Helsinki, 04/03/2022

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

chromium trioxide use: Formulation of chromium trioxide-based electrolyte for electroplating process

Submitting applicant

Maschinenfabrik Kaspar Walter GmbH & Co KG

ECHA/RAC/SEAC: AFA-O-0000007069-69-01/F

Consolidated version

Date: 04/03/2022

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 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to the following application for authorisation:

Applicant	**Maschinenfabrik Kaspar Walter GmbH & Co KG**
Role of the applicant in the supply chain	Upstream ☐[group of] manufacturer[s] ☒importer ☐[group of] only representative[s] ☐[group of] formulator[s] Downstream ☐[group of] downstream user[s]
Use performed by	☐Applicant ☒Downstream user of the applicant
Substance ID EC No CAS No	**Chromium trioxide** 215-607-8 1333-82-0
Intrinsic properties referred to in Annex XIV	☒Carcinogenic (Article 57(a)) ☒Mutagenic (Article 57(b)) ☐Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☐Other properties in accordance with Article 57(f) –
Use title	**Formulation of chromium trioxide-based electrolyte for electroplating process**
	Other connected uses: Chromium trioxide-based functional chrome plating of cylinders used in the

	rotogravure printing and embossing industry[1]
	Similar uses applied for: Formulation of mixtures (CTAC, Use 1)[2]
Number and location of sites covered	One site in Germany
Annual tonnage of the Annex XIV substance used per site	160-220 tonnes of CrO_3/year
Function of the Annex XIV substance	Chromium trioxide has no independent function within this use. The substance's function is only relevant for the subsequent hard chrome plating of printing and embossing cylinders described in Use 2.
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	Formulation of chromium trioxide-based electrolyte, which is used in Use 2 for electroplating process of printing cylinders used in high-quality printing applications required in the packaging, decorative, publication and embossing industry
Annex XIV substance present in concentrations above 0.1% in the products (e.g. articles) made	☒Yes ☐No ☐Unclear ☐Not relevant
Review period requested by the applicant (length)	12 years
Use ID (ECHA website)	0234-01
Reference number	11-2120881009-51-0001

[1] https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/62905/del/50/col/synonymDynamicField_1512/type/asc/pre/8/view
[2] https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/14304/del/50/col/staticField_-104/type/desc/pre/4/view

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	15/02/2021
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	10/05/2021
Was the application submitted by the Latest Application Date for the substance and can the applicant and their downstream users consequently benefit from the transitional arrangements described in Article 58(1)(c)(ii)?	☐Yes ☒No
Date of consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	19/05/2021-14/07/2021
Were comments received in the consultation?	☐Yes ☒No
Request for additional information in accordance with Article 64(3)	On 21/06/2021, 31/08/2021 (RAC), 01/09/2021 (SEAC) and 19/10/2021 Link: https://echa.europa.eu/applications-for-authorisation-consultation/-/substance-rev/28005/term
Trialogue meeting	Not held – reason: no need for additional information/discussion on any technical or scientific issues related to the application from the rapporteurs
Was the time limit set in Article 64(1) for the sending of the draft opinions to the applicant extended?	☐Yes, by Reason: ☒No
Did the application include all the necessary information specified in Article 62 that is relevant to the Committees' remit?	☒Yes ☐No
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: 26/11/2021, agreed by consensus
	SEAC: 08/12/2021, agreed by consensus
Date of sending of the draft opinions to the applicant	03/02/2022

Date of decision of the applicant not to comment on the draft opinions, in accordance with Article 64(5)	04/03/2022
Date of receipt of comments in accordance with Article 64(5)	Not relevant
Date of adoption of the opinion in accordance with Article 64(5)	RAC: 04/03/2022, adopted by consensus
	SEAC: 04/03/2022, adopted by consensus
Minority positions	RAC: No minority positions
	SEAC: No minority positions
RAC Rapporteur RAC Co-rapporteur	Rudolf VAN DER HAAR Riitta LEINONEN
SEAC Rapporteur SEAC Co-rapporteur	Martien JANSSEN John JOYCE
ECHA Secretariat	Arnis LUDBORŽS Sanna HENRICHSON Tytti MBANI

LIST OF ACRONYMS

ACH	Air Changes per Hour
AfA	Application for authorisation
AoA	Analysis of alternatives
bw	Body weight
CBA	Cost-benefit analysis
C-E	Cost-effectiveness
CSR	Chemical safety report
DNEL	Derived no-effect level
DU	Downstream user
ES	Exposure scenario
ECS	Environmental contributing scenario
LAD	Latest application date
LEV	Local exhaust ventilation
NUS	Non-use scenario
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
RR	Review report
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic Analysis
SP	Substitution plan
SSD	Sunset date
vPvB	Very persistent and very bioaccumulative
WCS	Worker contributing scenario

This document provides the opinions of the Committees for Risk Assessment and for Socio-economic Analysis based on their scientific assessment of the application for authorisation. It thus provides scientific input to the European Commission's broader overall balancing of interests.

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the operational conditions and risk management measures described, as well as
- other available information.

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

SEAC concluded that there are no technically and/or economically feasible alternatives available for the applicant or their downstream users with the same function and similar level of performance by the date of adoption of this opinion. Therefore, RAC did not evaluate the potential risk of alternatives.

RAC concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk, provided that they are adhered to. The proposed additional conditions for the authorisation are expected to strengthen this conclusion.

The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures implemented as a result of additional conditions and on associated trends in exposure during the review period. This information should also be included in a possible review report.

The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.

The exposure of workers and the general population to the substance is estimated to be as described in section 2 of the justification to this opinion.

The risk for workers and the general population from exposure to the substance is estimated to be as described in section 3 of the justification to this opinion.

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the suitability and availability of alternatives associated with the use of the substance taking into account the information in the application, as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises the Commission's Better Regulation guidance, the Guidance documents on applications for authorisation and the socio-economic analysis as well as specific guidance related to how SEAC evaluates the applications (e.g. dose-response functions, values of health endpoints).

SEAC took note of RAC's conclusion that it is not possible to determine DNEL(s) for the carcinogenicity properties of the substance in accordance with Annex I of the REACH Regulation.

The assessment of alternatives is not relevant for this use as the substance does not provide any specific function at the formulation stage.

SEAC has assessed the information provided by the applicant and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the applicant has demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to human health resulting from the granting of an authorisation.

The expected societal costs of not granting an authorisation are estimated to be at least €51-100 million per year consisting of economic impacts to the applicant and its supply chain and the social cost of unemployment. Additional societal impacts of not granting an authorisation have been assessed qualitatively but have not been monetised and consist of changes in product quality, changes in the market price for end consumers and changes in customer retention and market position. It should be noted that the societal costs relate to both Use 1 and Use 2, given that these are interlinked. SEAC notes that these impacts occur only once if either one or both uses are not granted an authorisation.

The risks arising from granting an authorisation, which considers:

- the endpoint relevant for listing the substance in Annex XIV of REACH;
- the 13 directly exposed workers;
- the general population exposed at local scale (approximately 10 000 persons) and at regional scale (0 persons);
- that the risk of continued use as assessed by RAC may result in approximately 0.0075 expected additional cases of cancer per year;
- the value of these expected additional cases has been monetised based on the willingness-to-pay methodology and corresponds to an estimate of approximately €21 200-35 300 per year.

It should be noted that the above monetisation of risks only relates to Use 1 of the application for authorisation. The human health impacts of both uses would be avoided by refusing the authorisation to either one of the uses applied for. Therefore, the societal costs outlined above should be compared with the combined monetised risk of Use 1 and Use 2. The combined monetised risk of the two uses would be €1.2-2 million per year.

SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

Additional conditions for the authorisation are proposed. These are listed in section 7 of the justification to this opinion.

Monitoring arrangements for the authorisation are proposed. These are listed in section 8 of the justifications to this opinion.

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

REVIEW PERIOD

Taking into account the information provided in the application for authorisation submitted by the applicant and any comments received in the consultation, a **12-year** review period is recommended for this use, i.e. until the end of 2032.

JUSTIFICATIONS

0. Short description of use

The applicant, Maschinenfabrik Kaspar Walter GmbH & Co KG, is a manufacturer of plating equipment for gravure printing and embossing cylinders and supplies customer-specific complete plating systems (plating lines) for different printing segments: packaging, decorative, publication and embossing. The applicant acts as importer, purchases chromium trioxide as a raw material from outside the EEA and has the formulations carried out by a third party.

Rotogravure printing is a technique based on the transfer of fluid ink from engravings on a printing cylinder to the surface of a substrate, or the material to be printed. Rotogravure is used primarily for long printing runs in applications such as magazines, catalogues, inserts, flyers, gift-wrap, and labels, among many others.

The affected production activity covered in this AfA has been segmented into two uses.

This opinion covers Use 1, which corresponds to the formulation of chromium trioxide-based electrolyte for the electroplating process. The formulation is performed by a contracted party (formulator) and the mixture is supplied back to the applicant to be used by its DUs.

In the second use (Use 2), the applicant is applying for authorisation for the application of CrO_3-based functional chrome plating of gravure printing and embossing cylinders used in high-quality printing applications e.g., in the packaging, decorative, and publication industry.

The total foreseen consumption of CrO_3 for the formulation (Use 1) during the review period is 160-220 t CrO_3/year[3] and is based on the estimated annual quantity of CrO_3 delivered to DUs. Information was obtained through a survey undertaken amongst the DUs. For more information about the survey, please see the AfA and opinion of Use 2. Moreover, the total tonnage was also reviewed and confirmed by the applicant based on its market knowledge and expectation about future demand.

The applicant foresees a gradual reduction of the CrO_3 consumption starting from 2025 and reaching full substitution by the end of the review period (end of 2032).

Both uses are covered by the CTAC authorisations[4] until 21 September 2024, and the applicant is currently not responsible for the import of the substance nor does it have direct control of the volumes purchased by its DUs. The applicant pointed out that once the authorisation for this application has been granted, the applicant will take over the role of importer and will cover its entire supply chain with the two uses applied for.

[3] The actual amount CrO_3 used per year is considered confidential information by the applicant but known to RAC.

[4] Authorisation decision C(2020)8797.
Use 1: ID 0032-01; RAC and SEAC Opinion on an Application for Authorisation for Chromium trioxide use: Formulation of mixtures ECHA/RAC/SEAC: AFA-O-0000006490-77-01/D: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/14304/del/50/col/staticField_-104/type/desc/pre/4/view
Use 2: ID 0032-02; RAC and SEAC Opinion on an Application for Authorisation for Chromium trioxide use: Functional chrome plating ECHA/RAC/SEAC: AFA-O-0000006490-77-02/D: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/14305/del/50/col/staticField_-104/type/desc/pre/4/view

For detailed information about the operational conditions (OCs), risk management measures (RMMs) and the exposure assessment, data were collected from the applicant's contracted formulator via detailed questionnaires and by a site visit.

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

The tasks reflect the overall frequency and duration within the formulator's site, including those destined for other clients of the formulator than the applicant. It was considered not feasible to divide the activities to fit only the amount of product (i.e. mixtures) produced for the applicant.

WCS 1: Delivery and storage of solid CrO_3

Solid CrO_3 (flakes and crystals) is delivered (1-2 times per week) to the production site in steel drums and stored in a dedicated storage area for oxidizing materials[5] (WCS 1). The room is dry, freeze-proof (≥ 15 °C). The storage area is accessible for the employees of the site. As containers are not opened during delivery and storage, there is no potential for exposure to CrO_3.

WCS 2: Preparation of the CrO_3 containing formulation

The drums with solid CrO_3 are transferred to the processing area where the preparation of CrO_3-containing formulations take place. There are two production rooms (Department A and B), each containing one mixing tank with a lid.

Department A is built over two levels. The mixing tank is situated at ground level and a filling unit is situated at the upper level. Closed vessels of solid CrO_3 are transferred to the upper level via a forklift. The solid CrO_3 is subsequently poured into a funnel directly from the drum without using any device. A circular edge extraction system is installed at the open funnel. The upper level is additionally equipped with water pipes to rinse remaining solid CrO_3 of the funnel, fill the mixing tank, and clean empty CrO_3 containers. The rinsing water is transferred into the mixing tank.

The mixing in department B is performed in mobile mixing tanks that are supplied with two mixing units and with two moveable LEV hoses that are connected to the tank with their opening inside the tank (air is extracted from inside the tank). A third moveable LEV hose is used and placed nearby the opening of the tank during manual filling of the solid CrO_3 into the tank. The CrO_3 flakes or crystals are poured directly from the drum into the tank. The LEV hoses are connected to a chrome scrubber. Water is transferred to the tank via a pellet truck with a built-in scale. To reduce dust formation and to facilitate the dissolving of the solid CrO_3, water is poured into the tank primarily. The empty vessels that contained the solid CrO_3 are rinsed, and the rinsing water is transferred and collected into the mixing tank.

The mixing tank size and mixing surface area are different between the two departments[6]. At both departments mixing is performed with a closed lid. After mixing the formulation is

[5] Storage is performed according to according to "Technical Rules for Hazardous Substances (TRGS) 510: Storage of hazardous substances in non-stationary containers".
[6] The mixing size are 0.5-2m^3 and 1.5-5m^3 for respectively Department A and B and the corresponding mixing tank surface area are 0.25-1.5 m^2 and 2-5 m^2.

transferred to distribution/shipping vessels using a pump. The surrounding area of the departments is cleaned of any residual CrO_3 formulation with water. The cleaning water is directly discharged to the wastewater treatment system via a drainage system on the floor. The emptied and cleaned containers are disposed of for waste management and disposal (see WCS 5) by an external contractor.

WCS 3: Sampling

For quality control analysis, samples of the CrO_3 containing formulation are taken manually twice per week by one employee. For sampling the CrO_3 containing solution, a 0.25 L plastic measuring jug is used, and its content is poured into a plastic bottle and transported to laboratory. As a worst case, the applicant assumed that the task is performed for ≤15 minutes twice per week (see Table 2 and Table 4).

WCS 4: Maintenance

The maintenance activities consist of checking visually the tanks and equipment. Moreover, the tanks, pumps and stirrers are checked by internal industrial engineers/maintenance personnel once to twice yearly. Every seven years (approximately) the funnel for filling solid CrO_3 is exchanged in Department A. The maintenance is only performed on the cleaned equipment. The maintenance tasks are performed by 2 workers. As a worst-case assumption, it is assumed that the maintenance activities are performed 2-3 times per week with a duration of 15 minutes (see Table 2 and Table 4).

WCS 5: Wastewater sampling and waste management (solid and liquid)

The produced wastewater is treated in an on-site wastewater treatment plant. Samples of the wastewater are drawn and filtered into a small (0.25 L) vessel daily by 1 worker. The task takes ≤ 15 minutes. The sample is drawn directly from the tank with the help of a sampler or using a drain valve at the tank. The cleaned solid waste (emptied and cleaned CrO_3 containers) and used PPE are collected in specific containers and are subsequently disposed of by an external contractor.

Table 1: Contributing scenarios presented in the use

Contributing scenario	ERC/PROC	Name of the contributing scenario	Size of the exposed population
ECS 1	ERC 2	Formulation of chromium trioxide-based electrolyte	Regional: - Local: 1 000
WCS 1	PROC 1	Delivery and storage of solid CrO_3	6 (max)
WCS 2	PROC 3	Preparation of the CrO_3 containing formulation	3
WCS 3	PROC 8b	Sampling	1
WCS 4	PROC 28	Maintenance	2

WCS 5	PROC 8b	Wastewater sampling and waste management (solid and liquid)	1

0.2. Key functions provided by the Annex XIV substance and technical properties/requirements that must be achieved by the products made with the Annex XIV substance

Chromium trioxide has no independent function during the formulation stage (Use 1). Hence, no analysis of alternatives was performed by the applicant for this use. Accordingly, no alternatives for Use 1 have been identified. The key functionalities needed for rotogravure printing and embossing (Use 2) are described in chapter 3.6.4 of the AoA. Rotogravure printing, embossing and preparation of the cylinders is described earlier in chapter 3.6. Although the end products of the printing and embossing are different, the electroplating process is the same and the key functionalities used to assess the performance of potential alternatives are also the same. These are further described in the opinion on Use 2.

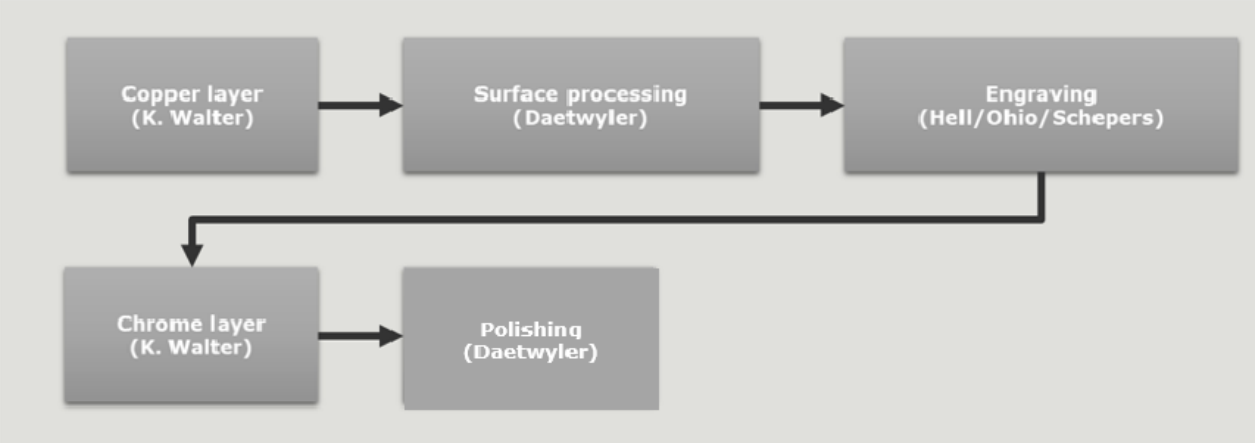
0.3. Type(s) of product(s) made with the Annex XIV substance and market sector(s) likely to be affected by the authorisation

The applicant is importer of chromium trioxide, commissions the formulation of the chromium (VI) electrolyte formulation by a third party and provides the chromium (VI) formulation and the equipment for the functional chrome plating of rotogravure and embossing cylinders that they produce for companies in three printing market sectors:

- Packaging gravure
- Publication gravure and
- Decorative gravure

Embossing of substrates plays a role in all the above three sectors. Embossing can increase the value of the print results by adding a 3D-structure and specific haptic to it. Since the same cylinder dimensions are used as in rotogravure printing, it is easy to provide the print with the appropriate structure directly after the printing process within the same process (printing + embossing).

The services that the applicant delivers are carried out in close cooperation with other subsidiaries within Heliograph Holding (Figure 1).



Note: Bauer offers logistic services for cylinders between the brands of the holding that operate the different manufacturing steps. This brand also provides storage solutions for large quantities of cylinders.

Figure 1. Production flow between K. Walter and other members within Heliograph Holding

Market sectors likely to be affected by the authorisation comprise the market sectors of the DUs being served by the applicant, but also the other subsidiaries within Heliograph Holding. These companies provide services to the production of rotogravure printing and embossing cylinders. The authorisation also affects the formulator that is commissioned by the applicant and competitive distributors that currently also deliver Cr(VI) formulations or solid Cr(VI) to the applicant's DUs. Upon SEAC's questions, the applicant indicated that it currently has a market share within the EEA of 55-65 % for the formulations covered by Use 1 and of 75-85 % for the plating units or machines covered by Use 2. The exact numbers are known by SEAC but claimed confidential. The DUs of the applicant for Use 2 comprise:

- printing companies that manufacture their own gravure and embossing cylinders,
- intermediate service providers that manufacture gravure and embossing cylinders and deliver these to printing companies, or
- a combination of both (companies manufacturing gravure and embossing cylinders for their own use and for other printing companies).

The service providers comprise 40 % of the applicant's DUs and are entirely dependent on Cr(VI) plating; 60 % of the applicant's DUs are printing companies that coat their own cylinders. Most gravure printing firms in the EEA do not have their own plating line and are dependent on intermediate service providers.

The applicant indicated that currently its DUs use both liquid formulations and solid Cr(VI) in their plating activities and that part of it is delivered by the applicant itself. The applicant has developed equipment for automatic dosing of the liquid formulation. The current authorisation request only covers the liquid formulation which may result in a shift among the DUs from solid Cr(VI) delivery to liquid formulation and which may provide the applicant with an advantage compared to its competitors delivering only solid Cr(VI).

1. Operational Conditions and Risk Management Measures

1.1. Workers

According to the applicant the following OCs and RMMs are implemented. These are summarised for each WCS in Table 2.

Technical Risk Management Measures:

- General ventilation system in place with at least 1 ACH.
- LEV nearby the opening where filling of the mixing tanks with solid CrO_3 takes place.
- The volume flow of the exhaust air system is monitored continuously and in case of disturbance or malfunction, the process stops immediately and an alarm signal alerts the workers.

Organisational Risk Management Measures:

- The chrome formulation areas and the CrO_3 storage area are restricted and only employees having an electronic chip can enter the site (within the site, all areas are accessible).
- Standard Operating Procedures (SOPs) are in place.
- Workers receive regular training regarding chemical risk management and how to properly wear Personal Protective Equipment (PPE).
- Use of disposable FFP3 masks when exposure to solid CrO_3 is expected besides other PPE (see Table 2). The masks are not reused after wearing.
- Occupational Health and Safety Management System in place. The formulator is certified for ISO14001 / ISO45001 / ISO9001.
- Specific risk assessments are conducted, documented and regularly reviewed and updated.
- Compliance with the company's rules which are based on several European Directives[7] is controlled by supervisors

[7] Directive 89/391/EEC, Directive 98/24/EC, Directive 89/391/EEC and Directive 89/656/EEC

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

Contributing scenario	Concentration of Cr(VI)	Duration and frequency of exposure	Engineering controls effectiveness as stated by the applicant	PPE + effectiveness as stated by the applicant	Organisational controls
WCS 1: Delivery and storage of solid CrO_3 PROC: 1	52 %	2 h, 1-2 times per week	Containment (closed containers) General mechanical ventilation	Protective clothing, safety footwear	Occupational Health and Safety Management System(3), trained workers
WCS 2: Preparation of the CrO_3 containing formulation PROC 3	52 % (solid) 10-50 % (4) (liquid)	3-4 h, daily	LEV (90 % eff.), General mechanical ventilation (ACH > 1)	Protective clothing, safety footwear, face protection, chemical resistant gloves, dust mask (FFP3)(1)(2)	Occupational Health and Safety Management System(3), trained workers
WCS 3: Sampling PROC 8b	≤ 34 %	≤ 15 min, 2× per week (6)	General mechanical ventilation (ACH > 1)	Protective clothing, safety footwear, face protection, chemical resistant gloves that reach above the elbows	Occupational Health and Safety Management System(3), trained workers
WCS 4: Maintenance PROC 28	1-5 %	≤ 15 min, 2-3× per week (5)	General mechanical ventilation (ACH > 1)	Protective clothing, safety footwear, face protection, chemically resistant gloves, dust mask (FFP3)(2)	Occupational Health and Safety Management System(3), trained workers
WCS 5: Wastewater sampling and waste management (solid and liquid)	0.01-0.1 %	≤ 15 min, daily	General mechanical ventilation (ACH > 1)	Protective clothing, safety footwear, face protection, chemical resistant gloves	Occupational Health and Safety Management System(3), trained workers

PROC 8b					

(1) RPE is used during the transfer of solid CrO_3 into the mixing tank
(2) APF = 30 according to the German BG rule "BGR/GUV-R190 "5. The applicant did not adjust the exposure estimate for the use of RPE (see also Table 4).
(3) The applicant is certified for ISO14001 / ISO45001 (formerly OHSAS18001) / ISO9001)
(4) The concentration is considered confidential information by the applicant and not known to RAC
(5) The frequency of the maintenance activities varies according to the tasks performed. For more detailed information see also Table 4.
(6) These values correspond to the data as presented in the CSR. In response to RAC's questions, the applicant clarified that the duration and frequency should be described as 5 minutes per day. However, the values in the CSR are used by the applicant for the risk assessment as a worst-case.

1.2. Environment/Humans via the environment

The production site is certified by ISO14001:2015 Environmental management systems.

Air

The captured exhaust air of the LEV systems is led to a connected chrome scrubber (one for each room). The water of the chrome scrubber is led to the on-site wastewater treatment plant.

There is only one measurement result available from 2012. The applicant informed that new air emission measurements are going to be performed later in 2021 as the formulator is currently covered by the CTAC AfA.

The applicant has calculated a release factor of 0.5×10^{-3} %-2×10^{-3} % based on the regulatory permitted limit value (see details in section 2.4).

Water

The formulator has an on-site wastewater treatment plant, where reductive treatment of Cr(VI) containing wastewater from the process takes place. In the answer to RAC's question, the applicant explained that wastewater is collected not only from the chrome scrubbers but also from cleaning activities (e.g. installations, the surrounding area). After reduction to Cr(III), the residual concentration of Cr(VI) is measured continuously (Limit of Quantification; LOQ = 0.05 mg/L for internal measurements) by taking daily samples. The reduction step is repeated until Cr(VI) concentrations are below the LOQ, and Cr(III) is precipitated afterwards. Subsequently, the wastewater is additionally measured by an external laboratory to ensure that the concentration of total chrome is below the permitted limit value of 0.1 mg/L for Cr(VI) in wastewater (German federal laws and *Land* laws apply). The treated wastewater is discharged automatically and batch-wise into the sewage system. Additionally, measurements are performed four times per year by an external laboratory. The applicant provided the latest measurements reported by an external laboratory from 2018 to the most recent measurement in 2021. All measured values (four measurements/year in 2018 and 2019, three in 2020, and one in 2021) were below 0.1 mg/L.

The applicant has calculated a release factor of 1×10^{-5} %-5×10^{-5} % based on a 0.05 mg/L limit that corresponds to the practice that reduction is repeated prior to precipitation until Cr(VI) concentrations fall below the LOQ 0.05 mg/L.

Soil

No direct release to the soil.

Waste (other than wastewater)

Solid and liquid waste containing Cr(VI) are collected and treated as hazardous waste. (e.g. cleaned CrO_3 containers, used and potentially contaminated PPE).

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated Effectiveness
Air	LEV, chrome scrubber	Permitted value.
Water	Reduction of Cr(VI) to Cr(III) in the on-site WWTP; liquid waste is treated as hazardous waste.	Reduction until Cr(VI) concentration is below 0.05 mg/L, based on measurements.
Soil	Solid waste is collected	No releases expected.

	and treated as hazardous waste.	

1.3. RAC's evaluation on the OCs and RMMs

Information about the operational conditions and risk management measures in place has been presented in the CSR and additional information has been provided in response to RAC's questions.

RAC considers that the OCs and RMMs to limit the workers' exposure in place are adequate (LEV in place at the opening where filling of the mixing tanks with solid CrO_3 takes place; mechanical general ventilation use of RPE to perform specific tasks).

However, RAC has some concerns about the manual tasks related to the filling of the mixing tanks with solid CrO_3 (WCS 2). As also mentioned by the applicant, this activity entails a certain potential for generation of dust that can lead to exposure notwithstanding the presence of LEV and the use of RPE by the workers. However, the applicant pointed out that although automatization of pouring of the solid CrO_3 into the mixing tank is, in theory, an option, this is not the case for the rinsing and cleaning of the emptied containers due to different conditions and varying sizes and/or diameters of the containers, taking also into account that the amount of residue at the inner side of the container differs between the products used. For this reason, the filling of the mixing tank was not automatized. The applicant also pointed out that it is the formulator's inherent task to produce liquid CrO_3 from solid CrO_3.

RAC notes from the photos provided in the CSR document that no enclosure is implemented at the filling point of solid CrO_3 into the mixing tank.

RAC notes that the applicant did not provide information about the maintenance of the LEV systems and no data have been provided that underpin the effectiveness of 90 %[8].

RAC points out that the Assigned Protection Factor (APF) provided by the German BG rule "BGR/GUV-R190" from December 2011 (APF = 30) was used by the applicant to determine the efficiency of RPE. It is noted that other countries allocate lower APFs than Germany[9].

The applicant informed that a 'fit check' of the seal of the FFP3 masks is not performed. RAC considers that performing a 'fit check' of the seal[10] of the RPE any time before entering the workplace and taking on relevant tasks is a minimum requirement to guarantee that the RPE will provide the intended level of protection during its use.

RAC has some minor concerns about the air abatement efficiency and the onsite WWTP efficiency at the applicant's site, because no specific information about these efficiencies has been provided by the applicant.

In addition, RAC has concerns about having only one air measurement result from 2012. Although there is a regulatory limit value set, annual measurements would verify the effectiveness of OCs and RMMs.

[8] The applicant used the default efficiency of 90 % for local exhaust ventilation (fixed capturing hood) as defined by the exposure modelling tool ART %

[9] For a full-Face Mask with P3 filter, the Health Safety Executive (HSE) assign an APF of 40. Health and Safety Executive. Respiratory protective equipment at work: A practical guide. (https://www.hse.gov.uk/pubns/books/hsg53.htm).

[10] A 'fit check' of the seal is also named a seal check or a fit test.

1.4. RAC's conclusions on the OCs and RMMs

The OCs and RMMs implemented for the workers' protection, including the selection of PPE are considered to be generally appropriate and effective and follow the hierarchy of control principles.

However, RAC has some concerns about the absence of any enclosure around the filling point of solid CrO_3 into the mixing tanks, the lack of information that would confirm the assumed LEV efficiency and that the workers do not perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks, and that therefore the intended level of protection might not be reached during its use.

In terms of environmental release minimisation RAC considers that the OCs and RMMs are generally effective and appropriate in limiting the risks to the general population. However, RAC has some concerns related to the lack of information on the efficiency of air abatement and the on-site WWTP and to having only one measurement result from 2012 on release to air.

The abovementioned concerns lead to proposed additional conditions for the authorisation (see section 7) and recommendations for the review period (see section 9).

Overall conclusion

Are the operational conditions and risk management measures appropriate[11] and effective[12] in limiting the risks?

Workers	☒Yes	☐No	☐Not relevant
Consumers	☐Yes	☐No	☒Not relevant
Humans via the environment	☒Yes	☐No	☐Not relevant
Environment	☐Yes	☐No	☒Not relevant

2. Exposure assessment

2.1. Inhalation exposure

Air monitoring

For WCS 2, the applicant performed in 2020 three personal measurements; one worker of department B that also covered the sampling of the formulation (WCS 3) and two workers of department A, using the IFA 7284 sampling and the IFA 6665 analytical procedure.

Two of the measurements were below the respective limit of detection (LOD) of 0.14 and 0.16 µg/m^3. For those measurements, half of the LOD was used for further calculation.

The measurements were run for around 160 minutes, which is similar to the expected duration of the activity. The applicant did not adjust the results for the duration of the task and

[11] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls as well as prevention or minimisation of releases in application of OCs and RMMs and compliance with the relevant legislation.
[12] 'Effectiveness' – evaluation of the degree to which the OCs and RMM are successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

considered them as a worst-case for a total shift exposure. One of the three personal measurements performed at the formulators site covered among others sampling of the formulation by a worker at department B.

Although the employees wear RPE with an APF of 30 during the transfer of solid CrO_3 into the mixing tank, the exposure reduction was not considered in the exposure estimate as the RPE is not worn during all the tasks covered by the personal measurements.

Since the number of measurements is rather low RAC decided to use the highest measurement result for the exposure assessment of this WCS instead of the 90th percentile as presented by the applicant.

Modelling

For WCS 3 (Sampling), WCS 4 (Maintenance) and WCS 5 (Wastewater sampling and waste management), the applicant presented exposure estimates (90th percentile) calculated using ART version 1.5.

Although sampling (WCS 3) was covered by one measurement (besides covering the tasks of WCS 2), the more conservative modelled value for WCS 3 was used for the risk characterisation as a worst-case approach.

According to the applicant exposure during the maintenance activities (WCS 4) is highly improbable since they are only performed on the cleaned equipment. The worst-case scenario of potential exposure is presented by summing up the calculated exposure estimates of two sub scenarios, namely the exposure corresponding to the maintenance of the chrome scrubbers during which the filters of the scrubber are rinsed out and the sampling of the rinse water of the scrubber to determine the concentration of CrO_3/Cr(VI) in laboratory analysis (see Table 4). The maximum Cr(VI) concentration of the rinsing water of the scrubber has been taken forward for the calculation.

Since all emptied CrO_3 containers are cleaned during the preparation of the formulation (WCS 2), the applicant considered that exposure during the waste management can be disregarded. Waste containers are handled in such a way that contamination e.g. of outer surfaces, is prevented.

The exposure estimation of WCS 5 covers only the wastewater sampling. As a worst-case, it is assumed that all sampling is conducted directly from the open surface of the tank. For the modelling a minute concentration (0.01 to 0.1 %) of Cr(VI) is assumed, representing a worst-case since the wastewater measurements showed that the permitted limit value of 0.1 mg Cr(VI) is not exceeded.

Table 4: Summary of exposure information –inhalation

Contributing scenario	Method of assessment	Exposure (8h TWA) µg Cr(VI)/m³	Duration and frequency of exposure	Exposure corrected for PPE and frequency µg Cr(VI)/m³
WCS 1: Delivery and storage of solid CrO_3	Qualitative	0	2 h, 1-2 times per week	0
WCS 2: Preparation of the CrO_3 containing formulation	Measurements (n = 3)	0.184 (90th percentile) 0.21 (max. value)	3-4 h, daily	0.21 (max value)(1)
WCS 3: Sampling	Estimated	0.39 (90th	≤ 15 min, 2× per	0.16 (2)

	(ART 1.5)	percentile)	week(6)	
WCS 4: Maintenance – rinsing of the scrubber	Estimated (ART 1.5)	0.034 (90th percentile)	≤ 15 min, 2× per week	4.5×10^{-4} (2)(3)
WCS 4: Maintenance – sampling of rinsing water of the scrubber	Estimated (ART 1.5)	0.034 (90th percentile)	≤ 15 min, 3× per week	2.0×10^{-2} (4)(5)
WCS 4: Maintenance - total				2.1×10^{-2}
WCS 5: Wastewater sampling and waste management (solid and liquid)	Estimated (ART 1.5)	6.8×10^{-4} (90th percentile)	≤ 15 min, daily	6.8×10^{-4}

(1): During the transfer of solid CrO_3 employees wear RPE with an APF of 30. The reduction was however not considered in the exposure assessment by the applicant as RPE is not worn during all tasks covered by the personal measurements.
(2): Adjustment factor of 0.40 for frequency was applied (2 working days per week)
(3): Concentration adjusted for the use of RPE (APF = 30)
(4): Adjustment factor of 0.60 for frequency was applied (3 working days per week)
(5): As a worst-case approach, the applicant did not consider the use of RPE
(6): These values correspond to the data as presented in the CSR. In response to RAC's questions, the applicant clarified that the duration and frequency should be described as 5 minutes per day. However, the values in the CSR are used by the applicant for the risk assessment as a worst-case.

2.2. Dermal exposure

Dermal exposure was not assessed by the applicant since according to RAC/27/2013/06 Rev.1, there are no data to indicate that dermal exposure to Cr(VI) compounds presents a potential cancer risk to humans.

2.3. Biomonitoring

Biomonitoring is performed at the formulator site but only the employee is contacted by the occupational physician in case of non-conforming results. The employer has no access to results.

2.4. Environmental releases

Exposure and risks for man via environment described in the ES are based on measurement data (measurement of residual Cr(VI) in the exhaust air and regular measurements on residual Cr(VI) concentrations in the wastewater) as well as information taken from the formulator's questionnaires.

Formulations are produced on 230 days per year. Over the last three years and in 2012 the average tonnage of chromium trioxide has been considerably greater than the tonnage applied

for in the current application. For the exposure estimates performed with Chesar 3, an annual tonnage of 160-220 tons[13] of CrO_3 was used as the tonnage covered in this AfA.

Air

One air emission measurement was performed in 2012. No further measurements are available at the moment. In the CSR the applicant based the exposure assessment on this value.

In the answer to RAC's question, the applicant explained that the one measurement in 2012 is representative also of the current situation. The tonnages in 2012 and 2018 (maximum tonnage) are consistent since the consumed tonnage was the same. Also, the measurement was performed after modernisation of the ventilation system and thus the installations are the same.

However, despite the overall comparability, additional information was received during the preparation of the answer to RAC's question. In 2012 only the exhaust of department B was measured, but not of department A. Therefore, the presented results are potentially underestimating the actual situation. In the measured department, approximately 5 % of the total tonnage of CrO_3 is consumed and the applicant decided to provide a new estimation including emissions from both exhausts. The applicant did not, however, use the ERC-based scenario because of the high release fraction of 2.5 % which they thought not to be likely.

Since a complete data set of measurement data was not available, the permitted limit value reported in the relevant German rules of 0.05 mg/m^3 for Cr(VI) compounds was taken forward in the worst-case assessment. Therefore, it was assumed that a concentration of 0.05 mg/m^3 Cr(VI) is emitted at a maximum nominal volume flow (value confidential but available to RAC) of both associated scrubbers. The calculated daily emission was 4.86×10^{-3} kg/day, which was multiplied with the $Cstd_{air}$[14] 2.78×10^{-4} mg/m^3 for concentration in air during release episode. The calculated local concentration in the air during release episode $C_{local\ air}$ was 1.35×10^{-6} mg/m^3. The corresponding release rate (value confidential but available to RAC) was derived with Chesar by applying the estimated $C_{local\ air}$ and the tonnage applied for in this application. An annual release of 1.77 kg was calculated.

In the answer to RAC's question the applicant provided a comparison of the information used for the calculation of the updated emission estimates.

Water

The LOQ of the internal Cr(VI) measurements is 0.05 mg/L, and reduction of Cr(VI) to Cr(III) is repeated prior to precipitation until Cr(VI) concentrations fall below the LOQ. Hence, as a worst-case, the LOQ was considered as the maximum Cr(VI) concentration in the wastewater. In the years 2017, 2018 and 2019, different wastewater volumes were discharged. Because a maximum tonnage was reported for the year 2018, the corresponding wastewater volume of 2018 was used for the calculations. In consideration of the worst-case concentration of 0.05 mg Cr(VI)/L, an annual release of 0.052 kg Cr(VI) was calculated.

In the answer to RAC's question, the applicant presented the latest external measurement results from 2018 and the most recent measurements in 2021 (DIN 38405-D24:1987:05).

Soil

No direct release to soil is expected.

[13] Actual annual tonnage has been claimed confidential but is known to RAC.
[14] $Cstd_{air}$ – concentration in air at source strength of 1 kg.d-1 as provided in Chemical Safety Assessment – Chapter R.16: Environmental exposure assessment (Version 3.0)

Table 5: Summary of releases to the environment

Release route	Release factor	Release per year (kilograms)	Release estimation method and details
Water	1×10^{-5} %-5×10^{-5} %	0.052	Based on measured data.
Air	0.5×10^{-3} %-2×10^{-3} % (*)	1.77	Based on regulatory permitted limit value.
Soil	0 %	0	No release.
Waste	0 %	0	No release.

(*) The release factor (calculated with the maximum tonnage from 2018) has not been used to calculate the PEC_{air} but it was derived directly from the regulatory permitted limit concentration (i.e. 0.05 mg/m^3) using tonnage covered in this application, see description in the main text).

The oral exposure route is also taken into account for the exposure of man via the food. This is to address the risk of intestinal cancer. Because no exposure to soil is assumed, only oral exposure via water (from the transfer of Cr(VI) into drinking water and fish via both surface water and deposition from air emissions) is considered relevant.

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

Parameter	Local
PEC in air (mg/m^3)	1.35×10^{-6}
Daily dose via oral route (mg/kg bw/d)	2.20×10^{-7}

Following the EU RAR 2005, the applicant has applied a reduction factor of 97 %[15] to the estimated dose of drinking water and fish to account for the rapid transformation of Cr(VI) to Cr(III) in the environment. Therefore, **the sum of the estimated dose of drinking water and fish results in** 6.61×10^{-9} mg/kg bw/day instead of 2.20×10^{-7} mg/kg bw/day.

2.5. RAC's evaluation of the exposure assessment

Workers exposure

RAC takes note that that qualitative exposure assessment, personal measurement data and modelled exposure estimates are taken forward for the risk assessment.

RAC agrees with the applicant's conclusion that for WCS 1 (Delivery and storage of solid CrO_3) no exposure exists.

RAC points out that for most WCSs the exposure estimates are modelled. RAC considers that the lack of measured exposure data that cover all WCSs is a key shortcoming in the exposure assessment. According to ECHA guidance, adequately measured, representative occupational exposure data should be available and should have been submitted in the application. This

[15] This approach was taken in accordance and based on the EU RAR 2005, where on p. 48 it is stated: *"For the risk assessment, it will be assumed that for acidic (or neutral, where high concentrations of reductants for Cr(VI) exist) soils, sediments and waters, Cr(VI) will be rapidly reduced to Cr(III) and that 3 % of the Cr(III) formed will be oxidised back to Cr(VI). The net result of this is that of the estimated Cr(VI) release to the environment, 3 % will remain as Cr(VI) and 97 % will be converted to Cr(III)."*

requirement is consistent with the requirements under the Chemical Agents Directive (98/24/EC) and Carcinogens and Mutagens Directive (2004/37/EC). For SVHCs, the exposure scenario needs to be detailed and conclusive.

RAC acknowledges that the applicant applied a conservative approach for the input parameters of the exposure modelling for WCS 3 by assuming that sampling is performed directly from the open surface of the tank.

RAC takes note that the exposure assessment for WCS 5 is based on the modelled exposure for the wastewater sampling and therefore does not take into account other tasks at the onsite WWTP that might have potential exposure to Cr(VI).

Contextual information of the measurements has been provided by the applicant (sampling period, detection limit) as well as the tasks performed during the measurements.

RAC notes that the number of measurements on which the exposure estimate for WCS 2 is based, is limited (N = 3), taking into account also that these measurement data are covering two similar but not identical scenarios of preparing the CrO_3 formulation, namely the departments A and B.

RAC takes note of the worst-case approach taken by the applicant for WCS 2 by considering the measured exposure estimate as an 8 h average and no adjustment is made for the use of the RPE.

The applicant pointed out that the formulator will continue with annual exposure measurements since currently the formulator is covered under the CTAC application, and measurements will be conducted according to the conditions set out therein.

RAC takes note that the formulator has no access to the biomonitoring results and also is not informed n case of non-conforming results.

RAC agrees that dermal exposure has not been assessed as dermal exposure to Cr(VI) compounds is not expected to present a cancer risk to humans (RAC27/2013/06 Rev 1).

Humans via the environment

The applicant is of the opinion that the revised air emission calculations based on the permitted limit value overestimate the actual releases and hence the associated risks of man via environment. Considering that the releases to air were below the LOQ in the measured department B, and similar technical installations and RMMs are installed in department A, the applicant assumed that the calculated concentration is not reached, even if higher consumption of CrO_3 in department A is considered. The applicant also refers to the CTAC AfA as a reference for typical emissions of formulators. The revised air emission value ($C_{local\ air}$) for this application is by a factor of approximately 27 higher than the 90th percentile of values used for the risk assessment in the CTAC application. RAC has some concerns about the air emission calculations. There are no recent and representative measurement data indicating that the formulator complies with the German emission limit.

The applicant provided the latest wastewater measurements performed by an external laboratory from 2018 to the most recent measurement in 2021 from the wastewater treatment plant effluent. All measured values (four measurements/year in 2018 and 2019, three in 2020 and one in 2021) were below 0.1 mg/L, no exact concentration was presented. The applicant has explained to be using the LOQ of the internal Cr(VI) measurements of 0.05 mg/L to

estimate the release to wastewater[16]. The reduction of Cr(VI) to Cr(III) is repeated prior to precipitation until Cr(VI) concentrations fall below the LOQ.

Release estimate to the air in the initial application was considered to be an underestimation in the course of the opinion making. The applicant revised the release estimate to correspond the permitted limit value in fugitive gases. RAC finds the emission estimate based on the permitted limit value reported in the relevant German rules generally acceptable. The applicant had only one measurement data available from 2012 (< 0.002 mg/m^3) to verify that the concentration in release to air was below the permitted limit value of 0.05 mg/m^3. Air monitoring is, therefore, needed to verify the emission estimates and the effectiveness of OCs and RMMs. The applicant informed in the answer to RAC's question that new air emission measurements are going to be performed later in 2021 to be in compliance with the CTAC authorisation decision requirements.

2.6. RAC's conclusions on the exposure assessment

RAC identified minor shortcomings in the exposure estimates for workers, due to the lack of measured exposure data for most WCSs and the limited number of measurement data for WCS 2.

RAC also identified minor shortcomings in the environmental release estimation. The measured wastewater concentrations provided by the applicant are from an external laboratory but they were not used for the release estimation. Instead, an internal LOQ was applied for the release calculation as the reduction of Cr(VI) to Cr(III) was carried out until the internal LOQ was not exceeded in wastewater. The detailed data from the internal measurements were not made available to RAC. The lack of recent air emission measurements also presents a minor shortcoming.

The abovementioned shortcomings lead to proposed monitoring arrangements for the authorisation and recommendation for the review period (see sections 8 and 9).

3. Risk characterisation

The cancer risk is estimated according to the RAC reference dose-response relationship for the carcinogenicity of hexavalent chromium (RAC 27/2013/06 Rev. 1, agreed at RAC 27)[17].

The applicant has conservatively assumed that all inhaled chromium trioxide particles are in respirable range and contribute to the lung cancer risk and therefore no exposure via the oral route (mucociliary clearance and swallowing of non-respirable fractions) needs to be

[16] The internal measured data not available to RAC.
[17] For workers for 40 years of exposure (8 h/day, 5 d/week):
Inhalation: excess life-time lung cancer risk of 4 × 10^{-3} per µg Cr(VI)/m^3
Oral intake: excess lifetime intestinal cancer risk of 2.0 × 10^{-4} per µg Cr(VI)/kg bw/day
For general population: for 70 years of exposure (24 hours/day, 7 days/week)
Inhalation: excess lifetime lung cancer mortality risk of 2.9 × 10^{-2} per µg Cr(VI)/m^3
Oral intake: excess lifetime intestinal cancer risk of 8.0 × 10^{-4} per µg Cr(VI)/kg bw/day.

considered[18], taking into account also that the excess lifetime risk for intestinal cancer is one order of magnitude lower than that for lung cancer.

3.1. Workers

The applicant presented for each WCS the exposure estimates with the corresponding excess risk (see Table 7).

As mentioned in section 2.1, RAC decided to take forward for the risk assessment the highest measured exposure value for WCS 2.

Table 7: Combined exposure and risk characterisation

Contributing scenario	Exposed population	Exposure value corrected for PPE and frequency µg Cr(VI)/m³	Excess risk*
WCS 1: Delivery and storage of solid CrO_3	6	0.0	0.0
WCS 2: Preparation of the CrO_3 containing formulation	3	0.21 (***)	8.4×10^{-4}
WCS 3: Sampling	1	0.16	6.2×10^{-4}
WCS 4: Maintenance	2	2.1×10^{-2}	8.3×10^{-5}
WCS 5: Wastewater sampling and waste management (solid and liquid)	1	6.8×10^{-4}	2.7×10^{-6}
Total exposure for 8 hours**		3.9×10^{-1}	1.6×10^{-3}

* Estimated individual risk resulting from exposure.

** The measured exposure value for WCS 2 has not been corrected for the duration of the task (3-4 hours) but handled as representative for the whole shift. Therefore, the sum of the tasks in the combined exposure assessment exceeds a period of 8 h, which was done to follow a worst-case approach.

*** No adjustment for the use of RPE has been applied by the applicant (see also Table 4).

3.2. Humans via the environment

For the general population, in addition to inhalation of chromium trioxide, oral exposure to chromium trioxide via the food is taken into account. Oral exposure via the food leads to an additional risk of small intestine cancer.

[18] In document RAC/27/2013/06 Rev.1 states that "in cases where the applicant only provides data for the exposure to the inhalable particulate fraction, as a default, it will be assumed that all particles were in the respirable size range."

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

Parameter	Local	
	Exposed population: 1 000	
	Exposure	**RCR or excess risk***
Humans via the environment – Inhalation	1.35×10^{-6} mg/m^3	3.92×10^{-5}
Humans via the environment – Oral	6.61×10^{-9} mg/kg bw/day	5.29×10^{-9}
Humans via the environment - Combined	Not applicable	3.92×10^{-5}

* Estimated individual risk resulting from exposure.

3.3. Environment

Not relevant.

3.4. RAC's evaluation of the risk characterisation

RAC notes that the risk characterisation is affected by shortcomings in the workers' exposure assessment and emissions to the environment.

These shortcomings are addressed and discussed in section 2.5 and summarized in section 2.6. RAC concludes that these shortcomings are not likely to affect the risk characterisation significantly.

For reference, the current binding Occupational Exposure Limit (BOEL) for this substance as of 17 January 2020 is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025).

3.5. RAC's conclusions on the risk characterisation

RAC is of the opinion that the application includes all relevant tasks and routes of exposure as well as endpoints and populations in cancer risk assessment and that there are no significant uncertainties in the characterisation of risk.

RAC considers that the estimates of excess cancer risk for workers based on the modelled exposure estimates and the highest measured exposure value and indirect exposure of humans (workers and general population) via the environment at local level calculated by the applicant allow a health impact assessment.

RAC notes that Cr(VI) is effectively reduced to Cr(III) in the environment. In addition, RAC agrees with the conclusions of the previous EU RAR for chromate substances that regional exposure may not be relevant. RAC, therefore, agrees with the applicant to only present the risk characterisation for the local scale.

4. Analysis of alternatives and substitution plan

4.1. Summary of the analysis of alternatives and substitution plan and of the comments received during the consultation and other information available

The application for authorisation for Use 1 considers the formulation of chromium trioxide-based electrolytes for electroplating processes. Given that chromium trioxide has no separate function during the formulation stage, no analysis of alternatives was performed by the applicant for Use 1 and, accordingly, no alternatives have been identified.

SEAC's evaluation of the applicant's approach to the analysis of alternatives and the substitution plan

Not applicable.

4.2. Availability and technical and economic feasibility of alternatives for the applicant and in the EU in general

Has the applicant demonstrated that there are no alternatives with the same function and similar level of performance that are technically and/or economically feasible for the applicant or their downstream users by the date of adoption of this opinion?

☒Yes ☐No

Is there information available in the application for authorisation or the comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible in the EU?

☐Yes ☒No

Not applicable.

SEAC's evaluation of the availability and technical and economic feasibility of alternatives for the applicant and in the EU in general

Not applicable.

4.3. Risk reduction capacity of the alternatives

Would the implementation of the short-listed alternative(s) lead to an overall reduction of risks?

☐Yes ☐No ☒Not applicable

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

4.4. Substitution activities/plan

Did the applicant submit a substitution plan?

☐Yes ☒No

The substitution of chromium trioxide for the formulation of electrolytes (Use 1) is tightly connected with the substitution of chromium trioxide used in the functional chrome plating of cylinders used in the rotogravure printing and embossing industry (Use 2). The applicant indicated that it sees no technical possibility nor reason to submit a substitution plan as part of Use 1 (formulation), given that:

- chromium trioxide has no specific function per se in the formulation of electrolytes (mixtures) supplied to DUs;
- it is acknowledged in documents published by ECHA that no AoA is needed e.g. formulation uses where the Annex XIV substance has no function per se and the same applies to other activities preceding the end-use of a substance; and
- the assessment of potential alternatives to chromium trioxide in the functional chrome plating of gravure cylinders and the substitution planning activities are covered in Use 2.

SEAC's evaluation of the substitution activities/plan

SEAC agrees with the justification provided by the applicant for not submitting a substitution plan for the use of Cr(VI) in the formulation of electrolytes (Use 1). Without considering the substitution process for the use of chromium trioxide in the functional chrome plating of cylinders used in the rotogravure printing and embossing industry (Use 2), a substitution plan for Use 1 is meaningless.

4.5. SEAC's conclusions on the analysis of alternatives and the substitution plan

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

- The applicant has demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the applicant or their DUs by the date of adoption of this opinion.
- There is no information available in the application for authorisation or the comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible in the EU.
- The applicant did not submit a substitution plan. The applicant's justifications for not submitting a substitution plan are reported in section 4.4.

The assessment of alternatives is not relevant for this use as the substance does not provide any specific function at the formulation stage.

5. Socio-economic analysis

Did the applicant demonstrate that the societal costs of not granting an authorisation are higher than the risks to human health?

☒Yes ☐No ☐Not relevant (the risk cannot be compared with the costs of non-use)

5.1. Human health and environmental impacts of continued use

The estimated number of additional statistical cancer cases as a result of continued use has been calculated using the excess risk value and the estimation of the number of exposed people provided by the applicant. Furthermore, the differences in the duration of the exposure of workers have been taken into account following the approach used by the applicant in the application for authorisation.

The endpoints assessed by the applicant were lung and intestinal cancers. For lung cancer, the total number of potentially directly exposed workers is 13. In the general population, i.e. the assessment of the health risk to human via environment, in the neighbourhood of the facility using Chesar, the regional exposure is estimated at 0 mg/m^3 and hence not considered further. The maximum number of people exposed locally via the environment is assumed to be 10 000. For intestinal cancer, the applicant only accounted for the number of people exposed locally via the environment. The number of people exposed in the proximity of the production site is estimated at 10 000.

The applicant assessed the human health impact based on the existing reference dose-response function established for carcinogenicity of hexavalent chromium (RAC/27/2013/06 Rev.1). The health impacts were monetised by applying the willingness-to-pay values for the reduction of cancer risk from the ECHA (2016) study[19], adjusted to the reference year of 2020 (since the ECHA values are based on year 2012), as shown in Table 9.

Table 9: Monetary values for human health assessment

	Lower bound	**Upper bound**
Value of statistical life for cancer (2012)	€3 500 000	€5 000 000
Value of cancer morbidity (2012)	€410 000	€410 000
Value of statistical life for cancer (2020)	€3 757 639	€5 368 055
Value of cancer morbidity (2020)	€440 181	€440 181

[19] Valuing selected health impacts of chemicals - Summary of the Results and a Critical Review of the ECHA study. [Online] February 2016. Available at: https://echa.europa.eu/documents/10162/17228/echa_review_wtp_en.pdf/dfc3f035-7aa8-4c7b-90ad-4f7d01b6e0bc

The applicant considered data on the disease latency and fatality rates, as well as inflation adjustment and discount rates of between 2 % (upper bound) and 4 % (lower bound).

The monetised potential health impacts over the 12-year review period for Use 1 is presented by the applicant using lower and upper bound estimates. For the potentially exposed workers, the monetised risk is €2 000-4 000. For the potentially indirectly exposed workers and human via environment local inhalation and oral, the monetised risk is €197 000-328 000. According to the applicant, the total monetised health risk for Use 1 is €197 000-328 000 over the 12-year review period or €21 000-35 000 per year.

SEAC's evaluation of the impacts on human health and the environment

SEAC considers that the applicant used the appropriate methodologies to estimate the human health impacts and presented a lower bound and upper bound range to account for the uncertainties. However, given that RAC took forward the highest measured exposure value for WCS 2 and corrected the exposure value for WCS 4, the individual excess risk is slightly higher than that presented by the applicant (8.4×10^{-4} instead of 7.36×10^{-4} for WCS 2 and 8.3×10^{-5} instead of 1.81×10^{-6} for WCS 4). In Table 10 SEAC has re-calculated the impacts on human health based on the values taken forward by RAC. This gives a slightly higher total cost of €199 000-332 000 over 12 years. Annualised, this results in the following monetised risks (which, when rounded, do not significantly differ from those used by the applicant):

- Exposed workers: €300-400 per year
- General population: €21 000-35 000 per year
- Total: €21 200-35 300 per year

Table 10: Summary of additional statistical cancer cases

	Excess lifetime cancer risk[1]	**Number of exposed people**	**Estimated statistical cancer cases (over 12 years)[5]**	**Value per statistical cancer case**	**Monetised excess risk (over 12 years)[5]**
Workers					
Directly exposed workers[2]	1.3×10^{-3} (lung cancer)	13	2.71×10^{-4} (non-fatal) 8.45×10^{-4} (fatal)	€0.4 to 5.4 million	€2 500 to €4 100
Indirectly exposed workers[3]	Included in the general population				
Sub-total					
General population					
Local	3.92×10^{-5} (lung cancer) 5.29×10^{-9} (intestinal cancer)	10 000	2.15×10^{-2} (non-fatal) 6.71×10^{-2} (fatal)	€0.4 to 5.4 million	€196 700 to €327 600

Regional					
Sub-total					
Total					**€199 000 to €332 000**
Latency (years)	10 years for lung cancer and 26 years for intestinal cancer				

Notes:

1. Excess risk is estimated over a typical lifetime working exposure (40 years) and via the environment over a typical lifetime exposure (70 years).
2. Directly exposed workers perform tasks described in the worker contributing scenarios, typically characterised by an 8-hour Time Weighted Average (TWA) exposure of a representative worker.
3. Indirectly exposed workers (bystanders) do not use the substance.
4. Derived from the lifetime risk of 40/70 years.

5.2. Societal costs of not granting an authorisation

Non-use scenario

For Use 1, the applicant initially described two possible non-use scenarios (NUS): outsourcing of chromium trioxide based liquid formulation to outside the EEA (NUS A) and switching to the use of solid chromium trioxide (NUS B). The applicant stated that NUS B would be the most likely non-use scenario, assuming that the authorisation for Use 2 is granted. However, SEAC questioned the choice of non-use scenario given that the use of solid chromium trioxide would not be covered by the authorisation for Use 2. After questions from SEAC, the applicant revised the non-use scenario. The most likely NUS for the applicant and its holding companies would be the relocation of its Cr(VI) related equipment production to outside the EEA. For the applicant's subsidiaries, it would be the shut-down of the Cr(VI) related production activities. The formulator would not relocate but would lose the income related to this use. The socio-economic impacts of the most likely NUS (relocation/shutdown of related production activities) assessed by the applicant include foregone profits for one year and job dismissals. The applicant would be unable to supply chromium trioxide formulations, consequently impacting the supply of chromium trioxide-coated rotogravure cylinders to its DUs (Use 2). For Cr(VI)-based plating machines, the applicant explained that their equipment and chemistry must match one another and that other plating machines cannot operate with a different electrolyte.

SEAC's evaluation of the societal costs of non-use

SEAC considers the corrected non-use scenario presented by the applicant as plausible. Use 1 (formulation of chromium trioxide-based electrolyte) is interlinked with Use 2 (functional chrome plating of cylinders). Hence, the socio-economic impacts of non-use would essentially be the same for both uses, and they would occur only once if either one or both uses are not granted an authorisation. Because of this, the reader is referred to Use 2 for the detailed discussion about the socio-economic impacts and SEAC's evaluation of them.

5.3. Combined assessment of impacts

Use 1 (formulation of chromium trioxide-based electrolyte) is interlinked with Use 2 (functional chrome plating of cylinders). Hence, the socio-economic impacts of non-use would essentially be the same for both uses, and they would occur only once if either one or both uses are not granted an authorisation. Because of this, the reader is referred to Use 2 for the detailed discussion about the socio-economic impacts and SEAC's evaluation of them.

5.4. SEAC's conclusion on the socio-economic analysis

Based on the analysis presented in the opinion on Use 2, SEAC concludes that the applicant has demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to human health resulting from the granting of an authorisation.

This conclusion of SEAC is made on the basis of:

- the application for authorisation,
- SEAC's assessment of the societal costs of non-use,
- SEAC's assessment of the availability, technical and economic feasibility of alternatives,
- any additional information provided by the applicant or their DUs, and
- RAC's assessment of the risks to human health.

SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

6. Proposed review period

☐Normal (7 years)

☒Long (12 years)

☐Short (4 years)

☐Other: … years

☐No review period recommended

When recommending the review period SEAC took note of the following substitution and socio-economic considerations:

The application for authorisation covers two inter-related uses of chromium trioxide: the preparation of Cr(VI) electrolyte formulation (Use 1) and the application of the Cr(VI) formulation in hard chrome plating of printing and embossing cylinders (Use 2). The substance's function is only relevant for the hard chrome plating of printing and embossing cylinders; chromium trioxide has no independent (separate) function at the formulation stage (Use 1). Therefore, SEAC considers that the review period for the formulation of chromium trioxide-based electrolytes (Use 1) should be aligned with considerations for the review period for the downstream use of chromium trioxide in the applicant supply chains (Use 2):

- SEAC considers that the applicant has been proactive in undertaking research on the alternatives since 2012 and is committed to continue the R&D efforts to implement alternatives for Cr(VI).
- SEAC concurs with the applicant that currently there is no technically and economically feasible alternative for Use 2 as demonstrated by the analysis of alternatives, the answers to SEAC's questions and the consultation.
- The applicant presents a substitution plan for Use 2 that is consistent with the duration of the review period that is proposed. According to the substitution timelines presented by the applicant, the time needed to complete substitution requires more than a normal review period of 7 years.
- Due to the speed of production of new equipment to replace the Cr(VI) equipment, the fine-tuning at the various DUs, and the long investment cycles of the applicant's DUs, as demonstrated in the AfA and the additional answers of the applicant, SEAC finds it credible that it would not be possible for the applicant to substitute within a normal review period for all the applicant's DUs.
- SEAC has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the risks to the environment associated with the continued use of the substance.

Taking into account all of the above points, a **12-year** review period is recommended for this use, i.e. until the end of 2032.

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☒Yes ☐No

7.1. Description

RAC

The applicant shall

- ensure that workers perform a 'fit check' of the seal[20,21] of their respiratory protective equipment (RPE) before taking on relevant tasks and workers will be trained to do this test adequately,
- investigate the feasibility to enclose the area around the filling point of the mixing tank to guarantee the maximum possible effectiveness of the LEV system.

[20] A 'fit check' of the seal is also named a seal check or a fit test.
[21] Health and Safety Executive. Respiratory protective equipment at work: A practical guide. Paragraph 80. (https://www.hse.gov.uk/pubns/books/hsg53.htm).

7.2. Justification

RAC

RAC is of the opinion that the operational conditions and risk management measures are considered to be generally appropriate and effective in limiting the risk, provided that they are adhered to.

Conditions for the authorisation are proposed to ensure that a 'fit check' of the seal of RPE[20, 21] is always performed by workers before they enter the workplace, so that the intended level of protection is reached during use.

The abovementioned feasibility study is justified since a more enclosed working area will improve the LEV system efficiency and consequently provide a better control for the workers' exposure.

The minor concerns identified in the operational conditions and risk management measures in place to protect workers and humans via the environment can be addressed via the proposed recommendations for the review report (Section 9).

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☒ Yes ☐No

8.1. Description

RAC

1. The applicant (or formulator) shall implement the following monitoring programmes:

(a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall:

(i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure;

(ii) be based on relevant standard methodologies or protocols;

(iii) comprise personal and/or static inhalation exposure sampling;

(iv) be representative of:

a. the range of all tasks undertaken where exposure to Cr(IV) is possible;

b. the operational conditions and risk management measures typical for each of these tasks;

c. the number of workers potentially exposed;

(v) include contextual information about the tasks performed and their frequency during measurements;

(b) Environmental releases:

(i) the applicant shall continue conducting their monitoring programme for Cr(VI) emission of wastewater;

(ii) the applicant shall conduct air emission measurements at least annually or more frequently in the periods following any possible changes in the process;

(iii) the monitoring programmes for wastewater and air emissions shall:

a. be based on relevant standard methodologies or protocols; and

b. be representative of the OCs and RMMs used at the formulator's site.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the operational conditions and risk management measures in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.

4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.

8.2. Justification

RAC

Although RAC considers the operational conditions and risk management measures described in the application in relation to both workers and humans via the environment to be generally appropriate and effective in limiting the risk from exposure through the inhalation and oral routes, the exposure assessment contains shortcomings due to:

- the lack of measured exposure data for most WCSs,
- the limited number of measurements for WCS 2,
- the lack of recent air emission measurements.

Although RAC considers that these shortcomings would not be expected to lead to significantly higher exposure estimates compared to those considered for the risk characterisation, the applicant shall address these shortcomings by obtaining representative measurements for workers' exposure and air emissions referred to in section 8.1, paragraph 1.

9. Recommendations for the review report

Were recommendations for the review report made?

☒Yes ☐No

9.1. Description

RAC

The results of the feasibility study as mentioned in section 7 and the results of the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, should be documented and included in any subsequent authorisation review report.

In addition, any subsequent authorisation review report should contain clear information that supports the air and wastewater abatement efficiencies.

9.2. Justification

RAC

Provision of the results of the feasibility study and the representative monitoring results would allow for a better evaluation of the actual and future situation at the applicant's sites, and would further confirm the appropriateness and effectiveness of RMMs and OCs as described in the application.

10. Applicant's comments on the draft opinion

Did the applicant comment the draft opinion?

☐Yes ☒No

10.1. Comments of the applicant

Was the opinion or the justifications to the opinion amended as a result of the analysis of the applicant's comments?

☐Yes ☐No ☒Not applicable – the applicant did not comment

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

Not applicable – the applicant did not comment.

10.3. Reasons for not introducing changes

Not applicable – the applicant did not comment.