Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

sodium dichromate use: Use of sodium dichromate as mordant in wool dyeing

ECHA/RAC/SEAC: AFA-O-0000006640-78-01/D

Consolidated version

Date: 07/07/2017

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:

Use of Sodium dichromate as mordant in wool dyeing

Intrinsic property referred to in Annex XIV:

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

Applicant:

Gruppo Colle s.r.l.

Reference number:

11-2120224482-64-0000

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 **27/10/2016 Gruppo Colle s.r.l.** submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **10/02/2017** 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 **08/02/2017**. Interested parties were invited to submit comments and contributions by **05/04/2017**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicant.

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 **07/07/2017**.

On **07/07/2017** 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 **07/07/2017**.

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 **09/06/2017**.

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 **07/07/2017**.

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 **15/06/2017**.

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 **07/07/2017**.

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, the information submitted by interested third parties, 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 limit the risk, provided that they are adhered to along with the suggested conditions and monitoring arrangements.

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, the information submitted by interested third parties, 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:

The authorisation should be restricted to dark colours only. The use applied for should therefore be amended as follows:

Use of Sodium dichromate as mordant in wool dyeing with dark colours

Description of conditions and monitoring arrangements for review reports:

The applicant must continue to implement regular programmes of occupational exposure measurements relating to the use of sodium dichromate described in this application. These monitoring programmes 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, the future programme 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 analyses of the biomonitoring data with sufficient contextual information on the sampling time related to shifts, the tasks performed and PPE worn.

The monitoring information so gathered 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.

Any review report have to include detailed and clear information related to the use of sodium dichromate. All tasks with potential exposure have to be described and connected with the respective WCS.

Emissions of Cr(VI) to wastewater must be subject to regular measurements, including sufficient contextual information (e.g. on the amount of sodium dichromate used related to the measurement), with the results of monitoring made available to enforcement bodies on request. The measurement programme shall be undertaken according to standard sampling and analytical methods and ensure a sufficiently low detection limit, where appropriate. Emissions data shall be presented in any subsequent review report.

REVIEW

Taking into account the information provided in the application for authorisation prepared by the applicant and the comments received on the broad information on use 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).

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

This application for authorisation relates to the use of sodium dichromate as a mordant in the dyeing of wool or other animal hair. The function of sodium dichromate is to fix dyes on fabrics by forming a coordination complex with the dye which then attaches to the fabric.

The tasks are conducted at the site of Gruppo Colle s.r.l. in Cantagallo, in the Province of Prato and in a second plant, named Color Fibre s.r.l., located in Agliana, in the Province of Pistoia. The applicant Gruppo Colle claimed that both sites apply exactly the same procedures and even though the Color Fibre plant (30 employees) is much smaller than the Gruppo Colle one (106 employees), the Exposure Scenario described for the latter is also considered to be representative for the Color Fibre plant.

Sodium dichromate is supplied in an aqueous solution (46% water) in 1,000 L tanks. The yearly consumption of sodium dichromate at both sites is < 50 tonnes of solution (4/5 of the tonnage is used at Cantagallo, 1/5 at Agliana). According to the applicant, the risk assessment is based on a worst case consumption of sodium dichromate to definitely cover both sites and to cover eventually higher consumptions in the next years due to increasing demands. According to the applicant, higher requests of the market might occur as the other companies in the Tuscany district actually using sodium dichromate will stop

the use of that substance.

During the trialogue, the applicant clarified that the dyeing process is a closed batch process at both sites. At the Gruppo Colle site, there are 59 dyeing vessels, at the Color Fibre site, there are 15. At both sites, the dichromate dosing occurs by using an automated closed chemical dosing system whereas dyes might be handled manually. However, it was confirmed by the applicant that during the dyeing process, the dyeing vessels are not opened routinely before Cr(VI) is consumed by a reducing agent (e.g. sodium metabisulphite, sodium hydrosulphite).

The dyeing phase lasts approximately 45 min at temperatures of about 70 °C to 98 °C and at pressures from 0.8 to 2 atm (81.1 to 202.7 kPa). It is followed by two washes of 15 min. Once out of the dyeing vessels, the material undergoes a preliminary centrifugation, followed by the application of warm air or radiofrequencies.

In the dyeing process, the acid dyes react with the woollen fibres forming an ionic bond with the wool protein keratin. Sodium dichromate is introduced as a mordant in the form of the dichromate anion. After binding ionically to the amino groups of the wool it reacts with amino acids within the wool which immediately reduces Cr(VI) to Cr(III) and forms an organometallic wool-Cr(III)-dye complex. However, according to the applicant, the precise chemical process has not yet been fully understood.

Nevertheless the applicant assured RAC that sodium dichromate is completely consumed under normal reaction conditions and any unreacted Cr(VI) is reduced to Cr(III) by adding a reducing agent to the dyeing vessel after finishing the dyeing process. Consequently, exposure of further downstream users and consumers has not been considered relevant by the applicant. This is underpinned by the applicant's explanation on RAC's request that the content of total chromium in their products is identified with a limit of detection (LoD) of 0.1 mg/kg according to the standard norm EN 16711-2:2015-11-30. The highest measured level on total chromium out of five measurements from April to July 2016 was 1.32 mg/kg.

Exposure scenario

The use is described in a single exposure scenario, concerning the industrial use of sodium dichromate at two sites and identified as follows:

"Use of Sodium Dichromate as mordant in wool dyeing"

The exposure scenario is comprised of two Worker Contributing Scenarios (WCS) and one Environmental Contributing Scenario (ECS).

Worker exposure

In their initial evaluation of the application, RAC considered that the workers' tasks, the corresponding operational conditions (OCs) and risk management measures (RMMs) were not sufficiently described in the CSR.

The applicant was asked to provide clarification in relation to a number of areas of their application, including the number of sites and representativeness of data, the task descriptions and basis for the exposure assessment, the risk management measures in place, contextual information related to the monitoring data, environmental monitoring and assessment (including humans via the environment), wastewater treatment and contaminated waste handling. Only after two rounds of questions and the trialogue (25/04/2017) were these questions partially answered. Contextual information about

tasks being performed during monitoring/sampling, for example, remained lacking.

Table 1: Summary of WCS/PROCs, technical RMMs, personal protective equipment (PPE) as well as duration and frequency of tasks

WCS / PROC	Technical RMMs	PPE*	Duration / frequency of tasks
WCS 1 / PROC 8b Dosing of the aqueous solution into the dyeing reaction vessel	Closed process. Mechanical ventilation: Six fans, each with an indicated air flow of 16,000 m^3 at Cantagallo, two fans of the same model (with the same capacity) at Agliana.	In case of potential exposure to sodium dichromate (e.g. connection of the sodium dichromate tank to the pipeline): Chemically resistant gloves made of PVC or nitrile (effectiveness of 95%), FFP3 facial masks (effectiveness of 95%), goggles, tyvet suit.	Duration: < 15 minutes per day; Frequency: 22 to 25 days / year
WCS 2 / PROC 13 Use as mordant in wool dyeing			Duration: < 4 hours per day; Frequency: 22 to 25 days / year;

* The applicant clarified on RAC's request that during the dyeing step no exposure is expected, so no PPE has to be worn.

The applicant did not present any WCS for the transportation of the tanks to the storage place after receiving them from the supplier as they do not expect any exposure for the workers performing this task.

There is no WCS provided for tasks where potential exposure to sodium dichromate might arise (e.g. the connection of the sodium dichromate tanks to the dosing system). The applicant simply indicated that "specific connectors are placed". However, they stated that an authorised, specifically trained worker is performing this task. Besides they pointed out that for tasks with potential exposure to Cr(VI) PPE as presented in Table 1 has to be used.

On RAC's request, the applicant explained that they did not provide any WCS for cleaning and maintenance either, as the tasks are not performed regularly. In addition, the applicant recapped in this context during the trialogue that in order to prevent any potential Cr(VI) residual in the vessel, every bath is neutralised after each batch with a reduction agent. Besides, the applicant pointed out that usually the batches are organised from light to dark colours in order to avoid any cleaning. However, if cleaning is needed this is done with bleaching agents like sodium hypochlorite.

In the answer to RAC's request for further information, the applicant confirmed that laboratory work is exempted from the application. However, they stated that the analytical activities are carried out under controlled conditions.

In their written answer subsequent to the trialogue, the applicant clarified that five workers at Gruppo Colle, and three workers at Color Fibre, are involved in tasks with potential exposure to sodium dichromate. For the risk characterisation, another worker, a mechanic, was also considered to be exposed.

Exposure estimation methodology:

Inhalation exposure:

The applicant's inhalation exposure assessment is based on the results of a static air monitoring programme and modelled data. Biomonitoring data were provided on RAC's

request.

According to the CSR and to information for clarification sent in response to a query from RAC, the exposure assessment of WCS 1 and WCS 2 was based on a single Cr(VI) workplace concentration measurement performed on 30 January 2015 over two hours in the working area of the process hall, between the reaction vessels at a height of 160 cm. The result of this measurement was below the LoD, indicated as 0.18 µg Cr(VI) per sample. Based on the collected volume of 0.420 m^3, the LoD of Cr(VI) for this measurement was calculated to be 0.428 µg Cr(VI)/m^3. This value was taken forward for the risk characterisation.

On RAC`s request for historical data, the applicant provided three further results of static measurements in the workplace air (two reports from the site in Cantagallo and one from the site in Agliana (report, 2011)). The measurements were performed on 7 November 2007 (use of about 11 kg of sodium dichromate in solution in the reactor vessel close to the measurement device) over 2 hours and 40 minutes, on 6 April 2011 (use of an eight litres solution of sodium dichromate) over 3 hours and 5 minutes and on 13 March 2017, over 2 hours and also near the reactor vessel. All of the results were below the respective LoD (< 0.24 µg Cr(VI)/m^3, < 0.31 µg/m^3, < 0.2 µg Cr(VI)/m^3). However, RAC notes that in general, the measurement reports suffer from lack of information (e.g. on the tasks performed during monitoring).

Additionally, ECETOC TRA (version 3.0) modelling was performed by the applicant applying PROC 8b for WCS 1 and PROC 13 for WCS 2. Although the applicant stated that PPE is only worn in cases where potential exposure to Cr(VI) might be expected (e.g. the connection of sodium dichromate tank to the pipeline), RPE with an effectiveness of 95% was used as an input parameter for both WCS. The other input data (e.g. duration of activity, concentration of substance in the mixture, air exchange rate) seem to be reliable.

Table 2: Exposure data (air monitoring and modelled data)

WCS	Measured data	Exposure value*, µg/m^3	Modelled data	Exposure value, µg/m^3
WCS 1 / PROC 8b	Static sampling	0.428	ECETOC TRA	2.5×10^{-5}
WCS 2 / PROC 13	Static sampling	0.428	ECETOC TRA	1.8×10^{-4}

* The value provided is the LoD of the method (see text above).

After being requested by RAC, the applicant provided biomonitoring data of total chromium in urine and in blood (plasma) from 11 workers[1] collected from 2014 to 2016 (> 30 results (7 of them from Color Fibre)). These data do not contradict the applicant's

[1] In the written answer subsequent to the trialogue, the applicant stated that also two workers weighing pre-metalized dyes are examined by biomonitoring. It is pointed out that these two workers are not exposed to sodium dichromate.

exposure assessment as such because more than 80% of the results were in the range of the background value for chromium in the general population. However, the proportion on higher chromium levels in the urine of workers compared to chromium levels in the urine of the general population is higher for the site at Agliana than it is for the site at Cantagallo. During the trialogue, the applicant confirmed that at Agliana, there was a need to improve the workers' compliance to follow the health and safety instructions in the past (last two years). Workers did not use PPE adequately for tasks with potential exposure to sodium dichromate respectively workers did not perform their tasks in the way they were instructed (e.g. connection of the sodium dichromate tank to the pipeline). In the written response subsequent to the trialogue, the applicant stated that due to this fact of non-compliance, further training on chemical substances and the use of PPE was organised and further monitoring of the workers behaviour was implemented.

Dermal exposure:

Dermal exposure was modelled by using MEASE (version 1.02.01) which is nominated as a first tier assessment tool for occupational exposure for metals and inorganic substances in the ECHA Guidance. The data were provided on RAC's request.

However, the applicant claimed that the modelled result (0.062 µg/kg bw/day) should be considered as an unrealistic worst case estimate as all operations are performed in automatic systems, without any manual intervention (e.g. no manual handling of the substance, no manual monitoring).

Combined exposure:

According to the applicant, worker exposure for WCS 1 and WCS 2 cannot be separated since the activities related to both WCS are performed within the same area, by the same workers under the same operating conditions. Therefore they claimed that the exposure assessment provided is also representative for combined exposure.

Uncertainties related to the exposure assessment:

The exposure assessment provided by the applicant is principally based on measured data. As the applicant did not consider any exposure of Cr(VI) for workers in the dyeing area, they provided only one single measurement in the CSR. The LoD of this measurement was used for risk characterisation, and therefore the actual risk would be less than that calculated. On RAC's request, the applicant could underpin their assumptions of "minimised Cr(VI) exposure levels in the workplace air" with three further measurements. Thus, the picture of workplace concentration on Cr(VI) is rather clear.

Nevertheless, RAC notes some minor uncertainties with regards to the air measurements particularly as the data are not connected with specific tasks and only static sampling was performed for exposure estimation. The applicant simply stated that "during sampling the workers had been around in the area performing their regular activities". The measurement reports neither provide information on the tasks conducted by workers in the dyeing area during sampling. Additionally, RAC notes that static measurements do not allow an accurate estimation of the exposure dose and personal sampling is generally preferred since it is more representative of the contaminant concentration in the workers breathing zone during tasks performance.

Due to biomonitoring results, the applicant was able to recognise that workers connecting the sodium dichromate tank to the pipeline had not used the PPE adequately. RAC acknowledged that the four results on total chromium levels in the urine provided in 2016

are lower in general than the three data points provided in 2015. So these results might demonstrate that measures were taken by the applicant to correct the situation described above. However, as contextual information on the biomonitoring data is lacking, RAC cannot further evaluate the dataset.

Considering the information related to the use of PPE as described above, RAC also recognises minor uncertainties in the applicant's claim that the dermal modelled result should be considered as an unrealistic worst case estimate because all operations are performed in automatic systems, without any manual intervention (e.g. no manual handling of the substance, no manual monitoring of the process).

In general RAC notes some uncertainties due to the sparse description of tasks with potential exposure to sodium dichromate. Due to the fact that the information in the CSR was unclear, sometimes even contradicting, RAC had some difficulties with the evaluation of the exposure assessment.

The ECETOC TRA modelled data for WCS 1, using PROC 8b "Transfer of the substance or mixture (charging and discharging) at dedicated facilities" with reliable input data underpin the applicant's exposure assessment as the result is an order of magnitude lower than the Cr(VI) concentration used for the risk characterisation for WCS 1 and WCS 2.

The modelled data for WCS 2, using PROC 13 "Treatment of articles by dipping and pouring" are connected with some uncertainties. The PROC does not seem to be sufficiently specific to cover the tasks related to this WCS but there is no better option. In addition, the input parameter regarding RPE might not be appropriate. According to the applicant, RPE is worn for specific tasks only. For the modelling, however, RPE with an effectiveness of 95% was considered for a time period of < 4 hours. Therefore RAC considers that the modelled data for WCS 2 do not represent the exposure scenario presented by the applicant and cannot be used to corroborate the measured dataset.

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

The applicant considered that "Use at industrial site leading to inclusion into/onto article" (ERC 5), is the most appropriate Environmental Contributing Scenario.

Estimation of releases

Release to air

The applicant clarified that sodium dichromate is supplied as aqueous solution in 1,000 L tanks and dosing into the reaction vessel is performed by automated closed system. Since the reaction vessels are also closed, there is no release of sodium dichromate to air (neither to the workplace nor to the environment).

For the exposure assessment, the applicant calculated the emission by multiplying the LoD from the workplace air measurement of 15 January 2015 (0.428 µg/m^3) with the cubature of the working area (5,000 m^3).

Release to water

According to the applicant, no release of Cr(VI) to waste water is expected as sodium dichromate is stoichiometrically calculated in order to react completely in the reaction vessel. In addition, a reducing agent (e.g. sodium metabisulfite, sodium hydrosulfite) is always added in the last reaction step to make sure that all of the Cr(VI) is converted into Cr(III).

In the CSR, eight measured data on Cr(VI) are presented of samples taken from reactor vessels at Catagallo by an external accredited laboratory from 2008 to 2015. Three of these results showed concentrations above the LoD (0.03 mg/L). The measured concentration was between 0.051 and 0.060 mg/L. During the trialogue, the applicant clarified that all these measurements were done before the reduction agent was added to the reaction vessel.

On RAC's request, the applicant provided 19 measured data (the dataset was already presented in the CSR) on Cr(VI) and total chromium in the wastewater from Catagallo from 2008 to 2016. 13 of 19 Cr(VI) measurement results were below the LoD (0.03 mg/L), five were ≤ 0.06 mg/L, one was at 0.15 mg/L (measured in 2015). For Agliana, three measured data on total chromium and four measured data on Cr(VI) were presented (from 2013 to 2016). One Cr(VI) measurement result was below the LoD, the other results were: 0.05 mg/L, 0.11 mg/L and 0.09 mg/L. The applicant claimed that all the measured results were below the requested limit (0.2 mg/L) according to national legislation.

The CSR also presented a further eight measurements of Cr(VI) and seven measurements of total chromium, performed in 2015 and 2016 at Catagallo. According to the rather limited contextual information accompanying these data, the measurements were made according to the guidelines of APAT (Auditory Processing Abilities Test) manual CNR IRSA 2003 by an external laboratory. The Cr(VI) concentrations were between the limit of detection (0.01 mg/L) and 0.162 mg/L.

All these samples on wastewater were taken at surface inspection points on the wastewater pipeline at the particular site. At Catagallo, there are three inspection points (pozzetto 1, 2 or 3) whereas at Agliana, there seems to be only one (pozetto 1).

On RAC's request and during the trialogue, the applicant clarified that wastewater treatment at the site(s) occurs via reducing agents and pH adjustments. According to information in the CSR, the wastewater is collected in a cistern as there is a limit of the yearly amount of wastewater discharge (e.g. 184,000 m^3). However, it is not completely clear if both companies have a cistern but as the applicant claimed that the RMMs and OCs at both sites are the same, there should be a cistern at Agliana, too. The applicant clarified that at both sites wastewater is sent to the municipal WWTP for additional treatment before discharge.

Irrespective of these measured data in wastewater, the applicant based their estimate of Cr(VI) release to wastewater on the residual Cr(VI) concentration in the reaction vessel, prior to the addition of reducing agents. According to the applicant, the maximum residual quantity of Cr(VI) per vessel is 1.8 mg. RAC notes that the 1.8 mg Cr(VI) is based on the LoD of measured Cr(VI) concentration in the vessel, multiplied by the content of the vessel (60 L).

Release to soil

According to the applicant, in general the dyeing process does not generate Cr(VI) containing solid waste as Cr(VI) is consumed in the process and bound to fibres as Cr(III). The containers of dyeing auxiliaries are partly returned to the supplier. In written information submitted by the applicant subsequent to the trialogue, the applicant stated that the sludge is sent to a specialised company for incineration.

Table 3: Releases to the environment

Releases	Release rate	Release estimation explanation / Justification
Air	Initial release factor: 50% Final release factor: 7.11×10^{-6}% Local release rate: 2×10^{-6} kg/day	The emission is calculated based on the LoD from a workplace air measurement (0.428 µg/m^3) and the cubature of the working area (5,000 m^3).
Water	Initial release factor: 50% Final release factor: 5.91×10^{-3}% Local release rate: 1.35×10^{-4} kg/day	The release is calculated by multiplying the Cr(VI) concentration (1.8 mg) in the reaction vessel by the rounded number of vessels in both companies (75).
Soil	Initial release factor: 1% Final release factor: 0 % Local release rate: 0	According to the applicant, there is no release on Cr(VI) to soil.

Exposure estimation methodology:

After being requested by RAC, the applicant provided an assessment of indirect exposure to humans via the environment at a local scale calculated by EUSES modelling (2.1.2).

Table 4: Summary of indirect exposure to humans via the environment

Protection target and units	Exposure estimate, EUSES, local scale
Humans via environment – Inhalation (mg/m^3)	5.54×10^{-10}
Humans via Environment – Oral (mg/kg bw/day)	1.86×10^{-7} (for drinking water) 1.07×10^{-8} (for fish)

The applicant considered both inhalation and oral routes of exposure for general population. Exposure via the oral route takes into account exposure from fish consumption and drinking water, but not other food. The applicant did not provide any further information on their assessment although they were requested to do so.

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

RAC notes the efforts made by the applicant to calculate the indirect exposure of humans via the environment. However, RAC is of the opinion that the level of certainty of the

exposure assessment would be strengthened by providing clear and detailed information (e.g. on wastewater discharge and the measuring points).

RAC notes that the applicant used log K_{ow} instead of measured partition coefficients when undertaking EUSES modelling. As such, there is additional uncertainty related to the results of the applicant's EUSES modelling.

RAC acknowledges that Cr(VI) will transform in the environment to Cr(III), which has been previously described in the EU RAR for chromate substances (EU RAR 2005). This will reduce the potential for indirect exposure to humans via the environment after release, particularly via the oral route of exposure. On this basis, the EU RAR only included oral exposure from drinking water and the consumption of fish. This might be the reason for the applicant's assessment for these two routes of exposure but due to the lack of information, there are some minor uncertainties related to the applicant's assessment.

Emissions to wastewater are based on the LoD of Cr(VI) concentrations in the reaction vessel before adding any reducing agent. So, the assessment is likely to tend to an overestimation of releases. A conservative approach was also taken for the estimate on air emissions since it was based on the LoD of a workplace air measurement.

Taking the uncertainties mentioned above into account, RAC considers that the indirect exposure calculated by the applicant is acceptable for risk characterisation and impact assessment.

Conclusion

- The description of use allows to draw conclusions related to exposure situations although not all of the issues were clarified by the applicant in the two rounds of questions and the trialogue.
- The methodology used and the information provided, related to exposure resulting from the use applied for, is sparse but considered to be sufficient for risk characterisation.
- Concerning workers' exposure via inhalation, there remain some uncertainties because of the missing contextual information on the measured data (air measurements as well as biomonitoring data) and the lack of personal sampling for inhalation exposure. Only the corroboration of the biomonitoring allowed RAC to evaluate the exposure assessment with any degree of certainty.
- Releases to the environment are uncertain but also at a rather low level.

Overall, the uncertainties identified in the exposure assessment are considered to be low for the exposure assessment to human via environment and low for workers. The uncertainties could be overcome with more detailed information on the tasks performed with potential exposure to sodium dichromate, on considerations about the assessment for humans via the environment and on the measured data provided.

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

The applicant stated that exposure is controlled and minimised by technical and organisational RMMs applied at both sites. According to them, workers do not have direct contact with Cr(VI) in general, only in cases of emergency. Potential exposure which implies the use of PPE, is applied for specific tasks (e.g. connection of the sodium dichromate tank to the pipeline).

Sodium dichromate is used in aqueous solution in tanks equipped with special valves to avoid any dispersion during use. Dosing is performed in automated, closed dosing systems. Automatic control overflow devices as well as low bath ratio apparatus are implemented.

The dyeing process is a closed batch process at both sites and all process stages are automated. The dyeing process takes place in closed vessels. In addition, at each site, closed dosing systems for sodium dichromate are installed.

Moreover, before opening the vessels and as a last dyeing step, reduction agents are added into the vessels guaranteeing that all the Cr(VI) is transformed to Cr(III).

Regarding the RMMs available to control the emissions to the environment, the applicant mentioned that the tank with dichromate solution is placed and stored in a dedicated area, with waterproof soil and containment vessel in case of accidental release. Before emptying the dyeing vessel, Cr(VI) is reduced to Cr(III) by adding reducing agents and by pH adjustments.

The applicant claimed that due to the implementation of an environmental management system in the past, the organisation and structure related to environmental safety has been improved, responsibilities have been defined, workers have been trained, measurements have been performed and effectiveness of RMMs have been reviewed regularly.

Additionally, and after being requested clarifications by RAC on the availability of the RMMs described in both sites, the applicant stated that RMMs for workers and environment are exactly the same for both plants, at both sites.

RAC considers that the implemented RMMs and OCs as described in the application are appropriate and effective in limiting the risks to workers and the general population, provided that they are adhered to.

Justification:

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

The applicant has conservatively assumed that all inhaled chromium trioxide particles are in respirable range and contribute to the lung cancer risk. So, 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 the LoD of a workplace concentration measurement, supported by further measured data below the LoD (at the same order of magnitude).

Table 5: Excess risk estimates for 40 years exposure for workers

Route of exposure	Exposure estimate µg Cr(VI) / m^3	Excess lung cancer risk
Inhalation	0.428	1.714×10^{-3}

RAC can accept the method of exposure and cancer risk calculation by the applicant.

Indirect exposure to humans via the environment

According to the applicant, no significant exposure can be expected to the environment, therefore no significant exposure of human via the environment can be expected (neither by the inhalation nor by the oral route). Nevertheless, the applicant has provided the following calculation.

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 scale based on EUSES modelling. As discussed in section 4, RAC considers this approach to be acceptable.

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

Protection target and units	Local scale	
	Exposure estimate	**Excess cancer risk**
Humans via Environment – Inhalation (mg/m^3)	5.54×10^{-10}	1.61×10^{-11} (lung cancer)
Humans via Environment – Oral (mg/kg/bw/day)	1.86×10^{-7} (for drinking water) 1.07×10^{-8} (for fish)	1.57×10^{-10} (intestinal cancer)
Humans via the environment - Combined		**1.73×10^{-10}**

RAC accepts these calculations. RAC also accepts that the applicant did not provide any exposure assessment for the regional scale.

Conclusion

- The RMMs appear to be appropriate and effective in limiting the risks to workers and the general population.
- RAC considers the methodology used for cancer risk calculation to be appropriate and that the estimates of excess lung cancer risk for directly and indirectly exposed workers are sufficiently reliable to allow health impact assessment for both workers and the general population.
- RAC agrees with the applicant's approach not to consider the regional scale for the exposure assessment for humans via the environment.
- Overall, the uncertainty related to the assessment of the risk for workers and humans via the environment are considered to be low.

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 (5 to 30 tonnes per year, exact figure confidential). By acting as a bridge between the wool and the dye, chromium affords the coloured textile with a high colour fastness.

1. Scope of the use

Initially the scope of the application was not completely clear to SEAC. While the use applied for is valid for the whole colour spectrum (light, medium and dark colours) and all types of wool, the application seems to focus on classical dark colours (navy blue, brown and black) and special types of wool (alpaca, lamb carbonized, sheep carbonized).

SEAC asked the applicant for clarifications regarding the scope and they indicated that the use applied for indeed covers the whole colour spectrum. The applicant explained that 90% of the application of mordants is linked to the dark dyes since these are especially difficult to substitute because of lower fastness and levelling properties (i.e. defects are more visible). After further questioning, the applicant stated during the trialogue that the use of mordant dyes for lighter colours has been completely substituted. They therefore agreed with SEAC to restrict the scope of the application to classical dark colours (navy blue, black and brown)[2]. Please see section 9 for this condition.

In their answers to SEAC's questions on the scope, the applicant likewise indicated that the scope intentionally covers all types of wool. The special types of wool[3] that were mentioned explicitly in the application can, according to the applicant, only be dyed using the current process and chemicals. For some more common types the applicant states that reactive dyes can potentially substitute mordant dyes. Laboratory tests and industrial trials show that the substitution can be implemented "over time"[4] for common types of wool, but not as of yet. SEAC understands and accepts the justification provided by the applicant and agree that all types of wool should be covered by the application.

2. Technical and economic feasibility

The applicant gave a good general overview of the wool dyeing process and its specificities. Several technical properties such as depth/intensity of tone, colour fastness, brightness and homogeneity/levelling are put forward and considered key when assessing alternatives.

The main issue of the initially submitted analysis of alternatives (AoA) is that it does not use this overview as a starting point for explaining to SEAC why substitution is not yet an option for the applicant.

For example, the AoA provides very short discussions on several categories of dyes. While advantages and disadvantages for the different categories are mentioned, these are not described in relation to the currently used process and chemicals. The applicant provided the required clarifications during the opinion development process.

One category, the reactive dyes, is discussed in more detail in the AoA, but without providing a link to their present use within the company. During the opinion development process the applicant did provide SEAC with a non-exhaustive, but comprehensive overview of the alternatives tested over the last 15 years. Additionally, the applicant gave more detailed technical information on select dyeing recipes where a comparison is made between the chrome dye and its corresponding potential alternative using the reactive dye. This was considered to be very helpful to SEAC even though some uncertainties remain since these comparisons showed great variance and the representativeness of

[2] See application from Ilario Ormezzano Sai Spa: "Use of Sodium Dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings."
[3] 1/3 of the entire wool production of the applicant.
[4] No specific timeline was given in relation to this statement.

these examples to the category of reactive dyes as a whole can be questioned to a certain extent.

SEAC understands that the textile dyers are to a large extent dependent on their clients who employ more subjective, non-technical standards as to whether the dyed wool is suitable for use or not. The Committee also acknowledges that some customers are mostly interested in the low fibre price that chrome dyes afford. The idiosyncrasies of this sector make it difficult to prepare a fully clear-cut discussion[5] of alternatives.

However, according to SEAC, the initial feasibility assessment provided by the applicant presents a high level of uncertainty because of the insufficient level of depth of the analysis of alternatives and the fact that discussions on product quality can be marred by the subjectivity of fashion trends and consumer aesthetic tastes. The Committee allowed the applicant to alleviate its concerns through additional questions and during the trialogue. Although the received answers did not and could not address the aforementioned issues completely and 100% satisfactorily, SEAC does acknowledge the applicant's relative success in taking away most of the Committee's concerns regarding the initial lack of depth and specificity of the assessment. As was mentioned earlier, this was done by providing a non-exhaustive list on alternatives that have been tested already. For some of those the applicant elaborated on why an alternative was not considered technically feasible by comparing the results from reactive and chrome dyes for certain key properties.

When it comes to the applicant's discussion on economic feasibility, this is also very general in nature (even after the Committee asked for further clarifications). In fact, the AoA refers to the SEA, more specifically to the discussion on NUS 2 (switch to a valid alternative), for information on economic feasibility. No distinction is made between the different alternatives that are mentioned in the AoA and from the applicant's discussion it becomes clear that 'valid alternative' should be understood as a reactive dye[6] (blue, brown or black). SEAC can therefore only come to a conclusion on economic feasibility for the category reactive dyes.

Conclusion

According to SEAC, sufficient information is available to allow the Committee to reach a conclusion on the suitability of the discussed alternatives. As discussed above, there are however some deficiencies in the analysis of alternatives that increase somewhat the uncertainty of the Committee's conclusions. The applicant tried to resolve the issues SEAC had, but it was not possible to do this completely and therefore some uncertainties remain. It is however important to emphasize that this is inherent to this kind of use and that discussions on product quality can be marred by the subjectivity of fashion trends and consumer aesthetic tastes.

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

☐ YES

☒ NO

[5] I.e. eschewing subjective standards and presenting technical feasibility information in an objective fashion.

[6] Reactive dyes are a group of colourants that would make the use of a mordant unnecessary since they, as their name suggests, themselves react with the wool.

Justification:

The applicant first discussed very briefly different categories of dyes for wool dyeing: acid levelling dyes, acid milling dyes, mordant dyes, 1:1 or 1:2 metal complex dyes and, finally reactive dyes. As stated in section 7.1, some advantages and disadvantages for the different categories are mentioned, but these are not described in relation to the currently used process. During the opinion development process, more specific information was however provided by the applicant on the different categories and how their properties compare to chrome dyeing. Since this information showed that most of the categories performed consistently and significantly worse than the chrome dyes, it became clear to SEAC why some of the categories of dyes were not discussed more in-depth and are not considered to be technically feasible.

Following that, the applicant briefly mentions the SUBSPORT paper[7] on alternatives for Cr(VI) and summarily dismisses most of the substances in that document. According to the applicant this is due to the fact that the alternative mordants listed are only applied in conjunction with natural dyes which provide subpar results in regards to levelling, fastness, reproducibility and uniformity. These potential alternatives are therefore most likely not technically feasible.

Next, the Lanasol and Realan reactive dye families were discussed in more detail. The problem is that these alternative dyes are not analysed in relation to the currently used process. Instead the applicant lists a number of advantages such as very good fiber levelness[8], high colour fastness, good reproducibility and preservation of the wool fiber[8]. It was therefore not made clear to SEAC why the applicant did not consider these alternatives to be technically feasible. After further requests for additional information, the applicant did make it clear that these advantages cannot be generalised and that technical issues with regard to colour intensity and depth need to be overcome to make the tested reactive dye formulations a technically feasible alternative (the applicant explained that the fastness of the dyes is considered to be good enough). To SEAC it seems relatively clear that reactive dyes are as of yet technically not feasible for darker colours (see section 7.1: scope). What strengthens the conclusion on infeasibility is that the applicant has indicated that their customers do not accept the results of the tests performed with reactive dyes since they cannot approximate the current results[9] with chrome dyes.

Finally, an alternative called Sulphur Black 001 is discussed in the AoA. Unlike for the other alternatives some comparisons are made to chrome and reactive dyes. The applicant states that sulphur dyes can be used to create deep black shades that are comparable to those obtained with chrome and reactive dyes. Likewise, the fastness properties are generally similar or better. The fibre damage after dyeing is however said to be a concern (reference to Cai, 2012 report is provided). According to the applicant this is still the only report that mentions the successful use of sulphur dyes for the use applied for. Based on the above-mentioned information SEAC can reasonably assume that this alternative is not yet technically feasible due to the low industrial maturity of the research in wool dyeing.

[7] Chapter 5 of the Subsport paper on Cr(VI) characterises alternative textile dye mordants: http://www.subsport.eu/wp-content/uploads/2015/06/chromium_vi.pdf
[8] Mentioned only for Lanasol reactive dyes.
[9] Both technical results and the resulting price of the dyed textile.

The economic feasibility is not discussed for the individual categories of dyes mentioned earlier in this section. This was not seen as a major problem by SEAC since the alternatives are already considered to be technically not feasible.

The applicant chose to refer to the SEA, more specifically the discussion on NUS 2 (switch to a valid alternative), for information on economic feasibility. From this it becomes clear that 'valid alternative' as used by the applicant should be understood as meaning a reactive dye (blue, brown or black).

According to the applicant the following costs would arise from a switch to reactive dyes:

1. 'Raw material costs' (= recipe/formulation costs): the applicant indicates that the use of reactive dyes causes the cost per kg of dyed fiber to increase on average by 20-50%.
2. 'Process costs': these costs are related to greater use of energy and water as well as a prolonged production/cycle time. This also leads to an increased load on the wastewater treatment plants (WWTP, more water and increased dye chemicals discharge). The cost per kg of dyed fiber is assumed to increase on average by 40% because of these factors.

The applicant stated that these costs cannot be passed on to their clients which is considered to be plausible by SEAC considering the textile market's specificities. The overall increase in costs due to the switch to reactive dyes is considered by SEAC not to be economically feasible for the applicant. The Committee did ask the applicant to provide more robust justifications for these cost elements. The applicant did this to large extent by offering SEAC several specific examples of raw material cost changes when switching to reactive dyes. These were considered to be very illustrative and further solidified the Committee's conclusion on the economic infeasibility of switching over to reactive dyes.

Conclusion

Because of deficiencies in the initially submitted analysis of alternatives, SEAC had difficulties to assess fully the technical and economic feasibility of the proposed alternatives. After welcome clarifications by the applicant, the Committee still finds a number of uncertainties in the analysis. It is however recognized that these uncertainties are inherent to this kind of use (discussions on product quality can be marred by the subjectivity of fashion trends and consumer aesthetic tastes). Nevertheless, SEAC concurs with the applicant that, by the sunset date, there are no suitable alternatives available to the applicant for the dying of dark colours.

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

Description:

The applicant described the efforts made to identify alternative substances. They pointed to a reference document providing an overview of alternatives, found on the Substitution Portal. In this report, there are seven alternatives presented, whereof five are applied in the dyeing of textile with natural dyes. Therefore these substances are not applicable for the use applied for whereas the other two chemicals listed in the report are the main representatives of two different families of reactive dyes for wool, according to the applicant.

The AoA describes α-bromoacrylamide Reactive Dyes (LANASOL®) and vinylsulpho-derivatives Reactive Dyes (Realan EHF®). For both families, the applicant described the hazards on a single representative, based on ECHA database and OECD or other sources. Both of the in more detail presented substances are Skin Sens. 1 (H317) and Resp. Sens. 1 (H334). Additionally to these both potential alternatives, Sulphur Black 001 dye was presented as an alternative but due to higher fibre damage some further work is required.

According to the information provided, none of the alternatives is considered to be a SVHC substance or mixture according to Regulation (EC) No. 1272/2008.

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

RAC notes that the applicant described the hazards for two representatives of the two families of potential alternatives. However, this information is incomplete. In addition, no exposure scenarios and risk assessment were presented. Therefore an evaluation of this issue is not possible.

7.5 If alternatives are suitable (i.e. technically, economically feasible and lead to overall reduction of risk), are they available before the sunset date?

☐ YES

☐ NO

☒ NOT RELEVANT

Justification:

No suitable alternatives are available before the sunset date.

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 evaluated two potential non-use scenarios: Scenario 1: “Stop production” and Scenario 2: “An alternative is found”. Scenario 2 is found as not realistic by the

applicant for two main reasons: the quality delivered by the alternative would not be at the same level and the market would not absorb the price increase generated by the doubling of the dyeing costs. Therefore, Scenario 1 is recognized by the applicant as the most likely scenario to occur if an authorisation is not granted. Additionally, the applicant claims that efforts to find and develop an alternative to chrome-dyes for classical dark colours would be continued even in the case that an authorisation is not granted. SEAC agrees with the applicant's approach and finds the non-use scenario presented to be plausible.

The applicant 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 provided by the applicant. It reflects the expected additional number of cancer cases for an exposure over the working life of workers and entire life for general population.

Table 9: Estimated additional statistical cancer cases for workers directly exposed (40 years of exposure)

WCS	**Number of workers**	**Excess cancer risk**	**Estimated statistical lung cancer cases** (inhalation exposure)
WCS 1 and 2	9*	1.714×10^{-3}	1.543×10^{-2}

***** *Number of workers involved in WCS 1and WCS 2 in both plants.*

Table 10: Estimated additional statistical cancer cases, general population (70 years)

Protection target	**Number of people exposed**	**Excess cancer risk**	**Estimated statistical cancer cases**
Man via Environment – Combined	10,000	1.73×10^{-10}	1.73×10^{-6}

In addition, RAC notes that the applicant considered the number of indirect exposed people to be 10,000. Although the standard population of 20,000 might be more appropriate according to sources of information on the internet (number of inhabitants of Agliana is 17,525 and of Cantagallo it is 3,118) it does not have a significant impact in the numbers since it is in the same order of magnitude and therefore the initial number provided by the applicant is accepted by RAC.

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 stop production until a valid alternative that is approved by the customers is found;
- the clients of the applicant (textile industry companies) would look for alternative suppliers (incurring additional time and cost) and, most likely, lose some market share;
- the final consumer will try to find products with suitable quality provided by other market operators, presumably from outside EU.

SEAC finds that the initial assessment of economic impacts undertaken by the applicant was not based on a well-established benefit-cost methodology. In response to SEAC's question, the applicant submitted an updated SEA that filled information gaps. However, SEAC cannot fully agree with several assumptions and statements made by the applicant since the justifications and clarifications provided did not remove uncertainties with respect to investment cost estimates and formulation cost. Nevertheless, the presented data allows calculating a plausible range for the socio–economic cost as input for the opinion making process.

Costs of continued use (risks)

The applicant carried out a quantitative human health impact assessment, based on the estimated excess cancer risk of workers and the general population in Cantagallo (the province of Prato) and Agliana (the province of Pistoia), arising from the exposure to Cr(VI) from the use of sodium dichromate. Lung and intestinal cancer have been identified as the main health endpoints associated with exposure to Cr(VI).

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, and permanent exposure of 70 years for the general population.

In response to SEAC's request, all calculations were updated by the applicant using values as defined in the report "*Valuing selected health impacts of chemicals: Summary of the Results and a Critical Review of the ECHA study*" (February 2016).

The applicant did not adjust the resulting risks to reflect the 10-year review period requested. The applicant produced estimates of combined 1.714×10^{-3} additional statistical cancer cases among on-site workers (exposed over a 40-year period) and the general population (exposed over a 70-year period).

The applicant did not evaluate morbidity risks and in the updated calculations used both the lower and upper bounds of a value per fatal lung cancer cost (€2.2 and 3.6 million, respectively). Based on the above values, the applicant monetised the health impacts and arrived at a worst-case combined value of €55,533 for both on-site workers and general population for 40-year and 70-year period of exposure, respectively.

At request of RAC, the applicant provided additional information regarding the number of workers potentially exposed to sodium dichromate. 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 9 and 10 above. Based on these figures, SEAC estimates the number of additional statistical cancer cases to be 3.86×10^{-3} for a 10-year review period resulting in a total human health present value cost of about €9,000 (lower bound value) to about €14,000 (upper bound value).

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

The applicant evaluated a potential non-use scenario (NUS) whereby the applicant would stop production until a valid alternative for dyeing of wool to classical dark colours would be found and approved by customers (as it was already indicated in section 7.1 the applicant stated during the trialogue that the use of mordant dyes for lighter colours has been completely substituted).

Discontinuation of dyeing of wool to classical dark colours according to the applicant would lead to the loss of sales of up to €5.4 million per year (worst-case scenario). It is assumed that the applicant would lose the majority of clients who buy products dyed with Cr(VI) dyes.

Even in the case where suitable alternative reactive dyes would be found and the dyeing of classical dark colour wool could be reintroduced, there are several challenges that would need to be addressed and additional costs to be covered by the customers of the applicant:

- Dyeing process with chrome dyes in comparison with reactive dyes requires shorter processing times and simplified processes with fewer temperature ramps;
- The simplicity and the short duration of the process of chrome dyeing result in a considerable energy and water saving in comparison when reactive dyes are applied. In accordance with the data as provided by the applicant this may lead to doubling of dyeing cost (also, formulation costs would increase if reactive dyes are used).

SEAC finds this NUS (Scenario 1 while continuing to develop alternatives) to be credible even though SEAC has expressed some concerns regarding the analysis of alternatives (see section 7.1 and 7.2).

The applicant identified, quantified and monetised several possible economic impacts related to the NUS:

- Sales and profit loss of the applicant;
- Investment in new equipment;
- R&D cost in order to adapt most of formulations with the use of reactive dyes;
- Production cost (water, electricity, raw materials) increase if alternatives are introduced.

The applicant also identified that there will be 25 to 38 job losses if authorisation is not granted (20 to 30 percent of the total workforce) but this socio-economic cost was not monetised.

The negative economic impacts (in terms of net present value) associated with a non-granted authorisation as estimated by the applicant are approximately €4.2 million. This cost does not include any economic loss that may be faced by the supply chain layer. This

potential cost is evaluated qualitatively by the applicant in the “Wider economic impacts” section of the SEA.

In response to SEAC’s questions, more detailed information was provided by the applicant with regard to:

- Lost profit of the applicant;
- Technological and economic aspects of the dyeing process;
- Additional information on unemployment if authorisation is not granted;
- More detailed information on adapting and optimizing existing dyeing formulations.

SEAC considers the economic impact of a non-authorisation on the applicant (€4.2 million) to be slightly overestimated. SEAC arrives at this conclusion primarily for two reasons:

- Costs related to the investment in new equipment and formulations to switch the dyeing process from chrome to reactive dyes would likely have to be made under any scenario as soon as suitable alternative dyes become available. According to the information by the applicant this should happen over the next 12 years. Therefore, authorisation would only defer the investment into those activities for 4 to 6 years. It shall be stressed that the applicant did not resolve all the uncertainties related to the required investments and the appraisal of the formulation cost. SEAC therefore considers that at least a part of the investment cost claimed under the non-use scenario would simply have to occur earlier than under the continued use.
- The applicant considers that the loss in revenues coming from the customers who buy chrome dyed products may vary in the range from 70% (optimistic scenario) to 30% (pessimistic scenario). The appraisal of the potential customer loss was done qualitatively by the applicant based on internal information. In its appraisal of the economic impacts, the applicant has used the pessimistic scenario as baseline scenario whereas third parties challenged that view during the trialogue.

SEAC evaluated the socio-economic impacts based on the additional information received during and after the trialogue and taking into consideration that necessary investments in new equipment and formulation activities are only deferred in time. SEAC based its assessment of the health impacts of continued use on the excess cancer risk levels, as provided by RAC.

Revalued results indicate that the benefits of continued use to the applicant are likely to be smaller than assessed by the applicant and the monetised risk is marginally higher than assessed by the applicant.

It should be emphasized that SEAC followed the approach used by the applicant and did not attempt to include the economic loss of redundancies resulting from the discontinuation of dyeing of wool to classical dark colours and economic loss potentially incurred by customers and suppliers of the applicant.

Conclusion

The analysis of the benefits of continued use (i.e. the costs of non-use) is based on the necessary investment costs, lost profits of the applicant and redundancies (not monetised by the applicant) resulting from the discontinuation of dyeing of wool to classical dark colours.

The applicant's assessment of the monetised risks to human health amounts to €55,533. Value was not adjusted to the 10-year review period.

SEAC recalculated the monetised health impacts using the excess cancer risk levels estimated by RAC, adjusted calculations to 10-year review period and arrived at a total human health cost in the range of €9,000 - 14,000 calculated for a 10-year period.

Based on the applicant's assessment, the benefits of continued use appear much larger than the associated risks to human health. In particular, the applicant reports that the net benefit of continued use is approximately €4.2 million.

While evaluating the results, SEAC arrived at a net benefit of continued use in the range of €1.8 – 2.6 million) ignoring unemployment costs. It shall be noted that this figure represents the costs expected for the 10-year period only to the applicant while it is clear that there would be social costs accruing due to the lay-off of workers and the negative impacts on the suppliers and customers of the applicant.

SEAC considers that the implied benefit-cost ratio of more than 120:1 clearly and with a sufficient margin of error 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:

The authorisation should be restricted to dark colours only. The use applied for should therefore be amended as follows:

Use of Sodium dichromate as mordant in wool dyeing with dark colours

Description for additional conditions and monitoring arrangements for review reports

The applicant must continue to implement regular programmes of occupational exposure measurements relating to the use of sodium dichromate described in this application. These monitoring programmes 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, the future programme 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 analyses of the biomonitoring data with sufficient contextual information on the sampling time related to shifts, the tasks performed and PPE worn.

The information gathered in the monitoring programme 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.

Any review report must include detailed and clear information related to the use of sodium dichromate, namely all tasks with potential exposure have to be described and connected with the respective WCS. Additionally, all the RMMs and OCs in place should be clearly described and what were in use during the sampling for the exposure assessment development.

Emissions of Cr(VI) to wastewater should keep to be subject to regular measurements, including sufficient contextual information (e.g. on the amount of sodium dichromate used related to the measurement), with the results of monitoring made available to enforcement bodies on request. Measurement programme shall be undertaken according to standard sampling and analytical methods and ensure a sufficiently low detection limit, where appropriate. Emissions data shall be presented in any subsequent review report.

Justification:

For the light and medium colours reactive dyes are used worldwide. During the trialogue it became clear that the applicant would not be able to make a case for the unsuitability of those dyes in their specific situation. During the trialogue the applicant confirmed that for lighter colours the use of mordant dyes has been discontinued. It was therefore agreed with them to limit the use applied for to classical dark colours only (black, brown, navy blue)[10].

An authorisation of a non-threshold carcinogenic substance should be based on a robust and well justified exposure assessment. In the present case, the recommended monitoring arrangements for workers exposure, as well as a more detailed contextual information on the measured (air monitoring) data provided would address the uncertainties in the exposure assessment. Additionally, combined personal and static measurements can provide a more solid picture of exposure at the workplace.

Moreover, all tasks with potential exposure to the substance in concern have to be clearly described.

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:

[10] See application from Ilario Ormezzano Sai Spa: “Use of Sodium Dichromate as a mordant in the dyeing of wool as sliver and/or yarn with dark colours in industrial settings.”

RAC's advice:

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

Other socio economic considerations

The applicant considers 10 years to be appropriate as a review period. This would allow them to find a suitable replacement for sodium dichromate and to prove its industrial viability. If a suitable alternative were to be found then customer validation and implementing the adaptation of the formulations (of which there are many thousands) is the logical next step. A precise justification for the length of the proposed review period was not given. The applicant only stated that 3-5 years would be needed to find a technical alternative and 4-6 years to implement the available alternative (adapt the thousands of existing formulations).

Because of deficiencies in the initially submitted analysis of alternatives SEAC had difficulties to assess fully and satisfactorily the suitability of the proposed alternatives. After welcome clarifications by the applicant, the Committee still finds a number of uncertainties in the analysis; it is however recognized that these uncertainties are inherent to this kind of use (discussions on product quality can be marred by the subjectivity of fashion trends and consumer aesthetic tastes).

The applicant has clearly shown that the benefits of continued use outweigh the risks (by more than a factor of 120). According to SEAC none of the other criteria for a longer review period than 7 years were met or properly justified.

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