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 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:

Use of Sodium Dichromate 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:

11-2120132745-57-0001

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.

The applicant must implement yearly training for workers on the adequate use of RPE.

Description for additional 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 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 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.

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 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 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 as sliver[1] and/or yarn with dark colours in industrial settings. 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 applicant, Ilario Ormezzano SAI SpA provided an upstream application for 11 downstream user sites located in the Biella area. Three of these sites are manufacturers and dyers and the others are dyers only.

All the sodium dichromate used in these sites is purchased from the applicant. The applicant pointed out that the annual use of sodium dichromate has been rather consistent during the past years, and is 80 tonnes/year.

Sodium dichromate is supplied in an aqueous solution containing 61% 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% water solution contains 24.2% active Cr(VI) by weight.

[1] [1] A ‘sliver’ (pronounced like ‘diver’) is a long bundle of fibre used to spin yarn

In the dyeing process, the acid dyes react with the woollen fibres forming an ionic bond with keratin. Sodium dichromate is introduced as the 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)-day complex.

The dyeing process is a closed batch process, conducted in reactor vessels made of stainless steel. After filling the reactor vessel with the proper amount of wool (sliver or yarn) the vessel is closed. The dyeing process starts with acid dyes. Then follows the "chromating phase" in which sodium chromate is charged (1 – 2.5% aqueous dichromate solution). Every dosing occurs by using an automated closed chemical dosing system. After 10 to 30 min, the reduction process is initiated by charging of sodium thiosulphate for about 30 min. Before washing/flushing processes, colour compliance is checked remotely or manually but this step is not always necessary.

The complete dyeing process takes 4 to 5 hours per batch. The temperature ranges from 95°C (dyeing) to 40°C (flushing). The dyeing process takes place in acidic solution (pH 3 to 5) and ammonia is used in pH adjustment during the washing stage. According to the CSR, most of the baths can be pressurised wherefore they are subject to regular inspections. However, there is no further information on this issue (neither with regards to the pressure used nor to how frequent high pressure is applied in the dyeing process).

Even if the process works in "batch" mode, the actual procedure in the batch reactor is continuous in nature, so that all process stages are automated, pre-programmable and remotely controlled. There is no need for any manual interventions once the reactor is closed until the dyeing process is complete.

The volume of the smallest baths is about 30 litres and the largest ca. 7,000 litres. One site may typically have 10-20 baths and the most typical size is about 1,000-2,000 litres.

Regarding dosing, the closed circuit dosing system is equipped with a consumption tank, (into which the chemical supplier let the liquid chemical agent flow). The position of the consumption tank ensures conveyance of any accidental release to the depuration plant and to prevent its drying. The dosing systems are also equipped with precise volumetric weighing system and automatic distribution to the dyeing devices by means of a piping network.

After finishing the dyeing process, any unreacted Cr(VI) is reduced to Cr(III) by adding sodium thiosulphate as a reducing agent to the dyeing vessel. According to the applicant, Cr(VI) does not end up in the final products in detectable amounts (detection limit < 0.5 mg/kg wool). The amount of non-bound Cr(III) in wool is also at low level (< 3 mg/kg wool). On RAC's request, results of analyses were provided from the past years which confirmed the applicant's declaration. Consequently, there is no need to take consumer exposure assessment into consideration. Therefore exposure of further downstream users and consumers has not been considered relevant by the applicant.

Exposure scenario

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

"Use of Sodium Dichromate 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 two Worker Contributing Scenarios (WCS) and one Environmental Contributing Scenario (ECS). According to the applicant, the exposure scenario includes all relevant processes and tasks associated with the use of sodium dichromate that could result in either environmental or human exposure.

Worker exposure

In their initial evaluation of the application, RAC considered that the workers' tasks (see Table 1) and the corresponding operational conditions (OCs) and risk management measures (RMMs) were not sufficiently described in the two WCSs 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 the RAC and SEAC rapporteurs on 03/02/2017.

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

- What was the reason for breaking down the WCS into only two contributing scenarios and not splitting it by tasks (e. g. "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 every of the above issues. Therefore uncertainties persist with regards to the exposure assessment.

Table 1: Summary of tasks , process categories (PROC), RMMs, OCs

Task[1] – PROC / WCS	Brief description of the tasks
1 - PROC 8b / **WCS 2**	Sodium dichromate solution is transported and charged to empty containers or unloaded in on-site consumption tanks. Transportation in IBC (25-1,000 kg).
2 – PROC 1 *No exposure expected*	Sodium dichromate solution is stored in IBC inside or outside, or in separate consumption tanks at dedicated Zone 21. The maximum amount of sodium dichromate stored at the chemical supplier site is 30 tonnes and at the downstream user sites the amount of storage range from 0.3 to 4.8 tonnes at a time.
3 – PROC 9 / **WCS 2**	Transferring containers and coupling sodium dichromate solution to the process line.
4 – PROC 1 / **WCS 1**	Process operator remotely control of dichromate feeding to closed process.
5 - PROC 19 / **WCS 1**	Loading dyeing machines (tops, cone, fabrics) - manual or automated task.
6 – PROC 9 *No exposure expected*	Weighing dyes – no chromates present.
7 – PROC 3 / **WCS 1**	Dyeing process stage (dye in acidic solution, 90-95 °C).
8 - PROC 3 / **WCS 1**	Chromating stage (initially added ca. 240-600 mg/L Cr(VI) at 1.10 wool/water ratio by weight) via a closed circuit automated dosing system.
9 – PROC 3 / **WCS 1**	Reducing stage (conversion of Cr(VI) to Cr(III) with thiosulphate.
10 – PROC 9 / **WCS 1**	Sampling (checking colour shade). Sometimes sampling is needed before flushing / washing steps.
11 – PROC 3 / **WCS 1**	Flushing/washing with water (automatic).
12 - PROC 19 / **WCS 1**	Unloading dyeing machines (tops, cone, fabrics) - manual or automated task.
13 - PROC 28 / **WCS 2**	Maintenance and cleaning, maintenance / servicing work of equipment: maintenance of tanks and chemical feeding equipment.
14 – PROC 8a / **WCS 2**	Cleaning of tanks, removal and disposal of aggregated precipitates.
15 – PROC 15 / **WCS 1**	Small scale laboratory testing of dyes.

[1] PROC descriptors are provided by the applicant to characterise the principal activities, but are not key to the exposure assessment as this has been performed using methodology that is independent of the use descriptor system.

The applicant pointed out that the involvement of all the companies with this application relates to use chromium as a mordant for dark colours. Some of the sites produce these specific shades continuously 260 days per year, but others less than 50 days per year.

The number of potentially exposed workers involved in the dyeing process and process control is five to 25 per site. The sites are run in two or three shifts (7.5 to 8 hour/shift). According to the applicant, the total number of workers that can be exposed is 125.

As the adequate use of PPE was questioned by RAC, the applicant stated that all employees receive training regarding the use of PPE (12-hour training course organised by qualified and certified teachers and 6-h refresher courses held every five years). In addition, instructions on the use of PPE are in place at each of the sites and supervisors are assigned to monitor the proper use of PPE by workers.

On RAC's request, the applicant clarified that PPEs are used for the handling of concentrated sodium dichromate solution (e.g. loading dichromate solution into storage tanks and maintenance of dosing equipment): protective suit, safety booths, chemical goggles or face shield, chemically resistant gloves (e. g. nitrile rubber, chloroprene rubber, butyl rubber) with an break-through time of 480 minutes, RPE (half mask with ABEK1 cartridge) for unloading of IBCs containing sodium chromate to other containers and for making couplings.

Exposure estimation methodology:

Inhalation exposure:

The inhalation exposure assessment provided by the applicant is based on the results of biomonitoring, supported by the results of air monitoring campaigns (personal and static sampling) and exposure modelling data, using MEASE (1.02.01) and ART (1.5).

According to the CSR, for exposure assessment of WCS 1 and WCS 2, Cr(VI) concentration in air was measured in the process halls (static measurement) of most of the dyeing sites but was not detected. In the CSR, static measurements of three different sites are presented. All results of these measurements were below the detection limit (LoD) which was < 0.1 µg Cr(VI)/m^3. The inhalation exposure for workers was also measured by personal sampling (LoD < 0.4 µg Cr(VI)/m^3). On RAC's request, two additional measurement reports were provided, including three personal samples, of which one was performed on 31/03/2015 over 2 hours 50 minutes at one of the 11 sites and two were performed on 20/04/2016 over 2 hours 40 minutes at another site. It is not completely clear to which WCSs they relate but as far as understood by RAC, two of these measurements might relate to WCS 1 and one to WCS 2.

Additionally, MEASE modelling was performed by the applicant applying PROC 3 "Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition" for WCS 1 and PROC 8a "transfer of substance or mixture (charging and discharging) at non-dedicated facilities" for WCS 2 (see table below). Furthermore, the applicant provided modelled exposure data using a higher tier model, i.e. ART 1.5. The input parameters for the MEASE and ART modelling reported by the applicant are shown in table 2 below.

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

WCS	Measured data	Exposure value*, µg/m³	Modelled data	Exposure value, TWA 8 h, µg/m³
WCS 1	Static sampling	< 0.1	MEASE, PROC 3 good general ventilation, 1-5% Cr(VI) solution, 95 °C	1 *(no RPE)*
	Personal sampling	< 0.4	ART 1.5 good general ventilation, 0.1% Cr(VI) solution, 95 °C	<0.001 *(no RPE)*
WCS 2	Static sampling	< 0.1	MEASE, PROC 8a task duration 60-240 min, liquid (> 25% Cr(VI), direct handling, contact level extensive	1 *(RPE - 95% effectiveness)*
	Personal sampling	< 0.4		

* The values provided is the LoD of the sampling method (see text above the table).

The applicant explained that their main focus to assess worker exposure at the sites had been on biomonitoring. According to the applicant, the oldest data provided are from 2009 and the latest ones are from 2016.

The biomonitoring method for sodium dichromate consisted of measuring chromium in urine for different workers that were potentially exposed to Cr(VI). According to the applicant, the results for biomonitoring are relatively complete for four of the sites and the dataset presented (see table 3) can be regarded as a representative set of data for all the sites.

Table 3: Biomonitoring results of chromium in urine from four dyeing sites from 2011-2015 (µg chromium/Litre, creatinine corrected)

Combined results (n=280)	Maximum	90th percentile	Median	Geo. mean
Chromium (µg/L) in urine	6.71	1.51	0.30	0.26
Range of values	2.34 – 6.71	1.21-3.5	0.25-0.30	0.21-0.44
Conversion to µg/m³	16.8	3.8	0.75	0.65
Range of values	5.9 – 16.8	3.0-8.8	0.63 – 0.72	0.52 – 1.1

The applicant also provided data from one dyeing site over several years (2011-2016). These data show a decrease of the chromium levels in the urine over the years. However, as the number of data highly varies between the different years (from 23 results in 2014 to 8 results in 2016), there are some uncertainties with regard to a factual decrease of the chromium urine levels.

For the same plant, the range of biomonitoring data related with different tasks were described (see table 4). What can be observed from this dataset is that the range of the chromium urine levels for "assistant tops/cone dyeing" (0.02 – 2.34 µg/L) and for "tops/cone dyeing sub-area" (0.01 – 2.08 µg/L) is relatively broad. As the applicant did not comment on this, nor provide any additional information that could justify the higher levels, RAC is aware of the broadness of the chromium urine levels, however, without any contextual information on the data (e.g. specific tasks performed before biomonitoring, chronic diseases, smoker status) RAC is not able to evaluate it further.

Table 4: Biomonitoring and related tasks with the range of results for one of the dyeing sites

Tasks	Number of persons	Number of measurements	Range of results (chromium, µg/L)
Chief dyeing	1	4	0.17 - 1.48
Assistant fabrics dyeing	2	8	0.01 - 1.71
Assistant tops/cone dyeing	2	8	0.02 - 2.34
Load/unload dyeing machine tops and cone	3	11	0.13 - 0.79
Maintenance in dyeing area	1	4	0.02 -1.46
Worker who weighs dyes	1	5	0.03 - 0.52
Laboratory technicians*	2	11	< 0.01 - 1.22
Fabrics dyeing sub-area	4	18	< 0.01 - 1.50
Tops/cone dyeing sub-area	2	9	< 0.01 - 1.59
Tops/cone dyeing sub-area (night shift)	2	9	< 0.01 - 2.08
Fabrics dyeing sub-area (night shift)	1	5	< 0.01 - 1.35

* As the laboratory work is exempted from the application, the exposure of laboratory technicians should only be considered in the assessment if they also perform work floor tasks. However, there is no information on the tasks of this type of workers.

On RAC's request for further justification of the representativeness of the biomonitoring data from the four sites, the applicant stated that they received information on the biomonitoring dataset from another company, a relatively small one, after submission of the application. These data from 2015 and 2016 (n=16) are in the range of 0.01-2.07 µg chromium /L urine).

For inhalation exposure assessment, the applicant converted the biomonitoring results into equivalent workplace air concentrations. They used the method proposed by the UK 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 average exposure value out of a number of 280 measurements was estimated to be 0.75 µg Cr(VI)/m^3 TWA (8 h). This value was used by the applicant for risk characterisation.

RAC notes that in general the 90th percentile value, representing the reasonable worst case exposure level of a distribution should be used as the exposure value for risk characterisation. This would result in 3.8 µg Cr (VI)/m^3 TWA (8 h) in this case. The conversion of the broadest range of chromium levels in urine of workers shown in Table 4 for a dyeing site (0.02 – 2.34 µg Cr/L) into air concentration, leads to exposure levels of 0.05 – 5.85 µg Cr (VI)/m^3. However, taking into account the measured exposure data provided in the CSR and on RAC's request, which show exposure levels below the LoD for static sampling (< 0.1 µg Cr (VI)/m^3) and personal sampling (< 0.4 µg Cr (VI)/m^3), and that the chromium urine levels are related to the uptake of total chromium and not only to Cr(VI) uptake, RAC accepts the applicant's method of exposure (and risk) characterisation.

Dermal exposure:

Dermal exposure was modelled by using MEASE (1.02.01) which is nominated as a first tier assessment tool for occupational exposure for metals and inorganic substances in the ECHA Guidance. Appling PROC 3 to the model results in a dermal exposure of 1 µg Cr (VI)/day. Considering the estimated exposure level of 0.75 µg Cr(VI)/m^3 (TWA, 8 h) which includes all routes of exposure as it is converted from biomonitoring results, RAC agrees with the applicant that this value is well below the agreed reproductive DNEL for workers exposed via the inhalation route of exposure (RAC/35/2015/09).

Combined exposure:

According to the applicant, there is no combined / aggregated exposure for the use applied for. Workers involved in WCS1 do not have to perform tasks of WCS 2 as maintenance of process equipment is carried out by specialised personnel. In the trialogue, however, the applicant altered their statement. They pointed out that at some sites there might be combined exposure but RAC did not receive clear information on this issue. However, as the biomonitoring data provided include all routes of exposure, the uncertainties related to this issue are considered minor by RAC.

Uncertainties related to the exposure assessment:

The exposure assessment provided by the applicant is principally based on biomonitoring data. While the applicant has not been able to connect specific tasks to the biomonitoring data in order to provide a detailed picture of worker exposure, the overall picture of exposure for a group of workers performing mixed tasks is rather clear.

There are some uncertainties due to the small number of biomonitoring results dedicated to WCS 2 (maintenance and cleaning, maintenance / servicing work of equipment). There were just four results provided from one worker representing these tasks at the dyeing area. Taking into account the applicant's statement in the trialogue that the equipment is rinsed before performing any maintenance work, RAC considers that the uncertainties related to the small sample size are low.

Moderate uncertainties relate to the fact that the biomonitoring data are coming from only four sites out of 11. In addition, measured air concentrations, which support the exposure assessment according to the applicant, are provided from four different sites. As the applicant noted that RMMs are the same at all sites but OCs may vary, this also introduces some uncertainties in the assessment. Furthermore, the measured data lack contextual information on the tasks conducted during the measurement campaigns. It is also unclear if the measurement devices for the static measurements were installed in areas where they are able to provide representative data for the inhalation exposure of workers. Usually, assessing exposure for broad exposure situations needs more data to ensure sufficient coverage of the scenario and to enable the evaluation of potentially relevant subsets. RAC notes, however, that all of the measured air concentrations were below the LoD.

The modelled data for WCS 1, using MEASE, are in the same order of magnitude as the exposure estimate obtained by converting the biomonitoring results to air concentrations (TWA, 8 h) and underpin the applicant's exposure assessment. The data calculated by ART are orders of magnitude lower. However, as only part of the expected input data was provided, the result of the ART modelling is related with some uncertainties.

For WCS 2, the modelled input data are not considered appropriate for the exposure scenario presented by the applicant. According to the information provided in the trialogue, the equipment is always rinsed before performing maintenance tasks. The applicant, however, used a concentration of > 25% as well as direct handling and RPE with an effectiveness of 95% as input parameters for the modelling tool. RAC notes that the RPE presented in the CSR does not apply any protection factor for Cr(VI) as it consists of single vapour cartridges without particle filters. RAC considers that the modelled data for WCS 2 do not represent the exposure scenario presented by the applicant and cannot be used therefore 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

Regarding emissions to air the applicant mentioned that all the sites covered in this application for authorisation apply completely closed dyeing machines and therefore there are not fugitive emissions from these air tightly closed reactors. According to the applicant, there might be some fugitive emissions from dichromate dosing and storage systems but only of very limited amount due to the intrinsic properties of the aqueous solution. This is

supported by measurements from workplace air showing results below the LoD (< 0.1 µg/m^3).

The release to air is estimated by using emission scenario tables (emission tables: A 3.14 (specific uses) and B 3.11 (general table)) of the Technical Guidance Document (TGD 2003, industry category: 13 Textile processing industry; use category: colouring agent, batch dyeing, metal complex). This release factor (0.0003 (0.03%)) comprises all possible on-site emission sources on total chromium from the process itself and fugitive emissions from chemical feeding equipment and storage tanks. It does not distinguish between the speciation of Cr(VI) or Cr(III).

Release to water

Regarding emissions to water, the applicant stated that the main proportion of sodium dichromate used is reduced to Cr(III) and washed and flushed at the end of the batch process. So the discontinuous, low concentrated emissions due to the washing and rinsing operations after dyeing include Cr(III) rather than Cr(VI).

On RAC's request the applicant stated that measurements of Cr(VI) with a LoD of 0.02 mg/L and of total chromium with a LoD of 0.01 mg/L to 0.05 mg/L are available. The applicant did not provide further information on the measurements but they pointed out that Cr(III) release is always higher than Cr(VI) release.

According to the CSR, at six sites the aqueous process waste streams are collected in on-site biological wastewater treatment plants (capacities 300 – 1,200 m^3/day) whereas wastewater from the other five sites are led to external industrial WWTP. Although RAC requested more clear information on three occasions, the only clear statements provided by the applicant were that at each of the sites a pre-treatment with sodium thiosulfate occurs which leads to reduction of Cr(VI) to Cr(III) and that wastewater is treated either by an on-site WWTP or by an external WWTP before discharge to a river / canal. Detailed information on the final discharge destination was not provided.

To estimate the release of Cr(VI) to wastewater, the applicant considered literature data according to which an emission factor of 50 mg total chromium per kg of wool treated is achieved corresponding to a chromium concentration of 5 mg/L in the spent chroming bath when a 1:10 liquor ratio is used (BREF 2003). Based on this information and site-specific release data, the emission factor has been estimated in the wool after chrome dyeing. The range of release factors to wastewater of initially applied chromium is < 1% to 5% and typically in the range 2% to 4%. The upper end (4%) of the typical range has been selected as the final release factor for total chromium (before WWTP).

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). Therefore the small fraction of the initially applied amount of chromium that enters the sludge of the WWTP is already reduced to Cr(III). The sludge, however, is sent to external waste treatment in accordance with local regulations. It is never applied to agriculture or horticulture according to the applicant.

The applicant pointed out that the amount of Cr(VI) in the waste (< 0.1% per weight), collected during cleaning and maintenance operations, is low at all of the sites. It is difficult to estimate but it may not exceed 50 kg per site a year according to the applicant.

Regarding secondary waste (other than process waste), the applicant stated that in

general at dyeing sites very low amounts of Cr(VI) containing packaging waste or other solid or liquid waste is generated as containers are recycled back to the supplier for refilling.

To sum up, release to soil is considered negligible by the applicant.

Table 5: Releases to the environment

Release	Release rate	Release estimation method and details
Water	Initial release factor: 50% Final release factor: 4% Local release rates: < 0.1-1.5 kg/day total chromium	The release factor is based on literature data, which indicate that the total chromium concentration in the spent chroming bath is 5 mg/L when a 1:10 liquor ratio is used (BREF 2003) and on site-specific release data.
Air	Initial release factor: 50% Final release factor: 0.03% (fugitive emissions) Local release rate: 0.012 kg/day	The final factor is default Technical Guidance Document (TGD 2003) emission factor for textile industry sector without any refinement. The emission was calculated based on annual use of Cr(VI) per each site.
Soil	Initial release factor: 1% Final release factor: 0.01% Local release rate: 0	The final factor is default TGD emission factor for the textile industry sector without any refinement.

Exposure estimation methodology:

The applicant provided an assessment of indirect exposure to humans via the environment at a local and regional scale calculated by EUSES modelling (version 2.1). The applicant made Tier 0 and Tier 1 calculations based on 80 t sodium dichromate regional use volume for the sites and 220 emission days per year.

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

Protection target and units	Local scale	
	Exposure estimate	**Excess cancer risk**
Humans via Environment – Inhalation (µg/m^3)	2.0×10^{-3} (100 m from source) 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)

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, 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 the 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.

For release to water total chromium was considered not Cr(VI).

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

RAC notes that the use of the default release factor for air of 0.03% from the TGD 2003 introduces uncertainty into the assessment as RMMs to prevent release to air were not described in detail. However, the applicant stated that "measurements from the workplace air support a conclusion that emissions of Cr(VI) from the equipment to air is negligible from the environmental point of view".

RAC acknowledges that the 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). However, RAC notes that the applicant refined the default assessment of indirect exposure through the use of a simplified Gaussian plume model to model inhalation 500 metres from the site. The applicant also refined the approach to assessing the oral route of exposure that take into account the transformation behaviour of Cr(VI) to Cr(III) once released into the environment.

As the applicant used the total chromium for calculating the release rate to wastewater (instead of measured releases on Cr(VI)), the obtained release rate might be overestimated. In addition, RAC notes that the applicant did not provide clear data, particularly regarding wastewater treatment at the different sites, so this leads also to some minor uncertainties.

In general, the methodology used by the applicant to calculate the release factors is not completely understandable for RAC what leads to further minor uncertainties on the environmental exposure estimates.

Conclusion

RAC considers that for both workers 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 moderate uncertainties due to the fact that biomonitoring data and air monitoring data were presented from four different sites out of eleven sites covered by the application. In addition, there remain some low uncertainties because of lacking contextual information on the measured data (air measurements as well as biomonitoring data).
- Releases to the environment are uncertain but at a rather minor level. Releases to water were derived from total chromium measurements and may therefore overestimate releases of Cr(VI).

Overall, the uncertainties identified in the exposure assessment are considered to be low for the exposure assessment to humans via the environment and moderate for workers. These uncertainties could be overcome with a set of biomonitoring and air monitoring data provided from all the sites, also including more detailed contextual information on the tasks performed during measurements and the OCs and RMMs in place. The data for indirect exposure could be overcome with measured data, particularly on emissions to wastewater.

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 all 11 sites. According to them, workers do not have direct contact on Cr(VI) in general, only in cases of emergency or in case of a fault in the automatic system.

On RAC's request, the applicant further clarified that the dyeing process is basically similar at the different sites and therefore the level of RMMs are comparable. The actual procedure

in the batch reactors is continuous in nature, so that all process stages are automated, pre-programmable and remotely controlled. The dyeing process takes place in closed reactors at all sites. In addition, at every site, closed chemical dosing systems are installed. However, the applicant noted that the OCs might be different (e.g. amount of sodium dichromate used, number of workers performing tasks related to potential exposure on Cr(VI)).

For opening and emptying the reactors, both manual and automatic mechanisms are in use. As the dyed material is wet, there might be some vapours in the air. According to the applicant, thiosulphate is added into the reactors at the end of the dyeing process to reduce Cr(VI) to Cr(III); therefore exposure to Cr(III) may be potentially significant at the opening of the reactors. However, the applicant did not explain the conditions during the unloading tasks. They only state that there are no fugitive emissions from the tightly closed reactors.

General mechanical ventilation systems in the dyeing halls may not be installed as there is no information provided on such kind of RMMs. In addition, the dyeing vessels might also lack of any ventilation systems, although most of them could be pressurised.

Sealed surfaces, channelled pavements, safety pools and / separate sewer system for possible leakages is in use to manage any leaks of chemicals, according to the applicant.

According to the applicant, operating and safety instructions on how to safely work with sodium dichromate, including how to use PPE if necessary, are implemented. However, RAC notes uncertainties with regard to the RPE in use, as the applicant refers to half mask with single ABEK1 cartridges for unloading and maintenance tasks whereas this type of cartridges might not be sufficiently protective for inhalable Cr(VI) particles due to the lack of particle filters. In addition, RAC notes that a 5-years-training interval on adequate use of PPE is not sufficient. Such training should be implemented on a yearly basis.

To sum up, there seem to be minor uncertainties related to implemented mechanical ventilation systems in the dyeing hall and on the reactor vessels as it is not clear to RAC if fugitive emissions occur due to opening the reactors or when they are working under pressure. However, the emissions contain Cr(III) rather than Cr(VI).

Uncertainties are noted regarding the RPE used - as no particles filters are foreseen according to the information provided - and in relation to the frequency of the trainings in the use of PPE.

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 This approach was supported by a small number of air measurements (personal and static samples) as the results of the air measurements were below the exposure estimate taken forward by the applicant.

Table 7: Excess risk estimates for 40 years exposure for workers

Route	Exposure value, TWA 8 h, µg/m³	Excess lung cancer risk
Inhalation	0.75 (median)*	3×10^{-3}

* Out of a number of 280 biomonitoring data, the median value was chosen to estimate exposure and risk.

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

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)/m³ 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 scale based on EUSES modelling. As discussed in section 4, RAC considers this approach to be acceptable.

Table 8: 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 the Environment – Inhalation (µg/m³)	5.4×10^{-4} (500 m from source)*	1.5×10^{-5} (lung cancer)
Humans via the environment – Oral (µg/kg bw/day)	8.6×10^{-3}	6.9×10^{-6} (intestinal cancer)
Humans via the environment - Combined		**2.2×10^{-5}**

* 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/m³.

RAC accepts these calculations.

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 appear not to be appropriate in limiting the risk to workers due to uncertainties related to the use of adequate RPE and the interval of trainings on PPE use. The RMMs and OCs are adequate and effective 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 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.

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 (80 tonnes per annum). By acting as a bridge between the wool and the dye, chromium achieves a coloured textile with a high colour fastness. At the moment alternatives have been found for the lighter and medium colours, but not for the classic dark colours which are covered by this application (e.g. black, navy blue, brown).

The applicant starts off with giving a good overview of their company and the rest of the value chain covered by this application. This is an upstream application, where the applicant is an importer that repacks and supplies (but does not use the substance) to 11 downstream users (8 dyeing companies, 3 textile manufacturers) who use the substance as a mordant. They also briefly discuss the economic characteristics of the textile market (especially competition issues). Following that, the applicant discusses concisely, but clearly, the substance function and how the efforts to identify alternatives are organised. This analysis of alternatives centres on two types: alternative complexing agents and reactive dyes (making the use of the mordant obsolete).

The main issue of the analysis of alternatives, as initially submitted, is that only a rather general discussion of technical feasibility is given which makes SEAC's job of assessing alternatives difficult. The Committee is told that groups of alternatives (e.g. alternative complexing agents, reactive dyes) cannot be used, but only brief and general qualitative arguments are provided which are not linked to specific alternatives (e.g. mixture of dyes that are black, navy blue or brown). SEAC is given and explained the characteristics that are deemed important for an alternative (metamerism, shade, fastness…), but these are only used in the briefest and most general way to discuss the tested alternatives (only some examples are listed). The decision to dismiss specific alternatives is not impressed upon SEAC in an entirely transparent way. In their answers to SEAC's questions and during the trialogue, the applicant did however provide compelling reasons on why subjective arguments are unfortunately inherent to most discussions regarding the part of the dyeing

sector involved with fashion. The applicant additionally tried and succeeded (to a certain extent) to present additional and more scientific results.

SEAC understands that the textile dyers are to a large extent dependent on their clients, the fashion houses and clothing manufacturers, who employ more subjective standards as to whether the dyed wool is suitable for use or not. The Committee also acknowledges that the tastes and level of acceptance of the consumers change from season to season. The idiosyncrasies of this sector make it difficult to prepare a fully clear-cut discussion of alternatives.

However, according to SEAC, the 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 some of the Committee's concerns. The applicant has also indicated that samples dyed with reactive dyes have been consistently rejected by their customers.

When it comes to the applicant's discussion on economic feasibility, this is focussed completely on the reactive dyes alternative and is also general in nature. SEAC can accept that operational cost increases are to be expected, but the applicant's calculations contain significant uncertainties (representativeness of used figures?). However, SEAC was still able to come to a conclusion on economic feasibility based on qualitative arguments.

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. Together with the applicant SEAC tried to resolve the issues, 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 taste.

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

☐ YES

☒ NO

Justification:

The applicant presented two groups of potential substitutes: alternative complexing agents and reactive dyes. The latter would make the use of a mordant obsolete.

1. Alternative complexing agents

The applicant indicates that the industry has performed in-depth research on this type of alternative, but that none of them were able to achieve the same level of quality as with

sodium dichromate. There is a significant shift in colour tone and the colour fastness was found to be unacceptable.

This was in essence the extent of the discussion on this type of alternative. SEAC asked the applicant to elaborate a bit more on this general discussion by using the Subsport paper on Cr (VI)[2] as a reference. In their answer the applicant states that the infeasibility of alternative complexing agents is a widely-known fact in the industry and that it was therefore not deemed relevant to discuss alternative complexing agents in further detail[3]. SEAC could not readily accept this argument since the Subsport document provides, in some cases, contradicting information to what the applicant states in his application. Even though, in SEAC's view, the Subsport document is not specific enough and transparent enough in relation to the use of mordants in the textile industry, not addressing this issue hinders the Committee's assessment of technical feasibility. During the trialogue similar arguments to the ones in the application were provided, as well as a somewhat more systematic, and therefore more helpful, discussion on alternative mordants which, according to the applicant, show that these alternatives are most likely not technically feasible.

SEAC can accept that this type of alternatives is not technically feasible even though some uncertainties remain. No information on economic feasibility was provided.

2. Reactive dyes

Reactive dyes are a group of colourants that would make the use of a mordant unnecessary since they themselves, as their name suggests, react with the wool. Textile manufacturers have been able to substitute chrome dyes with these reactive dyes mostly for light and medium colours, but not the darker colours (black, navy, blue, brown).

According to the applicant there are multiple problems with the already tested reactive dyes or dye mixtures.

There are **technical issues** which entail that the requirements for shade, metamerism[4], fastness[5] and crease/stretch resistance are not met. These terms are explained in the application, but were initially not linked to specific alternatives (dyes and/or dye formulations). This overly general discussion made SEAC's assessment difficult. In the initial application reference was made to "standard requirements and limit values" put forth by the Italian fashion association SMI. After further inquiries with the applicant, it became clear to SEAC that while some form of quantifiable limits are used, whether an alternative product will ultimately be accepted by the customers of their downstream users[6] still remains somewhat subjective and uncertain. This makes it difficult for the applicant to provide SEAC with a compelling case which would allow the Committee to come to a firm conclusion. During the trialogue the applicant provided more specific information on reactive dyes which show, according to the applicant, that this type of

[2] 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

[3] The applicant states in their answers to SEAC's questions that they were in contact with 1 dyeing chemicals manufacturing company who have studied alternative complexing agents from 1992-1993. The conclusion was that these were not usable. No further justification was provided.

[4] Colours can appear different under different light sources.

[5] Washing fastness, light fastness,… How fast does the colour fade?

[6] Fashion houses and clothing manufacturers.

alternatives is most likely not technically feasible yet. SEAC can accept the applicant's conclusion even though some uncertainties remain. The applicant has however indicated that samples dyed with reactive dyes have been consistently rejected by their customers, which strengthens the conclusion on infeasibility.

Besides these technical issues, the economic feasibility of the alternatives is briefly discussed. The applicant calculated the overall net changes in operational costs to be €4.6 million for all of the downstream users. According to the applicant this figure consists of 'recipe costs', 'production costs' and costs related to the prolonged production/cycle time (it takes longer to dye a batch of wool).

1. 'Recipe costs': the applicant indicates that the reactive dyes can, on average, be 20-50% more expensive, but that formulations made with the dyes can be less expensive. In their overall calculations of the net changes in operational costs, the applicant assumed that this recipe cost could be lower.
2. 'Production costs': the applicant defines the net changes in production costs as an increased cost associated with the use of more washing water due to the fact that reactive dyes are not completely consumed during the process and remain unfixed. This then leads to an increased load on the wastewater treatment plants (WWTP, more water and increased dye chemicals discharge).
3. Costs related to the prolonged production/cycle time: the applicant has indicated that the process time using reactive dyes is on average 26% longer than with chromium dyes. This entails that the companies covered by the application can only produce 1 batch of product instead of 2 or 3. SEAC finds this loss of productivity somewhat exaggerated considering the comparison of cycle times that was given in the application (chrome: 190 min, reactive: 220 min).

All of these cost elements were then combined to calculate an increase in cost per kg of dyed wool. In total 5 downstream users provided information on the net change in operational costs per kg of dyed wool which were said to be dependent on the company and its processes (e.g. level of automation). Based on this DU information a weighted average was calculated and then multiplied by the average amount of wool dyed per year. Discounting this figure over 7 years then provides SEAC with the net change in operational costs of €4.6 million for all of the downstream users.

The applicant has stated that it cannot pass along these increased production costs down the supply chain. According to the applicant this number also does not include some possible investment costs (e.g. increase in capacity of the WWTP).

While SEAC can accept the approach taken, the Committee would like to note that the average estimates for the different cost elements are based on information submitted to the applicant by a small portion of the companies covered by this application. The representativeness of these estimates for all the companies is therefore to some extent uncertain and the overall net change of the operational costs equally so. Due to this question of representativeness it is also difficult for SEAC to state with absolute certainty that reactive dyes are economically infeasible for all companies covered by the application. Having said all this however, SEAC can still accept the applicant's conclusion on economic infeasibility based on the expected qualitative impacts, such as the increased water consumption and need to treat the discharged water more intensively.

The applicant has indicated that the companies covered by this application will continue to test new dyes and dye mixtures to substitute the chrome dyes still in use.

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 does concur with the applicant that, by the sunset date, there are no suitable alternatives available to the applicant and his downstream users.

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 and technologies. They described the three different phases of their research:

The first phase involved the remove of sodium dichromate in aqueous solution by complexing agents like aluminium, iron, titanium and trivalent chromium salts combined with oxidizers. As none of these tested alternatives was able to replicate the quality achieved when using sodium dichromate as a complexing agent, the focus was turned to the replacement by investigating the reactive dyes.

The aim in the second phase was to find dyes that would render the function of sodium dichromate obsolete. This goal was partly achieved. Reactive dyes were able to substitute the chrome dyes mainly in bright colours. These reactive dyes are a relatively new group of colourants composed of e.g. mixtures of azo dyestuffs and / or anthraquinone dyestuffs. Reactive dyes are generally bifunctional, containing bromoacrylamide or vinylsulphone reactive groups.

The third phase has involved the replacement of chrome dyes for classical dark colours. As each of the alternative dyes has failed the quality tests made, therefore further research activities are still ongoing.

Nonetheless, the applicant described the hazards for some of the potential alternative substances. They presented a table with the notified classification and labelling according to CLP criteria for some components of the different alternative dyes.

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 some of the potential alternatives. However, this information does not seem to be complete. In addition, neither a harmonised C&L has been agreed for all of these alternatives nor any exposure scenarios and risk assessment were presented for them; therefore a judgement on this issue is rather difficult.

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 provided by the applicant. It reflects the expected statistical number of cancer case 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
WCS 1 and 2	125*	3×10^{-3}	3.75×10^{-1}

***** *In the SEA, the number of workers having access to the process hall is listed and 125 is the sum of all these.*

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

Protection target	Number of people exposed	Excess lung cancer risk	Estimated 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}

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 clients of the applicant (downstream users) - the dyers and textiles manufacturers would continue to test reactive dye alternatives, and introduce products produced with available reactive dyes. Until then, dyeing of wool to classical dark colours would be discontinued;
- the supply chain layer consisting of clothing manufacturers, wholesalers, tailors, fashion houses and retailers will search for alternative sources of the sliver, yarn and fabrics outside of the EEA.

The assessment of economic impacts undertaken by the applicant is based on a well-established benefit-cost methodology. SEAC cannot, however, fully agree with several assumptions and statements made by the applicant since the justifications and clarifications provided did not remove all uncertainties.

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 the Province of Biella, 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).

Exposure values were calculated based on the use of 80 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, and permanent exposure of 70 years for the general population.

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 8.2×10^{-2} additional statistical cancer cases among on-site workers of the downstream users and of 3.9×10^{-2} additional statistical cancer cases among the general population.

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, 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 net present value of €265,943 to €435,180 for both on-site workers and general population.

At the request of RAC, the applicant provided additional information regarding the number of workers potentially exposed to sodium dichromate and explanations on how ELR values were calculated. 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 6.8×10^{-2} for a 7-year review period resulting in a total human health cost of €156,300 (lower bound value) to €251,300 (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 clients of the applicant - the dyers and textiles manufacturers (downstream users) - would continue to test reactive dye alternatives, and introduce products produced with available reactive dyes. Until a suitable alternative reactive dye is available, dyeing of wool to classical dark colours would be discontinued.

Discontinuation of dyeing of wool to classical dark colours would lead to the loss of sales of approximately 28 percent (average value for all downstream users), according to the applicant. Profit loss is expected to be in the range of €6.5 to 23.2 million per year. In addition, there is significant risk to completely lose clients that are buying not only classical dark colour wool but a wider range of products supplied by the dyers and textile manufacturers.

Even in the case that a suitable alternative reactive dye will be found and the dyeing of classical dark colour wool can be reintroduced, there are several challenges that will need to be addressed and additional costs to be covered by the dyers and textiles manufacturers:

- The processing time of wool dyed with reactive dyes is longer than the processing time when chrome dyes are used. Dyers and textile manufacturers will be able to produce only 1 batch of product with reactive dyes in a day compared to 2-3 batches a day with chrome dyes. In order to retain production output, there will be a need for additional machinery;
- Due to prolonged processing time, significant increase in electricity and water consumption is expected. Investments will be required to increase the capacity of the waste water treatment plants and the water mains.

SEAC finds this NUS to be credible even though it 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 which are attributable to downstream users:

- 150 job losses or 9.8% of the total downstream users' workforce. Downstream users will lay off personnel in order to adapt their fixed cost base and compensate negative business changes (lost sales, profits and even customers);

- Investment in new machinery (due to insufficient production capacity when reactive dyes are introduced), waste water treatment plant and water mains (due to significantly increased water consumption);
- Production cost (water, electricity, raw materials) increase;
- Profit loss of the downstream users.

Negative economic impacts (NPV) associated with a non-granted authorisation as estimated by the applicant are in the range from €48 to €144 million. The applicant notices that this cost does not include any economic loss that may be faced by the supply chain layer consisting of clothing manufacturers, wholesalers, tailors, fashion houses and retailers.

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

- Technological and economic aspects of the dyeing process;
- Sources of information for necessary investment cost and necessity of those investments in the future even if authorisation is granted;
- Alternative sources of classical dark colour wool products from low cost countries outside the EEA;
- Additional information on employment layoffs if authorisation is not granted.

SEAC considers the total economic impact as assessed by the applicant to be overestimated and closer to the lower bound of the range set by the applicant. SEAC arrives at this conclusion primarily for two reasons:

- Necessary investments, most likely, shall be made within both - NUS and scenario where suitable alternative dyes are available. Thus, it is only deferral of the investment for 4 to 6-year period;
- SEAC concurs with the statement of the applicant that companies (downstream users) would adapt their business, e.g. by workforce layoffs and other cost reductions, to maintain the existing profit margin.

In response to SEAC's questions, the applicant provided only partial answers arguing that the applicant and downstream users are lacking information or there are only qualitative assumptions. Therefore, some uncertainty about the technological and economic aspects of the dyeing process and dyed wool markets still exists. For this reason, SEAC cannot reassess the total socio-economic cost with high precision. However, SEAC was able to calculate a range for the socio–economic cost that is considered a plausible input for the opinion making process.

SEAC reassessed the impacts based on additional information on changes in employment and taking into consideration that necessary investments of downstream users are only deferred in time. SEAC based its reassessment of the health impacts of continued use on the excess cancer risk levels, as provided by RAC.

Results of the reassessment indicate that the benefits of continued use to the applicant are likely to be slightly smaller than assessed by the applicant and the monetised risk is higher than assessed by the applicant.

It should be emphasized that SEAC's reassessment follows the approach used by the applicant and does not attempt to either include the potential loss of profits incurred by the customers and suppliers of dyers and textiles manufacturers or the other wider economic impacts, particularly those that are related to clothing manufacturers and

fashion houses. According to the applicant, the Italian textile/clothing sector brings €8 billion of profit to the Italian balance of payments and high-end wool formal clothing market is important part of the exports. NUS may lead to lower quality wool products that would cast a shadow over some sectors of the Italian fashion industry.

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 downstream users and redundancies 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 €265,943 to €435,180.

SEAC recalculated the monetised health impacts using the excess cancer risk levels estimated by RAC and arrived at a total human health cost of €156,300 (lower bound value) to €251,300 (upper bound value) calculated for a 7-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 benefits of continued use are €48 to €144 million.

SEAC does not entirely agree with the calculations made by the applicant and therefore reassessed the benefits of continued use. SEAC arrived at net benefits of continued use lower than provided by the applicant (in the range of €42 to €72 million). It shall be noted that potential economic cost of Italian textile/clothing sector was not monetised although it is clear that sector may face risks that may lead to *significant* economic loss.

SEAC considers that the implied benefit-cost ratio of more than 160:1 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:

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.

The applicant must implement yearly trainings on the adequate use of PPE.

Description for additional 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 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 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.

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 and ensure a sufficiently low detection limit, where appropriate. Emissions data shall be presented in any subsequent review report.

Justification:

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

A 5-years-training interval for the use of PPE is not considered to be adequate by RAC.

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 a more detailed contextual information on the measured (air monitoring and biomonitoring) data provided would address the uncertainties in the 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. 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 however clearly shown that the benefits of continued use outweigh the risks (by more than a factor of 160).

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