Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

sodium dichromate use: Repackaging of sodium dichromate to be supplied as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings

ECHA/RAC/SEAC: Opinion N° AFA-O-0000006599-57-01/D

Consolidated version

Date: 02/05/2017

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 an application for authorisation for:

Chemical name(s): sodium dichromate
EC No.: 234-190-3
CAS No.: 10588-01-9

for the following use:

Repackaging of Sodium Dichromate to be supplied as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings

Intrinsic property referred to in Annex XIV:

Article 57 (a), (b), (c) of the REACH Regulation

Applicant:

Ilario Ormezzano Sai Spa

Reference number:

11-2120132745-57-0000

Rapporteur, appointed by the RAC: **Susana VIEGAS**
Co-rapporteur, appointed by the RAC: **Sonja KAPELARI**

Rapporteur, appointed by the SEAC: **Simon COGEN**
Co-rapporteur, appointed by the SEAC: **Ivars BERGS**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On **21/03/2016 Ilario Ormezzano Sai Spa** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **31/10/2016** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **09/11/2016**. Interested parties were invited to submit comments and contributions by **09/01/2017**.

No comments were received from interested parties during the public consultation in accordance with Article 64(2)).

The draft opinions of RAC and SEAC take into account the responses of the applicant to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicant on **26/04/2017**.

On **02/05/2017** the applicant informed ECHA that they did not wish to comment on the opinions. The draft opinions of RAC and SEAC were therefore considered as final on **02/05/2017**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **15/03/2017**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of RAC was adopted as final on **02/05/2017**.

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of

the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **16/03/2017**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicant, the opinion of SEAC was adopted as final on **02/05/2017**.

THE OPINION OF RAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

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 risks related to the alternatives as documented in the application, as well as other available information.

RAC confirmed that it is not possible to determine a DNEL for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

RAC confirmed that there appear not to be any suitable alternatives that further reduce the risk.

RAC confirmed that the operational conditions and risk management measures described in the application do not limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation.

THE OPINION OF SEAC

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC has formulated its opinion on: the socio-economic factors and the availability, suitability and technical and economic feasibility 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 confirmation that it is not possible to determine a DNEL for the carcinogenic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC confirmed that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant.

SEAC considered that the applicant's assessment of: (a) the potential socio-economic benefits of the use, (b) the potential adverse effects to human health of the use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health, whilst taking account of any uncertainties in the assessment, provided that the suggested conditions and monitoring arrangements are adhered to.

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Description for additional conditions and monitoring arrangements for the authorisation:

Following a review of the selection of the most appropriate RMMs, in accordance with the hierarchy of control, where it is concluded that RPE is also needed, the applicant must evaluate which tasks require the use of RPE and ensure that appropriate RPE is selected to provide adequate protection for all of the different possible exposure situations.

Description of conditions and monitoring arrangements for review reports:

The applicant must continue to implement regular campaigns of occupational exposure measurements relating to the use of sodium dichromate described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit. They shall comprise personal inhalation exposure sampling and be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed. Besides, future campaigns should include sufficient contextual information about the tasks with possible exposure to Cr(VI). The results of the monitoring must be included in any subsequent authorisation review report submitted.

The applicant should provide an analysis of the biomonitoring data with sufficient contextual information on the sampling time related to shifts, the tasks performed and PPE worn.

Emissions of Cr(VI) to air and wastewater shall be subject to regular measurements with the results of monitoring made available to enforcement bodies on request. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate. Emissions data shall be presented in any subsequent review report.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions (OCs) to further reduce workers' exposure to Cr(VI) and emissions to environment.

The results of the monitoring and of the review of the OCs and RMMs must be retained, be made available to national enforcement authorities on request and included in any subsequent review report submitted.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant the duration of the review period for the use is recommended to be **7 years.**

JUSTIFICATIONS

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property / properties:

- ☒ 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):

2. Is the substance a threshold substance?

- ☐ YES
- ☒ NO

Justification:

Sodium dichromate has a harmonised classification as Carc. 1B (H350), Muta. 1B (H340) and Repr. 1B (H360FD) according to CLP.

Based on studies which show its genotoxic potential, the Risk Assessment Committee (RAC) has concluded that sodium dichromate should be considered as non-threshold substance with respect to risk characterisation for carcinogenic effects of hexavalent chromium (reference to the studies examined are included in the RAC document RAC/27/2013/06 Rev. 1 Final).

Based on studies which show reprotoxic effects of potassium and sodium dichromate, RAC has concluded that sodium dichromate should be considered as a threshold reprotoxicant with respect to risk characterisation (reference to the studies examined are included in the RAC document RAC/35/2015/09).

However, carcinogenicity is considered as the leading health effect as there is likelihood for genotoxic effect to occur following lower exposure levels.

3. Hazard assessment. Are appropriate reference values used?

Justification:

Sodium dichromate is included in Annex XIV based on three intrinsic properties: Carcinogen (category 1B), Mutagen (category 1B) and Toxic to reproduction (category 1B).

The molecular entity that drives the carcinogenicity of sodium dichromate is the Cr(VI)-containing ion, which is released when sodium dichromate solubilises and dissociates.

Chromium (VI) causes lung tumours in humans and animals by the inhalation route and tumours of the gastrointestinal tract in animals by the oral route. These are both local, site-

of-contact tumours – there is no evidence that Cr(VI) causes tumours elsewhere in the body.

RAC has established a reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev. 1), which was used by the applicant.

Dose-response relationships for these endpoints were derived by linear extrapolation. Extrapolating outside the range of observation inevitably introduces uncertainties. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be overestimated.

In the socio-economic analysis (SEA) the remaining human health risks are evaluated based on the dose-response relationship for carcinogenicity of hexavalent chromium (RAC27/2013/06 Rev.1).

Are all appropriate and relevant endpoints addressed in the application?

All endpoints identified in the Annex XIV entry are addressed in the application.

The current exposure of workers or the exposure of man via environment reported in this application is well below the DNELs for the reproductive toxicity (RAC/35/2015/09) for all exposure routes, therefore the risk of reproductive effects is considered to be adequately controlled.

Such exposures still may cause a risk of lung or intestinal cancer. Taking that into account the assessment of carcinogenic risk shall drive the risk-benefits analyses for authorisation purposes, given that for the estimated exposure levels the reproductive toxicity would not contribute to the total ill-health risk.

4. Exposure assessment. To what extent is the exposure from the use described?

Description:

Short description of the use

Ilario Ormezzano SAI SpA is a downstream user of sodium dichromate, based in Biella, Piemonte, Italy. The use comprises the repackaging of sodium dichromate for further supply as a mordant in the dying of wool as sliver and/or yarn. In response to a request from RAC, the applicant clarified that the maximum amount of sodium dichromate solution handled / stored is 130 tonnes per year.

According to the applicant, sodium dichromate is supplied in an aqueous solution that contains 61% (w/w) anhydrous sodium dichromate by weight (percentage calculated for the anhydrous salt). Anhydrous sodium dichromate contains 39.7% by weight active Cr(VI) and consequently the 61% of the aqueous solution contains 24.2% active Cr(VI) by weight.

The repackaging is performed by the applicant as an importer with the purpose to supply sodium dichromate in manageable quantities (25 kg to two tonnes) to their downstream users, who are textile manufacturers and dyers working in the textile industry sector in Biella area, Italy. These downstream users have contributed to the development of this CSR.

Exposure scenario

The use is described in a single exposure scenario, concerning an industrial use at a single site as follows:

"Repackaging of Sodium dichromate to be supplied as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings".

The exposure scenario is comprised of one Worker Contributing Scenario (WCS) and one Environmental Contributing Scenario (ECS). According to the applicant, the exposure scenario includes all relevant processes and tasks associated with this use of sodium dichromate that could result in either environmental or human exposure. Consumer exposure is not explicitly assessed by the applicant as supply is to downstream users only.

Worker exposure

RAC considers that tasks performed by workers were not sufficiently described by the operational conditions (OCs) and risk management measures (RMMs) outlined in the WCS provided in the CSR.

In an attempt to understand the process, RAC requested additional information from the applicant on two occasions. The applicant also participated in a trialogue meeting with RAC and SEAC rapporteurs.

The applicant was asked to provide clarification in relation to the following areas of their application:

- What was the reason for breaking down the WCS into a single contributing scenario and not splitting into several WCSs (e. g. for "Transportation of the substance, storage of the substance, unloading, etc.")?
- What tasks related specifically to the exposure measurements and model estimates provided?
- Additional details relating to the air monitoring and the biomonitoring data provided in the application (e.g. limit of detection, Time Weighted Average (TWA) calculations, the representativeness of monitoring data).
- What PPE are considered appropriate to each of the different tasks and if clear instructions are available to guarantee appropriate use of PPE?

The applicant did not succeed either through their answers to the written questions or in the trialogue in providing adequate clarifications on all of the above issues. Therefore some uncertainties remain with regard to the exposure assessment.

According to the CSR, there are in total seven trained operators permitted to undertake the truck unloading task and any one of them may act as a responsible operator for the emptying process. However, only one operator and one truck driver (out of a team of four) are involved in an unloading process which takes 120 to 180 minutes. The unloading is carried out five to six times a year. For the repackaging task, also seven workers are foreseen but only one of them performs the task at a time which takes 15 to 90 minutes with a frequency of 80 times a year. The unloading and repackaging occur outdoors.

However, the applicant considered the following number of workers are potentially exposed to sodium dichromate according to information provided on RAC's request: four workers are performing unloading and packaging tasks, three workers are loading the product on the trucks after packaging (logistic/forklift), three workers from the technical area have

free access to the site and therefore they can be exposed to the substance, four truck drivers and two workers are responsible for warehouse and have free access to the site and can also be exposed.

Exposure estimation methodology:

Inhalation exposure:

The inhalation exposure assessment provided by the applicant is principally based on the results of biomonitoring, supported by the results of air monitoring campaigns (personal and static sampling) and exposure modelling data.

The applicant stated that air measurements of Cr(VI) are conducted at the unloading/repackaging area every three years while biomonitoring is done every year. In the most recent sampling campaign performed in 2015, exposure has been measured by one static and two personal samplings (see table 1). However, one personal sample is related to laboratory work, according to the measurement report provided by the applicant at RAC's request. As laboratory work is claimed to fall under the exemption for scientific research and development, RAC notes that one of the results of the measurement campaign performed on 15/10/2015 is not of relevance for the exposure assessment.

For modelling the applicant used MEASE (1.02.01). They considered PROC 8b "Transfer of substance or mixture (charging and discharging) at dedicated facilities". The applicant stated that the results of the air measurements seem to be in line with the modelled result.

Table 1: Workplace exposure measurements results (2015) and modelled data

Method	Exposure value* (µg Cr (VI) / m^3)
Measured data: 1 static measurement	< 0.1
Measured data: 1 personal measurement	< 0.4
Modelled data: MEASE (1.02.01)	< 1 (RPE, APF 10)
	4 *(No RPE used)*

* The values provided are the respective LoD of the sampling method.

The applicant has acknowledged that sampling is the task that is most likely to result in exposure to Cr(VI). However, no further explanation was provided nor any measured or modelled data.

The biomonitoring method for sodium dichromate consisted of measuring chromium in the urine of workers that were potentially exposed to Cr(VI). (The data provided include 34 biomonitoring results from two years, with laboratory technicians included although laboratory work is considered to be exempted). It is not clear how closely the biomonitoring campaigns are related to tasks with potential exposure to Cr(VI), e. g. sampling tasks. Therefore the representativeness of the data provided in relation to the use applied for is not clear as tasks with potential exposure to Cr(VI) are not performed every day. So it is possible that the workers were not performing any tasks with potential exposure to Cr(VI) for several days before the biomonitoring campaign.

Table 2: Biomonitoring results of chromium in urine (µg chromium/Litre, creatinine corrected) from 2014

Packaging/filling/ Logistic/Forklift	Technical area	Forklift / truck drivers	Warehouse responsible	Laboratory* technicians
0.20	0.11	0.27	0.18	0.08
0.64		0.22		0.15
0.07		0.14		<0.01
< 0.01		0.08		
0.17				
0.60				
0.16				
0.05				

* Laboratory work is considered to be exempted.

Table 3: Biomonitoring results of chromium in urine (µg chromium/Litre, creatinine corrected) from 2015

Packaging/filling	Logistics/forklift drivers	Technical area	Truck drivers	Warehouse responsible	Laboratory* technicians
0.20	0.13	0.85	0.22	0.07	0.21
0.27	0.14	0.45	0.57	0.02	<0.01
0.09	0.16	0.04	0.10		
			0.03		

* Laboratory work is considered to be exempted.

The results of the biomonitoring data show that two values are above the background value for chromium in the general population (0.6 µg/L), based on the German "MAK-BAT-Werte-Liste 2016". One value is relatively close to 0.6 µg/L. All values are below the reference level derived by the UK Health and Safety Executive - HSE of 2 µmol/mol creatinine, which is equivalent to 1 µg/L chromium.

For the inhalation exposure assessment, the applicant converted the biomonitoring results (total Cr) into workplace air concentrations assuming that only Cr(VI) would be relevant to such exposures. They used the method proposed by the HSE based on a correlation between an air concentration of 50 µg Cr(VI)/m^3 and an urine level of 40 µmol chromium/mol creatinine (20 µg Cr/L) and assumed linearity. Based on this conversion the

maximum exposure value was estimated to be 2.1 µg Cr(VI)/m^3 and the 90th percentile was 1.25 µg Cr(VI)/m^3. The 90th percentile was used for risk characterisation.

Dermal exposure:

Dermal exposure was modelled by using MEASE (1.02.01). MEASE is nominated as a first tier assessment tool for occupational exposure for metals and inorganic substances in the ECHA Guidance. Applying PROC 8b to the model results in a dermal exposure of 14 µg Cr (VI)/day. Since sodium dichromate is used as an aqueous solution of 61 % and there is no regular contact to the substance as such, it is unlikely that dermal exposure would exceed the agreed workers' DNEL for the dermal route of exposure. This is supported by the estimated inhalation exposure level (90th percentile) of 1.25 µg Cr(VI)/m^3 (TWA, 8 h) which includes all routes of exposure as it is converted from biomonitoring results. Therefore RAC agrees with the applicant that this value is well below the agreed reproductive DNEL for workers exposed via inhalation (RAC/35/2015/09).

Combined exposure:

If workers at the site perform different tasks with potential exposure to Cr(VI), this would lead to aggregated / combined exposure. As biomonitoring data were considered as the basis for exposure assessment, the results would show values of aggregated exposure, including all routes of exposure. However, the representativeness of these data is not clear due to lack of contextual information on the biomonitoring data.

Uncertainties related to the exposure assessment:

The exposure assessment provided by the applicant is principally based on biomonitoring data. There are some uncertainties in this assessment as it is not clear from the dataset provided how closely the biomonitoring campaigns are related to tasks with potential exposure to Cr(VI). However, the uncertainties can be considered minor as the overall picture shows that most of the chromium levels in the urine are at similar levels to background chromium levels in the general population.

RAC notes that the applicant also provided measured and modelled data for inhalation exposure to support the exposure assessment. RAC notes that only two measurements were provided, one static (over 2.5 hours) and one personal sampling (over 3.5 hours), with overlapping sampling time. Due to the lack of contextual information on the tasks conducted during the measurements campaigns, there are some uncertainties related to these data. Not all of the relevant tasks and conditions that can result in exposure to Cr(VI) might be performed during the measurement campaigns. However, RAC notes that the measured air concentrations were below the LoD (< 0.1 µg Cr (VI)/m^3 for static sampling and < 0.4 µg C (VI) /m^3 for personal sampling) and well below the exposure estimate (1.25 µg Cr(VI)/m^3) taken forward for risk characterisation.

The modelled data for PROC 8b are in the same order of magnitude as the exposure estimates obtained by converting the biomonitoring results to air concentrations (TWA, 8 h). RAC notes, that there are some uncertainties as according to the CSR also PROC 28 (manual maintenance of machinery) is relevant for the use applied for but no modelled data were provided for this PROC. Therefore the modelled data may lack representativeness. In addition, the RPE in one modelled exposure estimate is considered with an assigned protection factor (APF) of 10. RAC, however, notes that a half mask with a ABEK1 cartridge does not provide protection for Cr(VI) exposure, as for exposure to this type of substance only particle filters are suitable.

Environmental releases / Indirect exposure to general population (humans via the environment)

The applicant considered that "Formulation" (ERC 2), is the most appropriate Environmental Contributing Scenario for this use.

The applicant stated that transportation and storage of concentrated sodium dichromate solution is well controlled and that only very limited releases to the environment should occur.

Estimation of releases

Releases to water

The applicant stated that the on-site WWTP collects the wastewater (including rainwater and spillages from the terminal pavement areas) from three separate sewer lines in a collection tank. After neutralisation, flocculation, sedimentation and separation of any further precipitates by passing a filter press, the treated wastewater is collected in a storage tank with a volume of 25 m^3. This tank is regularly emptied in a batch process to an external STP without carrying out lab analysis for each batch. After subsequent treatment the wastewater is discharged to the Cervo river.

The applicant stated that the Ilario Ormezzano SAI SpA has been able to operate within the concentration limits established by the municipal wastewater treatment works (total chromium < 4 mg/L; Cr(VI) <0.02 mg/L). On RAC's request, the applicant provided the results of two analyses of the concentration of Cr(VI) in wastewater after the on-site WWTP from 15 January and 20 May 2015. In both of them neither Cr(VI) nor total chromium were detectable (LOD = 0.02 mg/L).

Release to air

Regarding emissions to air, the applicant described that potential emission sources to air are tank losses from displacement during filling, equipment leaks from pump and valve seals, connectors and other piping items and fugitive emissions of IBC during ambient temperature changes. However, as the intrinsic tendency of sodium dichromate to evaporate is very low, it was presumed by the applicant that most of these diffuse emissions would enter wastewater rather than air.

The applicant clarified that gaseous releases from the storage tanks, due to ambient temperature changes, are treated in an on line connected scrubber with an efficiency of > 99%.

The scrubber outlet stack emission concentration of total chromium was measured to be < 0.1 µg/m^3. Only one set of measurements (LoD 0.1 µg/m^3) was performed to guarantee the proper function of the scrubber after its installation. Additionally, the applicant measured the concentration of total chromium in ambient air at the unloading platform by static sampling and obtained the result of < 0.1 µg/m^3.

Release to soil

According to the applicant, the amount of Cr(VI) containing waste in loading / unloading and storage operation is low as normally no package waste is generated since all IBC are reusable. There is also no need to wash the IBS and the smaller drums before refilling. Additionally, the applicant mentioned that there is no maintenance of the IBC containers since in case of damage they are disposed of rather than repaired (after washing them with sodium bisulphite solution and soda solution).

Regarding waste management, the applicant claimed that waste e.g. sludge obtained by wastewater treatment (< 10-40 tonnes) and contaminated material like PPE is handled according to national/Local legislation and sent off-site for disposal. Therefore releases to soil are considered to be negligible by the applicant.

Table 4: Releases to the environment

Release	Release rate	Release per year	Release estimation method and details
Water	Initial release factor: 2% Final release factor: 0.18% Local release rates: 0.1 kg/day total chromium	0.182 kg Cr(VI) 36.5 kg total chromium	Release calculated based on wastewater flow rates and total chromium permission limits in the effluents.
Air	Initial release factor: 2.5% Final release factor: < 0.03% Local release rate: 0.016 kg/day	< 5.84 kg total chromium	Final release factor calculated on basis of the efficiency of the scrubber.
Soil	0	0	0

Exposure estimation methodology:

The applicant only provided an assessment of indirect exposure to humans via the environment at a local scale based on modelling.

Table 5: Summary of indirect exposure to humans via the environment

Protection target	Exposure estimate, local scale
Man via Environment – Inhalation (µg/m^3)	2.0×10^{-3} (100 m from source) 0.54×10^{-3} (500 m from source)*
Man via Environment – Oral (µg/kg/bw/day)	8.6×10^{-3}

The applicant considered the inhalation and oral exposure route for exposure of general population. Exposure via the oral route was estimated using EUSES 2.1.2 and takes into account exposure from fish consumption, but not drinking water or other food. This was on the basis that drinking water for the local community was not obtained from a source affected by the site and that Cr(VI) transforms rapidly in the terrestrial environment to Cr(III). For refinement of inhalation exposure, the applicant used the simplified Gaussian Plume model (GPM tool, Arche Consulting) to predict inhalation exposure 500 metres* from the site boundary, rather than the default 100 metres.

RAC acknowledges the applicant's method to refine the default release factors of ERC 2 by using information on measured concentrations in effluents, discharge flow rates (water) and efficiency of the scrubber (air). The final release factors used by the applicant are lower than the initial default values for ERC 2.

Uncertainties related to the assessment of exposure to humans via the environment:

RAC acknowledges that assessment of indirect exposure to humans via the environment using default assumptions via EUSES is conservative, particularly at the local scale and could lead to an overestimation of risk (and number of statistical cancer cases).

RAC notes that the applicant made site-specific refinements to ERC default release factors to water and air based on measured data on releases / flow (wastewater) and the efficiency of the air scrubber system (> 99%), respectively. RAC also notes the applicant's refinements to the assessment of indirect exposure through the use of a simplified Gaussian plume model to model inhalation 500 metres from the site and refinements to the oral route of exposure that take into account the transformation behaviour of Cr(VI) to Cr(III) once released into the environment. However, as the applicant used the permission limit value for total chromium for calculating the release rate to wastewater (instead of measured releases), the obtained release rate might still be overestimated. What is more, RAC acknowledges that releases to wastewater will not occur in the extent considered by the applicant as the use applied for is related to loading and unloading tasks. These tasks should not lead to a regular release of Cr(VI) to water. Although some spills may occur during filling or due to leakages, no regular discharges are assumed to take place.

Conclusion

RAC considers that for both worker exposure and human exposure via the environment:

- The description of use allows to draw conclusions related to exposure situations.
- The methodology used and the information provided, related to exposure resulting from the use applied for, is considered to be sufficient for risk characterisation.
- Concerning workers' exposure via inhalation, there are some uncertainties as it remains unclear how closely the biomonitoring campaigns are related to the specific tasks with potential exposure to Cr(VI). However, as the biomonitoring based exposure estimate taken forward for risk characterisation is supported by two air measurements (one personal and one static sampling), the uncertainties are considered to be minor.
- Releases to the environment may be overestimated, particularly those to wastewater.

Overall, the uncertainties identified are considered to be minor and do not invalidate the applicant's exposure assessment.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

☒ NOT RELEVANT, NON THRESHOLD SUBSTANCE

Justification:

6. If adequate control is not demonstrated, are the operational conditions and risk management measures described in the application appropriate and effective in limiting the risk?

☐ YES

☒ NO

Evaluation of the Risk Management Measures

According to the applicant, exposure is controlled and minimised by technical and organisational risk management measures (RMMs).

Unloading operations are performed in a dedicated area. According to information in the CSR, the two fixed roof steel tanks are situated on a containment basis. Any gaseous releases from the storage tanks, due to ambient temperature changes, are treated in an online connected scrubber with an efficiency of > 99%.

Wastewater (including rainwater and spillages from the terminal pavement areas) are treated in on-site abiotic batch type WWTP.

The storage tank installation and its components as well as containers, piping, fittings, joint sealing, pumps, safety devices (e.g. leak indicators, overfill prevention devices, containment areas) and precautionary technical measures (e.g. sealed surfaces in the unloading/refilling area) are regularly checked.

Operating instructions and checking rules including service warnings, alarms and action plans as well as appropriate auxiliaries for incidents or accidents causing damage are kept up to date.

Operating and safety instructions as well as training of employees on how to safely work with sodium dichromate, including how to use the necessary PPE are implemented.

However, RAC notes uncertainties with regard to the RPE used as the applicant refers to half mask with single ABEK1 cartridges for repackaging of sodium dichromate whereas this type of cartridges might not be sufficiently protective for inhalable Cr(VI) particles due to the lack of particles filters.

Risk characterisation

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).

Worker

Based on exposure for 40 years (8 hours/day, 5 days/week), the excess lifetime lung cancer mortality risk according to the RAC reference dose response relationship is 4×10^{-3} per µg Cr(VI)/m^3.

The inhalation exposure assessment was based on biomonitoring data which were converted to air concentration values. The 90th percentile of the dataset (n=34) was used for risk characterisation by the applicant. This approach was supported by a small number of air measurements (one personal and one static sample).

Table 6: Excess risk estimates for 40 years exposure for workers calculated by the applicant

Route	Exposure value, TWA 8 h (µg/m^3)	Excess lung cancer risk
Inhalation	1.25 (90th percentile)	**5×10^{-3}**

RAC accepts the methodology used by the applicant for the estimation of exposure and excess cancer risks.

Indirect exposure to humans via the environment

Based on exposure for 70 years (24 hours/day, 7 days/week), the excess lifetime lung cancer mortality risk according to the RAC reference dose response relationship is 2.9×10^{-2} per µg Cr(VI)/m^3 and the excess lifetime intestinal cancer risk is 8×10^{-4} per µg Cr(VI)/kg bw/day.

The applicant provided the assessment of indirect exposure to humans via the environment at the local and regional exposure scale based on EUSES and simplified Gaussian plume modelling.

Table 7: Excess risk estimates for humans via the environment calculated by the applicant

Protection target and units	Local scale	
	Exposure estimate	**Excess cancer risk**
Humans via Environment – Inhalation (µg/m^3)	5.4×10^{-4} (500 m from source)*	1.5×10^{-5} (lung cancer)
Humans via Environment – Oral (µg/kg/bw/day)	8.6×10^{-3}	6.9×10^{-6} (intestinal cancer)

* For refinement of inhalation exposure, the applicant used the simplified Gaussian plume model (GPM tool, Arche Consulting) to predict inhalation exposure 500 metres from the site boundary, rather than the default 100 metres which would result in an exposure estimate of 2.0×10^{-3} µg/m^3.

As discussed in section 4, RAC considers this approach to be acceptable.

RAC notes that the applicant also reported regional exposure, however, as Cr(VI) is effectively reduced to Cr(III) in the environment, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be very relevant.

Conclusion

- RAC is of the opinion that the RMMs and OCs are not appropriate in limiting the risks to workers due to uncertainties related to the use of adequate RPE. RAC finds the RMMs and OCs are appropriate in limiting the risk to the general population.
- RAC considers the methodology used for cancer risk calculation to be appropriate and that the estimates of excess cancer risk for workers and for indirect exposure to humans via the environment are suitable for health impact assessment.
- RAC notes that not considering the regional scale for the exposure assessment for humans via the environment is appropriate in this case.

7. Justification of the suitability and availability of alternatives

7.1 To what extent is the technical and economic feasibility of alternatives described and compared with the Annex XIV substance?

Description:

Summary of the analysis of alternatives undertaken by the applicant

Sodium dichromate is used as a mordant in the dyeing of wool. By acting as a bridge between the wool and the dye, chromium affords the coloured textile with a high colour fastness. At the moment alternatives have been found for the lighter colours, but not for

the classical dark colours which are covered by this application (e.g. black, navy blue, brown).

Use 1 covers the repackaging of sodium dichromate for the sole purpose of supplying manageable quantities to its downstream users. For this use, 130 tonnes per annum of sodium dichromate are used. At the repackaging stage, sodium dichromate has no (separate) function, hence no analysis of alternatives was performed for the Use 1 by the applicant. An analysis of alternatives has been performed for the subsequent use 2 of this application for authorisation. For use 1 no alternatives have been identified.

Technical feasibility

Not applicable.

Economic feasibility

Not applicable.

Conclusion

See summary above.

7.2 Are the alternatives technically and economically feasible before the sunset date?

☐ YES

☒ NO

Justification:

Not applicable.

Conclusion

At the formulation stage, sodium dichromate has no (separate) function, hence no analysis of alternatives was performed by the applicant for use 1. An analysis of alternatives has been performed for the subsequent use 2 of this application for authorisation.

7.3 To what extent are the risks of alternatives described and compared with the Annex XIV substance?

Description:

Sodium dichromate does not have an independent function in relation to the use described in this application for authorisation and an analysis of alternatives and their risk reduction potential has not been performed and is considered not applicable.

7.4 Would the available information on alternatives appear to suggest that substitution with alternatives would lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

Conclusion

Sodium dichromate does not have an independent function in relation to the use described in this application for authorisation and an analysis of alternatives and their risk reduction potential has not been performed and is considered not applicable.

8. For non-threshold substances, or if adequate control was not demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT, THRESHOLD SUBSTANCE

Justification:

The applicant evaluates one potential non-use scenario and provides evidence that the benefits of continued use outweigh the associated risk.

Additional statistical cancer cases estimated by RAC

The estimated number of additional statistical cancer cases has been calculated using the excess risk value presented in section 6 and the estimation of the number of exposed people as 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 entire life for general population (70 years).

Table 8: Estimated additional statistical cancer cases for workers directly exposed (40 years of exposure)

WCS	Number of workers performing the activity	Excess cancer risk	Estimated statistical cancer cases
WCS 1	16*	5×10^{-3}	8×10^{-2}

* After the trialogue, the applicant clarified in writing that 16 workers are potentially exposed to Cr(VI) with the exemption of laboratory workers.

For the general population, the applicant considered only exposure at the local scale. They state that regional exposure is not relevant given that Cr(VI) is effectively reduced to Cr(III) in the environment.

Table 9: Estimated additional statistical cancer cases for general population, for the requested review period (70 years)

Protection target	Number of people exposed	Excess cancer risk	Estimated statistical cancer cases
Man via Environment – Inhalation	1,000	1.5×10^{-5} (lung cancer)	1.5×10^{-2} (lung cancer)
Man via Environment – Oral	1,000	6.9×10^{-6} (intestinal cancer)	6.9×10^{-3} (intestinal cancer)
Man via Environment – Combined		2.2×10^{-5}	2.2×10^{-2}

RAC notes that the estimated cancer cases for 70 years exposure might be overestimated as the calculations are based on the population density per km^2 of the city of Biella instead of considering the people living at a local scale of 1 km^2.

Assessment of Impacts

The assessment of impacts which has been undertaken by the applicant includes a quantitative monetary assessment of the societal impacts associated with the non-use scenario (i.e. assuming authorisation is not granted).

The assessment of impacts is based on impacts occurring within the EU and which are incremental to the baseline situation; these impacts being defined in terms of a non-use scenario in which the applicant would no longer supply sodium dichromate to its downstream users for the use applied for. The applicant would cease trading in this chemical.

Costs of continued use (risks)

The applicant carried out a quantitative human health impact assessment based on the estimated excess cancer risk of workers from the exposure to Cr(VI) from the use of sodium dichromate. Lung cancer has been identified as the main health endpoint associated with exposure to Cr(VI).

Exposure values were calculated based on the use of 130 tonnes/year of sodium dichromate.

The dose-response relationship published by ECHA was used in the applicant's assessment, assuming workers are exposed during 8 hours per working day over a work life of 40 years.

SEAC concurs with the approach followed and the values used.

The applicant adjusted the resulting risks to reflect the 7-year review period requested and thereby produced estimates of 7.6×10^{-3} additional statistical cancer cases among on-site workers.

Using the values derived from “Valuing Selected Health Impact of Chemicals: Summary of the Results and a Critical Review of the ECHA Study” (ECHA, February 2016), the applicant

used both lower and upper bounds of a value per fatal lung cancer cost (2.2 and 3.6 million EUR, respectively). The average mortality rate for lung cancer was presumed to be 80%. Morbidity risks were evaluated.

Based on the above values, the applicant monetised the health impacts over a 7-year period (ignoring latency periods) and arrived at a value of €16,844 to €27,563 for on-site workers.

At the request of RAC, the applicant provided additional information regarding the number of workers potentially exposed to sodium dichromate (16 workers against 7 workers initially reported). RAC recalculated the estimated statistical cancer cases for lifetime exposure (40 years for workers and 70 years for the general population) as shown in tables 8 and 9 above. Based on these figures, SEAC estimates the number of additional statistical cancer cases to be 1.62×10^{-2} for a 7-year review period resulting in a total human health cost of €29 thousand (lower bound value) to €47 thousand (upper bound value) calculated for a 7-year period.

Benefits of continued use (cost of non-use scenario)

The applicant evaluated a potential non-use scenario (NUS) whereby the applicant would no longer supply sodium dichromate to its downstream users. SEAC finds it credible since no drop-in alternative will be available at the sunset date.

The applicant identified one possible economic impact related to a loss of sales and profits. The applicant identifies that sodium dichromate accounts for 0.3% of the business and not granting authorisation would decrease sales by €0.19 million per annum. Data on exact profits is claimed to be confidential, but the values provided by the applicant during the trialogue allowed SEAC to assess welfare effects (lost profits of the applicant).

It should be emphasized that the assessment by the applicant does neither attempt to include the potential loss of profits incurred by the applicants' and its downstream users' customers and suppliers, nor other wider economic impacts, particularly those that are related to clothing manufacturers and fashion houses.

Conclusion

The applicant's analysis of the benefits of continued use (i.e. the costs of non-use) is based on the lost sales and profits of the applicant.

The monetised health impacts calculated by the applicant amounts to €16,844 to €27,563. SEAC recalculated this figure using the excess cancer risk levels estimated by RAC and arrived at a total human health cost of €29 thousand (lower bound value) to €47 thousand (upper bound value) calculated for a 7-year period.

SEAC calculated the lost profits using data provided by the applicant and industry averages. Although the exact figures are confidential, they are above the monetised health impacts as estimated by SEAC.

Additionally, it shall be noted that:

- interruption of sales of sodium dichromate to the downstream users (Use 2) will produce an economic loss in the range of €42 to €72 million;
- the potential economic loss for the Italian textile/clothing sector was not monetised by the applicant although it is clear that the sector may face risks that may lead to significant economic loss.

SEAC considers that the implied benefit-cost ratio of more than 1 demonstrates that the benefits outweigh the risks of continued use.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

Description for additional conditions and monitoring arrangements for the authorisation:

Following a review of the selection of the most appropriate RMMs, in accordance with the hierarchy of control, and where it is concluded that RPE is also needed, the applicant must evaluate which tasks require the use of RPE and ensure that appropriate RPE is selected to provide adequate protection for all of the different possible exposure situations to sodium dichromate

Description of conditions and monitoring arrangements for review reports:

The applicant must continue to implement regular campaigns of occupational exposure measurements relating to the use of sodium dichromate described in this application. These monitoring campaigns must be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit. They shall comprise personal inhalation exposure sampling and be representative of the range of tasks with possible exposure to Cr(VI) and of the total number of workers that are potentially exposed. Besides, future campaigns should include sufficient contextual information about the tasks with possible exposure to Cr(VI). The results of the monitoring must be included in any subsequent authorisation review report submitted.

The applicant should provide an analysis of the biomonitoring data with sufficient contextual information on the sampling time related to shifts, the tasks performed and PPE worn.

Emissions of Cr(VI) to air and wastewater shall be subject to regular measurements with the results of monitoring made available to enforcement bodies on request. Measurement campaigns shall be undertaken according to standard sampling and analytical methods, where appropriate. Emissions data shall be presented in any subsequent review report.

The information gathered in the monitoring campaigns shall be used by the applicant to review the risk management measures (RMMs) and operational conditions (OCs) to further reduce workers' exposure to Cr(VI) and emissions to environment.

The results of the monitoring and of the review of the OCs and RMMs must be retained, be made available to national enforcement authorities on request and included in any subsequent review report submitted.

Justification:

There are uncertainties as to whether the RPE is sufficient to provide protection for all potential exposure situations.

RAC considers that measured data (air monitoring / biomonitoring) should be presented with sufficient contextual information to enable an adequate interpretation / evaluation of the dataset. The applicant provided results of air measurements for worker inhalation exposure to corroborate the biomonitoring data. However, both datasets (biomonitoring data, air monitoring data) are of limited merit due to the lack of contextual information.

An authorisation of a non-threshold carcinogenic substance should be based on a robust and well justified exposure and emissions assessment. In the present case, the recommended monitoring arrangements for workers' exposure and release to the environment as well as more detailed contextual information on the measured (air monitoring and biomonitoring) data provided would address the uncertainties in the exposure/emission assessment.

10. Proposed review period:

☒ Normal (7 years)

☐ Long (12 years)

☐ Short (4 years)

☐ Other:

Justification:

In identifying the review period SEAC took note of the following considerations:

RAC's advice:

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

Other socio economic considerations

The applicant considers that their analysis of alternatives provides sufficient justification for a review period of 7 years, which would allow them to find a suitable replacement for sodium dichromate and to prove its industrial viability. It would also provide enough time for the downstream users of the applicant to adapt their facilities.

In identifying the proposed review period SEAC took note of the following considerations:

- As described above, chromium trioxide has no function at the repackaging stage and no analysis of alternatives was performed by the applicant for this use. An analysis of alternatives has been performed for the subsequent use 2 of this application for authorisation. For use 1 no alternatives have been identified;
- In this case use 1 and 2 are inextricably linked. Use 1 is repackaging with the express purpose of performing use 2. The review period for use 1 should therefore be the same as that decided for use 2;

- The benefits of continued use outweigh the risks by more than a factor of 1.

Based on the above considerations, SEAC recommends a 7-year review period.

11. Did the Applicant provide comments to the draft final opinion?

☐ YES

☒ NO

11a. Action/s taken resulting from the analysis of the Applicant's comments:

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

Reasons for introducing the changes

Changes made to the opinion OR Reasons for not amending the opinion