020, 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,
- the assessment of the hazards and and risks related to the alternatives as documented in the application, as well as
- other available information.

RAC concluded that it was not possible to determine DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC concluded that currently there are no technically and economically feasible alternatives available for the applicants 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 expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report.

The exposure to workers was estimated to be: 9.0×10^{-3} µg/m³ (inhalation route) and 11.36 µg/kg bw/day (dermal route). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m³ (with a transitional value of 10 µg Cr(VI)/m³ until 17 January 2025). The exposure to the general population was estimated to be Inhalation: 1.07×10^{-7} µg/m³ and Oral: 1.10×10^{-8} µg/kg bw/d.

The excess lifetime cancer risk for workers is estimated to be inhalation 3.54×10^{-5} per µg/m³ (for 8 h TWA exposure for 40 years), per year, for the review period, and 3.14×10^{-9} per µg/m³ (for 24 h exposure for 70 years), per year, for the review period for the general population. The RCR for reprotoxicity (arising from dermal exposure of workers) was estimated to be 0.26.

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 DNEL for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

The alternatives have been assessed (See Section 4 of the Justifications).

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

- By the time of adoption of this opinion[2] 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 €3.6 million (discounted at 4 %) per year.

- Considering:
    - the endpoints relevant for listing the substance in Annex XIV of REACH;
    - the 8 directly exposed workers;
    - the general population exposed at local scale approximately 10 000 persons; the risk of continued use as assessed by RAC may result in up to 1.48×10^{-4} additional cases of cancer per year
    - the monetised risk of continued use is up to €14 per year and other important risks have been assessed qualitatively but have not been quantified.
- Risks to human health 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 monetised risks to human healthand/or the environment associated with the continued use of the substance[3].

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

- be taken up by market actors operating outside the EU

SEAC noted that:[4]

- Social impacts in terms of unemployment in the EU were referred to by the applicant (if an authorisdation was refused), but not used in the analysis.

PROPOSED CONDITIONS AND MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

Monitoring arrangements are proposed. These are listed in section 8 of the justification to this opinion.

REVIEW PERIOD

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

[2] For AfAs submitted before the LAD
[3] The formulation of this conclusion may be adapted in future versions of this format.
[4] 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(s) in the supply chain	Upstream ☐ [group of] manufacturer[s] ☐ [group of] importer[s] ☐ [group of] only representative[s] ☐ [group of] formulator[s] Downstream ☒ downstream user
Number and location of sites covered	1 site (Italy)
Annual tonnage of Annex XIV substance used per site (or total for all sites)	4.36 tonnes/year of sodium chromate
Function(s) of the Annex XIV substance.	Sodium chromate is used as a corrosion inhibitor in a pressurised carbon steel sealed circuit of the gas absorption heat pumps, these machines are to be used as part of the permanent heating systems in residential and other buildings. Key functionalities of sodium chromate for this use are: Corrosion resistance in absence of oxygen and in high NH_3 concentrations, prevention of gas formation, high operating temperatures (up to 200 ^oC), high operating pressure (exceeding 20 bars) and long lifetime services (at least 24 years).
Type of products (e.g. articles or mixtures) made with Annex XIV substance and their market sectors	The end-product is a factory-built sealed system with high operating pressure designed not to be opened by non-professionals. The construction resembles systems used in (gas powered) fridges.
Shortlisted alternatives discussed in the application	Alternative substances: nitrite, molybdate, soluble silicon compounds, zinc, strong alkaline solutions, phosphates and phosphonate compounds, rare earth metal salts (REMS), inhibitor 7. Replacement of gas absorption heat pump technology
Annex XIV substance present in concentrations above 0.1 % in the products (e.g. articles) made	☐Yes ☒No, after a short period of time the chromium (VI) will be passivated to chromium (III) and welded to the inner surface of the sealed circuit. ☐Unclear ☐Not relevant
Number of workers exposed per site	Directly: 8

Number of humans exposed via the environment	Local scale: 10 000
Releases to the environmental compartments	☒Air ☐Water ☐Soil ☐None
The applicant(s) has used the DNEL Dose response relationship recommended by RAC	☒Yes – https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf https://www.echa.europa.eu/documents/10162/21961120/rac_35_09_1_c_dnel_cr-vi-_en.pdf/8964d39c-d94e-4abc-8c8e-4e2866041fc6 ☐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
Adequate control demonstrated by applicant(s) for the relevant endpoint(s)	☒Yes, for reprotoxicity ☐No ☒Not Applicable – non-threshold substance for carcinogenicity
Level of (combined, daily / shift-long) exposure/release used by applicant(s) for risk characterisation	Workers: Inhalation: 9.0 × 10^{-3} µg/m^3 for maintenance and cleaning Dermal: 11.4 µg/kg bw/day for maintenance and cleaning Humans via environment: Inhalation: 1.07 × 10^{-7} µg/m^3 Oral: 1.10 × 10^{-8} µg/kg bw/d Environment: Air: 5.6 × 10^{-7} kg/day Water: 0 Soil: 0

Risk Characterisation	Workers: inhalation 3.54 × 10^{-5} , Workers: dermal RCR 0.26 Humans via environment: 3.14 × 10^{-9}
Applicantis seeking authorisation for the period of time needed to finalise substitution (‘*bridging application*’)	☐Yes ☒No ☐Unclear
Review period argued for by the applicant(s) (length)	20 years
Most likely Non-Use scenario	The applicant presents one non-use scenario (NUS 1): suspension of on-going EU research and development (R&D) and planning for EU manufacturing processes related to GAHP technology and the relocation of R&D and planned manufacturing processes to a non-EU country.
Applicant concludes that benefits of continued use outweigh the risks of continued use	☒Yes ☐No ☐Not Applicable – threshold substance with adequate control
Applicant’s benefits of continued use	€1.6 million (discounted at 4 %) [Annualised]
Society’s benefits of continued use	€3.6 million (discounted at 4 %) [Annualised]
Monetised health impact on workers	€12 [Annualised]
Distributional impacts if authorisation is not granted	EU/Italy Avoided CO_2 emissions and secured energy savings
Job loss impacts if authorisation is not granted	Social impacts in terms of unemployment in the EU were referred to by the applicant, however their estimates were not used in the cost-benefit analysis (CBA).

SUMMARY OF RAC AND SEAC CONCLUSIONS[5]

1. Operational Conditions and Risk Management Measures

1.1. Conclusions of RAC

Conclusion for workers:

RMMs and OCs are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

As the application refers to a future installation, the applicant should validate the effectiveness of the OCs and RMMs (both for worker protection and for reduction of emissions to the environment) to be implemented and used on site, by using relevant on site monitoring data.

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

☒Yes ☐No

Conclusion for Humans via environment (HvE):

RMMs and OCs are expected to be appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

As the plant is not operational yet there is no site specific measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels. RAC points out that actual on site measurements should be used to prove the effectiveness of the RMMs to be implemented and used on site.

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

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

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

☐Yes ☒No

2. Exposure Assessment

Combined exposure level used by RAC for risk characterisation:

Workers: Direct exposure

- Inhalation: 9.5 × 10^{-4} µg/m^3 for loading and emptying, 9.0 × 10^{-3} µg/m^3 for maintenance and cleaning
- Dermal: 0.555 µg/kg bw/day for loading and emptying, 11.36 µg/kg bw/day for maintenance and cleaning
- Oral: 1.36 × 10^{-4} µg/kg bw/day for loading and emptying, 1.26 × 10^{-3} µg/kg bw/day for maintenance and cleaning

Consumer exposure : No exposure during the daily use of gas absorption heat pumps is expected.

Humans via environment

- Inhalation: 1.07 × 10^{-7} µg/m^3
- Oral: 1.57 × 10^{-9} (acidic), 1.10 × 10^{-8} (alkaline) µg/kg bw/d

Releases to the environmental compartments:

- Water: 0
- Air: 5.6 × 10^{-7} kg/day
- Soil: 0

Conclusions of RAC

RAC considers that the description of the use provided in the CSR and in the applicant's answers to RAC's requests is sufficient to conclude on the reliability of the exposure assessment (for workers and HvE).

RAC considers that the exposure assessment (for workers and human via the environment) lacks site-specific workplace air measurement and environmental emission data, and notes that the potential exposures from the future installation have all been modelled.

RAC considers that this shortcoming would not be expected to lead to significantly higher exposure estimates in comparison with those selected for further risk characterisation.

Does RAC propose additional conditions[6] related to exposure assessment for the authorisation?

☐Yes ☒No

[6] 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.

Does RAC propose monitoring arrangements[7] 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

RCR or Risk level used for health impact assessment calculated by RAC:

Workers: The highest calculated excess cancer risk for combined exposure for inhalation is **3.54×10^{-5}**, (for maintenance and cleaning). The highest RCR for dermal exposure is 0.26 (maintenance and cleaning)

Consumers: No risk for end-consumer estimated, as no exposure expected

Humans via environment: The highest excess cancer risk calculated for humans via the environment (local scale for combined routes (inhalation and oral)), is **3.13×10^{-9}** (acidic conditions) and **3.14×10^{-9}** (alkaline conditions)

Conclusions of RAC:

RAC considers that the estimates of excess cancer risk for workers and for indirect exposure of humans (workers and general population) via the environment calculated by the applicant allow a health impact assessment.

4. Analysis of alternatives and substitution plan[8]

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

4.36 tonnes of sodium chromate

Are there alternatives with the same function and similar level of performance that are technically and economically feasible to the applicant by the time of adoption of this opinion?

☐Yes ☒No

[7] 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.

[8] 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*".

Has the applicant submitted a substitution plan?

☒Yes ☐No

Conclusions of SEAC

SEAC notes the Applicant's activity in the i-GAP project as an active effort towards finding an alternative in the future. The substitution plan was credible and consistent with the analysis of alternatives and the socio-economic analysis.

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(s) 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 the risks of continued use?

Conclusions of SEAC:

☒Yes ☐No

The overall approach to the analysis is in line with ECHA guidance and uncertainties were reasonably described and accounted for in a sensitivity analysis. The cost and benefit estimates appear plausible. Adjusting for uncertainties does not affect the overall conclusion. The analysis concludes that there are clear net losses to society if the authorisation is not granted. The main impacts related to foregone profits, energy saving and reduced carbon emissions. SEAC considers the conclusion of the applicant on the benefits and on the risks of continued use plausible.

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 workers	☐Yes	☒No
For the environment	☐Yes	☒No

SEAC

Additional conditions: ☐Yes ☒No

8. Proposed monitoring arrangements for the authorisation

RAC

Monitoring arrangements:

For workers ☒Yes ☐No
For the environment ☒Yes ☐No

SEAC

Monitoring arrangements ☐Yes ☒No

9. Recommendations for the review report

RAC

For workers ☒Yes ☐No

For the environment ☒Yes ☐No

SEAC

AoA ☐Yes ☒No

SP ☐Yes ☒No

SEA ☐Yes ☒No

10. Applicant(s) comments on the draft opinion

Has the applicant commented the draft opinion?

☒Yes ☐No

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

☒Yes ☐No

JUSTIFICATIONS

0. Short description of use

Sodium chromate is used as a corrosion inhibitor in the carbon steel sealed[9], pressurised circuit of the gas absorption heat pumps. In these heat pumps the refrigerant is driven by a thermal compressor[10], which allows a high thermal lift[11] of 80 °C required to heat even radiators. The heat pumps are used for heating both residential as well as other buildings. They are installed and serviced by professionals.

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

This is an Application for Authorisation (AfA) submitted by Ariston Thermo SpA. for the future use of sodium chromate that will take place at the new applicant's facility located in Albacino, Fabriano, Italy. The overall tonnage of sodium chromate used is 4.36 t/year (1.4 t/year Cr(VI)/year). The concentration of Cr(VI) in mixture (in sealed circuit) is 0.7 % by weight. The mixture is integrated into the gas absorption heat pumps during their factory production. The pumps are used as part of the built-in heating systems in residential, as well as in other, buildings.

Table 1: Contributing Scenarios presented in the Use

Contributing scenario	ERC / PROC	Name and description of the contributing scenario	Size of the exposed population
ECS1	ERC 5	Use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr(VI)) in the refrigerant solution	Regional: - Local: 10 000
WCS 1	PROC 1	Delivery and storage of the 20 L barrels containing the aqueous sodium chromate solution; *installed in a sealed mixing cell in which the empty barrels are*	No of workers: 2

[9] Sealed here means a pressurised, air-tight, factory-built system, with the lifetime over 20 years, designed not to be opened by non-professionals.

[10] The thermal compression is composed of a phase of absorption (releasing heat), and a phase of desorption driven by the gas burner. The refrigerant used for the absorption heat pump is a water-ammonia solution. The process of the GAHP starts with the heating of the refrigerator solution in the generator by natural gas, which separates the gaseous refrigerant (NH_3) from the liquid sorbent (H_2O). The highly concentrated gaseous ammonia at high pressure becomes liquid under emission of heat at the condenser, then the condensed refrigerant passes through an expansion valve to reduce the pressure. Due to the low pressure of the refrigerant, heat from the environment can be used at the air heat exchanger to evaporate the ammonia refrigerant again. In the gaseous form, the refrigerant flows into the absorber where it is absorbed by the low pressure sorbent (H_2O). This exothermal reaction releases again heat, which is transferred to the heating system. The liquid solution is then carried by a solution pump which needs only a small energy input back into the burner where the circuit starts again.

[11] The difference in temperatures between the sink (radiator) and the source side (outdoor air) of the thermodynamic cycle is named "thermal lift". In the case of space heating heat pumps, this thermal lift can easily reach 80 °C. To achieve such thermal lift levels while maintaining a good thermal efficiency, GAHP appliances use a water/ammonia thermodynamic cycle named GAX-GAHP, where the temperature inside the desorber can reach 200 °C.

		stored until collection by the supplier.	
WCS 2	PROC 8b	Loading of the aqueous sodium chromate solution to an automated dosing system by *connecting/disconnecting the barrels* and mixing of the aqueous sodium chromate solution with demineralised water and aqueous sodium hydroxide in a close processing equipment.	No of workers: 3
WCS 3	PROC 3	Automated filling of the gas absorption heat pump circuit *Introduction of the pump in the testing cell, filling the circuit with the refrigerant solution via high and low pressure connection valves, then sealing of the circuit; manual connection/ disconnection of the flexible hoses to the two loading connections in the circuits of the gas absorption heat pump's, automated filling of the final refrigerant solution and start-up the testing phase.*	No of workers: 5
WCS 4	PROC 8b	Emptying of the refrigerant solution from the sealed circuits in the malfunctioning gas absorption heat pumps *via high and low pressure connection valves. The recovery refrigerant solution to be ducted to a special tank for disposal. Manual connection/ disconnection of the dedicated flexible hoses from the closed circuits of the gas absorption heat pump.*	No of workers: 5
WCS 5	PROC 28	Maintenance of the equipment in contact with sodium chromate a) Maintenance of equipment in the mixing cell b) Maintenance of equipment in the testing cell. *Consists of regular maintenance and cleaning of installations in both the mixing and the testing cells. Non-routine maintenance activities also considered as a minor fraction of regular maintenance due to the specific design, plus Mean Time Between failure (MTBF) and Mean Time to Repair (MTTR).*	No of workers: 3

ECS2	ERC10a ERC11a	Use of gas absorption heat pump, including sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr(VI)) in the refrigerant solution	
	AC2	Service life of the gas absorption heat pump *Short description:* *Operation of gas absorption heat pump in a sealed circuit, which cannot be opened after filling. Cr(VI) will be passivated to Cr(III) and welded to the inner surface of the circuit.* *No risk to end consumer is possible during daily use.*	

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

Key functionalities of sodium chromate for this use are:

- Corrosion resistance in absence of oxygen and in high NH_3 concentrations
- Prevention of gas formation
- High operating temperatures (up to 200 ^oC)
- High operating pressure (exceeding 20 bars)
- Long lifetime services (at least 24 years).

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

Sodium chromate is used only in the carbon steel sealed circuit of the gas absorption heat pumps, as the natural refrigerant solution based on NH_3 and H_2O mandatorily requires the use of an inhibitor, due to high potential of corrosion, erosion and gas formation of the solution and operation at high temperature and pressure. Once filled in the sealed circuit of the gas absorption heat pump, the sodium chromate is reduced to Cr(III) and forms a passivation layer onto the inner surface of the surface. The gas absorption heat pumps are used for built-in heating systems in residential and other buildings especially in cases where the heating system of an existing building is renewed. The gas absorption heat pump sealed circuit cannot be opened, and therefore there is no risk to end consumer during normal daily use.

1. Operational Conditions and Risk Management Measures

1.1. Workers

The applicant plans to implement technical measures for those activities where they have identified an exposure potential to Cr(VI), supplemented and further supported by an Occupational safety and health (OSH) management system including organisational and personal risk management measures.

The operational conditions (OCs), technical risk management measures (RMMs) and personal protective equipment (PPE) taken into consideration in exposure assessment per WCS, with their effectiveness as described by the applicant, are summarised in Table 2. Overall, the following RMMs will be implemented in the newly refurbished production site that, according to the applicant, is planned to become operational as soon as the authorisation is granted:

Technical measures:

- Enclosed system, closed cells[12].
- General ventilation (3-5 ACH) and LEV: fixed extraction hoods with a capture velocity of, at least, 0.5 m/s.
- Dedicated vacuum system with ammonia/sodium chromate abatement system in place with HEPA filter.
- Emptying of the refrigerant solution in the hoses by a vacuum cycle automatically activated before disconnection.
- Dedicated hoses and additional equipment for the discharge of the waste refrigerant solution to avoid contamination of the equipment.
- Entirely closed material transfer in the testing cells, using high containment valves (split butterfly valves and direct couplings consist of two sections connect together to allow the opening of the valve). At the end of the material transfer the two valves are separated, forming a seal on both the process equipment and the material container to minimise the surface area of the material or valves.

Organisational measures:

- Restricted access to authorised and trained staff to both mixing and testing cells.
- Preventing maintenance programmes and prescriptions for the PPE selection, use, conservation, wearing and disposal after use, mentioned by the applicant at RAC's request.
- Sodium chromate added to the process as an aqueous solution (rather than in its pure solid form, limiting the potential of Cr(VI) to become airborne) with a maximum concentration of 50 % sodium chromate, then diluted in the refrigerant solution (up to 0.7 % Cr(VI)).
- Storing of hoses with opening upwards to avoid dripping.
- Good standard of personal hygiene implemented.

[12] "Closed cells" are equipped with all the devices of detection and intervention necessary to ensure the protection of the health and safety aspects of toxicity and flammability of fluids in it treated. The floors shall be of stainless steel, easy to be cleaned, making collection function in case of spills or abatement systems or intervention. All detection devices (both of toxicity and of fire) will be calibrated to different thresholds with gradual intervention logic, from a simple alarm until the activation of the different intervention systems for progressively higher levels of severity. Wastewater from spillage or abatement system will be conveyed to an appropriate storage tank for later disposal of special waste by third parties. No release to the waste water system possible.

- Effective housekeeping practices in place.
- Cleaning and maintenance procedure including regular rinsing of the floor in the mixing and in the testing cells.

As mentioned in the CSR, and in response to RAC's questions, the applicant stated that future monitoring programmes for the new plant will include measurements of Cr(VI) in the workplace atmosphere as well as environmental air monitoring. The measurements in the workplace atmosphere will be undertaken at different functioning stages.

Some additional details about the PPE used, which were provided by the applicant, are listed below:

- Respiratory protective equipment (RPE): full mask with ABEK1P3 filter, open circuit compressed air breathing apparatus with full mask with ABEK1P3 filter in case of unpredictable event or accident,
- Gloves suitable for protection against sodium chromate in aqueous solutions (breakthrough time ≥ 480 min.) made of nitrile rubber/nitrile latex (thickness 0.6 mm or ≥ 0.11 mm) tested according to EN 374,
- Protective overalls, safety glasses with side-shields tested according to EN 166 and safety shoes.

Table 2: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs)

Contributing scenario	**Concentration of the substance**	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV) **+ effectiveness as stated by the applicant**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the applicant**	**Organisational controls** (access control, procedures, training)
WCS 1 Delivery and storage of the barrels containing the aqueous sodium chromate solution PROC 1	10-50 % sodium chromate	Duration: < 1 h Frequency: Not mentioned	- General ventilation: 3-5 ACH -Containment: Closed system		- Sodium chromate solution delivered in sealed 20 L barrels, - restricted access, - specific training, - specific hygiene instructions
WCS 2 Loading of the aqueous sodium chromate solution to an automated dosing system and mixing of the aqueous sodium chromate solution with	10-50 % sodium chromate	Duration: 45 min. total /2-3 times/d Frequency: 260 ×/ year	- General ventilation: 3 ACH - LEV: fixed extraction hood, with a capture velocity of at least 0.5 m/s -Containment: Closed system except	- chemical resistant gloves (nitrile rubber tested to EN 374, 0.6 mm), RPE: full face mask with ABEK1P3 filter (APF of 20, effectiveness 95 %), goggles, safety	-same as for WCS 1

demineralised water and aqueous sodium hydroxide in a close processing equipment PROC 8b			connecting/ disconnecting of the flexible hoses	standard clothing, safety shoes	
WCS 3 Filling of the activated water in the circuits of the gas absorption heat pumps and then testing of the gas absorption heat pump PROC 3	0.7-1.2 % as Cr(VI)	Duration: Max. 480 min/d (2.5 min for connecting disconnecting of the hoses for each gas absorption heat pump) Frequency: 260 × / year	- General ventilation: 3 ACH - LEV: fixed capturing hood, capture velocity at least 0.5 m/s. -Containment: Closed system except connecting/ disconnecting of the flexible hoses	- chemical resistant gloves (nitrile rubber tested to EN 374, 0.11 mm), goggles, safety standard clothing, safety shoes	- low and high pressure side connections to the gas absorption heat pump circuits -control system for discharge of the non-condensable gases (1L) + same as for WCS 1
WCS 4 Emptying of the refrigerant solution from the sealed circuits in the malfunctioning gas absorption heat pumps PROC 8b	0.7 % as Cr(VI)	Duration: 5 min/d Frequency: 4 × / year	- General ventilation: 3 ACH - LEV: fixed capturing hood, CV at least 0.5 m/s. -Containment: Closed system except connecting/ disconnecting of the flexible hoses	- chemical resistant gloves (nitrile rubber tested to EN 374, 0.11 mm), goggles, safety standard clothing, safety shoes	- same as for WCS 1
WCS 5 Maintenance of the equipment in contact with sodium chromate a)Maintenance of equipment in the mixing cell b)Maintenance of equipment in the testing cell PROC 28	1-5 % as Cr(VI)	Duration: Max. 480 min./d 120 min/d for subtask a, 360 min/d for subtask b Frequency: 5 × / year	- General ventilation: 3 ACH - LEV: fixed capturing hood, CV at least 0.5 m/s -Containment: Open process during standard operation	- chemical resistant gloves (nitrile rubber tested to EN 374, 0.6 mm), RPE: full face mask with ABEK1P3 filter (APF of 20, effectiveness 95 %), goggles, safety standard clothing, safety shoes	-same as for WCS 1

At RAC's request for clarification, the applicant mentioned that non-routine maintenance activities of the equipment are not expected due to the new selected components, to the specific design which will minimise wear and tear and to the absence of load critical factors as pressure, flow or operating temperatures. In case of unexpected events, the sodium chromate system will be closed, the fluid in the piping system will be discharged to a waste container and the piping system will be rinsed with fresh water.

1.2. Environment / Humans via Environment

Technical measures in place for control of emissions to:

Air:

Releases to air are expected to be led through a dedicated ducted vacuum system with filtration and ammonia/sodium chromate abatement system (99 % efficiency). Such filtered air will be led through an exhaust chimney to the outside of the building, in an area (e.g. roof) not accessible to manufacturing operators and more than 10 meters away from any passage or presence of humans. For the filtration HEPA filters will be used, which will be regularly controlled/changed by trained maintenance personnel. HEPA filters are disposed as hazardous waste.

Water:

The substance will be handled in closed cells. Wastewater will be conveyed to an appropriate storage tank for later disposal of special waste by authorized third parties. No discharge of sodium chromate to sewage treatment plant (STP) is expected. The floors shall be of stainless steel with collection function in case of spills. NH_3 sensors are in place to detect any leakage. Wastewater from spillage or abatement system will be conveyed to an appropriate storage tank for later disposal of special waste by third parties.

Soil:

No direct release to soil is expected.

Waste:

Solid waste will be treated as hazardous waste including used filters. Waste of sodium chromate (from rinsing activity of emptying process) or solid wastes (e.g. contaminated articles like gloves, paper for cleaning, waste from filters) will be collected into special tanks for disposal of special toxic waste and picked up by a specialized company.

At the end of service life, the sealed circuit containing the refrigerant solution (NH_3 and Cr(VI)) will be emptied and collected by a specialised company. Each gas absorption heat pump will be picked up by authorised installers. Every heat pump is considered as toxic waste and recycled based on national laws and requirements.

Table 3: Environmental RMMs

Compartment	RMM	Stated Effectiveness
Air	Filters and abatement systems for exhaust air	99 %
Water	Special waste disposal by third parties	Not specified. Wastewater will be collected and not discharged into the environment.
Soil	-	-

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

RAC notes that the RMMs described in the CSR include essentially a closed system (described in section 1.1). The main RMMs are: general ventilation (3-5 ACH) and LEV: fixed capturing hoods with a capture velocity of at least 0.5 m/s, a dedicated vacuum system with ammonia/sodium chromate abatement system in place with HEPA filter. Wastewater will be conveyed to an appropriate storage tank for later disposal of special waste from authorized third parties, thus there will be no discharge into the environment.

PPE such as the use of RPE, gloves, protective clothing etc. for short-term tasks with potential Cr(VI) exposure and organisational measures (training, supervising, housekeeping practices, monitoring programme) are also included. Regarding the RMMs to reduce worker exposure and environmental emissions, RAC identified some residual uncertainty due to the fact that – as the plant is not operational yet – there is no measured data available to confirm that the planned OCs and RMMs will deliver the claimed protection levels. RAC also notes that PPE, which is typically used to minimise the exposure, should be used as a last resort thus, after the monitoring results will become available, the applicant should re-evaluate the type of RPE initially proposed and, based on such evaluation, decide what kind of RPE, if any, is needed for minimisation of exposures. Overall, RAC considers that the RMMs and OCs presented by the applicant are adequate, covering source containment as well as organisational measures, taking into account the given low Cr(VI) concentrations estimated using modelling.

Even though some shortcomings have been identified, due to the lack of measured data for workers and environmental exposure, RAC considers that they are relatively minor and is of the opinion that, overall, the RMMs described in the application can be considered to be appropriate and effective in limiting the risk to workers and general population via the environment.

1.4. Conclusions on OCs and RMMs

Overall conclusion: RMMs and OCs as proposed in the application would be appropriate and effective in limiting the risk, if implemented.

As the application refers to a future installation, the applicants should validate the effectiveness of the OCs and RMMs (both for worker protection and reducing emissions to the environment) to be implemented and used on site by using relevant on site monitoring data]

Are the operational conditions and risk management measures appropriate[13] and effective[14] 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

[13] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls in application of RMMs and compliance with the relevant legislation.
[14] '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.

2. Exposure assessment

2.1. Inhalation exposure

As this application is for a future use, no monitoring data from Ariston were provided in the application.

Inhalation exposure assessment is based on qualitative assessment for WCS 1 and modelling data using the Advanced REACH Tool (ART, version 1.5) for the other WCSs.

Where applicable, modulations of the exposure assessment have been performed to consider the relevant parameters (e.g. duration, frequency, sodium chromate concentration) of the future plant.

Monitoring:

Company specific measured data could not be presented before the authorisation is granted. No measured data from similar facilities were provided by the applicant.

Modelling:

Modelled exposure data for Cr(VI) using the higher tier tool ART 1.5 was presented by the applicant, as this model can be applied for specific tasks with potential exposure to Cr(VI) such as connecting/disconnecting of the flexible hoses. The future plant input parameters used were described by the applicant in the CSR. The predicted 90th percentile 8 h TWA exposure estimate values are used for the exposure and risk assessment, as an appropriately conservative scenario.

The applicant has stated that future monitoring programmes for the new plant will include measurements of Cr(VI) in the workplace atmosphere as well as environmental air monitoring. The measurements in the workplace atmosphere will be undertaken at different functioning stages: before and after the equipment and plant is commissioned, every six months for the following two years, and once a year after this.

2.2. Dermal exposure

Modelling

The applicant included a dermal exposure assessment for sodium chromate, using MEASE 2.0 model. Estimated sodium chromate values were recalculated for Cr(VI). The site specific input parameters used for dermal modelling were presented by the applicant.

2.3. Biomonitoring

The biomonitoring will be conducted annually, no data available now from other similar sites.

The results of the inhalation, dermal and oral exposure assessment are presented in Table 4. Figures in bold, estimated taking into account the frequency for the new Ariston site, are considered for risk characterisation.

Table 4: Exposure – inhalation, dermal and oral

Contributing scenario	Route of exposure	Method of assessment	Exposure value	Exposure value corrected for PPE	Exposure value (8h TWA) corrected for PPE and frequency
WCS 1	Inhalation	Qualitative	-	-	-
	Dermal	Qualitative	-	-	-
	Oral	Qualitative	-	-	-
WCS 2	Inhalation	Modelled (ART 1.5) 90th perc.	1.9 × 10^{-2} µg/m^3	9.5 × 10^{-4} µg/m^3 (effectiveness 95 %)	**9.5 × 10^{-4} µg/m^3(1)**
	Dermal	Modelled (MEASE)	0.445 µg/kg bw/day	-	**0.445 µg/kg bw/day**
	Oral	Derived	-	1.36 × 10^{-4} µg/kg bw/day	1.36 × 10^{-4} µg/kg bw/day
WCS 3	Inhalation	Modelled (ART 1.5) 90th perc.	8.2 × 10^{-6} µg/m^3	-	**8.2 × 10^{-6} µg/m^3(1)**
	Dermal	Modelled (MEASE)	1.01 µg/kg bw/day	-	**1.01 µg/kg bw/day**
	Oral	Derived	-	1.17 × 10^{-6} µg/kg bw/day	1.17 × 10^{-6} µg/kg bw/day
WCS 4	Inhalation	Modelled (ART 1.5) 90th perc.	5.0 × 10^{-8} µg/m^3	-	**0.77 × 10^{-9} µg/m^3(2)**
	Dermal	Modelled (MEASE)	0.11 µg/kg bw/day	-	**0.11 µg/kg bw/day**
	Oral	Derived	-	7.14 × 10^{-9} µg/kg bw/day	0.11 × 10^{-9} µg/kg bw/day
WCS 5a	Inhalation	Modelled (ART 1.5) 90th perc.	6.3 µg/m^3	0.32 µg/m^3 (effectiveness 95 %)	**0.6 × 10^{-2} µg/m^3(3)**
	Dermal	Modelled (MEASE)	4.54 µg/kg bw/day	-	**4.54 µg/kg bw/day**
	Oral	Derived	-	4.57 × 10^{-2} µg/kg bw/day	0.88 × 10^{-3} µg/kg bw/day
WCS 5b	Inhalation	Modelled (ART 1.5) 90th perc.	2.8 µg/m^3	0.14 µg/m^3 (effectiveness 95 %)	**0.3 × 10^{-2} µg/m^3(3)**
	Dermal	Modelled (MEASE)	6.82 µg/kg bw/day	-	**6.82 µg/kg bw/day**
	Oral	Derived	-	2.0 × 10^{-2} µg/kg bw/day	0.38 × 10^{-3} µg/kg bw/day

(1) Considered frequency 260 × /year for the new site.

(2) Considered frequency 4 × /year for the new site.

(3) Considered frequency 5 × /year for the new site.

At RAC's request, the applicant specified that the possible exposure during non-routine maintenance activities has been considered in the modelling assumptions for WCS 5.

Combined exposure

The applicant identified two types of combined activities:

- A worker in a full shift can undertake the loading of the sodium chromate solution (WCS 2) and the emptying of the refrigerant solution activities (WCS 4).
- Another worker in a full shift can undertake both maintenance and cleaning of the mixing and testing cells (WCS 5 a+b).

The corresponding combined exposure estimates is presented in Table 4a.

Table 4a: Combined exposure – dermal and inhalation

Combined tasks	Estimated exposure value (8h TWA) corrected for PPE and frequency (µg/m³)*	Dermal exposure (µg/kg bw/day)	Oral exposure* (µg/kg bw/day)
WCS 2 + WCS 4 (loading and emptying)	9.5×10^{-4} µg/m³	0.555 µg/kg bw/day	1.36×10^{-4} µg/kg bw/day
WCS 5 a+b (maintenance and cleaning in the mixing cells and in the testing cells)	9×10^{-3} µg/m³	11.36 µg/kg bw/day	1.26×10^{-3} µg/kg bw/day

* Considered predicted future values for duration and frequency of the specific tasks for the new site.

2.4. Environmental exposure

Water:

Sodium chromate operates in a sealed circuit in the gas absorption heat pump. During use, Cr(VI) adheres to the surface of the pipes.

Air:

The system works in closed cells. Release to air is possible only during the loading and mixing of fresh sodium chromate solution with demineralised water and in the course of charging and testing of the gas absorption heat pump. After treatment with filters, exhaust air is in accordance with regulations and laws. No measured data have been provided at this stage. PECs have been derived for the air compartment to be able to calculate the daily intake of Cr(VI) via the air (inhalation) at local scale. At RAC's request, the applicant confirmed that the estimate of $PEC_{local,air}$, which is used for general population exposure assessment, was based on a modelled concentration at 100 m from a point source, which is consistent with the default assumptions used in the EUSES model for local scale assessments.

According to the applicant, for environmental exposure, measurements after the HEPA filter will be conducted in a future monitoring program to estimate the release to the environment.

There is no release expected from the use of gas absorption heat pump during the service life to any environmental compartment.

Soil:

No direct release to soil.

Table 5: Summary of environmental emissions

Release route	Release factor	Release per year	Release estimation method and details
Water	0 %	0 kg/year	
Air	1×10^{-5} %	5.6×10^{-7} kg/year	Based on final release into the environment after treatment
Soil	0 %	0 kg/year	

Table 6: Summary of indirect exposure to humans via the environment

Parameter	Local
PEC in air (mg/m^3)	1.07×10^{-10}
Daily dose via oral route (mg/kg bw/d)*	1.57×10^{-12} (acidic) 1.10×10^{-11} (alkaline)

* Intake from drinking water and fish (food) consumption

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

Workers exposure

RAC notes that in the CSR and in the answers to RAC questions, the applicant provided sufficient information on the tasks and work organisation under each WCS and on the exposure estimation approach.

RAC notes that inhalation exposure estimates were based only on modelling data using ART 1.5, 8 h TWA, 90th percentile, subsequently corrected for PPE effectiveness and predicted frequency of the tasks. No measured data from similar facilities were presented to support the modelled data. This can introduce some uncertainty due to the fact that modelling exposure results are by default approximate values and the input parameters may not always be exactly accurate for the worker exposure. The choice of using the 90th percentile values is made to, compensate, at least partly, for this uncertainty.

RAC notes that the applicant also provided modelled dermal exposure estimates together with the input parameters used for modelling and oral exposure estimates.

Combined exposures:

RAC accepts the combined exposure described by the applicant as a realistic worst case exposure.

Humans via the environment

Humans can be exposed via the environment due to Cr(VI) emissions during the usage of the substance and the heating pumps. A quantitative assessment has been performed at local and regional scale.

Human health effects via environment are considered locally for the region next to the production facilities. The applicant also presented a release to man via the environment by the regional concentrations approach, calculated to cover all eventualities and to represent the absolute worst case. In accordance with the European Union Risk Assessment Report (2005),

released Cr(VI) is expected to be reduced to non-hazardous Cr(III) in most situations in the environment. Therefore RAC did not take the regional exposure of humans via the environment into consideration in the risk assessment.

Based on the EU RAR, two environmental conditions have been assessed, acidic and alkaline conditions. The conventional approach of EUSES with a model concentration in air 100 m from the source of exposure has been used. RAC considers that the default assumptions used for the local scale exposure assessment in EUSES are conservative and are likely to overestimate risks.

Shortcomings related to the exposure assessment:

RAC points out that workplace exposure measurement data and measured environmental emission data are not available for the planned Ariston installation. As a result, worker exposure and environmental releases are based on modelled estimations.

Taking into account the exposure assessment performed by the applicants as well as all of the information provided on the intended process and the planned OCs and RMMs, RAC considers the shortcomings detailed above to be of relatively minor significance for the purpose of exposure and further risk assessment, due to the conservative choices made in the modelling, which assumed the maximum duration of the potential exposure and frequency for each WCS as a worst case scenario.

2.6. Conclusions on exposure assessment

RAC considers that the description of the use provided in the CSR and in the applicant's answers to RAC's requests is sufficient to conclude on the reliability of the exposure assessment (for workers and HvE).

RAC considers that the exposure assessment (for workers and HvE) contains some residual uncertainty due to:

i) lack of workplace air measurement data for the future installation;
ii) lack of environmental emissions data for the future installation.

RAC considers that the lack of measured data would not be expected to lead to significantly higher exposure estimates in comparison with those selected for further risk characterisation. The methodology used to derive exposure levels is suitable.

However, the applicant should confirm the results of the modelling by measurements. Their future worker exposure assessment (for all WCSs) should be based on a representative monitoring data set (personal and/or stationary measurements for exposure estimation). The applicant should also confirm their environmental release estimates by obtaining representative measurements for releases to all relevant environmental compartments.

RAC notes that the validity of the exposure assessment (for workers and HvE) depends on the effectiveness of implemented RMMs.

Nevertheless, the information provided related to exposure resulting from the use applied for, is considered to be sufficient to be used for the risk characterisation.

3. Risk characterisation

3.1. Workers

The applicant has estimated cancer risk according to the RAC reference dose response relationship for carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev.1, agreed at RAC-27). Thus, the excess lifetime lung cancer risk is 4×10^{-3} per µg Cr(VI)/m^3 for 40 years of exposure (8 h/day, 5d/week). The applicant also performed a dermal risk assessment for reprotoxic effects, using the reference dermal DNEL as proposed by RAC (RAC/35/2015/09, Discussed at RAC-35).

Oral exposure and ingestion the non-respirable fraction in inhalation exposure

As the inhalation exposure to Cr(VI) can be in a range of particle sizes, the 'inhalable non-respirable fraction' of Cr(VI) particles exposure can have a potential for risk of cancer of the small intestine. Based on a 40 year working life (8 h/day, 5 days/week) and an age-derived assessment factor of 1, an excess lifetime intestinal cancer risk = 2.0×10^{-4} per µg Cr(VI)/kg bw/day is used for the risk characterisation.

The applicant also characterised the risk for two types of combined activities: the loading of the sodium chromate solution (WCS 2) and the emptying of the refrigerant solution activities (WCS 4) and the maintenance and cleaning of the mixing and testing cells (WCS 5 a+b).

The results of the risk characterisation are presented in Table 7.

Table 7: Combined exposure and risk characterisation

Contributing scenario	Route	Exposure value corrected for PPE and frequency	RCR or Excess risk[15]	
			Excess risk lung/intestinal	RCR (for reprotoxicity)
WCS 1	Inhalation	-	-	-
	Dermal	-	-	-
	Oral*	-	-	-
WCS 2	Inhalation	9.5×10^{-4} µg/m^3	3.80×10^{-6}	-
	Dermal	0.445 µg/kg bw/day	-	0.01
	Oral*	1.36×10^{-4} µg/kg bw/day	2.71×10^{-8}	-
WCS 3	Inhalation	8.2×10^{-6} µg/m^3	3.28×10^{-8}	-
	Dermal	1.01 µg/kg bw/day	-	0.02
	Oral*	1.17×10^{-6} µg/kg bw/day	2.34×10^{-10}	-
WCS 4	Inhalation	0.77×10^{-9} µg/m^3	3.08×10^{-12}	-
	Dermal	0.11 µg/kg bw/day	-	< 0.01
	Oral*	0.11×10^{-9} µg/kg bw/day	2.20×10^{-14}	-
WCS 5a	Inhalation	0.6×10^{-2} µg/m^3	2.46×10^{-5}	
	Dermal	4.54 µg/kg bw/day	-	0.10
	Oral*	0.88×10^{-3} µg/kg bw/day	1.76×10^{-7}	
WCS 5b	Inhalation	0.3×10^{-2} µg/m^3	1.08×10^{-5}	
	Dermal	6.82 µg/kg bw/day	-	0.16
	Oral*	0.38×10^{-3} µg/kg bw/day	7.69×10^{-8}	
Combined exposure				
WCS 2+ WCS 4	Inhalation	9.5×10^{-4} µg/m^3	3.80×10^{-6}	-
	Dermal	0.555 µg/kg bw/day	-	0.01
	Oral*	1.36×10^{-4} µg/kg bw/day	2.71×10^{-8}	-
WCS 5a+b	Inhalation	0.9×10^{-2} µg/m^3	**3.54×10^{-5}**	-

[15] Estimated individual risk resulting from exposure

	Dermal	11.36 µg/kg bw/day	-	**0.26**
	Oral*	1.26 × 10^{-3} µg/kg bw/day	**2.53 × 10^{-7}**	**-**

*The intestinal cancer risk estimates for workers are mainly for illustrative purposes, to show that estimated intestinal cancer risk for each scenario is secondary in comparison to the excess lung cancer risks also in the case where all the inhalable particles are regarded non-respirable. It is noted that oral exposure was totally based on estimated inhalation exposure therefore it leads to double counting of risks and exposure. These estimates will therefore not be taken forward for human health impact calculations.

3.2. Humans via Environment

The environmental risk assessment is performed in the form of Cr(VI) to allow a comparison of the reference dose response relationship for the carcinogenicity of hexavalent chromium reported by the RAC in the document RAC/27/2013/06 Rev.1, the including tonnage and all fate properties are based on the Cr(VI) and not directly on sodium chromate.

An excess life-time lung cancer risk is 2.9 × 10^{-2} per 1 µg of Cr(VI)/m^3 for 70 years of exposure (24 h/day, 7 d/week) and an excess life-time intestinal cancer risk is 8 × 10^{-4} per 1 µg Cr(VI)/kg bw/day over an exposure duration of 70 years (24 h/day, 7 d/week).

Table 8: Exposure and risk to humans via the environment – local scale

Parameter	**Local**	
	Exposure	**RCR or Excess risk**
Human via Environment – Inhalation	1.07 × 10^{-10} mg/m^3	3.10 × 10^{-9}
Human via Environment – Oral*	3.72 × 10^{-11} mg/kg bw/day (acidic) 4.67 × 10^{-11} mg/kg bw/day (alkaline)	2.98 × 10^{-11} (acidic) 3.74 × 10^{-11} (alkaline)
Human via Environment – Combined		3.13 × 10^{-9} (acidic) 3.14 × 10^{-9} (alkaline)

* Exposure via non-respirable particles and food consumption

RAC acknowledges that the assessment of indirect exposure to humans via the environment using default assumptions in the model are likely to overestimate exposure, particularly at the local scale, leading to an overestimation of risk (and number of statistical cancer cases)

3.3. Shortcomings or uncertainties in the risk characterisation

RAC notes that the remaining uncertainties related to the intrinsic limitations of the modelling and to the lack of measurement data from similar facilities, which have been discussed and addressed in the relevant sections above, are minor and not likely to affect the risk characterisation significantly.

3.4. Conclusions on risk characterisation

RAC concludes that:

- The highest calculated excess cancer risk estimate for 40 years exposure for combined exposure is **3.54 × 10^{-5}**, estimated for WCS 5 a+b (maintenance and cleaning of the mixing and testing cells) considering the predicted values for duration and frequency of the tasks for the new Ariston site.

- The highest excess cancer risk calculated for humans via the environment (local scale for combined routes (inhalation and oral)), is **3.13 × 10^{-9}** (acidic conditions) and **3.14 × 10^{-9}** (alkaline conditions)
- The resulting RCRs for dermal exposure (as sodium chromate is also reprotoxic) are below 1 for all tasks, considering the modelled estimates. Therefore, the risk is expected to be adequately controlled.
- There are no significant shortcomings to the risk characterisation.

RAC considers that the estimates of excess lung/intestinal cancer risk for workers and for indirect exposure of humans (workers and general population) via the environment calculated by the applicant allow a health impact assessment.

However, RAC also notes that the evaluation/confirmation of the appropriateness and effectiveness of OCs and RMMs would be strengthened in the future by basing it on site specific measurement data.

4. Analysis of Alternatives and substitution plan[16]

This AfA covers the industrial formulation of a sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of Gas Absorption Heat Pumps (GAHP) up to 0.70 % by weight (as Cr^{6+}) in the refrigerant solution. The functionality of sodium chromate as an anticorrosion agent: in basic media sodium chromate as corrosion inhibitor oxidises iron on the steel surface and forms a protective layer which contains iron oxide and chromium (III) oxide. The reliability of the function during the total lifetime of the system exceeds the average of 24 years. The tonnage band for this application is estimated to be < 10 tonnes per year (4 360 kg/year at maximum production capacity during the review period).

Applicant states it will refurbish a recently purchased production site in Albacina (Italy) for the manufacturing of renewable energy products and the manufacturing of the GAHP products is planned to start as early as the release date.

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

< 10 tonnes per year (4 360 kg/year)

At maximum production capacity during the review period.

[16] 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*".

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

As the GAHP is a new product development, the Applicant does not yet hold the capacity and knowledge to do specific substance based research on the alternatives by themselves. As the Applicant is one of the major industry players for heating, ventilation, and air conditioning (HVAC) systems for thermic comfort (wall-hung boilers, water heaters, heat pumps etc.), it is quite familiar with the technology used in the heat pumps.

Applicant's research on alternatives encompasses literature review and input from consultancy and experts, and identified possible alternatives based on information available in earlier authorisation applications for similar use scenarios by other applicants.

4.1.1 – Summary of search strategy for alternatives:

The applicant has conducted a literature review and a patent search. Furthermore, the Applicant involved experts, consultancy and networking with universities, research institutes, suppliers and other HVAC companies to find proven alternatives. Besides a literature review and networking, the Applicant has undertaken analysis of publicly available reports on Analysis of Alternatives of companies, which have earlier applied or already obtained authorization for the use of chromium (VI) in absorption refrigerators (e.g. Dometic GmbH, 2015 application).

4.1.2 – Summary of Alternatives Identified:

The Applicant has identified alternatives in two different levels:

- Alternative 1: Substitution of sodium chromate as corrosion inhibitor (the assessment of the technical suitability of the alternative another corrosion inhibitor as drop-in substances).
- Alternative 2: Replacement of GAHP technology (a change of the complete system/technology to satisfy customer needs, including condensing boiler, electrical heat pump, hybrid heat pump and biomass, where condensing boilers and electrical heat pumps were evaluated more in detail as shortlisted alternatives).

In the responses to questions asked by SEAC, the Applicant provided conclusions on screening performed for potential substitutes for carbon steel itself, where it is in contact with ammonia water refrigerant solution. Copper and copper alloys, aluminum and its alloys, glass, sintered ceramics (i.e., tungsten carbide) and plastic materials was discussed, concluding on non-suitability for GAHP technology due to different reasons: reactions with ammonia (copper, aluminum and their alloys), porosity and high fragility or low resilience (glass, ceramics) and the ability to withstand the mechanical stresses at the operating temperatures of the GAHP application (plastics). As for different steel alloys, the use of corrosion inhibitor is still needed.

4.1.3 – Summary of the Comments received during the Consultation:

No comments were received during the consultation for this application. SEAC notes that the Applicant has mainly based their analysis on the information available from analysis of publicly available Analysis of Alternatives mentioned above. Furthermore, the Applicant has been

actively involved in literature search and identification of alternatives by assessing available patents and scientific papers.

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

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

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 by the time of adoption of this opinion?

☐Yes ☒No

4.3.1. Past Substitution R&D Efforts

4.3.1.1. Literature Review

The applicant conducted a literature review and shortlisted potential drop-in alternative substances for sodium chromate as corrosion inhibitor in GAHPs based on functional requirements (corrosion resistance, effectiveness at high operating temperature, high pH and high pressure, long lifetime service, prevention of gas formation), hazardous substance profile, experience at industrial scale and economic criteria (market availability). The eight selected alternatives to sodium chromate are: 1) Soluble silicon compounds, 2) Molybdates, 3) Sodium nitrite, 4) Zinc containing corrosion inhibitors, 5) Strong alkaline solutions, 6) Phosphates and phosphonate compounds, 7) Rare Earth Metal Salts, and 8) Inhibitor 7 (Potentially suitable new inhibitor described in Dometic GmbH application).

4.3.1.2. In-house experiments conducted

There were no results of in-house experiments conducted by the applicant presented in the application. As claimed by the Applicant, the long-term agreement with the local university (previously involved in several GAHP technology development projects) for support and research of possible alternatives to substitute sodium chromate is currently being defined. As stated by the Applicant, Ariston Thermo Innovative Technologies (R&D Center of Ariston Thermo for innovative/renewable technologies) is investing in creating an endurance test area where the validation tests will be performed.

4.3.2. Short-listed Alternatives

4.3.2.1. Alternative 1 – Substitution of sodium chromate as corrosion inhibitor

For shortlisting of alternatives, the literature review and analysis of other publicly available Analysis of Alternatives of companies, which have applied for the use of chromium (VI) or already have obtained authorization in absorption refrigerators (Dometic GmbH) was performed. In-house research activities concerning substitution of the substance were not reported in AoA.

Basis for shortlisting of alternatives considered includes functional requirements defined based on technological requirements and analysed based on literature information available. Following functional requirements were defined and justified by the Applicant:

- ***Suitability for anaerobic conditions*** – to avoid corrosion of carbon steel, that can lead in reduction of strength of the metal in the system that have to withstand the inner pressure of 26 bar. Furthermore, rust particles from the corrosion process may furthermore create sludge in the machine or even block the valves in the system.
- ***Effectiveness in high NH_3 concentrations and high pH levels*** – requirements for GAHP technology stated by the Applicant is up to 40 weight percent of ammonia in aqueous solution (in boiling conditions up to 100 % NH_3) that leads also to high pH levels in the system.
- ***Effectiveness in operating temperature up to 200 °C*** – in order to deliver an output temperature up to 70 °C to the radiators of the end-users, high pressure (up to 20 bar) and temperatures up to 200 °C is needed.
- ***Prevention of gas formation*** - the corrosion of steel as well as thermal decomposition of ammonia can form non-condensable gases in the refrigerant solution which could result in a reduction of efficiency or even in a complete breakdown of the GAHP. As working fluid recirculates in a substantially closed system, the non-condensable hydrogen accumulates in the system and hampers the condensation and absorption of ammonia from the vapour phase, significantly reducing the absorption and condensation capacity of the system.
- ***Approved suitability for industrial GAHP application*** – the Applicant performs analysis, whether the shortlisted alternatives have been tested in industrial scale or laboratory environment and if tested, whether the test conditions were suitable for GAHP process.
- ***Long lifetime service tested*** – the Applicant performs analysis, whether long term testing with the requirements for GAHP have been performed.

SEAC considers the list of functional requirements logical and helpful for identifying a suitable alternative. SEAC notes that the analysis of functional performance of 8 shortlisted alternatives is supported by literature references (11 patents, 3 scientific papers and Dometic GmbH application in 2015) and by the Applicant's responses to the SEAC questions.

A summary of Applicant's assessment in the AoA for each of 8 shortlisted alternatives:

1. **Soluble silicon compounds** – Not suitable for anaerobic conditions as oxygen is an essential part for sodium silicate to provide a maximum corrosion protection. Effective in high NH_3 concentrations and high pH levels. Effective in operating temperature > 200 °C. No approved suitability for GAHP in industrial scale has been shown so far – only small-scale testing within chillers have been performed. No long-term testing with the requirements for GAHP has been performed so far. Conclusion: to evaluate the

suitability for GAHP, further long-term testing under real conditions needs to be performed.

2. **Molybdate** – Not suitable for anaerobic conditions as presence of dissolved oxygen is needed in case of ammonium molybdate. Not effective in high NH_3 concentrations and high pH levels. No information available on efficiency in operating temperature > 200 °C. No approved suitability for GAHP in industrial scale has been shown so far - tests have been mainly performed under laboratory scale. No long-term testing with the requirements for GAHP has been performed so far. Conclusion: molybdates cannot be considered as suitable alternatives for GAHP.
3. **Nitrite** – Suitable for anaerobic conditions. Not effective in high NH_3 concentrations and high pH levels, as best performance pH range is between 8 and 10. Not effective in operating temperature > 200 °C as nitrite is rapidly consumed at high temperatures and the thin protective layer will not be present after short period of time. No approved suitability for GAHP in industrial scale and long-term service - reported life of a unit was only 1 year. Conclusion: nitrite cannot be considered as suitable alternatives for GAHP.
4. **Zinc containing corrosion inhibitors** - Suitable for anaerobic conditions. Not effective in high NH_3 concentrations and high pH levels, as the solubility of zinc highly depends on the pH value of the medium. No information available on efficiency in operating temperature > 200 °C. No approved suitability for GAHP in industrial scale as generation of high amounts of non-condensable gases within low temperature appliances reported in literature. No long-term testing with the requirements for GAHP has been performed so far. Conclusion: due to generation of non-condensable gases, zinc containing corrosion inhibitors are not a suitable alternative.
5. **Strong alkaline solutions** – Suitable for anaerobic conditions. Effective in high NH_3 concentrations and high pH levels. Significant hydrogen generation in operating temperature > 200 °C. No information is available from literature on approved suitability for GAHP in industrial application. No long lifetime service tests reported - under laboratory conditions for periods less than 5 years only. Conclusion: strong alkaline solutions are considered as not suitable as on high temperature conditions significant hydrogen formation was observed.
6. **Phosphates and phosphonate compounds** – Not suitable for anaerobic conditions as presence of oxygen is needed to form to form the passivation layer of a Fe_2O_3/phosphate film. Not effective in high NH_3 concentrations and high pH levels. No information available on efficiency in operating temperature > 200 °C. No information is available from literature on approved suitability for GAHP in industrial application. No long-term testing with the requirements for GAHP has been performed so far. Conclusion: Phosphates cannot be considered as suitable alternatives for GAHP.
7. **Rare earth metal salts (REMS)** - Suitable for anaerobic conditions. Effective in high NH_3 concentrations and high pH levels. Effective in operating temperature > 200 °C. No approved suitability for GAHP in industrial scale has been shown so far - tests have been mainly performed under laboratory scale. No long-term testing with the requirements for GAHP has been performed. Conclusion: to evaluate the technical suitability of this method, further investigation and long-term testing under real use conditions would need to be performed. Currently rare earth metal salts cannot be considered as suitable alternatives for use in GAHP.
8. **Inhibitor 7** – Not effective in operating temperature > 200 °C, as reported the reduced corrosion protection at high temperatures (> 180 °C). Conclusion: due to limited amount of information available the applicant considers the alternative as unsuitable for the use in GAHP.

As a summary of assessment on substance alternatives, Applicant concludes the following:

“none of the potential drop-in alternatives fulfils the technical requirements to exclude corrosion and non-condensable gas formation with sufficient extend to ensure safe work of ammonia absorption heat pumps for the whole lifetime of 24 years”.

In the Applicant’s response to the SEAC’s questions, additional information on properties and performance of aforementioned candidates was provided. SEAC is satisfied with the clarity of information and with the clear conclusion, noting only that referencing of additional information could have been improved. Based on the information given, SEAC finds the applicant’s conclusion acceptable.

4.3.2.2. Replacement of GAHP technology

The analysis of two shortlisted technical alternatives (electrical heat pumps and condensing boilers) is performed by the Applicant and compared with the performance requirements of GAHP technology. The concise descriptions of alternative technologies include main function, energy efficiency, segments of target installations, environmental concerns and running costs. Few references within the analysis of the Alternative 2 is provided by the Applicant.

A summary of main Applicant’s conclusions on Alternative 2 are as following:

- The electrical heat pump technology is not applicable for retrofit and for high or medium temperature sectors.
- The lower efficiency, higher energy consumption and higher running costs of condensing boilers are main disadvantages compared to GAHP technology.

SEAC notes with a satisfaction that the applicant is planning R&D activities which would potentially lead to strengthening of the knowledge base on alternatives and could further contribute to the decrease of quantities used or even elimination of sodium chromate from the GAHP technology in the future.

4.3.3. Availability of the short-listed alternatives

The sunset date for Na_2CrO_4 was 21/09/2017. This section considers whether the short-listed alternatives are technically and economically feasible and available before release date, as the manufacturing of the GAHP products is planned to start as early as the release date.

Alternative 1 – Substitution of sodium chromate as corrosion inhibitor

Alternative 1 is introduced in Section 4.3.1. in the AoA.

The analysis of the alternatives is based on the literature review, input from consultancy and already identified possible alternatives. The applicant has not demonstrated in-house research activities. Along with the Applicant’s conclusion on non-availability of alternatives, the applicant refers to other applications, already submitted for authorisation for similar uses (totally 6 applications, where opinions are adopted, or decision of EU commission is provided). In all of the previous analysis of alternatives, the final conclusion was, that no suitable alternatives are available. Furthermore, it should be noted that the applicant explained that the Inhibitor 7, mentioned in the Application for Authorisation of Dometic GmbH as a potential corrosion inhibitor, is not known and therefore not available to the Applicant.

Technical Feasibility

As no substitute of sodium chromate as corrosion inhibitor in the manufacturing of the GAHP has been identified at the release date, the technical feasibility is not relevant.

Economic Feasibility

This parameter has not been analysed by the applicant as no suitable substitutes have been

identified.

Alternative 2 – Replacement of GAHP technology

Alternative 2 is introduced in Section 4.3.2 in the AoA.

The two alternative shortlisted technologies were analysed by the applicant. The applicant has concluded that neither of alternative technologies can provide both required characteristics: high efficiency and application for retrofit in high or medium temperature sectors. The Applicant's conclusion seems plausible for SEAC.

Timeframe of identification and implementation of suitable alternatives

Applicant is willing to invest in research and development to further improve the GAHP technology and to expedite the replacement of sodium chromate. As stated by the applicant, the long lifetime expectancy of more than 24 years is a critical aspect for the validation duration. In the AoA and in the response to SEAC questions, the Applicant anticipates that based on the requirements a replacement process from research to market implementation will take up to 20 years including following steps: Monitoring/Research, Identification (up to 3 years), Validation (5 to 7 years), Product development (up to 5 years) and Market implementation (up to 2 years).

SEAC notes that in case of Alternative 7 – shortlisted substance REMS – the Applicant has concluded that "In laboratory scaled tests rare earth metal salts as drop-in inhibitor showed some potential for corrosion inhibition in combination with prior treatment of the inner metal surfaces. To evaluate the technical suitability of this method for GAHPs, further investigation and long-term testing under real use conditions would need to be performed". In their response to the SEAC questions, the Applicant states that even if the potential substance would be identified, the total time for substitution is still expected to take 12 to 15 years.

Given the information presented by the applicant in the AoA and in the answers to SEAC questions, it appears that less than 20 years could suffice to identify and implement suitable alternative.

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

Although not included in the initial AoA, the applicant provided on SEAC's request a concise summary on screening performed for potential substitutes for carbon steel itself, where it is in contact with ammonia water refrigerant solution. The applicant still expects carbon steel and its alloys to remain the most likely solution.

SEAC notes that the information provided in the analysis of alternatives is largely based on patents and literature available and on analysis presented in the earlier authorisation AoA(s) (Dometic GmbH) and views the overall analysis as such to be plausible.

Taking into account the information provided by the applicant in the AoA and in the responses to the SEAC questions, SEAC can concur with the applicant's conclusions that alternatives analysed are not suitable and not available at this point in time and that based on this the substitution is expected to take not less than 12 years.

4.4. Substitution activities / plan

Has the applicant submitted a substitution plan?

☒Yes ☐No

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

The applicant is involved in the i-GAP project which is co-financed by the European Regional Development Fund with a term from 2014-2020 and aims to develop the technology of small gas absorption heat pumps for residential building heating.

The applicant presented confidential numbers of investments in GAHP R&D program and plans to commit in investigation in three directions:

- Monitoring research activity at university and research labs for new solutions and patents - further testing on alternatives identified under industrial scale as well as long term in-service use will be performed.
- Testing programmes to progressively decrease the concentration of sodium chromate to the lowest possible level compatible with GAHP application – these activities have already started.
- Performing regular strategic market researches to monitor activities and developments of competitors in and outside the European Economic Area.

The applicant noted that they are finalising a Strategic Agreement with the local university. The Applicant is also investing in creation of an endurance test area where the validation tests will be performed.

Conclusions of SEAC

SEAC notes the Applicant's activity in the i-GAP project as an active effort towards finding an alternative in the future.

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

SEAC welcomes the applicant's plans in the future to perform R&D activities that could further contribute to the decrease of quantities used or even elimination of sodium chromate from the GAHP technology.

SEAC acknowledges that the Applicant included in the current AoA information from the analysis of publicly available AoA(s) of companies, which have applied or already obtained authorization for the use of chromium (VI) in absorption refrigerators.

SEAC considers that the Applicant has demonstrated that there will not be suitable alternatives at the time of adoption of this opinion and given the current situation with no suitable alternatives, the substitution is expected to take not less than 12 years. The demonstration of the work for finding alternatives could further benefit from more careful referencing of the information used. The substitution plan was credible and consistent with the analysis of alternatives and the socio-economic analysis.

5. Benefits and risks of continued use

Has (Have) the applicant(s) adequately assessed the benefits and the risks of continued use?

☒ Yes

☐ No

5.1. Human health and environmental impacts of continued use

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 3 and the estimation of the number of exposed people provided by the applicant. It reflects the expected statistical number of cancer cases for an exposure over the working life of workers (40 years) and the entire life for the general population (70 years).

RAC notes that these calculations are based on the estimation of exposed populations as provided by the applicant.

Table 9: Summary of additional statistical cancer cases:

	Excess cancer risk[2]	**Number of exposed people**[4]	**Estimated statistical cancer cases**	**Value per statistical cancer case**	**Monetised excess risk per year**[1]
Workers					
Directly exposed workers[3]	3.54×10^{-5}	3	1.17×10^{-4}	€4 131 496	€ 12
General population					
Local	3.1×10^{-9} inhalation 3.74×10^{-11} Oral	10 000	3.1×10^{-5} 3.74×10^{-7}	€4 131 496 €1 667 724	€2 €< 1
Sub-total					€2
Total					€14
Latency (years)	10				

Notes:

1. Annualised to a typical year based on the time horizon used in the SEA;
2. Excess risk is estimated over a lifetime working exposure (typically 40 years) and via the environment over a typical lifetime exposure (typically 70 years);
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8 hour Time Weighted Average (TWA) of a representative worker; for simplicity, only the most significant excess cancer risk (and number of involved workers) is reflected here. The applicant in his calculations has correctly taken into account all contributing activities and number of involved workers to estimate the statistical cancer cases.
4. Total number of workers potentially exposed from the different activities is 8

Released chromium (VI) is expected to be reduced to non-hazardous chromium (III) in most situations in the environment. The applicant conservatively assessed human health impacts at

the local scale, close to the production site. The assessment of human health of workers is limited to inhalation (lung cancer). Dermal exposure to Cr(VI) was not assessed. Oral exposure was considered via the food chain (man via environment oral). The assessment in the CSR was based on a worst-case approach, leading to an overestimation of human health impacts. The results of the exposure and subsequent risk assessment are derived using a modelled approach and the applicant considers that the modelled results may overestimate the human health impacts. The applicant considered the maximum production volumes for the applied for review period (20 years), possibly overestimating the risk for the general population. The applicant recognised the high uncertainties linked to the development of the new production line and the training of new workers and consequently applied the worst-case to assess the impacts. ECHA guidance (2014) on monetisation of health impacts was appropriately applied. Lower and standard discount rates were applied, with 2 % and 4 % percent analysed. The lower rate reflecting individuals' increased value on health and safety benefits as their living standards increase. Lower bound estimates for Value of Statistical Life (VSL) and Value Cancer Morbidity (VCM) are estimated by the applicant. The prices for the health risk are adjusted using the Gross Domestic Product (GDP) deflator of the EU-28 (Eurostat). SEAC confirms that the applicant applied ECHA methodological guidance and appropriately adjusted to the base year to estimate net present values (NPV), using GDP deflator indexes, to adjust the value to the proper year. SEAC finds the specific approach and assumptions used to derive the health benefits are clear, transparent and based on standard assessment practices, such that the estimates derived are robust and valid.

5.2. Benefits of continued use

Non-use scenario

The applicant presents one non-use scenario (NUS 1): suspension of on-going EU research and development (R&D) and planning for EU manufacturing processes related to GAHP technology and the relocation of R&D and planned manufacturing processes to a non-EU country. The applicant provided detailed analysis of the consequences of NUS 1.

The applicant indicated that in preparation for a launch of GAHP technology, R&D and the processes related to identifying and qualifying new suppliers in the EU is on-going, implying that the applicant has incurred some search costs in the process of developing GAHP technology. The applicant also indicated that in terms of competition, they are closest to a product launch. The applicant operates in an oligopoly context, with few other major companies in the EU market.

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

- 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?

- Social impacts in terms of unemployment in the EU were referred to by the applicant, however their estimates were not used in the CBA.

Economic impacts of continued use

The applicant's analyses focus on the costs of transferring remaining R&D and planning of manufacturing processes to a non-EU country. Search costs relate to the recruitment of specialised workers and subsequent knowledge transfer to these workers. These costs are calculated by the applicant and an appropriate discount rate was used. In addition to the search costs, these processes will create a delay in the development and product launch to market process of up to 24 months. They assume that no staff will be transferred from the EU. The described costs, delays and assumptions are plausible. Additionally, the applicant will incur search and enforcement cost related to identifying and qualifying new suppliers and enforcement costs related to checking the quality of production parts (up to 24 months, although some of this can be performed in parallel to the training). As 100 % of production will be transferred to a non-EU country, lead times will not be an issue. However, transport of finished products to the EU (from a non-EU country) will incur additional transport and logistic costs. These costs are plausible. Some costs are incurred sequentially, and others in parallel. In summary, the applicant indicated that these processes will lead to additional costs (over and above those incurred if the production processes were to remain in the EU) and lead to a delay in the product launch of up to 48 months (due to combined factors of hiring, training and supply chain sourcing/adjustments). Additional consequences are presented qualitatively by the applicant and include loss of competitive advantage (in the medium term) and knowledge generation through R&D within the EU. These consequences are plausible. In the trialogue, the applicant confirmed their understanding that importing from a non-EU country to the EU will not impose any regulatory impacts in regard to Sodium Chromate.

The applicant estimates the economic impacts for the duration of the transition phase (four years) until manufacturing operations are established in a non-EU country. The economic impacts include private and public costs. The estimates of economic impacts (private costs to Ariston) of relocation to a non-EU country are calculated with the appropriate discount rate and base year. These private costs are plausible. The postponement of the launch to market corresponding to the transition phase (four years) will lead to foregone profits. Furthermore, the applicant anticipates reduced sales after the transition phase. Beyond the transition phase, additional costs related to transport and logistic costs from importing products from non-EU country have been estimated by the applicant, however, they have not been taken forward in the CBA analysis. At a 4 % discount rate, the estimated private costs to Ariston in the transition period is €18 745 883.

Avoided societal impacts (i.e. avoided CO_2 emissions) and secured energy savings were calculated by the applicant. The costs are discounted at 4 % and presented for the transition period (four years) and estimated at €23 265 430 for energy saving costs and €1 377 480 for CO_2 savings. The applicant was questioned regarding the methodology used to arrive at the estimates on energy saving and responded with an adjusted estimate based on EU guidance, which is slightly lower than the applicant's original estimate. This adjustment is not significant and would not significantly affect the conclusion (the above estimate includes the adjustment). Similarly, the applicant was questioned regarding the estimates the value of carbon saved as a result of the uptake of the GAHP technology. The applicant was specifically questioned regarding the methodology used to arrive at the carbon saving and responded with an adjusted saving based on EU guidance, which is slightly lower than the applicant's original estimate (the above estimate includes the adjustment). Both estimates were monetised, and an appropriate discount rate was applied. The estimates were presented for the four-year transition period. The adjustments made were not significant in terms of the overall magnitude of the estimates and would not affect the conclusion.

The applicant highlighted uncertainties regarding the development and introduction of a new

product on the market and sales forecasting. In addition, the market price of gas and carbon certificates are unlikely to remain constant in the transition period. To account for these uncertainties the applicant, as a sensitivity check, applied a higher discount rate (15 %) on the combined costs of the non-use scenario. These are the lower bound estimates. The total economic costs (private, public and environment) are estimated at €31 555 423.

Social impacts in terms of unemployment in the EU were referred to by the applicant, however their estimates were not used in the CBA.

In the trialogue, the applicant indicated that in finding a substitute it is not a question of economic feasibility, but a question of technical feasibility and that sodium chromate is a precondition for GAHP technology. Furthermore, the applicant indicated that a reason that they applied for a 20-year review period was connected to the business case (a long term strategic scenario that matches the scaling processes to achieve maturity in this product market category) and risk analysis (a compliance risk) related to the high-volume manufacturing processes and the CAPEX investments underpinning such processes. The applicant did not present any significant socioeconomics (quantitative or monetary) arguments to justify a 20-year review period. While the applicant did not provide a detailed quantitative analysis, the net result of granting a 12-year review period (as opposed to a 20-year period) will result in a perceived higher compliance risk for the business based on GAHP technology and the applicant indicated that this is a critical factor in the decision making around the business case.

Table 1: Socio-economic benefits of continued use

Description of major impacts	**Quantification of impacts [€ million per year]**
1. Benefits to the applicant(s) and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	
1.2 Avoided profit loss due to ceasing the use applied for[17]	€1.6 (at 4 % discount)[18]
1.3 Avoided relocation or closure cost	Not included
1.4 Avoided residual value of capital	Not included
1.5 Avoided additional cost for transportation, quality testing, etc.	Not included
Sum of benefits to the applicant(s) and / or their supply chain	€1.6
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[19]	Not included
2.2 Foregone spill-over impact on surplus of alternative producers	Not included
2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	Not included

[17] Profit losses counted in only for the first 4 years, see SEAC note on economic surplus changes (not yet available).
[18] Presented here by the rapporteurs as combined costs to Ariston €18 745 883 divided by 12 (assuming a 12-year review period).
[19] 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).

2.4 Avoided other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	€2.1 (Discounted at 4 %)
Sum of impacts of continuation of the use applied for	
3. Aggregated socio-economic benefits (1+2)	€3.6[20] (Discounted at 4 %) €2.6 (Discounted at 15 %)

5.3. Combined assessment of impacts

A summary of the impacts is presented in Table 11. The impacts are annualised across the socioeconomic benefits of continued use and the monetised excess risks associated with continued use. The quantitative data is presented as ranges for confidentiality reasons, as requested by the applicant.

Table 2: Socio-economic benefits and risks of continued use

Socio-economic benefits of continued use		**Excess risks associated with continued use**	
Benefits [million € per year]	€1.6 million (discounted at 4 %)	- Monetised excess risks to workers directly exposed in the use applied for [annualised to € per year]	€12
Quantified impacts of the continuation of the SVHC use applied for	€2.1 million (discounted at 4 %)	Monetised excess risks to the general population and indirectly exposed workers [annualised to € per year]	€2
Additional qualitatively assessed impacts	Unemployment, competitiveness	Additional qualitatively assessed risks	
Summary of socio-economic benefits	€3.6 million (discounted at 4 %) €2.6 million (discounted at 15 %)	**Summary of excess risk**	€14

Table 3: Cost of non-use per year

	Per year
Total cost[1] (€) [million € per year]	€3.6 million (discounted at 4 %) €2.6 million (discounted at 15 %)
Monetised risk with continued use	€14
Ratio[2]	**260 000: 1 (discounted at 4 %)** **190 000: 1 (discounted at 15 %)**

Notes:
1. "Total cost" (of non-authorisation) = Benefit of authorisation
2. "Ratio" = Total cost / Monetised risk

[20] The aggregated socio-economic benefits (1+2) divided to 12 years properly rounded *after* the summation is €3.6M, although the summation of the rounded (1+2) appears €3.7m in the table.

Table 4: Distributional impacts of continued use

Affected group	Economic impact	Health and environmental impact
Economic operator		
Applicant	€1.6 million (discounted at 4 %)	
Suppliers of alternatives in the EU	Not included	Not included
Suppliers of alternatives outside the EU	Not included	Not included
Competitors in the EU	Not included	Not included
Competitors outside the EU	Not included	Not included
Customer group 1 (identify[2])	Not included	Not included
Customer group 2 (identify)	Not included	Not included
Public at large in the EU (identify)	€3.6 million (discounted at 4 %)	
Geographical scope		
Region or Member State x	EU/Italy	EU/Italy Avoided CO_2 emissions and secured energy savings
Region or Member State y		
Within the applicant's business		
Employers/Owners		
Exposed workers		€12
Non-exposed workers and other employees		€2

Notes: Adapted from Table 12 (Chapter 4.2.3.) of SEA Guidance on the preparation of SEA in the Applications for Authorisation.

5.4. SEAC's view on Socio-economic analysis

The applicant has appropriately applied ECHA methods guidance. No comments were received during the consultation. The cost and benefit estimate appear plausible. The applicant has presented upper and also lower bound estimates to account for uncertainties related to new product launches, like the price of gas and carbon credits, which are key variables in the analysis. Under the applicant's non-use scenario, the analysis concludes that there are clear net losses to society. The main impacts relate foregone profits, energy saving and reduced carbon emissions. SEAC also notes that the Applicant refers to additional costs related to transport and logistics when importing products from non-EU country after the transition phase, and to social impacts in terms of unemployment in the EU, however these estimates have not been taken forward in the CBA analysis. SEAC considers the both of these cost elements relevant and notes this to make the benefit analysis more robust. SEAC considers the benefits and the risks of future use over the analytical timeframe used by the applicant and acknowledge the small negative human health impacts associated with the applicants use

of sodium chromate, and the substantial benefits of continued use of sodium chromate.

5.5. Conclusion on the socio-economic analysis

The overall approach to the analysis is in line with ECHA guidance and uncertainties were reasonably described and accounted for in a sensitivity analysis. The cost and benefit estimates appear plausible. Adjusting for uncertainties does not affect the overall conclusion. The analysis concludes that there are clear net losses to society if the authorisation is not granted. The main impacts related to foregone profits, energy saving and reduced carbon emissions. SEAC considers the conclusion of the applicant on the benefits and the risks of continued use plausible.

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

SEAC has been informed that RAC has no advice concerning the length of the review period.

6.2. Substitution and socio-economic considerations

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

- The applicant is planning R&D activities which would potentially lead to strengthening of the knowledge base on alternatives and could further contribute to the decrease of quantities used or even elimination of sodium chromate from the GAHP technology in the future.
- The information provided in the analysis of alternatives is largely based on patents and literature available and on analysis presented in the earlier authorisation AoA(s) (Dometic GmbH).
- SEAC can concur with the applicant's conclusions that alternatives analysed are not suitable and not available at this point in time and that based on this the substitution is expected to take not less than 12 years.
- 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. The applicants' impact assessment was considered by SEAC to provide robust conclusions in this respect.

Although it is difficult to assess the longer term prospects for the development of suitable alternatives, SEAC, having taken into account the above points, considers that a realistic prospect for substitution will not be possible within the timelines of a short or normal review

period. However, SEAC notes the risk level reported and that the case considers future use, thus no any monitoring data of the process is yet available. **Taking into account these points, SEAC recommends a 12 year review period.**

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

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements[22] proposed for the authorisation?

☒ Yes

☐ No

8.1. Description

(a) The applicant shall implement and conduct an initial measurement programme and, at least, annual exposure monitoring programmes for Cr(VI) thereafter. Those programmes shall be based on relevant standard methodologies or protocols, comprise static and/or personal inhalation exposure sampling and be representative of:

(i) the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance workers;

(ii) the OCs and RMMs typical for each of these tasks;

[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.

(iii) the number of workers potentially exposed;

(b) the applicant shall implement and conduct an initial measurement campaign and, at least, annual monitoring of Cr(VI) emissions to wastewater and air. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicants site.

(c) the information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicant to review and confirm the effectiveness of proposed RMM and OCs and, if needed, to introduce measures to further reduce workplace exposure to sodium chromate and emissions to the environment to as low a level as technically and practically feasible;

(d) the applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles (e.g. appropriateness of RPEs) and refine worker and HvE assessment if necessary;

(e) the measurements referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place;

(f) following implementation of the RMMs and OCs proposed for the new installation, the applicant may reduce the frequency of measurements, once the applicant can clearly demonstrate to the national competent authority, of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the RMMs and OCs function appropriately.

8.2. Justification

RAC considers that the exposure assessment (for workers and HvE) contains some residual uncertainty due to lack of workplace air measurement and environmental emissions data for the future installation. RAC also considers that exposure estimates should be based on a comprehensive dataset to ensure their representativeness. Therefore, monitoring arrangements were proposed for the authorisation.

Although RAC considers that these shortcomings would not be expected to lead to significantly higher exposure estimates compared to those considered for the risk characterisation, RAC is of the opinion that the applicant should address these shortcomings by obtaining representative measurements for workers exposure and environmental releases.

9. Recommendations for the review report

Were recommendations for the review report made?

☒ Yes

☐ No

9.1. Description

The information gathered via the measurements referred to in section 8 points (a) and (b) as

well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report.

9.2. Justifications

Provision of the representative monitoring results for both worker exposure and environment would allow for better evaluation of the actual situation in the applicant's site and would confirm the appropriateness and effectiveness of OCs and RMMs actually used.

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(s) did not comment

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

In their comments on the draft opinion, the applicant submitted a substitution plan. Some information on the factors affecting substitution had already been provided in the AoA/SEA as part of the initial application, with additional clarifications provided in response to SEAC's questions. SEAC now changed the opinion to state that a substitution plan has been provided.

Additionally, a few editorial changes were incorporated based on the applicant's comments.