CHEMICAL SAFETY REPORT

Non-confidential version

Legal name of applicant(s):	Indestructible Paint Ltd. (StC) PPG Industries (UK) Ltd. (StC, PHD)		
Substances:	Strontium chromate (StC)	EC 232-142-6	CAS 7789-06-2
	Potassium hydroxyocta-oxodizincate-dichromate (PHD)	EC 234-329-8	CAS 11103-86-9
Uses applied for:	Use 1: Formulation of primer products with strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains		

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Preliminary Remark

This Chemical Safety Report (CSR) has been prepared on behalf of the applicants by the Aerospace and Defence Chromates Reauthorisation (ADCR) Consortium.

Photos are for illustrative purposes only. PPE shown in the photos might be also driven by site-specific considerations and by exposures other than to chromates. PPE requirements are laid down in the Condition of Use tables.

Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

The risk management measures implemented for the use applied for are documented in detail in the exposure scenario in Chapter 9 of this CSR.

A succinct summary table of the risk management measures, and operational conditions is submitted with this review report.

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

We declare that the risk management measures described in the exposure scenarios in Chapter 9 of this CSR are implemented at the sites of the applicants.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

Not applicable.

Part B

This review report uses the dose-response relationship established by the ECHA Committee on Risk Assessment (RAC) (see below). In this case, Chapters 1-8 of the CSR do not need to be provided as described in the ECHA document 'How to apply for authorisation' (ECHA, 2021). Relevant physico-chemical and environmental fate data used for modelling are taken from the literature as documented in section 9.1.2.

9 EXPOSURE ASSESSMENT (AND RELATED RISK CHARACTERISATION)

9.1 Introduction

9.1.1 ADCR dossiers on primer products

The Aerospace and Defence Chromates Reauthorisation (ADCR) Consortium on behalf of the applicants has developed several review reports and new applications. These applications cover formulation and use of primer products containing chromates considered to be relevant by the ADCR consortium members (i.e., strontium chromate (StC), potassium hydroxyoctaoxodizincate dichromate (PHD), and pentazinc chromate octahydroxide (PCO)) in Great Britain. Although formally they are upstream applications submitted by manufacturers, importers or formulators of chromate-containing chemical products, the applications are based on sector-specific data and detailed information obtained from actors throughout the supply chain.

The ADCR consortium developed dossiers for these three substances with the following uses:

- Formulation of primer products with strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains
- Use of bonding primers containing strontium chromate in aerospace industry and its supply chains
- Use of wash primers containing pentazinc chromate octahydroxide and/or potassium hydroxyoctaoxodizincate dichromate in aerospace industry and its supply chains
- Use of primer products other than wash or bonding primers containing strontium chromate, pentazinc chromate octahydroxide or potassium hydroxyoctaoxodizincate dichromate in aerospace and defence industry and its supply chains.

Table 9-1 provides an overview on ADCR's dossiers for chromates in primer products used in aerospace and defence industry and its supply chains, together with applicants and the total EEA tonnages per substance and use.

This chemical safety report refers to the use "**Formulation of primer products with strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains**".

This CSR follows largely the methodology and requirements as given under EU REACH. ADCR developed similar chemical safety reports for these uses for the situation in the European Economic Area (EEA) with the same approach. Exposure data from the EEA were partly used in this report where suitable to support the assessment for GB sites.

Table 9-1: Overview on ADCR review reports on chromates in primer products

Use	**Submission type**	**Strontium chromate (StC)**		**Potassium hydroxyoctaoxodizincate dichromate (PHD)**		**Pentazinc chromate octahydroxide (PCO)**	
Formulation of primer products	ARR	Indestructible Paint Ltd PPG Industries (UK) Ltd	**CBI ***	PPG Industries (UK) Ltd	**CBI ***		
Use of wash primers	ARR			PPG Industries (UK) Ltd	**0.02tpa**		
	New AfA			Boeing Distribution (UK) Inc. Wesco Aircraft EMEA Ltd	**0.02tpa**	Boeing Distribution (UK) Inc. Wesco Aircraft EMEA Ltd	**2.35tpa**
Use of bonding primers	ARR	Cytec Engineered Materials Ltd in its legal capacity as Only Representative of Cytec Industries Inc Wesco Aircraft EMEA Ltd	**14.74tpa**				
	New AfA	Boeing Distribution (UK) Inc. Henkel Ltd	**14.74tpa**				
Use of primer products other than wash or bonding primers	ARR	Cytec Engineered Materials Ltd in its legal capacity as Only Representative of Cytec Industries Inc Wesco Aircraft EMEA Ltd Indestructible Paint Ltd PPG Industries (UK) Ltd	**51.22tpa**	PPG Industries (UK) Ltd	**2.38tpa**		
	New AfA	Akzo Nobel Car Refinishes B.V. Mapaero SAS Boeing Distribution (UK) Inc. Mankiewicz UK LLP in its legal capacity as only representative for Finalin GmbH	**51.22tpa**	Boeing Distribution (UK) Inc. Wesco Aircraft EMEA Ltd	**2.38tpa**	Boeing Distribution (UK) Inc. Wesco Aircraft EMEA Ltd	**4.01tpa**

* see information on amounts used per site in sections 9.2.3.1 and 9.2.4.1

9.1.2 Introduction to the assessment

9.1.2.1 Classification of the substances

Strontium chromate (StC; Entry No. 29) and potassium hydroxyocta-oxodizincate dichromate (PHD; Entry No. 30) have been included into Annex XIV of Regulation (EC) No 1907/2006 (EU REACH) due to their intrinsic property to be carcinogenic. Table 9-2 shows that StC is classified as carcinogenic Cat. 1B while PHD is classified as carcinogenic Cat. 1A. According to Article 62 (4)(d) of this Regulation, the chemical safety report (CSR) supporting an Application for Authorisation (AfA) needs to cover only those risks arising from the intrinsic properties specified in Annex XIV. Therefore, only the human health risks related to the classification of the chromate as carcinogenic are addressed in this CSR. This requires investigating the potential exposure of workers as well as exposure of humans via the environment.

Table 9-2: Substance classification

Substance name	CAS No.	EC No.	Annex XIV Entry No.	Intrinsic properties referred to in Art. 57	Formula	Mol. weight [g/mol]	Cr(VI) mol. weight fraction
Cr(VI)	-	-	-		Cr^{6+}	52.00	1
Strontium chromate (StC)	7789-06-2	232-142-6	29	Carc. 1B [1]	CrO_4Sr [2]	203.61	0.26
Potassium hydroxyocta-oxodizincate dichromate (PHD)	11103-86-9	234-329-8	30	Carc. 1A [3]	$Cr_2HKO_9Zn_2$	418.85	0.25

The carcinogenicity of StC and PHD is driven by the chromate ion (with Cr in oxidation status +6 (or Cr(VI))), which is released when the substances solubilise and dissociate. Exposure to chromates is expressed in units of Cr(VI) (converted by using the molecular weights of the substances). Also, the exposure-risk relationships proposed by the Committee for Risk Assessment (RAC) express exposure as Cr(VI).

It has to be noted that some primer products may contain additional chromates, which can contribute to Cr(VI) exposure, e.g. barium chromate (RAC Opinion for harmonised classification as carcinogenic, Cat. 1B, adopted in June 2023[4]). Barium chromate is currently not listed in Annex XIV of EU REACH.

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[1] C&L inventory on ECHA's website: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/53759; assessed in June 2023

[2] Formula and molecular weight for StC: https://www.chemicalbook.com/ChemicalProductProperty_EN_CB1184992.htm; assessed in June 2023

[3] PHD and PCO are members of the group "zinc chromates including zinc potassium chromate" which is harmonised classified in the C&L inventory on ECHA's website: https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/153421; assessed in June 2023

[4] Registry of CLH intention until outcome for barium chromate: https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1848d1fab; assessed in October 2023

9.1.2.2 Grouping approach for Cr(VI) compounds

A grouping approach is used in this CSR, because

- All substances share this common toxic moiety (chromate, measured as Cr(VI)), and are therefore expected to exert effects in an additive manner,
- At some sites several chromates may be used in parallel (e.g., because products containing different chromates are manufactured at the same site), leading to additive exposure for workers and additive environmental emissions.

An advantage of using the grouping approach is that a larger database of worker exposure and environmental emission data can be considered for this use (data using both chromates are included in the assessment).

9.1.2.3 Exposure-risk relationships (ERRs) for carcinogenic effects used for the assessment

The hazard evaluation follows recommendations given by RAC (ECHA, 2015)[5] for assessing carcinogenic risk, exposure-risk relationships are used to calculate excess cancer risks.

ECHA published on December 4, 2013 the document "*Application for Authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium*"[6] (ECHA, 2013c), which states the opinion of RAC that hexavalent chromium is a non-threshold carcinogen. Consequently, demonstrating adequate control is not possible and the socioeconomic analysis (SEA) route is applicable. The exposure-risk relationships published in this document from ECHA (2013c) are used to calculate excess cancer risks associated with the use(s) of Cr(VI) covered by this application. However, the resulting risk estimates likely overestimate the cancer risk. RAC states in its publication of the ERR (ECHA, 2013a): "As the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be an overestimate".

The excess cancer risk characterisation for workers is solely based on inhalation exposure and the risk for lung cancer, as no information on the fraction of inhalable, but non-respirable particles is available, which prevents a differentiated consideration of inhalation and oral exposure of workers. This is also the standard procedure proposed by ECHA (2013c), as ECHA states: *"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".* Therefore, it is assumed that all Cr(VI)-bearing particles are of respirable sizes, and thus no oral exposure route is considered for worker inhalation. This is a conservative approach, since the potential lung cancer risk is at least an order of magnitude higher compared to the potential cancer risk for the digestive tract.

The following exposure-risk relationships are used for estimating excess lung cancer risks for workers (inhalation).

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[5] *Amendment of the RAC note "Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent chromium" to include the intrinsic property "Toxic to reproduction" of the Cr(VI) compounds*: https://echa.europa.eu/documents/10162/21961120/rac_35_09_1_c_dnel_cr-vi-_en.pdf/8964d39c-d94e-4abc-8c8e-4e2866041fc6; assessed in June 2023

[6] ECHA Website: https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf/facc881f-cf3e-40ac-8339-c9d9c1832c32; assessed in June 2023

Table 9-3: Exposure-risk relationships for inhalation exposure of workers used for calculating cancer risks due to Cr(VI) exposure (from ECHA, 2013a)

TWA Cr(VI) inhalation exposure concentration [µg/m^3]*	Excess lung cancer risk in workers [x 10^{-3}]
25	100
12.5	50
10	40
5	20
2.5	10
1	4
0.5	2
0.25	1
0.1	0.4
0.01	0.04

TWA: Time-weighted average, expressed in micrograms of Cr(VI) per cubic meter of air

* Based on a 40-year working life (8h/day, 5 days/week).

For the general population, oral (via drinking water and food) and inhalation exposure is considered, following recommendations of RAC (RAC did not identify cancer risks after dermal exposure for workers or the general population). For inhalation exposure, RAC again presented an exposure-risk relationship for lung cancer, whereas for oral exposure the focus was on an increased risk for tumours of the small intestine (ECHA, 2013c). As considered above for the assessment of worker exposure, it is assumed that all particles are in the respirable size range for inhalation exposure of the general population.

The following exposure-risk relationships are used to characterise risks of the general population after exposure (over 70 years) of humans via the environment.

Table 9-4: Exposure-risk relationships for inhalation exposure of general population used for calculating cancer risks due to Cr(VI) exposure (from ECHA, 2013a)

Average Cr(VI) exposure concentration in ambient [µg/m^3]*	Excess lung cancer risk in the general population [x 10^{-3}]
10	290
5	145
2.5	72
1	29
0.5	14
0.25	7
0.1	2.9
0.01	0.29
0.001	0.029
0.0001	0.0029

* Based on an exposure for 70 years (24h/day, every day).

Table 9-5: Exposure-risk relationships for oral exposure of general population used for calculating cancer risks due to Cr(VI) exposure of humans via environment (from ECHA, 2013a)

Constant average oral daily dose of Cr(VI) [µg/kg bw/day]*	Excess small intestine cancer risk in the general population [x 10^{-4}]
10	80
5	40
2.5	20
1	8
0.5	4
0.1	0.8

* Based on an exposure for 70 years (24h/day, every day)

9.1.2.4 Environment

<u>Scope and type of assessment</u>

The chromates in Table 9-2 are not listed in Annex XIV for endpoints related to concerns for the environment. Therefore, no environmental assessment has been performed. However, the applicants duly apply risk management measures derived by the registrants due to other substance properties, which they communicated via the Safety Data Sheets (SDS).

9.1.2.5 Exposure of humans via the environment

9.1.2.5.1 Scope and type of assessment

Exposure of humans to Cr(VI) via the environment (HvE) as a result of wastewater and air emissions from the sites of the applicants covered by this CSR is considered in section 9.2.3.1. With regard to oral exposure of humans via the environment, it has to be acknowledged that Cr(VI) is rapidly reduced to Cr(III) in many environmental compartments (ECB, 2005). Therefore, exposure to Cr(VI), estimated based on the release of Cr(VI) into environmental compartments may significantly overestimate human exposure via the environment. Moreover, several of the parameters necessary for environmental modelling (in particular the partition coefficients) are based on the log of the octanol-water partition coefficient (Kow) of a given substance. This parameter is of no relevance for inorganic substances such as Cr(VI), and therefore the calculated partition coefficients are not applicable.

Apart from that, there is only limited data on the presence of Cr(VI) in food. In most cases, only total chromium was measured. According to a few studies, Cr(VI) generally amounts to less than 10% of total chromium (range 1.31-12.9%) (EFSA, 2014). Furthermore, some studies even indicate that foods of plant origin do not contain Cr(VI) at all and that the Cr(VI) levels measured are analytical artefacts (EFSA, 2014). The same may be the case with foods of animal origin. Based on these data, the EFSA-CONTAM Panel concluded ‘that there is a lack of data on the presence of Cr(VI) in food’ and ‘decided to consider all the reported analytical results in food as Cr(III)’ (EFSA, 2014). Furthermore, the CONTAM Panel concluded that it can be assumed ‘that all the chromium ingested via food is in the trivalent form (i.e., Cr(III)), in contrast to drinking water where chromium may easily be present in the hexavalent state’, primarily due to the use of strong oxidizing agents in the treatment of drinking water (EFSA, 2014). These considerations of the CONTAM Panel support the earlier evaluation of the EU Risk Assessment Report for chromates, in which the indirect oral exposure of HvE was assessed only on the basis of exposure via (drinking) water and the consumption of fish (ECB, 2005). The same approach is therefore followed here.

This assessment focuses primarily on the carcinogenicity of Cr(VI) released from the chromates as the most relevant endpoint and compares the exposure estimates with the exposure-risk relationship derived by the RAC for the general population, as shown below in Table 9-6.

Table 9-6: Type of risk characterisation required for humans via the environment

Route of exposure and type of effects	**Endpoint considered and type of risk characterisation**	**Hazard conclusion** **Dose – response relationship**
Inhalation: Systemic Long Term	Carcinogenicity Quantitative	RAC dose-response relationship based on excess lung cancer risk (ECHA, 2013c) For general population; based on 70 years of exposure; 24h/day: Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 2.9x10^{-2} *
Oral: Systemic Long Term	Carcinogenicity Quantitative	RAC dose-response relationship based on excess cancer risk for tumours of the small intestine (ECHA, 2013c) For general population; based on 70 years of exposure: Exposure to 1 µg Cr(VI) /kg bw/day relates to an excess risk of 8x10^{-4}

* The cancer risk characterisation by inhalation for humans via the environment is solely considering risk for lung cancer, as no information on the fraction of inhalable, but non-respirable particles is available, which prevents a differentiated consideration of inhalation and oral exposure of humans via the environment.

9.1.2.5.2 Comments on assessment approach

In this section, we describe the approach to assess human exposure to Cr(VI) via the environment (HvE) resulting from the use of the chromates covered in this CSR. Exposure via ambient air and oral exposure (through drinking water intake and consumption of fish) has been assessed at local levels. No regional assessment has been carried out as it can be assumed that Cr(VI) from any source will be reduced to Cr(III) in most environmental situations and therefore the effects of Cr(VI) as such are likely to be limited to the area around the source, as described in the EU Risk Assessment Report for chromates (ECB, 2005). The approach to not perform a regional assessment for human Cr(VI) exposure via the environment as part of AfAs for chromate uses was also supported in compiled RAC and SEAC (Socio-economic Analysis Committee) opinions on existing authorisations, as described for example in the *Opinion on an Application for Authorisation for the use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains* (assessed on ID 0117-01[7]). This states that regional exposure of the general population is not considered relevant by RAC due to the transformation of Cr(VI) to Cr(III) that will occur rapidly under most environmental conditions.

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[7] RAC/SEAC *Opinion on an Application for Authorisation for the use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains*, consolidated version, 2018; https://echa.europa.eu/documents/10162/d2348195-b031-01bb-0ab8-04b9f7a53c44; assessed in December 2022

EUSES modelling of human exposure via the environment

The assessment of human Cr(VI) exposure via the environment is based on emission measurements in air and wastewater from representative sites. Distribution and exposure modelling are carried out with the European Union System for the Evaluation of Substances (EUSES) software (v. 2.1.2).

Release days

For the considered exposure pathways air, water, and fish, 365 release days are always assumed. This approach is considered justified, because:

- The air concentration (*annual average local "Predicted environmental concentration" (PEC) in air (total)*) and the concentration in fish (calculated from the bioconcentration factor in fish and from the *annual average local PEC in surface water (dissolved)*) are based on annual average PEC values, on which the number of release days has no impact.
- The Cr(VI) concentration in drinking water is based on the higher of the two values "*annual average local PEC in surface water (dissolved)"*, which is independent of the number of release days, as described above, and "*local PEC in pore water of agricultural soil"*, where fewer release days would lead to an intermittently higher PEC value. If the concentration in drinking water is based on the "*local PEC in pore water of agricultural soil"* and if this value is temporarily increased due to intermittent release (of sewage sludge to agricultural soil with temporarily higher Cr(VI) concentrations), the concentration in drinking water would be temporarily higher than under the assumption of 365 release days. This is a very unrealistic scenario since a spatial and temporal distance between pore water of agricultural soil and drinking water would compensate for variations in Cr(VI) drinking water concentrations due to intermittent release of Cr(VI) to wastewater. Furthermore, the use of an intermittently elevated drinking water concentration for the calculation of a lifelong cancer risk via drinking water consumption would be an overestimation of the realistic risk and therefore, by considering 365 release days, a stable concentration in drinking water is calculated.
- In this latter case, the "*local PEC in pore water of agricultural soil*" is simply equated by EUSES software with the "*local concentration in groundwater*", which is taken as the concentration in drinking water (if the concentration is higher than the one derived from surface water; see above). As noted in the EUSES background report, equating the soil pore water concentration with the groundwater concentration 'is a worst-case assumption, neglecting transformation and dilution in deeper soil layers'. This conservatism would increase the unrealistic nature of intermittent release further and the use of an annual average exposure estimate is considered more adequate in the present context.

Sewage treatment plant (STP)

For sites where wastewater is sent to a biological sewage treatment plant (STP) (not relevant for the formulation sites covered by this CSR), we have adjusted the default distribution of Cr(VI) in the sewage treatment plant (STP) used in EUSES (99.9% in water and 0.1% in sludge) to 50% in water and 50% in sludge. This is based on the description given in the EU Risk Assessment Report (ECB, 2005) that during biological treatment 50% of Cr(VI) are released into the effluent and 50% are absorbed to sewage sludge. The application of sludge on agricultural soil (rate: 5000 kg/ha/year) and grassland (rate: 1000 kg/ha/year) was considered according to the EUSES standard setting unless there was information to the contrary.

Oral uptake via drinking water and fish

The intake of pollutants via drinking water and fish, as modelled in EUSES, is unreasonably conservative and therefore, specific reduction factors are applied for risk calculations in the environmental contributing scenario (see section 9.2.3.1). The arguments why the EUSES calculations are overly conservative for these pathways, and derivation of reduction factors are described below:

- Drinking water

  a) Local concentration in drinking water based on the local PEC in surface water (*"annual average local PEC in surface water (dissolved)")*:

  - The approach chosen is likely to *"overestimate the actual indirect exposure as the conversion of Cr (VI) to Cr (III) is expected to occur under the vast majority of environmental conditions"* (ECB, 2005). This reduction is not considered in the exposure values calculated in EUSES.
  - EUSES typically specifies a "purification factor" that accounts for removal processes from surface water in deriving the concentration in drinking water, e.g., by evaporation or adsorption to suspended solids. However, the latter is estimated by log Kow and not by specific distribution coefficients. This approach is not feasible for inorganic substances and therefore the estimate does not account for adsorption to suspended particles as a removal process before and during drinking water purification. Although these effects are difficult to quantify, the value of 50% (i.e. reduction by factor 2) for adsorption to sewage sludge as applied in the EU RAR (ECB, 2005) (as described above) can serve as an indicator of the degree of Cr(VI) adsorption to suspended solids in surface water.
  - The local PEC in surface water is calculated for the mixing zone, neglecting the fact that for drinking water preparation additional water sources are added and dilution takes place.

  b) Local concentration in drinking water based on the "*local PEC in pore water of agricultural soil*":

  - The Cr(VI) concentration in groundwater is taken directly from the pore water concentration in the soil, which in turn is modelled from the Cr(VI) concentration in the soil. Cr(VI) reduction in soil is a well-known process and the EU Risk Assessment Report states that "*chromium (VI) is reduced to chromium (III) by organic matter and this process occurs reasonably readily in soils*" and assumes "*chromium present in soil following application is in the form of chromium (III)*" (ECB, 2005). This reduction is not considered in EUSES modelling.
  - In addition, EUSES calculates the deposition (the main relevant pathway of groundwater contamination) for a circle around the source with a radius of 1000 m (RIVM, 2004), so that the resulting groundwater concentration only applies to the groundwater below this area.
  - EUSES modelling of the concentration in groundwater is based on a simple algorithm that equates the concentration of a substance in groundwater with its concentration in the pore water of the soil (RIVM, 2004). These authors state that "*this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers*".
  - Like for surface water, any additional dilution with other groundwater or surface water for drinking water preparation is not considered.

  Overall, the conservatism of EUSES with respect to exposure to drinking water is classified as "worst case" by the software developers (RIVM, 2004).

Against the background of these substance-specific and model-inherent considerations, the estimate for local exposure via drinking water is regarded as unreasonable. The effects of all these issues are not quantifiable, but a general reduction of the local Cr(VI) concentration in drinking water, calculated in EUSES, by a factor of 5 due to the above factors, seems to be appropriate. Still, this is considered to result in a conservative exposure estimate.

- Fish

  1) In EUSES, a default consumption of 115 g fish per day is used, which overestimates the realistic human daily intake of fish on a long-term basis. According to the food consumption data for humans in Europe, as accessible in the *PRIMo – Pesticide Residue Intake Model*[8] (v.3.1) of the European Food Safety Authority (EFSA), the maximum of the mean consumption of fish (and fish- and marine-/freshwater-products) is 29.3 g per day[9]. This amount is approximately 4-fold lower (factor 3.9) than the default consumption used in EUSES, most likely due to the fact that it reflects a long-term estimate (i.e., most people do not eat fish every single day).
  2) It must be noted, that "*(p)eople do not consume 100% of their food products from the immediate vicinity of a point source. Therefore, the local assessment represents a situation which does not exist in reality*" (ECHA, 2016b).

  From argument 1) (almost) a reduction factor of 4 can be assumed and although argument 2) is not scientifically verifiable, it certainly makes up more than a factor of 1.25. Thus, combining these two arguments, a **total reduction factor of 5** can be derived, which is assumed to be sufficiently conservative to also cover, for example, that some countries have not indicated long-term consumption quantities to EFSA (and are thus not represented in the PRIMo Model). Adding further to the conservatism, it must be noted that the value derived from the data in the PRIMo model relate to the consumption of '*fish, fish products and other marine and freshwater food product'* and therefore include food items that are unlikely to be sourced from the immediate vicinity of the site assessed.

Inhalation exposure

The following must be considered for local inhalation risks: The concentration in air and deposition are estimated in EUSES with the Operational Priority Substances (OPS) model that is embedded in EUSES (de Bruin et al., 2010, Toet and de Leeuw, 1992). When EUSES was developed, conservative input values were chosen (e.g., stack height of 10 m, no excess heat of the plume emitted compared to environmental temperature and an ideal point source). For a stack height of 10 m, the maximum concentration is modelled at a distance of 100 m from the source and this distance was set as the default distance for the local PECair in EUSES. The developers of the OPS model at the Dutch RIVM analysed the impact of these conservative default settings on the estimated concentration in air and on the total deposition. For example, they noted that '*[i]ncreasing the stack height from 10 to 50 m lowers the maximum concentration by a factor 40*' and – considering all factors – concluded that '*air concentration and total deposition used for risk assessment purposes are likely to be overestimated due to over-conservative default settings used in the standard scenario in EUSES*' (de Bruin et al., 2010).

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[8] In the *PRIMo – Pesticide Residue Intake Model* (v.3.1) of the European Food Safety Authority (EFSA) food consumption data for individuals of different age groups in numerous European countries are listed. The model can be accessed via https://www.efsa.europa.eu/en/applications/pesticides/tools (accessed in December 2022).

More detailed information on the model is under the following links:
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5147 and
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2019.EN-1605

[9] The value was provided for Germany (general population) based on the daily intake (reported in the PRIMo model in g/kg bw and day), multiplied by the body weight (reported in kg). The value represents the maximum of the mean values reported for different countries and population groups (e.g., children, adults, general population).

In the light of these findings, the inhalation risk estimates presented in this report are highly conservative.

Site-specific release fractions

Data for monitoring of Cr(VI) releases to air are available from several sites in the EEA. Release fractions for Cr(VI) emissions to water, air and soil were derived from the site-specific emission data and tonnages of used chromates. These releases are generally governed by, and comply with, local worker and environmental regulatory requirements.

Wastewater

Wastewater containing Cr(VI) may occur for example from cleaning activities (i.e., rinsing water). At both sites covered by this CSR wastewater is collected and then sent to an external waste management company (licensed contractor) where it is treated as hazardous waste.

Air

Air from working areas where aerosols/dusts containing Cr(VI) arise (e.g., from handling solid substances) is exhausted and treated through air filters prior to external release.

Soil

There is no direct release to soil, based on equipment and procedures in place.

Waste

Solid waste containing Cr(VI) may arise for example in the form of empty chemical containers, cleaning materials (e.g., rags, wipes), contaminated equipment (e.g., filters, disposable PPE). Waste materials containing Cr(VI) are classified and treated as hazardous wastes according to UK regulations. Any solid or liquid waste is collected and forwarded to an external waste management company (licensed contractor) for disposal as hazardous waste.

Substance-specific input values

We use the substance-specific physico-chemical properties of StC as an input to model the behaviour of Cr(VI) with EUSES. A comparative EUSES assessment, where an identical example exposure scenario was calculated with the different substance-specific physico-chemical properties of StC, PHD, and PCO showed that the results were identical. Accordingly, EUSES modelling based on environmental emission measurements, where chromates other than StC contribute to the measured Cr(VI) concentration, allows a risk assessment to be performed with the physico-chemical parameters of StC, without underestimating the predicted environmental concentrations. The physico-chemical properties of PCO and PHD, which were used for modelling, and the results of the comparative EUSES assessment, are provided in Annex I of the CSR.

The physico-chemical properties of StC are used in this assessment to model the environmental release. For environmental fate modelling, data available for Cr(VI) are used, as the chromate ion is the moiety relevant for distribution via water and soil. Table 9-7 shows the physico-chemical properties of StC and the environmental fate properties of Cr(VI) required for EUSES modelling, as given in the EU Risk Assessment Report (ECB, 2005).

Table 9-7: Physico-chemical properties of StC and environmental fate properties of Cr(VI) required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
Molecular weight	203.61 g/mol	100 g/mol	Refers to StC; value used in Annex XV dossier for StC (ECHA, 2013b)
Melting /freezing point	n/a, decomposes at ca. 500 °C into chromium (III) oxide	500°C	Refers to StC; value used in Annex XV dossier for StC (ECHA, 2013b)
Boiling point	n/a, decomposes at ca. 500 °C into chromium (III) oxide	500°C	Refers to StC; value used in Annex XV dossier for StC (ECHA, 2013b)
Vapour pressure	n/a: inorganic ionic compound	0.00001 Pa	n/a; dummy value entered
Log Kow	n/a: inorganic ionic compound	0	n/a; dummy value entered
Water solubility	ca. 1.2 g/L at 20 °C	1.2 g/L at 20 °C	Refers to StC, value used in Annex XV dossier for StC (ECHA, 2013b)
Kp *suspended matter*		1100 L/kg	Refers to Cr(VI); value for acidic and alkaline conditions given in ECB (2005), mean value is used; see text below for details
Kp *sediment*		550 L/kg	Refers to Cr(VI); value for acidic and alkaline conditions given in ECB (2005), mean value is used; see text below for details
Kp *soil*		26 L/kg	Refers to Cr(VI); value for acidic and alkaline conditions given in ECB (2005), mean value is used; see text below for details
Bioconcentration factor fish	1 L/kg	1 L/kg	Refers to Cr(VI); value used in ECB (2005)

We derived the solids-water partition coefficients in suspended matter (Kp *suspended matter*), in sediment (Kp *sediment*) and in soil (Kp *soil*) for Cr(VI) from Table 9-7 as follows (see Table 9-8). In the EU Risk Assessment Report for chromates (ECB, 2005), the Cr(VI) partition coefficients are given for suspended matter, sediment and soil under acidic and alkaline conditions. The mean value of the partition coefficients under acidic and alkaline conditions was calculated for each compartment because (a) it reflects the range of values and (b) the underlying data – especially for Kp *suspended* *matter* and Kp *sediment* – are not very well founded, which hinders a more reliable prediction of these parameters.

Table 9-8: Partition coefficients for Cr(VI) for suspended matter, sediment and soil under acid and alkaline conditions, as given in ECB (2005)

Partition coefficient *	Acid conditions (pH ≤5)	Alkaline conditions (pH ≥6)	Mean
Kp *suspended matter*	2 000 L/kg	200 L/kg	1 100 L/kg
Kp *sediment*	1 000 L/kg	100 L/kg	550 L/kg
Kp *soil*	50 L/kg	2 L/kg	26 L/kg

* All Kp values refer to partitioning between water and the solid phase indicated.

In the absence of any specific data for StC and PHD, we use these mean partition coefficients for EUSES modelling. However, we consider this to be a conservative approach due to the low water solubility of the three chromates (between 1.5 and 0.02 g/L), which would be expected to be associated with higher partition coefficients (the higher the solids-water partition coefficient, the less substance enters the water phase). The studies described in the EU Risk Assessment Report for chromates (ECB, 2005) are mostly related to total chromium and Cr(VI) in the environment but conclusions on the source chromate are usually not possible. Assuming, that the data available in the EU Risk Assessment Report include also the poorly water-soluble chromates, it can be expected that their partition coefficients are rather at the upper end of the range described in the EU Risk Assessment Report, i.e., more in the range of the partition coefficients described for acidic conditions.

To assess the impact of the selected partition coefficients, we conducted a sensitivity analysis with EUSES, where an exemplary exposure scenario (with use of biological STP) was carried out using (a) the coefficients for alkaline conditions, (b) the calculated mean values or (c) the coefficients for acidic conditions. Using the mean partition coefficients, a total risk (sum of dose from drinking, fish, and air) of 2.59E-05 was calculated, compared to a risk of 1.43E-05 using the highest partition coefficients (under acidic conditions). The detailed results are given in Annex II of this report.

9.1.2.6 Workers

9.1.2.6.1 Scope and type of assessment

No professional or consumer uses are applied for in this application for authorisation, and such uses are therefore not part of this chemical safety report (CSR).

The three chromates have been included in Annex XIV of the REACH Regulation for their carcinogenic properties. As regards this toxicological effect, the assessment is limited to the inhalation exposure pathway: indeed, according to RAC "*there are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans*" (ECHA, 2013). Therefore, the quantitative occupational exposure estimation and risk characterisation for carcinogenic effects focuses on inhalation exposure of workers.

Table 9-9: Type of risk characterisation required for workers

Route of exposure and type of effects	Endpoint considered and type of risk characterisation	Hazard conclusion DNEL/dose – response relationship
Inhalation: Systemic Long Term	Carcinogenicity Quantitative	RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c) For workers; based on 40 years of exposure; 8h/day; 5 days/week Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 4x10^{-3} *

* The cancer risk characterisation for workers by inhalation is solely based on inhalation exposure and the risk for lung cancer, as no information on the fraction of inhalable, but non-respirable particles is available, which prevents a differentiated consideration of inhalation and oral exposure of workers.

A qualitative risk characterisation with respect to the skin sensitising properties of StC (classified as Skin Sens. 1 based on respective joint entries of registrants) and PHD (harmonised classification as classified as Skin Sens. 1) is outside the scope of this CSR, as they have been included in Annex XIV to Regulation (EC) No 1907/2006 (REACH) solely due to their carcinogenic properties (see section 9.1.2.1). According to REACH, Article 62(4)(d), the CSR supporting an AfA needs to cover only those potential risks arising from the intrinsic properties specified in Annex XIV. The applicants duly apply risk management measures derived by the registrants of the chromates due to other substance properties related to human health concerns, which they communicated via the Safety Data Sheets (SDS).

9.1.2.6.2 Comments on assessment approach

General approach

The potential for exposure depends on the specific tasks identified for each use, as described below in the respective sections. Based on the process characteristics and properties of chromates as non-volatile substances, all potential inhalation exposure will be due to aerosols/dusts containing Cr(VI).

Inhalation exposure of workers is assessed via reliable and representative workplace air measurements. We have assigned exposed workers to “Similar Exposure Groups” (SEGs), which comprise groups of workers performing similar tasks and, hence, are assumed to experience similar exposures. Measured data covering main tasks of a certain SEG are pooled.

Note that some primer products contain barium chromate in addition to the chromates covered under the present use, which then contributes to Cr(VI) exposure of workers. It is not possible to quantify and proportionally allocate part of the measurement according to each chromate used. Accordingly, measurement values with contributions of exposure from such chromates can lead to an overestimation of exposure from the present use.

Measurement methods with varying sensitivity are applied. For values below the limit of quantification (LOQ), EN 689:2018 (Workplace exposure – Measurement of exposure by inhalation to chemical agents – Strategy for testing compliance with occupational exposure limit values) recommends statistical approaches to estimate the arithmetic or geometric mean in case of values below LOQ. However, due to the heterogeneity of our datasets (which come from different sites, with measurements performed by different service providers) these approaches are not feasible. Two other methods for treating such values, the use of LOQ/√2 or LOQ/2, are discussed in literature. The use of

LOQ/2 is preferred for data sets with a geometric standard deviation >3 and the use of LOQ/√2 is preferred for data sets with a geometric standard deviation <3 (Morton and Lion, 2016, Succop et al., 2004). The resulting values of both methods likely overestimate mean values but are expected to have no influence on the 90th percentile of worker measurements considered in this CSR for exposure estimation. Since the use of LOQ/2 is a frequently used practical approach accepted by ECHA for the environmental part, we have used LOQ/2 for values <LOQ in the present exposure assessments (ECHA, 2016b, U.S. EPA, 2019).

Personal monitoring data, with sampling heads in the worker's breathing zone and with sampling durations which allow to acquire sufficient analytical mass and interpret measured values as shift-average values are preferred for inhalation exposure assessment. **Stationary (also called static) measurements** are included in the descriptions of worker exposure but are only used as supporting information.

As the focus of the exposure assessment is on carcinogenic risks over a work life, the long-term average (chronic) exposure would be the most appropriate measure. ECHA Guidance on Information Requirements and Chemical Safety Assessment, R.14: Occupational exposure assessment recommends use of the 90th percentile, without differentiating between health endpoints (ECHA, 2016a). We have followed the recommendation in the ECHA guidance to use the 90th percentile, although this is considered very conservative (as the data reflect measurement uncertainty as well as day-to-day (intra-individual) and inter-individual variation of exposure).

Biological monitoring is an additional tool to assess exposure to chromium at the individual level. It allows to capture exposures from various pathways (inhalation, dermal exposure) at an individual level. However, we do not use biomonitoring data for quantifying risks because no accepted correlation between biomarkers and cancer risk is established. Also, biological indicators have some limitations:

- The measure of chromium in erythrocytes is the only one which is specific to Cr(VI). However, the available literature data on the general population and on workers are insufficient to determine reference values and limit values for this indicator (ANSES, 2017).The German method provides a correlation between biomonitoring in erythrocytes and inhalation exposures but only for CrO_3 concentrations above 30 µg/m^3, which is above what is expected in these exposures (Greim, 2000). Additionally, few sites apply biomonitoring in erythrocytes, as it is an invasive method using blood sampling and is thus difficult to use consistently as a method of estimating exposure.
- Urinary biomonitoring does not allow a differentiation between Cr(III) and Cr(VI) (Drexler and Hartwig, 2009). A biological monitoring guidance value (BMGV) of 10 µmol Cr/mol creatinine was established in the UK to assess total chromium in urine.
- Finally, chromium levels in biomonitoring studies are influenced by factors other than occupational exposure (e.g., geographical region, smoking status, intake from food and drinking water etc.), making the interpretation of the measurements as regards their relation to occupational exposures difficult.

Therefore, we consider biological monitoring an additional exposure control tool allowing assessment of higher exposures via various pathways but do not use them for the quantitative exposure and risk assessment. Biomonitoring data from one GB formulation site are reported in the respective contributing scenarios and in Annex V.

Comments on assessment approach related to toxicological hazard:

There are no differences in the hazard profile compared to the initial applications regarding carcinogenic risks. Dose-response relationships for carcinogenic effects as proposed by RAC are used for risk characterisation.

Comments on assessment approach related to physico-chemical hazard:

Physico-chemical hazards are not in the scope of this document.

General information on risk management related to toxicological hazard:

Information on risk management measures implemented and a comparison with obligations from initial applications for authorisation are provided in chapter 9.2.1.

General information on risk management related to physico-chemical hazard:

Physico-chemical hazards are not in the scope of this document.

9.1.2.7 Consumers

Consumer uses are not subject of this review report.

9.2 Use 1: "Formulation of primer products with strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains"

9.2.1 Introduction

9.2.1.1 Relationship to previous applications

This review report is for Use 1: **"Formulation of primer products with strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains**". It was prepared on behalf of the applicants by the Aerospace and Defence Chromates Reauthorisation (ADCR) consortium to cover uses of chromium (VI) compounds in their supply chains in Great Britain. The review report is based on sector-specific knowledge provided by companies producing primer products for the aerospace and defence industry and its supply chains.

In line with the approach taken by the ADCR consortium, considering the comparable handling of the various chromates during formulation, this chemical safety report covers formulation activities with the two poorly soluble Cr(VI) compounds strontium chromate (StC) and potassium hydroxyoctaoxodizincate dichromate (PHD) in a grouping approach (see section 9.1.2.2 for the justification). The following table shows the initial applications to which this review report refers.

Table 9-10: Overview of initial applications

Application ID/ authorisation number	Substance	CAS #	EC #	Applicants	Use name
0046-01: 28UKREACH/20/7/3, 29UKREACH/20/7/7	StC	7789-06-2	232-142-6	Various applicants (CCST consortium)	Formulation of mixtures intended exclusively for uses bearing authorisation numbers REACH/20/7/10 to REACH/20/7/19
0047-01: 26UKREACH/20/6/0	PHD	11103-86-9	234-329-8	PPG Industries (UK) Ltd. (CCST consortium)	Formulation of mixtures intended exclusively for uses REACH/20/6/5 to REACH/20/6/9

The European Commission issued several obligations with the initial authorisation. Table 9-11 describes the comparison between the initial and the current applications in a concise way, while the individual exposure scenarios describe in more detail the measures already implemented.

Table 9-11: Key obligations in EC Implementing decisions

Initial application 0046-01	Initial application 0047-01	Current application
Art. 2, 2. AH shall develop representative specific exposure scenarios for the different types of formulation, application of primers and specialty coatings, machining processes and individual tasks, describing risk management measures and operational conditions applied in all sites where the authorised uses take place and which are used to control worker exposure to chromium (VI) and its emissions to the environment in each of the specific scenarios. The exposure scenarios shall contain information on the exposure levels resulting from the implementation of those risk management measures and operational conditions.	Art. 2, 2. AH shall develop specific exposure scenarios for the different types of formulation, application of primers and coatings, machining processes and their individual tasks, describing risk management measures and operational conditions applied in all sites at which the authorised uses take place and which are used to control worker exposure to chromium (VI) and its emissions to the environment in each of the specific scenarios. The exposure scenarios shall contain information on the exposure levels resulting from the implementation of those risk management measures and operational conditions.	The consortium responsible for the initial application developed specific exposure scenarios and made them available to the DUs. Starting from that, we further developed and refined the exposure scenarios provided in section 9.2.3.1 to 9.2.3.6 and 9.2.4.1 to 9.2.4.6 of this report, together with the risk management measures described there.
Art. 2, 6. DU and AH shall implement best practices to reduce workplace exposure to strontium chromate and its emissions to the environment to as low a level as technically and practically feasible, including by using closed systems and automation, when possible. Where use of closed systems and automation is not possible, the AH and DU users shall use local exhaust ventilation (LEV) systems that are designed, dimensioned, located and maintained to capture and remove strontium chromate.	Art. 2, 6. DU shall implement best practices to reduce workplace exposureto potassium hydroxyoctaoxodizincate dichromate and emissions to the environment to as low a level as technically and practically feasible, including by using closed systems and automation, when possible. Where use of closed systems and automation is not possible, the DU shall use local exhaust ventilation (LEV) systems that are designed, dimensioned, located and maintained to capture and remove potassium hydroxyoctaoxodizincate dichromate.	The exposure scenarios in section 9.2.3.2 to 9.2.3.6 and 9.2.4.1 to 9.2.4.6 describe the conditions of use including the technical and organisational measures to reduce and control workplace exposure.
Art. 2, 7. Where respiratory protective equipment (RPE) is needed to control exposure, it shall be used in accordance with standard procedures for use and maintenance, including procedures for fit testing of RPE masks, applied in accordance with relevant standards.	Art. 2, 6. Where respiratory protective equipment (RPE) is needed to control exposure to potassium hydroxyoctaoxodizincate dichromate, AH and DU shall use it in accordance with standard procedures for use and maintenance, including procedures for fit testing of RPE masks, applied in accordance with relevant standards.	Organisational measures to control and maintain adequate functioning and use of respiratory protective equipment (RPE) are described in section 9.2.2.3.1.2.

Art. 2, 8. The AHs and DUs shall implement - annual monitoring programmes for air monitoring of occupational exposure, based on relevant standard methodologies or protocols and representative for the tasks undertaken - monitoring programmes for Cr(VI) emissions to wastewater and air from LEV, based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures used at the individual sites	Art. 2, 9. The AHs and DUs shall implement - annual monitoring programmes on occupational exposure to chromium (VI), based on relevant standard methodologies or protocols and representative for the tasks undertaken - monitoring programmes for Cr(VI) emissions to wastewater and air from LEV, based on relevant standard methodologies or protocols and be representative of the operational conditions and risk management measures used at the individual sites	Monitoring programmes are implemented by the formulators, and data from these programmes were used for developing exposure assessments of workers and of humans via the environment.
Art. 2, 9. AH and DU shall use the information gathered via the measurements referred to in paragraph 8 and related contextual information to regularly review the effectiveness of the risk management measures and operational conditions in place and to introduce measures to further reduce exposure and emissions.	Art. 2, 10. AH and DU shall use the information gathered via the measurements referred to in paragraph 9 and related contextual information to regularly review the effectiveness of the risk management measures and operational conditions in place and to introduce measures to further reduce exposure and emissions.	Sites regularly review the effectiveness of risk management measures and operational conditions in place.
Art. 4, 1. AH and DU shall develop and implement standard operational procedures to minimise release of dust into the air during the preparation, transfer and storage of empty bags, filters and other process waste in accordance with the hierarchy of control provisions	Art. 4, 1. AH and DU shall develop and implement standard operational procedures to minimise release of dust into the air during the preparation, transfer and storage of empty bags, filters and other process waste in accordance with the hierarchy of control provisions	Procedures are in place to avoid dust exposure from empty bags (see sections 9.2.3.2 and 9.2.4.2).
Art. 4, 1. When technically and practically possible, AH and DU shall conduct waste management activities under LEV	Art. 4, 1. When technically and practically possible, AH and DU shall conduct waste management activities under LEV	Disposal of empty bags is performed under LEV (see section 9.2.3.2 and 9.2.4.2).
Art. 6. If an AH submits a review report, it shall include - representative specific exposure scenarios, including a detailed guidance on how to select and apply risk management measures, data from the monitoring programmes and - a refined assessment of the exposure to Cr(VI) of HvE, as well as of the resulting risks. This assessment shall be performed using a higher-tier exposure assessment model going beyond the default assumptions of the Guidance on IR and CSA and of EUSES model and making use of site-specific emission information. All reasonably foreseeable routes of exposure of humans via the environment, including the oral route, shall be included in the assessment.	Art. 6. If an AH submits a review report, it shall include - specific exposure scenarios, including detailed guidance on how to select and apply risk management measures, data from the monitoring programmes and - a refined assessment of the exposure to Cr(VI) of HvE, as well as of the resulting risks. That assessment shall be carried out using a higher-tier exposure assessment model going beyond the default assumptions of the Guidance on IR and CSA and of EUSES model and shall make use of site-specific emission information. All reasonably foreseeable routes of exposure of humans via the environment, including the oral route, shall be included in the assessment.	Detailed information on the adequate RMMs for each activity are included in the exposure scenarios of this review report, together with information on the adequate RMMs for each activity (as described below in the individual exposure scenarios). The assessment of exposure of HvE is performed based on measured emission data from the sites. Oral and inhalation exposure from emissions to air is considered.

AH: Authorisation holder; DU: Downstream user; IR and CSA: Information Requirements and Chemical Safety Assessment; HvE: Humans via the Environment

Enforcement activities by Member State Enforcement Authorities

We are not aware of any enforcement activity with relation to the use described here.

9.2.1.2 Overview of use and exposure scenarios

9.2.1.2.1 Deviations from the exposure scenarios and contributing scenarios in the original submission

The exposure scenarios (ES) and contributing scenarios of this review report deviate from those included in the original submission in the following ways:

1) This review report follows a grouping approach (see section 9.1.2.2). At one of the sites, more than one chromate is used in parallel or in subsequent steps to formulate a variety of products. Exposure of workers and of humans via the environment may come from different substances and therefore, an assessment considering all of them is appropriate.
2) In this review report we have identified similar exposure groups (SEGs) of workers for the uses considered here, and the SEGs are described in separate worker contributing scenarios (in order to respond adequately to the EC Implementing decision and RAC/SEAC recommendations to *develop specific exposure scenarios for representative processes, operations and individual tasks*, as described in Table 9-12).

   Each contributing scenario covers the relevant processes and individual tasks performed by the respective group of workers in relation to the use and describes the operating conditions (OCs) and risk management measures (RMMs) for the individual tasks involving Cr(VI) exposure. The Cr(VI) exposure from these activities is quantified by personal air measurements. In this way, Cr(VI) inhalation exposures from all relevant tasks performed by a SEG during its daily work are considered and combined for risk assessment.

   In the initial applications, no SEGs were determined. Instead, for a general worker, separate tasks with potential Cr(VI) exposure were described in each individual worker contributing scenario. Available monitoring data were considered for combinations of the main tasks performed. For other tasks Cr(VI) exposure was modelled with Advanced REACH Tool (ART 1.5).
3) In the environmental contributing scenario of this review report the assessment of humans via the environment is considered via the inhalation route and the oral route. Emission data of measured releases to air serve as a basis for EUSES modelling of human exposure via several environmental media (ambient air, drinking water, fish) at the local scale. No emission to wastewater occurs at the formulation sites covered by this review report. However, oral exposure from emissions to air is considered.

   In the initial applications, only the inhalation route was considered for EUSES modelling and emissions to wastewater were described as negligible and, thus, not considered. Releases were estimated by using specific environmental release categories (spERCs) or by measured release data.

Due to differences in the structure of the current and initial applications, especially due to the assignment of tasks to SEGs, a direct comparison is not easy to perform. Table 9-12 provides an overview on major differences between the review report and the initial applications. In the first column, the PROCs assigned to different SEGs are shown. The PROCs from the initial applications corresponding to these tasks are listed in the second column. Differences in PROCs used are described in the third column.

Table 9-12: Activities and descriptors in current and initial applications

Current application	Initial applications	Remarks
ECS 1- Environmental contributing scenario - ERC 2	Formulation of mixtures (ERC 2)	
WCS 1 – Operators handling solid chromates operators [a] PROC 5, PROC 8a, PROC 8b, PROC 28, (Comp B: in addition PROC 9)	Decanting and weighing of solids (PROC 8b) Transfer to mixing vessel (PROC 8b) Mixing by dilution, dispersion, wet-grinding (closed or open process) (PROC 2-5, 26) Cleaning of equipment (PROC 8b) Maintenance of equipment (PROC 8b) Waste management (PROC 8b)	For cleaning PROC 28 is regarded more appropriate in the current application
WCS 2 – Operators handling liquid products [a] PROC 8b, PROC 28 (Comp A: in addition PROC 5, 9)	Transfer to mixing vessel (PROC 8b) Mixing by dilution, dispersion, wet-grinding (closed or open process) (PROC 2-5, 26) Transfer to small containers (including filtering) (PROC 9) Cleaning of equipment (PROC 8b) Maintenance of equipment (PROC 8a) Waste management (PROC 8b)	PROC 5 is considered adequate for describing the production process For cleaning PROC 28 is regarded more appropriate in the current application
WCS 3 – Laboratory technicians [a] PROC 15	Laboratory analysis (PROC 15)	
WCS 4 – Maintenance and cleaning workers [a] PROC 28	Maintenance of equipment (PROC 8a)	For maintenance and cleaning PROC 28 is regarded more appropriate in the current application
WCS 5 – Incidentally exposed workers [a] PROC 0		Incidentally exposed workers were not considered in initial application
	Delivery and storage of raw material (PROC 1) Storage of formulation (PROC 1)	Not considered relevant in this review report, as these activities are not part of the use described in this CSR or do not lead to Cr(V) exposure

[a] For detailed descriptions of tasks assigned to the individual PROCS see worker contributing scenarios in sections 9.2.3.2 to 9.2.3.6 and 9.2.4.2 to 9.2.4.6.

The exposure scenario and contributing scenarios of this review report are shown below in Table 9-13.

9.2.1.2.2 Scope of use – supply chain considerations

This CSR covers the manufacture of primer products containing StC and/or PHD for being used in the aerospace and defence industry and its supply chains. This use is performed in Great Britain (GB) in exclusively industrial settings at two companies specialised in formulation activities.

Table 9-13 lists all the exposure scenarios (ES) and contributing scenarios assessed in this CSR. As workers exposure conditions differ to some extent between production of large and small batches, we prepared two separate sub-scenarios. Companies may either only produce large batches, small batches or both.

Table 9-13: Overview of exposure scenarios and their contributing scenarios

ES number	**ES Title**		**Environmental release category (ERC)/ Process category (PROC)**
ES1-F1	Formulation of primer products with StC and/or PHD for use in aerospace and defence industry and its supply chains		
Environmental contributing scenario(s)			
ECS 1	Formulation into mixture		ERC2
Worker contributing scenario(s)			
	Company A	Company B	
WCS 1	Operators handling solid chromates Sub-scenario 1: large batches Sub-scenario 2: small batches	Operators handling solid chromates	Comp. A: PROC 5, 8a, 8b, 28 Comp B: PROC 5, 8a, 8b, 9, 28
WCS 2	Operators handling liquid products	Operators handling liquid products	Comp. A: PROC 5, 8b, 9, 28 Comp B: PROC 8b, 28
WCS 3	Laboratory technicians	Laboratory technicians	PROC 15
WCS 4	Maintenance and cleaning workers	Maintenance workers	PROC 28
WCS 5	Incidentally exposed workers	Incidentally exposed workers	PROC 0
Exposure scenario for formulation: ES1-F1			

9.2.1.2.3 Relationship between uses

This CSR is for the single use “Formulation of primer products with strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains”. The primer products containing Cr(VI) compounds are manufactured to meet the high quality standards in the aerospace and defence supply chains. This step therefore is a prerequisite for achieving the required results in surface treatment. This CSR covers the manufacture of products with StC and/or PHD relevant for all uses described in the other dossiers prepared by the ADCR consortium as explained in section 9.1.1.

9.2.2 Detailed information on use

9.2.2.1 Process description

Cr(VI)-containing primer products are produced at industrial sites specialised in formulation activities. Primer products are liquid, water- or solvent-based dispersions of StC and/or PHD. The products contain further resins and additives to achieve the required performance characteristics. Primer products are liquid dispersions of low viscosity (solvent-based products are slightly higher viscous than water-based; viscosity is also influenced by the size of the dispersed particles). Production of primer products comprises the main steps:

- Preparation of concentrated liquid dispersions from solid chromates
- Milling (wet-grinding) and dispersion, potentially followed by further dilution with resins, additives and solvents
- Filling of product containers (including small volume packages).

The chromates do not have an own functionality during formulation. The purpose of this activity is to provide mixtures adequate for fulfilling technical requirements in subsequent surface treatment processes in aerospace and defence industry and its supply chains.

9.2.2.2 Teams and employees involved

Identified Similar exposure groups (SEGs) comprise the following groups:

- Operators handling solid chromates
- Operators handling liquid products
- Laboratory technicians
- Maintenance and cleaning workers
- Incidentally exposed workers (without direct Cr(VI)-related activities).

Operators handling solid chromates

Handling of solid chromates occurs under high scrutiny. The process is physically separated from other activities in the company or access to the relevant area is restricted otherwise. The operators are typically performing the following tasks:

- Transport of solid substances in closed bags from the storage area to the mixing area (sometimes also done by logistics workers)
- Weighing of solid chromate
- Filling solid substances (and other additives) into the mixing tanks
- Surveying the milling and dispersion process
- Dilution/mixing of the dispersion with resins, additives and solvents
- Closing/covering the mixing tanks for transport
- Cleaning of workplaces and equipment
- Emptying of lines in case of repairs.

Operators handling liquid products

These operators are mainly responsible for the transfer of the liquid products and filling product containers. Their tasks are:

- Transfer of final products to storage tanks and/or product containers
- Filling medium-size and large product containers (0.5 to 200 L)
- Filling small packages (up to 150 mL) (Company A only)
- Cleaning of workplaces and equipment.

In Company A, the two steps of handling solid chromates and liquid dispersions may be performed by the same operators. However, they are described in separate WCS because conditions of use differ. In section 10.1.1 for the situation of operators performing both parts of the work is discussed.

Laboratory technicians

Laboratory technicians are responsible for quality control of products. Typical tests comprise control of the particle size of the dispersed substances. Spraying low quantities of product on small surfaces is performed to control product performance. Handling of Cr(VI) containing materials comprises only (small) parts of shifts of the lab technicians.

At the companies covered by this CSR, laboratory technicians are not engaged in taking samples.

Maintenance and cleaning workers

High precautionary measures are applied in areas and for tasks where exposure to chromate-containing dust is possible. Maintenance and cleaning activities in these areas are performed using the same risk management measures as the handling of the solid chromates itself.

Maintenance work in relation to equipment used for handling liquid mixtures is infrequent. It may comprise repair of mills, pumps, valves, and plumbing. Many of these activities can be done in situ, without a need for opening lines and without potential for exposure. When line opening is required, lines are emptied, cleaned, and prepared by operators, before maintenance workers are allowed to remove equipment, according to standard procedures.

In case of company B the main maintenance task performed is the change of the filters of the air abatement system.

Typically, maintenance workers spend a small fraction of their time only on activities with potential for Cr(VI)-exposure.

Incidentally exposed workers

Incidentally exposed workers are defined as workers, who spend a relevant part of their time in areas where Cr(VI) substances are handled, without being involved in these activities. As exposure via inhalation cannot be excluded in closed halls, potential exposure of bystanders is considered.

In case of formulation activities, the number of these workers is low. Incidental exposure might occur where several mixing vessels or filling stations are placed in a large hall and only one or few of these vessels is dedicated to the production of chromate containing mixtures. Also, supervisors might belong to that group.

Incidental exposure only occurs from activities with liquid mixtures, as no other staff is allowed where solid chromates are handled.

9.2.2.3 Technical and organisational risk management measures

9.2.2.3.1 Workers

At both sites, only well-trained personnel are allowed to handle chromates. Workplaces are assessed regularly regarding the handling of hazardous substances according to the respective national schemes, i.e., according to the Control Of Substances Hazardous to Health (COSHH) Assessment rules in the UK.

9.2.2.3.1.1 Technical measures

Standard technical measures for reducing exposure at sites formulating Cr(VI) substances are

- Mixing vessels are (semi-)closed systems, the openings of which are covered by lids or foils when not needed for adding raw materials
- Mixing vessels have local exhaust ventilation (LEV) and automated stirrers (with stirrer velocity adjusted to avoid aerosol generation)
- Liquid mixtures are transferred via closed lines and pumps between vessels and containers, where possible
- Weighing and allocating solid chromates are avoided by adjusting recipes so that only complete bags are used. Where weighing is indispensable, LEV is provided at the point at which solid chromates are weighed.

Efficiency of LEV

LEV systems are installed at the mixing vessels and are regularly inspected and controlled according to the specifications of the manufacturers of the systems. The sites follow the manufacturer requirements and perform preventative maintenance of equipment to maintain the stated efficiencies of the LEV systems.

9.2.2.3.1.2 Organisational measures

The following organisational measures to reduce workplace exposure are implemented at all sites:

- The effectiveness of the risk management measures and operational conditions in place are regularly reviewed, and measures are introduced to further reduce exposure and emissions, as applicable.
- Appropriate standard operating procedures are implemented to minimise the generation and release of dust during the handling of empty bags of solid chromates, in accordance with the hierarchy of control provisions set out in Article 5 of Directive 2004/37/EC.
- Companies restrict access to the areas where solid chromates are handled on the days of production by physical barriers or adequate procedures.
- The LEV systems installed are inspected and maintained according to the manufacturer´s specification.
- The provision of PPE for the workers is organised by a designated responsible person.
- The conditions of the PPE are checked regularly.
- Standard procedures are available for use and maintenance of respiratory protective equipment (RPE) (including procedures for fit testing of RPE masks which are applied in accordance with relevant standards).

- A program of PPE management is implemented on site which includes PPE selection, training for correct wear/removal of the PPE, storage of PPE, cleaning or renewal and distribution of the PPE, communication via workplace signage or working instructions at the workplace.
- Training for handling of dangerous substances (environmental, health and safety training) is given regularly, by responsible facilitators (internal or external) or delivered via e-learning platforms.
- On the job training is given and activity-related work instructions are available on how to carry out specific tasks, e.g., for opening lines in case of maintenance activities.
- Safety data sheets or other adequate workplace instructions are available at workplaces with exposure to hazardous substances.
- Specific procedures are in place to minimise exposure, e.g., to avoid splashes.
- Cleaning of company supplied uniforms is organised by the site, or contaminated clothes are renewed.
- Chemical products are stored in a designated area.
- Effective cleaning practices are implemented to prevent surface contamination in the vicinity of the tanks.
- No sampling from raw materials (solids) takes place.

This high level of awareness for hazards from CMR substances and the organisational measures taken to reduce risks are summarised in the conditions of use tables in section 9.2.3 as “Advanced occupational health and safety management system”.

9.2.2.3.1.3 Personal Protective Equipment

For all tasks with potential direct Cr(VI) exposure, standard operating procedures are available at the sites, wherein the appropriate PPE to be worn is specified (selected based on risks and in accordance with the exposure scenarios). The following PPE is applied for activities where exposure to Cr(VI) is possible, in order to control Cr(VI) exposures:

- Chemical protective clothing, where necessary (plus coveralls for specific tasks)
- Eye protection as per relevant risk assessment
- Chemical-resistant gloves
- Respiratory protection, worn during all tasks not performed under an LEV for which industrial hygiene exposure assessment confirms RPE use is required.

Gloves

Chemical-resistant gloves tested according to EN 374 are used when handling primer products. As StC and PHD are poorly soluble and contained in the primer products as dispersions (i.e., undissolved solid particles) their penetration through any kind of gloves material and through the skin is minimal. Therefore, the selection of material and thickness of gloves is driven by other substances in the primer products (e.g., solvents) and by other substances handled in parallel by the respective group of workers. Gloves and other PPE are selected based on a careful consideration of all conditions of a specific workplace as part of the companies’ industrial hygiene exposure assessment.

Respiratory protection equipment (RPE) - Use of Assigned Protection Factors (APFs)

The European Standard EN 529 – “Respiratory protective devices. Recommendations for selection, use, care and maintenance” provides guidance on the selection and use of RPE. It also lists “Assigned protection factors” as recommended in various EEA countries and in the UK. APFs as used in this report are given in the Table to Annex IV.

We noted that large differences exist in the APFs for ambient air-independent breathing apparatuses in the UK and in EEA countries. HSG 53 gives APFs ranging from 40 to 2000, whereas much larger APFs are used in several EEA countries (see Annex IV). Examples:

- fresh air hose breathing apparatus (EN 138): UK: APF 40, Germany: APF 1000, Sweden: APF 500
- constant flow airline breathing apparatus with full mask (EN 14594): UK: APF 40, France: APF 250.

We asked HSE for assistance in choosing adequate APFs and were referred to the British Standards Institutions (BSI). BSI explained that these APFs were discussed many years ago and cited recent publications (Connell and Lynch, 2023). These authors describe some potential reasons for the differences, among them different types of data used (data from compliant and non-compliant programs were used according to Connell and Lynch (2023) in the UK) and the use of a safety factor. Considering these uncertainties and for the sake of a harmonised assessment of risks in the UK and the EEA based on the same type of data (an APF of 250 is used in respective ADCR EU applications for chromates in primer products, this being the lowest APF reported in an EEA country) in this report for various types of ambient air-independent breathing apparatuses (e.g. fresh air hose breathing apparatus, constant flow airline breathing apparatus with full mask or hoods/helmet demand valve compressed air breathing apparatus), an APF of 250 is used for calculating exposure concentrations.

The specific PPE for each task is described in detail in the worker contributing scenarios in sections 9.2.3.2 to 9.2.3.6 and 9.2.4.2 to 9.2.4.6.

9.2.2.3.2 Environment

9.2.2.3.2.1 Emissions to air

The following technical and organisational measures are implemented to reduce environmental air emissions to the maximum extent possible:

- Mixing vessels are equipped with LEV systems. The local exhaust air is collected and released via exhaust stacks. The local exhaust air is treated (by dry air filters) before it is released to the environment.
- Regular monitoring programmes for Cr(VI) emissions to air from LEV systems are implemented and the effectiveness of the risk management measures and operational conditions in place are regularly reviewed.

Efficiency of air abatement technology

Efficiency of air abatement technology is regularly controlled.

Air filters can be checked by comparative measures with and without the use of the filter, or between the duct inlet and outlet.

9.2.2.3.2.2 Emissions to wastewater

Processes for manufacturing primer products are essentially led without water. Where water is used for cleaning purposes the Cr(VI)-containing wastewater is gathered and sent directly to a waste management company (licensed contractor) for disposing it as hazardous waste. Therefore, no emissions to wastewater occur at the companies covered by this review report.

9.2.2.3.2.3 Emissions to soil

For preventing environmental emissions to soil the indoor and outdoor surfaces where chemicals are handled are sealed. Chemicals and solid waste containing Cr(VI) are stored in closed containers, either inside or outside.

9.2.2.3.3 Solid waste

Solid waste generated at the sites comprises Cr(VI) contaminated objects from activities related to the formulation activities (e.g., empty bags, filters, waste from cleaning activities such as wipes and cloths, contaminated PPE). The Cr(VI)-contaminated solid waste are disposed of as hazardous waste. This hazardous solid waste is stored in closed containers and forwarded to an external waste management company (licensed contractor) for disposal.

9.2.2.4 Tonnages and mass balance considerations

9.2.2.4.1 Tonnages

This chemical safety report covers the manufacture of chromate-containing primer products at two sites in GB. The site-specific tonnage formulated in GB for manufacturing products used by the aerospace and defence industry and its supply chains is given for both sites in sections 9.2.3.1.1 and 9.2.4.1.1, resp.

9.2.2.4.2 Mass balance considerations

Consumption during process

During formulation, practically all of the Cr(VI) is introduced into the mixtures, as this is the purpose of the activity. Potential losses result from spills or residues in vessels or containers.

Amount of Cr(VI) released to wastewater

There is no release to wastewater from the companies producing primer products. Small amounts of water used for cleaning purposes are gathered and sent to external waste management companies (licensed contractors). As the concentrations are not measured the amount of Cr(VI) cannot be quantified.

Amount of Cr(VI) discharged as waste

Cr(VI) in solid waste occurs only in the form of contaminated cleaning materials, filters and PPE. Also, liquid waste may occur, e.g. solvent used for cleaning purposes. Both types of waste are sent to an external company certified for disposing of liquid hazardous waste. These quantities are low, highly variable, and not consistently quantifiable.

Amount of Cr(VI) released via fugitive emissions

No measurement data is available for fugitive emissions. However, due to the low vapour pressure of the chromates, the amount is considered low.

Amount of Cr(VI) released to the atmosphere

The amount which is released with exhaust air via stacks is estimated to be 0.016 kg Cr(VI) per year for Company A and 0.00055 kg Cr(VI) per year for Company B (as described below in sections 9.2.3.1.2 and 9.2.4.1.2).

9.2.3 Exposure scenario 1 for Use 1: "Formulation of strontium chromate and/or potassium hydroxyoctaoxodizincate dichromate for use in aerospace and defence industry and its supply chains for surface treatments – Company A"

Market sector: -

Sector of use: SU 9

Article categories: not relevant

Environment contributing scenario(s): ERC 2

Worker/Consumer contributing scenario(s): PROC 0, PROC 5, PROC 8a, PROC 8b, PROC 9, PROC 15, PROC 28

Subsequent service life exposure scenario(s): not relevant

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): not relevant

Description of the activities and technical processes covered in the exposure scenario:

Manufacture of primer products (liquid dispersions of poorly soluble chromates) (see detailed use information in section 9.2.2.1).

Explanation on the approach taken for the ES:

We established the exposure scenario based on sector-specific information provided by the company performing these activities.

9.2.3.1 Environmental contributing scenario 1

As StC or PHD are not listed in REACH Annex XIV due to environmental effects, no environmental exposure assessment is performed here. However, we assessed the exposure of humans via the environment in the following sections.

9.2.3.1.1 Conditions of use

Table 9-14: Conditions of use – Environmental contributing scenario 1

Product (article) characteristics	
Product A:	Solid StC, pure substance (100%); 26% Cr(VI)
Product B:	Solid PHD, pure substance (100%); 25% Cr(VI)
Amount used, frequency and duration of use (or from service life)	
Product A:	
Total amount used annually at GB site A:	Up to (0.5 – 10) t Cr(VI)/year as StC
Process type:	Batch process
Frequency:	Up to 365 days/year (see section 9.1.2.4.)
Product B:	

Total amount used annually at GB site A:	Up to (0.1 – 5) t Cr(VI)/year as PHD
Process type:	Batch process
Frequency:	Up to 365 days/year (see section 9.1.2.4.)
Technical and organisational conditions and measures	
Technical measures (all products)	
Air	Mixing vessels are equipped with LEV
	Exhaust air is treated by air filters before it is released via stack(s)
Wastewater	No emission to wastewater
Soil	Indoor and outdoor surfaces where chemicals are handled are sealed and chemicals and solid waste containing Cr(VI) are stored in closed containers
Organisational measures (all products)	
Air	Cr(VI) air emission measurements are performed regularly at identified exhaust stack(s) where the process emissions are released
Wastewater	Water used for cleaning is gathered and sent to an external company certified for disposing as hazardous waste or for an industrial process under a specific permit
Conditions and measures related to sewage treatment plant	
All products	N/A (no emission to wastewater)
Conditions and measures related to treatment of waste (including article waste)	
All products:	Solid waste contaminated with Cr(VI) (e.g. wipes, used PPE, empty bags, drums) are disposed as hazardous waste. Hazardous solid waste is stored in closed drums and containers and forwarded to an external waste management company (licensed contractor) for disposal
Other conditions affecting environmental exposure	
All products:	Processes are carried out at ambient temperature
	Mixing vessels are covered by lids or foils when transported inside the premises
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
	None

Manufacture of chromate-containing primer products as described here for use in the aerospace and defence industry and its supply chains is carried out at one dedicated industrial formulation site in GB. Production is batch-wise.

Air emissions

Production facilities are equipped with local exhaust ventilation. Emissions are treated by abatement technology, consisting of particle filters.

Particle filters are checked and changed regularly. Used filters are collected and disposed by an external company certified for disposing hazardous waste.

Wastewater emissions

Cr(VI) containing water mainly arises from using water for cleaning purposes. Contaminated water is collected and sent to an external waste management company (licensed contractor) for disposal. There is no emission of Cr(VI) to wastewater from the manufacture of primer products.

Soil emissions

There is no direct release to soil, based on equipment and procedures in place.

9.2.3.1.2 Releases

Releases to environmental media at the site only occur via exhaust air. Contaminated water is gathered and disposed of by a certified waste management company.

Total chromium emissions from the production area of coatings (Coatings First Floor, LEV23) were measured by Envirocare in 2024. Sampling was performed according to BS EN 14385 and chromium was analysed by ICP-MS (analytical procedure M31(U)). The gas flow at the stack was 3573 m^3/hour and a concentration of 0.015 mg/m^3 was determined.

Total release and the release fraction from the production site is shown in Table 9-15. The release fraction is calculated from the annual amount of Cr(VI) used at the site and the amount of Cr(VI) emitted to air. The site-specific release is used as input for EUSES modelling of the environmental concentrations. As the site does not release Cr(VI) to wastewater the respective release fraction is zero.

Table 9-15: Local releases to the environment

Release route	Release fraction [a]	Release [kg/year] [a]	Explanation/Justification
Water	0	0	No release to wastewater
Air	(5.0E-07 – 5.0E-05) [b]	0.016	Measured release (site-specific data)
Soil [b]	0	0	No release to soil is possible

[a] Releases and release fractions to air are based on recent release data and tonnages provided by the site

[b] Release fraction is given as range because exact figures would allow to recalculate use amounts

Releases to waste

Solid wastes are disposed of as described above by a certified company specialised in hazardous waste disposal. No emissions from solid wastes are expected.

Release fraction to waste from the process: 0

9.2.3.1.3 Exposure and risks for the environment and humans via the environment

These releases resulted in modelled (EUSES) environmental concentrations and human exposures as shown in the following table. The resulting estimated overall risk from exposure of humans via the environment is 3.54E-07 (Table 9-16).

This low risk is expected as a small fraction of a small amount of substance is released to air only, and no emissions to wastewater occur.

Table 9-16: Exposure concentrations and excess cancer risk estimates for humans via the environment – on local scale (Company A)

Inhalation			**Oral**			
Local Cr(VI) PEC in air [µg/m^3]	**Excess lung cancer risk [1/(µg/m3)]** [a]	**Inhalation risk**	**Oral exposure (water and fish) [µg Cr(VI)/kg x d]** [b]	**Excess cancer risk for tumours of the small intestine [1/(µg/kg bw/day)]** [c]	**Oral risk**	**Combined risk**
1.22E-05	2.90E-02	3.54E-07	6.03E-08	8.00E-04	4.82E-11	**3.54E-07**

[a] RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 2.9x10^{-2} for the general population, based on 70 years of exposure; 24h/day.

[b] combined exposure from drinking water (6.02E-08 µg Cr(VI)/kg x d) and fish consumption (8.26E-11 µg Cr(VI)/kg x d)

[c] RAC dose-response relationship based on excess cancer risk for tumours of the small intestine (ECHA, 2013c): Exposure to 1 µg/m³ Cr(VI) relates to an excess risk of 8x10-4 for the general population, based on 70 years of exposure; 24h/day.

Note that the modelling of local air concentrations with EUSES is generally acknowledged as being overly conservative, as described in detail in section 9.1.2.5.2.

For the exposure via drinking water and fish a reduction factor of 5 was applied, as described in section 9.1.2.4.2 of the CSR. However, due to the absence of emissions to wastewater, the risk from oral exposure is orders of magnitude lower than that from inhalation anyway.

Conclusion on risk characterisation:

Carcinogenicity

Combined risks of cancer by inhalation and by the oral route from the local assessment for Company A result in a combined excess cancer risk of 3.54E-07. This theoretical cancer risk is based on a conservative, linear ERR. Further, due to the overly conservative nature of the predictions of the EUSES model for the local air concentrations the risk level can be considered an overestimation.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The assessment of exposure of humans via the environment in this chemical safety report is based on measured emission data for emissions to air. For this assessment combined exposure of humans via the inhalation (air) and the oral (uptake of water and fish) route is considered.

Total exposure is estimated to be 1.22E-05 µg/m^3 (inhalation exposure) and 6.03E-08 µg/kg x d (oral), resulting in an estimated excess cancer risk for both pathways combined of 3.54E-07.

In the initial applications only the inhalation route was considered for the assessment of human exposure via the environment. The following exposure and risk were estimated to be:

Application ID	local PEClocal air [µg/m^3]	Excess lung cancer risk
0046-01 (StC)	9.52E-04	2.80E-05
0047-02 (PHD)	9.52E-04	2.80E-05

Our risk estimate based on measured release data is almost two orders of magnitude lower than the risks calculated in the initial applications.

9.2.3.2 Worker contributing scenario 1 – Operators handling solid chromates

As handling solid, non-dispersed chromates requires special precautionary measures, these activities are described in a separate contributing scenario. Further processing of wet dispersions to produce the final primer products is subject of WCS 2 (Operators handling liquid products).

Operators handling solid chromates are typically performing the following main tasks:

- Task 1: Weighing of solid material (PROC 8a)
- Task 2: Charging the mixing vessels with solid material (PROC 8b) and surveying the dispersion process (PROC 5)
- Task 3: Cleaning of workplaces and equipment (PROC 28)
- Task 4: Waste management – disposal of solid waste (PROC 8b)

In the following sections, the conditions of use for each task with potential direct Cr(VI) exposure are specified and the individual activities are described in more detail.

9.2.3.2.1 Conditions of use

Table 9-17 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

Table 9-17: Conditions of use – worker contributing scenario 1 – Operators handling solid chromates - Production of large batches

Product (article) characteristics	
Task 1: Weighing of solid material (PROC 8a)	
Maximum Cr(VI) concentration in product [%]	100% StC: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Maximum Cr(VI) concentration in product [%]	100% StC or PHD: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Maximum Cr(VI) concentration in product [%]	100% StC or PHD: up to 26% Cr(VI)
Product type and dustiness	low amounts of dust or liquid spills

Task 4: Waste management – disposal of solid waste (PROC 8b)	
Maximum Cr(VI) concentration in product [%]	up 70% StC or PHD: up to 18% Cr(VI)
Product type and dustiness	Residues of liquid dispersion, solid waste
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Weighing of solid material (PROC 8a)	
Amount [L]:	up to 30 kg/d StC or PHD
Duration of activity [min/event]:	up to 15 min/d
Frequency of task [1/shift]	up to 15 days/year
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Amount [L]:	up to (1000 – 4000) kg/d StC or PHD
Duration of activity [min/event]:	up to 8 h/day (1-4 h/d charging solid chromates, 1-4 h/d charging additives and surveying dispersion process)
Frequency of task [1/shift]	up to 15 days/year (see above)
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	0.5 h/d
Frequency of task [1/shift]	up to 15 days/year
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Amount [L]:	n.a.
Duration of activity [min/event]:	0.5 h/d
Frequency of task [1/shift]	up to 15 days/year
Technical and organisational conditions and measures	
Task 1: Weighing of solid material (PROC 8a)	
LEV:	yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Organisational measures:	Open bags are stored in sealed buckets Procedures in place to minimize dust generation during weighing
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
LEV:	yes
Type of LEV	Enclosing hood
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH

Technical measures:	Coverage of mixing tanks for transport Bags are lifted to level of tank opening Slide for disposing of empty bags or waste container directly adjacent to tank
Organisational measures:	Restriction of access: spatial separation (separate working platform); restriction of access via signage or physical barrier Complete bags are used for most recipes - weighing reduced to minimum Procedures in place to minimize dust generation from empty bags
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 3: Cleaning of workplaces and equipment (PROC 28)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 4: Waste management – disposal of solid waste (PROC 8b)	
LEV:	Yes (for folding empty bags)
Type of LEV	Enclosing hood
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Weighing of solid material (PROC 8a)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)

Eye protection	Eye protection as per relevant risk assessment
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Weighing of solid material (PROC 8a)	
Place of use	Indoors
Temperature	Ambient temperature
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Place of use	Indoors
Temperature	Ambient temperature
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Place of use	Indoors
Temperature	Ambient temperature
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

[a] For selection of APF see Annex IV of this report.

Table 9-18: Conditions of use – worker contributing scenario 1 – Operators handling solid chromates - Production of small batches

Product (article) characteristics	
Task 1: Weighing of solid material (PROC 8a)	
Maximum Cr(VI) concentration in product [%]	100% StC or PHD: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Maximum Cr(VI) concentration in product [%]	100% StC or PHD: up to 26% Cr(VI)

Product type and dustiness	Solid, powder - fine dust
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Maximum Cr(VI) concentration in product [%]	100% StC or PHD: up to 26% Cr(VI)
Product type and dustiness	low amounts of dust or liquid spills
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Maximum Cr(VI) concentration in product [%]	up 70% StC or PHD: up to 18% Cr(VI)
Product type and dustiness	Residues of liquid dispersion, solid waste
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Weighing of solid material (PROC 8a)	
Amount [L]:	up to 30 kg/d StC or PHD
Duration of activity [min/event]:	up to 15 min/d
Frequency of task [1/shift]	up to 10 days/year
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Amount [L]:	up to 250 kg/d StC or PHD
Duration of activity [min/event]:	up to 4 h/d (up to 1 h/d charging solid chromates, up to 3 h/d charging additives and surveying dispersion process)
Frequency of task [1/shift]	up to 10 days/year
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	0.5 h/d
Frequency of task [1/shift]	up to 10 days/year
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Amount [L]:	n.a.
Duration of activity [min/event]:	0.5 h/d
Frequency of task [1/shift]	up to 10 days/year
Technical and organisational conditions and measures	
Task 1: Weighing of solid material (PROC 8a)	
LEV:	yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Organisational measures:	Open bags are stored in sealed buckets Procedures in place to minimize dust generation during weighing
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
LEV:	yes
Type of LEV	Capturing hood or LEV inside tank

Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Technical measures:	Coverage of mixing tanks for transport Waste container directly adjacent to tank
Organisational measures:	Restriction of access: restriction of access via signage or physical barrier Complete bags are used for most recipes - weighing reduced to minimum Procedures in place to minimize dust generation from empty bags
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 3: Cleaning of workplaces and equipment (PROC 28)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 4: Waste management – disposal of solid waste (PROC 8b)	
LEV:	Yes (for folding empty bags)
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Mechanical ventilation
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Weighing of solid material (PROC 8a)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment

Task 3: Cleaning of workplaces and equipment (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Weighing of solid material (PROC 8a)	
Place of use	Indoors
Temperature	Ambient temperature
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Place of use	Indoors
Temperature	Ambient temperature
Task 3: Cleaning of workplaces and equipment (PROC 28)	
Place of use	Indoors
Temperature	Ambient temperature
Task 4: Waste management – disposal of solid waste (PROC 8b)	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

[a] For selection of APF see Annex IV of this report.

9.2.3.2.2 Exposure and risks for workers

Primer products are manufactured batch-wise (on demand) and the number of campaigns and production days per year can vary. Solid chromates are used with high safety precautions in designated areas only, the access to which is restricted. So produced concentrated dispersions are transported to other areas for further processing and manufacture of the final products (see WCS 2, section 9.2.3.3).

One or two operators are engaged in adding solid chromates to mixing vessels. These workers may belong to the same group of workers responsible for preparing the final product. For a discussion of possible consequences for the operators' individual risks see section 10.1.1.

Task 1: Weighing of solid material (PROC 8a)

Weighing of solid chromate is required for a few recipes only.

Weighing of solid chromate (up to 30 kg per day) is performed on a floor mounted weighing scale in a separate room designated for handling solid chromates. Typically, weighing the required amounts takes 5 to 15 min per batch. The chromate is carefully transferred from a bag into a container with a shovel until the required amount is achieved. A mobile LEV is applied during this process. The opened bag is stored in a sealed bucket (clearly labelled) with a lid, which is then stored in a designated area, together with unopened bags.

Weighed material is transported in the closed container to the mixing tank nearby and added via the opening.

Task 2: Charging the mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)

Slightly different conditions apply to large- and small-scale activities.

Large quantities – segregated areas

A physically segregated area (separated working platform) is used to handle large quantities (>250 kg/d StC or PHD).

Bags with chromates (25 kg) are lifted to the level of the tank opening or funnel by forklift and positioned at the tank opening. LEV is applied (enclosing hood). Rooms where solid chromates are handled are equipped with efficient mechanical ventilation. Bags are opened and its content carefully released into the mixing tank (which already contains liquid). Following detailed procedures, empty bags are folded in the direction of the LEV to minimise and capture any dust released during this process. Empty bags are put in a waste container (with lid) positioned directly adjacent to the mixing tank.

After having added all required ingredients and having completed this first dispersion process, the tanks are cleaned from any spills or contaminations by wet wipes, closed and transported to the milling stations (see WCS 2, section 9.2.3.3). The workplace is cleaned by vacuum cleaners (with HEPA filters) and/or wipes soaked with water or solvent, which are disposed of as solid hazardous waste.

Small quantities

At the station to handle smaller quantities up to 250 kg chromate (StC or PHD) per day are used. However, depending on the recipe and the size of the batch, batches often contain much smaller amounts.

Similar procedures as for large quantities are used, with the following differences:

- The area is not always physically segregated from other activities, but access is restricted by signage.
- Bags are sometimes lifted to the tank opening manually.

Task 3: Cleaning of workplaces and equipment (PROC 28)

The workplaces around the mixing vessels are cleaned regularly (daily). In most cases contaminations are restricted to minor splashes and/or small amounts of solid material around the mixing vessels. Small splashes or amounts are taken up with wipes. Wipes are disposed of as solid waste.

The rim and the inner upper part of the mixing tank is cleaned with spatula, brush and/or a cloth soaked with water or solvent. Any wastewater or solvent resulting from such cleaning processes is gathered in separate tanks (e.g., IBC) for disposal by a certified external company.

Any contaminated tool or material (brush, wipes) either remains in the separated area and is reused or is disposed of as hazardous waste.

The workplace is carefully cleaned by vacuum cleaners (with HEPA filters) and/or wet wipes or cloths at the end of each production day.

Task 4: Waste management – disposal of solid waste (PROC 8b)

Solid waste produced during this process consists of empty bags, contaminated PPE, and wipes and equipment used for cleaning. Bags with chromate are carefully emptied under LEV and folded following strict procedures to make sure that dust containing air is released towards the extraction system. Folded bags are immediately disposed of in sealable waste containers.

Solid waste is collected and forwarded to an external waste management company (licensed contractor) for disposal as hazardous waste.

9.2.3.2.2.1 Inhalation exposure

Measured inhalation exposure concentrations

The following workplace measurements from the primer production area of Company A are available.

Table 9-19: Workplace measurements performed at Company A in the area where primer products were produced

Year	Substance	Type of measurement	Duration (min)	Concentration (µg Cr(VI)/m3) (without APF for RPE)
2016	StC or PHD	personal	Unknown	0.82 *
2016	StC or PHD	personal	Unknown	0.60 *
2017	StC or PHD	personal	Unknown	1.02 *
2017	StC or PHD	personal	Unknown	2.52 *
2018	StC or PHD	personal	Unknown	1.73 *
2018	StC or PHD	personal	Unknown	0.40 *
2019	StC or PHD	personal	Unknown	1.33 *
2021	Stc	personal	Unknown	7.13 *
2022	-	static	249	<0.6 **
2022	StC and PHD	static	259	<1

***** Calculated as 8 h TWA

** represents background concentration

Further, workplace exposure concentration from another production area in Company A are available. In this area, solid magnesium chromate is used to produce formulations in a similar way.

Table 9-20: Workplace measurements performed at Company A with exposure to magnesium chromate

Year	Substance	Type of measurement	Duration (min)	Concentration (µg Cr(VI)/m3) (without APF for RPE)
2023	$MgCrO_4$	personal	240	<0.02
2023	$MgCrO_4$	personal	241	0.04
2023	$MgCrO_4$	personal	240	<0.02
2023	$MgCrO_4$	static	240	<0.02
2023	$MgCrO_4$	static	238	0.04

As this database is not considered large enough to base the risk characterisation on it, the assessment of workers exposure is based on information from four formulation sites in the EEA where solid chromates are handled under similar conditions to produce primer products.

Forty-six personal and 21 static measurements are available for these activities. Of the 46 personal monitoring data, 13 are long-term (≥2h)[10] and 33 are short-term (<2h) measurements. Stationary measurements consist of six long-term and 15 short-term values.

Most of these measurements come from processes where StC was used; three short-term personal measurements cover processing of PCO, one long-term value belongs to handling of PHD.

Table 9-21: Overview of available inhalation exposure measurements from EEA sites for WCS 1 – Operators handling solid chromates

	Total	**>LOQ**	**<LOQ**
Personal			
- Long-term (≥2h)	13	13	0
- Short-term (<2h)	33	31	2
Stationary			
- Long-term (≥2h)	6	6	0
- Short-term (<2h)	15	15	0

Table 9-22 shows the summary statistics of workplace measurements for formulation operators handling solid chromates. For values <LOQ, we considered half of the LOQ (LOQ/2) for statistical evaluation. All measurements are from the period 2019-2024. Annex III of this report provides a summary on the analytical methods for inhalation exposure monitoring and information on their LOQs. The individual measurements can be provided upon request.

Table 9-22: Summary statistics of inhalation exposure measurements from EEA sites for WCS 1 – Operators handling solid chromates

Personal – long-term (measurement period 2019 - 2022)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	13	100	6.51	8.10	2.40	18.2
Specific evaluation:						
- all measurements of at least 60 min duration	24	100	6.16	7.27	2.61	18.1
Personal – short-term (measurement period 2019 - 2023)						

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[10] All long-term measurements (≥2h) are considered as shift-representative measurements and used as such as 8h exposure values; no recalculation has been performed. Measurements <2h were not used to calculate shift-representative exposure values.

	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	33	100	8.50	11.3	3.60	20.8
Specific evaluation:						
- all measurements of <60 min duration	22	100	9.90	12.9	5.00	29.0
Stationary – long-term (measurement period 2017 - 2022)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	6	100	2.32	0.78	2.45	3.05
Stationary – short-term (measurement period 2018 - 2023)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	15	100	36.1	40.6	7.9	87.2

Personal measurements – long-term

The 90th percentile of the long-term personal measurements (>120 min) is 18.2 µg/m³. Few long-term measurements are available as companies try to reduce the exposure time for handling the solid chromates to a minimum. These processes, also depending on the size of a certain batch produced, often are shorter than two hours. The longest measurement duration of the 13 long-term measurements was 355 minutes but all others were <178 minutes. Therefore, we performed an additional evaluation including all datapoints with a measurement duration of at least 60 minutes (n=24, see Table 9-22) to characterise exposure for this WCS. The resulting exposure concentrations are essentially the same. The 90th percentile for this set of data is 18.1 µg/m³. We consider this value to adequately representing the personal exposure in periods during which solid chromates are handled.

At one site personal (short-term and long-term) measurements were performed with the sampling device inside the helmets of the powered filtering devices worn. In order to make these results comparable we multiplied the measured concentrations by the APF of 40.

Personal measurements – short-term

The 33 short-term personal measurements (<120 min) support this interpretation. They all cover activities with handling solid chromates exclusively, including weighing. The resulting 90th percentile is slightly higher (20.8 µg/m³) than the 90th percentile of long-term values discussed above (18.2 µg/m³).

If all short-term measurements with duration <60 min are evaluated the 90th percentile increases to 29.0 µg/m³, as a few higher exposure concentrations were measured during 15 minutes exposure periods.

No differences in exposure levels were noted between substances. Measurements on PCO- or PHD-related activities were in the range observed for StC-related work at the same sites.

Note that two short-term values (duration 15 min in both cases) with high LOQs (<18 and <36 µg/m^3) were not excluded despite the high LOQ because further measurements of the same campaign resulted in exposure level in the same range.

Stationary measurements – long-term

Lower exposure concentrations were obtained from six stationary long-term measurements (all >240 minutes). The 90th percentile was 3.05 µg/m^3.

Stationary measurements – short-term

Short-term measurements resulted in a higher exposure level at the 90th percentile. This was caused by a subset of measurements from one site in 2019 (six values ranging from 62 to 110 µg/m^3). Repeating these measurements in 2020 resulted in concentrations from 0.6 to 16 µg/m^3 (8 values). Therefore, the data from 2019 are considered to be less reliable.

The risk characterisation is based on the longer-term personal measurements (with durations >60 minutes), with a 90th percentile of 18.1 µg/m^3. All these measurements cover activities where exclusively solid chromates were handled.

To allow for the possibility that large or small batches are produced by the same worker, in a conservative way we add activities from both producing small and large batches, according to the conditions as given in Table 9-17. Large batches are produced at up to 15 days/year (including cleaning and waste disposal: 9 hours per batch), resulting in an exposure time of 7.0%. Small batches are produced at up to 10 days per year (with all exposure-relevant activities requiring 5 hours per day), resulting in 2.6% of the operators' time being relevant with regard to exposure to solid chromates.

In total, for the case of the same operators producing large and small batches, the total exposure-relevant time is 9.6%. A time correction factor of 0.096 is applied.

Table 9-23 shows the resulting long-term inhalation exposure concentration for formulation operators handling solid chromates used for risk assessment. As RPE (at least powered filtering device – TH3, TM3) is worn during all critical exposure periods, an APF of 40 is used for calculating exposure.

Table 9-23: Inhalation exposure assessment for WCS 1 –Operators handling solid chromates

Type of measure-ment	Number of measure-ments	Exposure value [a] [µg/m^3]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m^3]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [µg/m^3]
Personal	20	18.1	40	0.453	0.096	0.0434

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on 90th percentile of measurements.

[b] RPE is used, see above.

[c] See explanations for the time correction factor in text (above table).

9.2.3.2.2.2 Biomonitoring

Biomonitoring data are not available for this group of workers.

9.2.3.2.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-24 shows the risk characterisation for carcinogenicity for operators handling solid chromates during manufacture of primer products. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-24: Risk characterisation for carcinogenicity for WCS 1 – Operators handling solid chromates

Route of exposure and type of effects	**Long-term exposure [µg/m^3]**	**Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m^3]**	**Excess lifetime cancer risk (ELCR)**
Inhalation: Systemic Long Term	0.0434	4.00E-03	1.74E-04

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of $4x10^{-3}$ for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

<u>Carcinogenicity:</u>

The excess life-time cancer risk for operators handling solid chromates is **1.74E-04.**

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the 90th percentile of the reported long-term measurements,
- these measurements were not corrected for their duration but assumed to be representative for the relevant exposure periods.

As explained above, up to two mixing operators are involved in these activities per day.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The excess life-time cancer risk for operators handling solid chromates in the present assessment is **1.74E-04.**

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0046-01 (StC)	Formulation (measured) (all activities including mixing, grinding and maintenance)	0.26 µg Cr(VI)/m^3	1.04E-03

0047-01 (PHD)	Formulation (measured) (all activities including mixing, grinding and maintenance)	0.26 µg Cr(VI)/m³	1.04E-03
Exposure and risk based on measured data in this assessment is almost one order of magnitude lower than calculated in the initial applications. Note that two separate WCS (WCS 1 and 2) are described here to cover handling of solid and liquid forms of chromates.			

9.2.3.3 Worker contributing scenario 2 – Operators handling liquid products

Formulation operators are typically performing the following tasks:

- Task 1: Production of liquid products – charging mixing vessels (PROC 8b), milling and dispersion (PROC 5), transfer to storage tanks (PROC 8b)
- Task 2: Sampling (PROC 9)
- Task 3: Filling of medium-size and large product containers (PROC 8b)
- Task 4: Filling of small product containers (e.g., touch-up kits) (PROC 8b)
- Task 5: Cleaning of workplaces, equipment and mixing tanks (PROC 28)
- Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28).
- Task 7: Waste management – disposal of solid waste (PROC 8b).

In the following sections, the conditions of use for each task with potential direct Cr(VI) exposure are specified and the individual activities are described in more detail.

9.2.3.3.1 Conditions of use

Table 9-25 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

Table 9-25: Conditions of use – worker contributing scenario 2 – Operators handling liquid products

Product (article) characteristics	
Task 1: Charging the mixing vessels with liquid material (PROC 8b), milling and dispersing (PROC 5)	
Maximum Cr(VI) concentration in product [%]	Up 70% StC or PHD (w/w): up to 18% Cr(VI) (w/w)
Product type and viscosity	liquid, low viscosity
Task 2: Sampling (PROC 9)	
Maximum Cr(VI) concentration in product [%]	Up to 30% StC or PHD (w/w): up to 8% Cr(VI)(w/w)
Product type and viscosity	liquid, low viscosity
Task 3: Filling of medium-size and large product containers (PROC 9)	
Maximum Cr(VI) concentration in product [%]	Up to 30% StC or PHD (w/w): up to 8% Cr(VI)(w/w)
Product type and viscosity	liquid, low viscosity
Task 4: Filling of small product containers (PROC 9)	

Maximum Cr(VI) concentration in product [%]	Up to 30% StC or PHD (w/w): up to 8% Cr(VI)(w/w)
Product type and viscosity	liquid, low viscosity
Task 5: Cleaning of workplaces and equipment (PROC 28)	
Maximum Cr(VI) concentration in product [%]	Up to 30% StC or PHD (w/w): up to 8% Cr(VI)(w/w)
Product type and viscosity	liquid, low viscosity
Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28)	
Maximum Cr(VI) concentration in product [%]	Up to 30% StC or PHD (w/w): up to 8% Cr(VI)(w/w)
Product type and viscosity	liquid, low viscosity
Task 7: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)	
Maximum Cr(VI) concentration in product [%]	Up to 30% StC or PHD (w/w): up to 8% Cr(VI)(w/w)
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Charging the mixing vessels with liquid material (PROC 8b), milling and dispersing (PROC 5)	
Amount [kg]:	Up to 2300 kg pre-mix/shift
Duration of activity [min/event]:	8 h/shift
Frequency of task [1/shift]	25 days/year
Task 2: Sampling (PROC 9)	
Amount [L]:	0.05 - 1 L product (in rare cases up to 5 L)
Duration of activity [min/event]:	Up to 30 min/shift
Frequency of task [1/shift]	1 - 3/shift
Task 3: Filling of medium-size and large product containers (PROC 9)	
Amount [kg]:	Up to 8000 kg product/shift
Duration of activity [min/event]:	8 h/shift
Frequency of task [1/shift]	25 days/year
Task 4: Filling of small product containers (PROC 9)	
Amount [kg]:	Up to 100 kg product/shift
Duration of activity [min/event]:	8 h/shift
Frequency of task [1/shift]	Up to 25 days/year
Task 5: Cleaning of workplaces, equipment and mixing tanks (PROC 28)	
Amount [L]:	N/A
Duration of activity [min/event]:	60 min/shift
Frequency of task [1/shift]	Up to 25 days/year
Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28)	
Amount [L]:	N/A
Duration of activity [min/event]:	4 h/day

Frequency of task [1/shift]	up to 5 days/year
Task 7: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)	
Amount [L]:	N/A
Duration of activity [min/event]:	0.5 h/d
Frequency of task [1/shift]	Up to 25 days/year
Technical and organisational conditions and measures	
Task 1: Charging the mixing vessels with liquid material (PROC 8b), milling and dispersing (PROC 5)	
LEV:	Yes
Type of LEV	Capturing hood or tank extraction
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 2: Sampling (PROC 9)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 3: Filling of medium-size and large product containers (PROC 9)	
LEV:	Yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 4: Filling of small product containers (PROC 9)	
LEV:	Yes (for filling reservoirs)
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 5: Cleaning of workplaces, equipment and mixing tanks (PROC 28)	

LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 7: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Charging the mixing vessels with liquid material (PROC 8b), milling and dispersing (PROC 5)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Task 2: Sampling (PROC 9)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Task 3: Filling of medium-size and large product containers (PROC 9)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes

Eye protection	Eye protection as per relevant risk assessment
Task 4: Filling of small product containers (PROC 9)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Task 5: Cleaning of workplaces, equipment and mixing tanks (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Task 7: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Charging the mixing vessels with liquid material (PROC 8b), milling and dispersing (PROC 5)	
Place of use	Indoors
Temperature	From ambient temperature up to 50°C
Task 2: Sampling (PROC 9)	
Place of use	Indoors
Temperature	Ambient temperature
Task 3: Filling of medium-size and large product containers (PROC 9)	
Place of use	Indoors
Temperature	Ambient temperature
Task 4: Filling of small product containers (PROC 9)	
Place of use	Indoors
Temperature	Ambient temperature
Task 5: Cleaning of workplaces, equipment and mixing tanks (PROC 28)	
Place of use	Indoors
Temperature	Ambient temperature
Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28)	
Place of use	Indoors
Temperature	Ambient temperature

Task 7: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

9.2.3.3.2 Exposure and risks for workers

Task 1: Production of liquid products – charging mixing vessels (PROC 8b), milling and dispersion (PROC 5), transfer to storage tanks (PROC 8b)

Mixing tanks containing the liquid dispersions manufactured from solid chromates are transported to the milling stations (with tanks covered by foil) or the mixing tank is directly linked to the mill via closed lines, with no need to move the mixing tank. Dispersions are fed into the bead mills via closed lines. The grinding and dispersion process can be repeated several times to achieve the required product characteristics.

Ready product is either fed into storage tanks (movable mixing tanks, covered by foil, are transferred to the storage tanks and product is transferred to the storage tank by pumping via closed lines or by gravity, with mixing tanks positions directly above storage tanks) or product containers are directly filled from the mixing tanks.

After mixing, the stirrer is let to drip off over a new tank. Remaining product may be scraped from the stirrer and the inside walls of the emptied tanks by using a scraper/puller, spatula or brush. Empty tanks (and scraper or brush) are rinsed with wash solution to prevent them from drying and are covered by foil again. Rinsing water or solvent is collected in IBCs and forwarded to an external waste management company (licensed contractor) for disposal as hazardous waste.

Task 2: Sampling (PROC 9)

Samples are always taken by the operators. Laboratory technicians are not involved in sampling. Samples (up to three per batch) are taken from the liquid dispersions, either from the mixing tanks or storage tanks, by submerging a small disposable cup or beaker into the liquid and carefully filling a sample vessel.

Task 3: Filling of medium-size and large product containers (PROC 8b)

Large product containers (≥5 L up to 200 L) are placed on a scale and filled by the line from the storage tank or directly from the mixing tank until the correct weight is achieved. A mobile LEV is placed on top of the opening of the container. The containers are closed manually.

For medium-size containers (0.5 to 5 L) automated filling lines are used. The filling line automatically is equipped with exhaust ventilation. It automatically fills the containers with the correct volume and provides containers (up to 25 L) with labels. It also allows for automatic cleaning of the lines before filling the next batch and for taking samples.

Task 4: Filling of small product containers (PROC 8b)

Small volume products (touch-up kits) are products which contain low amounts of primers (10 to 150 mL) and, in separate chambers, additional components such as hardener. These products are used for small-scale touch-up activities. The primers from these products are ready for use, without the need for mixing components in separate vessels.

Typically, the respective filling stations are filled by pouring primers from a product container (e.g., 5 or 25 L containers) into a reservoir (LEV is in place), from which it is released by valves and the packages are filled by gravity, pressure or suction.

For cleaning the system, lines and filling stations are flushed with solvent and the used solvent is gathered in IBCs and sent to external service provider for disposal as hazardous waste.

Task 5: Cleaning of workplaces, equipment and mixing tanks (PROC 28)

Operators are responsible for cleaning workplaces. Only minor contaminations occur, if any, mainly around mixing vessels. These are taken up by wet wipes or cloths. Stirrers of mixing tanks are cleaned by immersion into a tank with solvent or water. Equipment such as scrapers or brushes are cleaned by immersion into water or solvent and stored in buckets for reuse or are disposed of as hazardous waste if too contaminated.

Bead mills are cleaned by circulating solvent through it (via pumps). Used solvent is gathered in IBCs or drums and sent to external service provider for disposal as hazardous waste.

Empty tanks are cleaned by the operators by rinsing with water or solvent (depending on the product produced) and wipes.

Automated filling stations are cleaned by circulating solvent in the system, which is gathered afterwards for disposal by an external certified company as hazardous waste. In a similar way, lines and filling stations for filling small volume devices are cleaned by flushing with solvent.

Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28)

Most maintenance and repair activities do not need opening of lines. Unscheduled repairs requiring opening of lines are infrequent and concern, e.g., broken pumps or similar equipment. In such a case, lines are emptied and flushed with water or solvent by operators. Visual contamination is cleaned with wet wipes. After these cleaning steps, cleaned parts can be removed by maintenance workers (WCS 4, Maintenance and cleaning workers, section 9.2.3.5).

Task 7: Waste management – disposal of solid waste (PROC 8b)

Solid waste (wipes, contaminated PPE, etc.) occurring during production is gathered in closed waste containers and is transported to storage areas awaiting disposal by an external certified company as hazardous waste. Empty drums are discharged without cleaning as hazardous waste.

9.2.3.3.2.1 Inhalation exposure

Measured inhalation exposure concentrations

No exposure measurements are available for these tasks at Company A.

Eighteen long-term personal measurements are available for covering handling liquid dispersions of chromates in primer products from EEA formulation sites. With the exemption of one short-term value covering both StC and PHD handling, all personal measurements come from processes where StC was used. One long-term static measurement covers manufacturing of a product containing PCO.

Table 9-26: Overview of available inhalation exposure measurements from EEA sites for WCS 2 – Operators handling liquid products

	Total	>LOQ	<LOQ
Personal			
- Long-term (≥2h)	18	8	10
- Short-term (<2h)	3	3	0
Stationary			
- Long-term (≥2h)	1	1	0
- Short-term (<2h)	0	0	0

Table 9-27 shows the summary statistics of workplace measurements for formulation operators handling liquid products. For values <LOQ, we considered half of the LOQ (LOQ/2) for statistical evaluation. All measurements are from the period 2019-2023. Further, specific evaluations analyse the role of individual tasks or differences between certain activities. Annex III of this report provides a summary on the analytical methods for inhalation exposure monitoring and information on their LOQs. The individual measurements can be provided upon request.

Table 9-27: Summary statistics of inhalation exposure measurements from EEA sites for WCS 2 – Operators handling liquid products

Personal – long-term (measurement period 2019 - 2023)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	18	100	0.0640	0.0714	0.0500	0.127
Specific evaluations:						
- exclusively filling of product containers	3	12	0.0416	0.0463	0.0164	*
Personal – short-term (measurement period 2016)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	3	100	0.0857	0.0025	0.0860	**
Stationary – long-term (measurement period 2024)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	1	100	0.0500***	***	***	***

*No 90th percentile calculated; individual values: <0.190; <0.0327; <0.0270 µg/m³

**No 90th percentile calculated; individual values: 0.083; 0.088; 0.086 µg/m³

*** Single value: 0.0500 µg/m³

Personal measurements – long-term

The 90th percentile of the long-term personal measurements is 0.127 µg/m³, confirming that exposure from handling the liquid dispersions leads to low exposures (as expected, exposure is considerably lower than compared to handling solid chromates). These data include tasks such as mixing and milling as well as filling product containers and cleaning workplaces. The three values exclusively covering workers engaged in filling product containers were all below the LOQ (highest LOQ 0.19 µg/m³). One of the values (<0.027 µg/m³) was from a worker filling small product containers (flat packs).

Personal measurements – short-term

Three personal measurements (15 min periods) from 2016 from milling operations resulted in similar concentrations of 0.0800 – 0.0900 µg/m³. No difference of handling StC products versus both StC and PHD was observed.

Stationary measurements – long-term

In a recent measurement campaign with static sampling close to a mill where a dispersion containing PCO was produced (sampling duration 152 minutes) a concentration of 0.0500 µg/m³ was found.

Risk characterisation is based on all long-term personal measurements with a 90th percentile of 0.127 µg/m³. In total, on average 5 workers are engaged in tasks 1 to 7, for 25 days per year (10.4%). A respective time correction factor of 0.104 is applied.

Table 9-28 shows the resulting long-term inhalation exposure concentration used for risk assessment for formulation operators handling liquid products.

Table 9-28: Inhalation exposure assessment for WCS 2 – Operators handling liquid products

Type of measurement	Number of measurements	Exposure value [a] [µg/m³]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m³]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [µg/m³]
Personal	18	0.127	1	0.127	0.104	0.0132

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on 90th percentile of measurements.

[b] No RPE is used, see above.

[c] See explanations for the time correction factor in text (above table).

9.2.3.3.2.2 Biomonitoring

No biomonitoring data are available for this group of workers.

9.2.3.3.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-29 shows the risk characterisation for carcinogenicity for operators handling liquid primer products. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-29: Risk characterisation for carcinogenicity for WCS 2 – Operators handling liquid products

Route of exposure and type of effects	Long-term exposure [µg/m^3]	Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m^3]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.0132	4.00E-03	5.28E-05

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of $4x10^{-3}$ for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for operators handling liquid products containing StC or PHD is **5.28E-05**.

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the 90th percentile of the reported long-term measurements,
- these measurements were not corrected for their duration but assumed to be shift-representative concentrations.

As explained above, on average 5 workers are engaged in performing these tasks.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The excess life-time cancer risk for operators handling liequid chromates in the present assessment is **5.28E-05.**

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0046-01 (StC)	Formulation (measured) (all activities including mixing, grinding and maintenance) (combined assessment for WCS 2- 7)	0.26 µg Cr(VI)/m^3	1.04E-03

0047-01 (PHD)	Formulation (measured) (all activities including mixing, grinding and maintenance) (combined assessment for WCS 2- 7)	0.26 µg Cr(VI)/m³	1.04E-03
Exposure and risk based on measured data in this assessment are lower than the initial applications. Note that two separate WCS (WCS 1 and 2) are described here to cover handling of solid and liquid forms of chromates.			

9.2.3.4 Worker contributing scenario 3 – Laboratory technicians

Laboratory technicians may be involved in activities with potential for Cr(VI)-exposure during their handling of samples for quality control purposes. These tasks only account for a small fraction of their time and most of their work is not related to handling Cr(VI) containing materials. Typically, at a site chromate-related activities are performed by one technician for approx. 30 min up to 2 hours per shift.

Typical activities with possible Cr(VI) exposure performed by laboratory technicians are:

- Task 1: Laboratory analysis of samples (PROC 15)

Typical activities in the laboratory are determination of the chromate concentration in samples, determination of viscosity, particle size and other parameters.

Laboratory technicians in companies producing primer products are not engaged in taking samples in the production area. Sampling is performed in these companies by production operators.

As the handling of substances in laboratories for quality control purposes under controlled conditions and in amounts below 1 t/year falls under the exemption for authorisation for the use of substances in scientific research and development[11] according to REACH Art. 56(3), no exposure assessment is performed for the laboratory work such as quality control of samples.

9.2.3.5 Worker contributing scenario 4 – Maintenance and cleaning workers

Activities with potential Cr(VI) exposure performed by maintenance and/or cleaning workers are summarized for the present assessment as the following tasks:

- Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters of LEV systems (PROC 28)
- Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)

These activities of maintenance and cleaning related to the use with potential direct exposure to Cr(VI) as well as the working conditions are described below in detail.

9.2.3.5.1 Conditions of use

Table 9-30 summarises the conditions of use for maintenance and cleaning workers with Cr(VI) exposure related to formulation of chromates.

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[11] Q&A Reference number: ID 0585; https://echa.europa.eu/de/support/qas-support/browse/-/qa/70Qx/view/ids/585-1442-1443-1498-1565; assessed in March 2021

Table 9-30: Conditions of use – worker contributing scenario 4 – Maintenance and cleaning workers

Product (article) characteristics	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Maximum Cr(VI) concentration in product [%]	100% StC or PHD: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)	
Maximum Cr(VI) concentration in product [%]	up 30% StC or PHD: up to 8% Cr(VI)
Product type and viscosity	liquid, low viscosity
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	up to 6 h/day
Frequency of task [1/shift]	up to 10 days/year
Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	up to 4 h/day
Frequency of task [1/shift]	up to 5 days/year
Technical and organisational conditions and measures	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Mechanical ventilation (alternatively: LEV from inside tank leading to similar room air exchange) (change of dust filters may occur from outside)
Air changes per hour (ACH) of general ventilation:	≥4 ACH
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)	
LEV:	Natural ventilation
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	

Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40)
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Place of use	Indoors (change of dust filters may occur from outside)
Temperature	Ambient temperature
Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

9.2.3.5.2 Exposure and risks for workers

We describe below in detail the relevant activity with direct Cr(VI) exposure for maintenance and cleaning workers and the working conditions.

Maintenance workers are responsible for various tasks and comprise electricians, fitters, and other types of workers. Only few of them (typically fitters) are expected to come into contact with chromates during repair and maintenance work and also this group spends only a minor amount of time on chromate-related activities.

Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters of LEV systems (PROC 28)

Maintenance and cleaning work potentially involving exposure to dust containing Cr(VI) are activities performed in the area where solid chromates are handled (cleaning, maintenance of equipment in these areas) and change of filters of the LEV systems. Such activities are typically done by maintenance and cleaning workers.

Typical tasks are:

- General cleaning activities of workplaces and equipment in the areas where solid chromates are used (once per year during shutdown, up to 4 days/a): thorough cleaning of tanks and work environment, with water and cloth (done by maintenance workers or operators)

- Maintenance of equipment in rooms where solid chromates are handled: activities such as cleaning, checking of cables and connections, performance of the vacuum pump, change of filter bag; check of stirrers (done by maintenance workers)
- Change of filters from exhaust ventilation and vacuum cleaning systems (done by maintenance workers).

For all activities with potential exposure to Cr(VI) dust, detailed working instructions including advice on PPE exist, compliance with which is mandatory. RPE is worn and access to the area is restricted by signage. Used filters are put in plastic bags, which are closed before being removed from the area. Dust filters contaminated with Cr(VI) are disposed of by a certified external company as hazardous waste.

Task 2: Cleaning and maintenance tasks without exposure to chromate dust (PROC 28)

Daily cleaning of workplaces and equipment is done by the formulation operator at the end of their shifts. Typical tasks are:

- General cleaning activities of workplaces and equipment in the areas where liquid primer products are manufactured
- Maintenance and repair of equipment (maintenance of pearl mill including filter changes, maintenance of pumps etc.).

Specific parts and workplaces are cleaned carefully by flushing with water or solvent by the formulation operator. If dismantling is required before maintenance, parts are further cleaned with cloth or wipes. Only some of the activities are potential sources of Cr(VI) exposure. Activities such as calibrating rheometers at the bead mills are maintenance activities without Cr(VI) exposure. Repair usually takes place in companies' own workshops and – in rare occasions - by a specialized external company. The same procedures as during shutdown periods apply if equipment breaks down during normal production periods. However, such events are extremely rare (<1 per year). RPE is worn during some activities, based on site-specific assessment.

Empty tanks are usually cleaned by the operators by rinsing with water or solvent (depending on the product produced) and wipes (see section 9.2.3.3.2).

9.2.3.5.2.1 Inhalation exposure

No exposure measurements are available for these tasks at Company A.

Eleven personal measurements are available for Task 1 (activities with potential dust exposure) (nine from EEA formulation sites and two measurements at GB company B (change of filters at the main stack of the air abatement system). Nine measurements refer to activities with StC, two measurements are related to PCO exposure. Further, two measurements are available for Task 2 (without dust exposure). Table 9-31 gives an overview on available personal measurements.

Table 9-31: Personal measurements from four EEA and one GB site for WCS 4 – Maintenance and cleaning workers – Task 1 and 2

Task	Duration (min)	Measured concentration (µg Cr(VI)/m3)	Description of activity
1	150	0.8	Change of filters by external workers in room where solid chromates are handled; measurement inside helmet of RPE,

			concentration <LOQ, recalculated by multiplying LOQ/2 with APF 40
1	161	2.4	Change of filters by external workers in room where solid chromates are handled; measurement inside helmet of RPE, concentration 0.06 µg Cr(VI)/m^3, recalculated by multiplying with APF 40
1	89	9.6	Maintenance of specific equipment by external workers in room where solid chromates are handled; measurement inside helmet of RPE, concentration 0.24 µg Cr(VI)/m^3, recalculated by multiplying with APF 40
1	41	2.4	Maintenance of specific equipment by external workers in room where solid chromates are handled; measurement inside helmet of RPE, concentration <LOQ, recalculated by multiplying LOQ/2 with APF 40
1	111	0.8	General maintenance and cleaning of equipment by internal workers in room where solid chromates are handled; measurement inside helmet of RPE, concentration <LOQ, recalculated by multiplying LOQ/2 with APF 40
1	130	0.8	General maintenance and cleaning of equipment by internal workers in room where solid chromates are handled; measurement inside helmet of RPE, concentration <LOQ, recalculated by multiplying LOQ/2 with APF 40
1	120	2.6	Various maintenance tasks in production unit, exposure to solid chromate possible, RPE worn
1	17	0.48*	dust collector drain operator: collection of dust
1	86	2.2*	dust collector cleaning operator: change of filters
1	38	<0.4 **	Change of filters of air abatement system
1	18	1.94 **	Change of filters of air abatement system
2	86	1.15	Maintenance of bead mill contaminated with primer; following site assessment performed with RPE; concentration given without consideration of APF for RPE
2	170	0.022	Operator of washing machine (see description above in text); value below LOQ of 0.043 µg Cr(VI)/m^3

*PCO-related activity

** GB formulation company B, see section 9.2.4.5.2.1.

These measurements were typically performed for the full duration of these activities. They do not represent shift-representative values.

Table 9-32 gives the summary statistics of the eleven measurements available for Task 1 (see the individual values in Table 9-31).

Table 9-32: Summary statistics of inhalation exposure measurements from four EEA and one GB site for WCS 4 – Maintenance and cleaning workers – Task 1

Personal – long-term (measurement period 2019 - 2023)							
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th perc [µg/m³]**	**Max [µg/m³]**
Total	11	100	2.20	2.61	1.94	2.60	9.60

Few data only are available for general maintenance in the production area where no solid chromates are handled. Therefore, we rely on long-term personal measurements of maintenance and cleaning workers from EEA sites in the aerospace and defence industries and their supply chains where primer products are used. Activities there mainly consist of maintaining and cleaning of equipment (e.g., repair of pumps) and is therefore considered comparable to the areas in formulation companies where liquid primer products are produced. The following table provides an overview on this dataset.

Table 9-33: Summary statistics of available inhalation exposure measurements for Maintenance and/or cleaning workers (excluding spray areas) at sites applying primer products in the aerospace and defence industries and their supply chains

Personal – long-term (measurement period 2018 - 2022)						
	N	**% of total**	**AM [µg/m³]**	**SD [µg/m³]**	**Median [µg/m³]**	**90th Perc. [µg/m³]**
Total	42	100	0.110	0.233	0.0200	0.226

One available measurement for maintenance workers at a formulation site - Task 2 (maintenance of bead mill, see Table 9-31) is above the 90th percentile for maintenance and cleaning workers as reported in Table 9-33. However, this is not a contradiction as for this work, based on a site assessment, RPE had to be used. With applying the respective APF to the measured concentration of 1.15 µg/m³, a concentration lower than the 90th percentile would result.

As for Task 1 maintenance activities (with possible dust exposure) wearing RPE is mandatory (at least powered filtering device, APF 40), the resulting exposure levels are very similar: the maximum value of 9.60 µg/m³ with an APF of 40 results in a concentration of 0.24 µg/m³, which is slightly higher than the 90th percentile reported in Table 9-33.

In conclusion, with support from the data on maintenance workers from the sites using primer products, the risk characterisation is based on the maximum value reported for Task 1-related activities.

Maintenance and cleaning activities are infrequently performed (note that regular workplace cleaning is performed by the formulation operators and is covered by WCS 1 and 2). According to reports from formulation companies Task 1-related activities are performed up to 10times per year (6 hours per event) and Task 2-related activities occur up to 5times per year (for 4 hours per event). The total number of days spent on Tasks 1 and 2 together therefore is 15 days per year, which equals to 6.25%. It is assumed that the work is carried out by teams of two maintenance workers (although it is reported by companies that in many cases one worker only is engaged).

Table 9-23 shows the resulting long-term inhalation exposure concentration for maintenance and cleaning operators used for risk assessment. As RPE (at least powered filtering device – TH3, TM3) is worn for Task 1-activities and Task 2 is resulting in much lower concentrations (see discussion above), an APF of 40 is used for calculating exposure.

Table 9-34: Inhalation exposure assessment for WCS 4 – Maintenance and cleaning workers

Type of measure-ment	Number of measure-ments	Exposure value [a] [µg/m³]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m³]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [e] [µg/m³]
Personal	11	9.6	40	0.240	0.0625	0.0150

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on maximum of Task 1 measurements.

[b] RPE is used, see above.

[c] See explanations for the time correction factor of 0.0625 in text (above table).

9.2.3.5.2.2 Biomonitoring

No biomonitoring data are available.

9.2.3.5.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-35 shows the risk characterisation for carcinogenicity for maintenance and cleaning workers. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-35: Risk characterisation for carcinogenicity for WCS 4 – Maintenance and cleaning workers

Route of exposure and type of effects	Long-term exposure [µg/m³]	Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m³]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.0150	4.00E-03	6.00E-05

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m³ Cr(VI) relates to an excess risk of $4x10^{-3}$ for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for maintenance and cleaning workers is **6.00E-05**.

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the maximum value reported for Task 1 and is in agreement with the 90th percentile of the reported long-term measurements for Task 2,
- these measurements were not corrected for their duration but assumed to be representative for the relevant exposure periods.

As explained above, up to two maintenance workers are involved in these activities per day.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The excess life-time cancer risk for maintenance and cleaning workers in the present assessment is **6.00E-05.**

Risk estimates in initial applications (maintenance was assessed as part of regular activities of formulation workers):

Application	Activity	Exposure estimate	Risk
0046-01 (StC)	Formulation (measured) (all activities including mixing, grinding and maintenance) (combined assessment for WCS 2- 7)	0.26 µg Cr(VI)/m^3	1.04E-03
0047-01 (PHD)	Formulation (measured) (all activities including mixing, grinding and maintenance) (combined assessment for WCS 2- 7)	0.26 µg Cr(VI)/m^3	1.04E-03

The excess cancer risk calculated in this assessment is significantly lower than estimated in the initial applications.

9.2.3.6 Worker contributing scenario 5 – Incidentally exposed workers

Incidentally exposed workers are defined as workers who spend a relevant part (10% or more) of their working time in the work area where chromates are handled, but do not carry out tasks with direct Cr(VI) exposure potential themselves. At the formulation site relevant here, the number of incidentally exposed workers is low. The activities performed by incidentally exposed workers are summarized for the present assessment as the following task:

- Task 1: Activities with indirect Cr(VI) exposure (PROC 0)

In the following sections, we specify the conditions of use under which indirect exposure these workers can occur, and we describe typical activities they perform while indirectly exposed.

9.2.3.6.1 Conditions of use

Table 9-36 summarises the conditions of use for various tasks performed by incidentally exposed workers.

Table 9-36: Conditions of use – worker contributing scenario 5 – Incidentally exposed workers

Product (article) characteristics	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Maximum Cr(VI) concentration in product [%]	up 30% StC or PHD: up to 8% Cr(VI)
Product type and viscosity	liquid, low viscosity
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Amount [kg]:	n.a.
Duration of activity [min/event]:	up to 480 min/d
Frequency of task [1/shift]	up to 240 days/year
Technical and organisational conditions and measures	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Gloves	Standard PPE (not intended for protection against chromates) as described in work instructions for the tasks
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

9.2.3.6.2 Exposure and risks for workers

Task 1: Activities without direct Cr(VI) exposure

Mixing vessels dedicated to producing non-chromate products can be placed in the same production hall. Therefore, operators surveying the respective processes are located in the same hall, however at some distance to the Cr(VI)-related processes. Only production of liquid mixtures from liquid stock solutions is located adjacent to non-Cr(VI) processes, implying low background exposure levels. No bystanders are allowed in the areas where solid chromates are handled and therefore no exposure from solid chromates is possible for incidentally exposed workers.

Further, supervisors and/or logistics operators may spend part of their time in the production area where liquid products containing chromates are handled.

Overall, up to two incidentally exposed workers can be present.

9.2.3.6.2.1 Inhalation exposure

Typically, incidentally exposed workers are not expected to be exposed at relevant levels and therefore, not many data are available.

For quantifying potential risks for incidentally exposed workers in a conservative way

- we use the data available for operators handling liquid products (WCS 2), as they are typically working in the same areas
- and consider shorter duration of exposure (e.g., for supervisors or logistics workers) by applying a time correction factor of 0.500. This factor is also expected to cover the reduction of exposure of operators working farer away from chromate products.

As exposure is only possible to occur during production campaigns, exposure duration is limited to 25 days per year (see WCS 2), resulting in an overall correction factor of 0.0521

A 90th percentile of personal long-term measurements of 0.127 µg/m^3 was identified for WCS 2. The resulting long-term exposure concentration used for risk characterisation is given in Table 9-37.

Table 9-37: Inhalation exposure assessment for WCS 5 – Incidentally exposed workers

Type of measure-ment	Number of measure-ments	Exposure value [a] [µg/m^3]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m^3]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [µg/m^3]
Personal	18	0.127	1	0.127	0.0521	0.00662

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on 90th percentile of measurements.

[b] No RPE is used, see above.

[c] Correction factor to take into account shorter exposure duration and/or larger distance, see explanation in text (above table).

9.2.3.6.2.2 Biomonitoring

No biomonitoring data are available.

9.2.3.6.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-38 shows the risk characterisation for carcinogenicity for incidentally exposed workers. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-38: Risk characterisation for carcinogenicity for WCS 5 – Incidentally exposed workers

Route of exposure and type of effects	Long-term exposure [µg/m³]	Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m³]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.00662	4.00E-03	2.65E-05

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m³ Cr(VI) relates to an excess risk of 4×10^{-3} for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for incidentally exposed workers containing StC or PHD is **2.65E-05**.

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the 90th percentile of the reported long-term measurements,
- these measurements were not corrected for their duration but assumed to be shift-representative concentrations.

As explained above, it is assumed that on average two incidentally exposed workers may be present at the site.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications

Exposure of incidentally exposed workers was not considered in previous applications.

9.2.4 Exposure scenario 2 for Use 1: “Formulation of strontium chromate for use in aerospace and defence industry and its supply chains for surface treatments – Company B“

Market sector: -

Sector of use: SU 9

Article categories: not relevant

Environment contributing scenario(s): ERC 2

Worker/Consumer contributing scenario(s): PROC 5, PROC 8a, PROC 8b, PROC 9, PROC 15, PROC 28

Subsequent service life exposure scenario(s): not relevant

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): not relevant

Description of the activities and technical processes covered in the exposure scenario:

Manufacture of primer products (liquid dispersions of poorly soluble chromates) (see detailed use information in section 9.2.2.1).

Explanation on the approach taken for the ES:

We established the exposure scenario based on sector-specific information provided by the company performing these activities.

9.2.4.1 Environmental contributing scenario 1

As StC is not listed in REACH Annex XIV due to environmental effects, no environmental exposure assessment is performed here. However, we assessed the exposure of humans via the environment in the following sections.

9.2.4.1.1 Conditions of use

Table 9-39: Conditions of use – Environmental contributing scenario 1

Product (article) characteristics	
Product A:	Solid StC, pure substance (100%); 26% Cr(VI)
Amount used, frequency and duration of use (or from service life)	
Product A:	
Total amount used annually at GB site B:	Up to (0.1 – 1) t Cr(VI)/year as StC
Process type:	Batch process
Frequency:	Up to 16 days/year (for calculations see section 9.1.2.4.)
Technical and organisational conditions and measures	
Technical measures (all products)	
Air	Mixing vessels are equipped with LEV
	Exhaust air is treated by air filters before it is released via stack(s)

Wastewater	No emission to wastewater
Soil	Indoor and outdoor surfaces where chemicals are handled are sealed and chemicals and solid waste containing Cr(VI) are stored in closed containers
Organisational measures (all products)	
Air	Cr(VI) air emission measurements are performed regularly at identified exhaust stack(s) where the process emissions are released
Wastewater	Water used for cleaning is gathered and sent to an external company certified for disposing as hazardous waste or for an industrial process under a specific permit
Conditions and measures related to sewage treatment plant	
All products	N/A (no emission to wastewater)
Conditions and measures related to treatment of waste (including article waste)	
All products:	Solid waste contaminated with Cr(VI) (e.g. wipes, used PPE, empty bags, drums) are disposed as hazardous waste. Hazardous solid waste is stored in closed drums and containers and forwarded to an external waste management company (licensed contractor) for disposal
Other conditions affecting environmental exposure	
All products:	Processes are carried out at ambient temperature (higher temperatures may occur due to exothermic blending)
	Mixing vessels are covered by lids (except during charging)
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
	None

This ECS concerns manufacture of chromate-containing primer products for use in the aerospace and defence industry and its supply chains performed at one specific site in GB. Production is batch-wise at approx. 16 days per year (8 days for preparing the products, 8 days for filling product containers).

Air emissions

Production facilities are equipped with local exhaust ventilation. Emissions are treated by abatement technology, consisting of particle filters.

Particle filters are checked and changed regularly. Used filters are collected and disposed by an external company certified for disposing hazardous waste.

Wastewater emissions

Cr(VI) containing wastewater only arises from using water for cleaning or rinsing purposes, or as liquid hazardous waste from the laboratory. At the site, wastewater is collected in an IBC and sent to an external waste management company (licensed contractor) for disposal.

Soil emissions

There is no direct release to soil, based on equipment and procedures in place.

9.2.4.1.2 Releases

Releases to environmental media at the site only occur via exhaust air. Chromium in exhaust air is measured regularly. Exhaust air from various sources is gathered at one main stack in the production area. Further, emissions can occur from the area where product is filled into containers. The following table summarises data from several campaigns over the last 6 years.

Table 9-40: Chromium VI concentrations measured at outlets of production and filling area

Year	Main stack		Filling area	
	mg/m^3	g/hour	mg/m^3	g/hour
2018	0.0002	0.0013		
2021	0.002/0.002/0.002	0.01/0.01/0.01		
2023	0.0001/0.0006	0.0004/0.003	0.002/0.0004	0.020/0.004

Data from the 2023 measurements are used for the assessment, as they represent the actual situation and include data from both areas where emissions can occur. A product containing strontium chromate was manufactured during the measurement period. The means of two measurements from both sources are used. The monitoring was done according to BS EN ISO 23210 (Technical procedure ETC-SE-32, Impactor – UV Spectrometry, Envirocare 2023).

The release fraction from the production site is shown in Table 9-41. It is calculated from the annual amount of Cr(VI) used at the site and the amount of Cr(VI) emitted to air. The site-specific release is used as input for EUSES modelling of the environmental concentrations. As the site does not release Cr(VI) to wastewater (all contaminated water is gathered and sent to a certified service provider for disposal) the respective release fraction is zero.

Table 9-41: Local releases to the environment

Release route	Release fraction [a]	Release [kg/year] [a]	Explanation/Justification
Water	0	0	No release to wastewater
Air	(1.0E-07 – 1.0E-05) [b]	0.00055	Measured release (site-specific data)
Soil [b]	0	0	No release to soil is possible

[a] Releases and release fractions to air are based on recent release data and tonnages provided by the site

[b] Release fraction considers that barium chromate is present in some primer products and contributes to releases; release fraction is given as range because it contains CBI

Releases to waste

Solid wastes are disposed of as described above by a certified company specialised in hazardous waste disposal. The waste management company reduces Cr(VI) to Cr(III) using a common reduction process with either sodium or calcium metabisulfite. The reduction process produces a filter cake which they have the relevant permits to dispose of safely and to current legislation.

No emissions from solid wastes are expected.

Release fraction to waste from the process: 0

9.2.4.1.3 Exposure and risks for the environment and humans via the environment

These releases resulted in modelled (EUSES) environmental concentrations and human exposures as shown in the following table. This results in a very low estimated overall risk from exposure of humans via the environment of 1.21E-08 (Table 9-42).

This low risk is expected as a small fraction of a small amount of substance is released to air only, and no emissions to wastewater occur.

Table 9-42: Exposure concentrations and excess cancer risk estimates for humans via the environment – on local scale (Company B)

Inhalation			**Oral**			
Local Cr(VI) PEC in air [µg/m^3]	**Excess lung cancer risk [1/(µg/m3)]** [a]	**Inhala-tion risk**	**Oral exposure (water and fish) [µg Cr(VI)/kg x d]** [b]	**Excess cancer risk for tumours of the small intestine [1/(µg/kg bw/day)]** [c]	**Oral risk**	**Combined risk**
4.18E-07	2.90E-02	1.21E-08	2.06E-09	8.00E-04	1.65E-12	**1.21E-08**

[a] RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 2.9x10^{-2} for the general population, based on 70 years of exposure; 24h/day.

[b] combined exposure from drinking water (2.06E-09 µg Cr(VI)/kg x d) and fish consumption (2.82E-12 µg Cr(VI)/kg x d)

[c] RAC dose-response relationship based on excess cancer risk for tumours of the small intestine (ECHA, 2013c): Exposure to 1 µg/m³ Cr(VI) relates to an excess risk of 8x10-4 for the general population, based on 70 years of exposure; 24h/day.

Note that the modelling of local air concentrations with EUSES is generally acknowledged as being overly conservative, as described in detail in section 9.1.2.5.2.

For the exposure via drinking water and fish a reduction factor of 5 was applied, as described in section 9.1.2.4.2 of the CSR. However, due to the absence of emissions to wastewater, the risk from oral exposure is orders of magnitude lower than that from inhalation anyway.

Conclusion on risk characterisation:

Carcinogenicity

Combined risks of cancer by inhalation and by the oral route from the local assessment for Company B result in a combined excess cancer risk of 1.21E-08. This theoretical cancer risk is based on a conservative, linear ERR. Further, due to the overly conservative nature of the predictions of the EUSES model for the local air concentrations the risk level can be considered an overestimation.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The assessment of exposure of humans via the environment in this chemical safety report is based on measured emission data for emissions to air. For this assessment combined exposure of humans via the inhalation (air) and the oral (uptake of water and fish) route is considered.

Total exposure is estimated to be 1.21E-08 µg/m^3 (inhalation exposure) and 2.06E-09 µg/kg x d (oral), resulting in an estimated excess cancer risk for both pathways combined of 1.21E-08.

In the initial applications only the inhalation route was considered for the assessment of human exposure via the environment. The following exposure and risk were estimated to be:

Application ID	local PEClocal air [µg/m^3]	Excess lung cancer risk
0046-01 (StC)	9.52E-04	2.80E-05

Our risk estimate based on measured release data is three orders of magnitude lower than the risks calculated in the initial applications for StC.

9.2.4.2 Worker contributing scenario 1 –Operators handling solid chromates

These operators are typically performing the following tasks:

- Task 1: Weighing of solid material in dedicated area (PROC 8a, 8b)
- Task 2: Charging the mixing vessels (PROC 8a, 8b) and surveying mixing process (PROC 5)
- Task 3: Sampling (PROC 9)
- Task 4: Cleaning of workplaces and equipment (PROC 28)
- Task 5: Waste management – cleaning of containers, disposal of solid waste (PROC 8b).

In the following sections, the conditions of use for each task with potential direct Cr(VI) exposure are specified and the individual activities are described in more detail.

9.2.4.2.1 Conditions of use

Table 9-17 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

Table 9-43: Conditions of use – worker contributing scenario 1 – Operators handling solid chromates

Product (article) characteristics	
Task 1: Weighing of solid material (PROC 8a)	
Maximum Cr(VI) concentration in product [%]	100% StC: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Maximum Cr(VI) concentration in product [%]	100% StC: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Task 3: Sampling (PROC 9)	

Maximum Cr(VI) concentration in product [%]	20% StC: up to 5.2% Cr(VI)
Product type and dustiness	Liquid dispersion
Task 4: Cleaning of workplaces and equipment (PROC 28)	
Maximum Cr(VI) concentration in product [%]	100% StC: up to 26% Cr(VI)
Product type and dustiness	Low amounts of dust or liquid spills
Task 5: Waste management – disposal of solid waste (PROC 8b)	
Maximum Cr(VI) concentration in product [%]	up 70% StC: up to 18% Cr(VI)
Product type and dustiness	Residues of liquid dispersion, solid waste
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Weighing of solid material (PROC 8a)	
Amount [L]:	up to 70 kg/d StC
Duration of activity [min/event]:	up to 15 min/d
Frequency of task [1/shift]	up to 8 days/year
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Amount [L]:	up to 500 kg/d dispersed product
Duration of activity [min/event]:	up to 8 h/day (1 h/d charging solid chromate, 1-6 h/d charging additives and surveying dispersion process) for up to 8 days/year
Frequency of task [1/shift]	up to 8 days/year (see above)
Task 3: Sampling (PROC 9)	
Amount [L]:	up to 0.5 L/d liquid product
Duration of activity [min/event]:	up to 5 min/d
Frequency of task [1/shift]	up to 8 days/year
Task 4: Cleaning of workplaces and equipment (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	up to 60 min/d
Frequency of task [1/shift]	up to 8 days/year
Task 5: Waste management – disposal of solid waste (PROC 8b)	
Amount [L]:	n.a.
Duration of activity [min/event]:	Up to 10 min/d
Frequency of task [1/shift]	up to 8 days/year
Technical and organisational conditions and measures	
Task 1: Weighing of solid material (PROC 8a)	
LEV:	yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Natural ventilation
Organisational measures:	Open bags are stored in sealed buckets Procedures in place to minimize dust generation during weighing

Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
LEV:	yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Natural ventilation
Organisational measures:	Procedures in place to minimize dust generation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 3: Sampling (PROC 9)	
LEV:	yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 4: Cleaning of workplaces and equipment (PROC 28)	
LEV:	no
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 5: Waste management – disposal of solid waste (PROC 8b)	
LEV:	Situation-dependent
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Weighing of solid material (PROC 8a)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 2: Charging mixing vessels with solid material (PROC 8b) and surveying dispersion process (PROC 5)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)

Eye protection	Eye protection as per relevant risk assessment
Task 3: Sampling (PROC 9)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 4: Cleaning of workplaces and equipment (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a] (where exposure to chromate dust is possible)
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 5: Waste management – disposal of solid waste (PROC 8b)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (APF 40) [a]
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Tasks 1 to 5:	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

[a] For selection of APF see Annex IV of this report.

9.2.4.2.2 Exposure and risks for workers

Task 1: Weighing of solid material in dedicated area (PROC 8a, 8b)

For manufacturing the products small amounts of StC are weighed on a floor mounted weighing scale and transferred to another container using a scoop (under LEV). Typically, weighing and aliquoting the required amounts takes up to 15 min per batch. Weighed material is transported in a container with closed lid to the mixing area. During this task, the operator wears a coverall, gloves, and respiratory protection.

Task 2: Charging the mixing vessels with solid (PROC 8a, 8b) and surveying mixing process (PROC 5)

StC is filled into the mixing vessel with the scoop and by pouring the remaining material. The mixing vessel (batch volume up to 1 m^3) is equipped with an internal automatic stirrer and LEV. The LEV is running during this process. Feeding the vessel takes up to 1 hour per batch, the whole mixing process may take up to 3 days (no manual intervention necessary during this time). The final product is pumped via closed lines to a storage vessel.

Task 3: Sampling (PROC 9)

Typically, one sample is taken per produced batch for quality control. The sample is taken from the mixing vessel. The size of the sample bottle is up to 500 mL. Samples are taken from the mixing vessel, while LEV is running.

Task 4: Cleaning of workplaces and equipment (PROC 28)

The workplaces around the mixing vessels are cleaned regularly (daily). In most cases contaminations are restricted to minor splashes and/or small amounts of solid material around the mixing vessels. Very little contamination occurs during filling of containers with the products.

Small splashes or amounts are taken up with wipes. Wipes are disposed of as solid waste.

Around vessels where solid chromates are used, a plastic foil is used to line the workplace surfaces. After filling all raw materials, the foil is folded and disposed of as solid waste, thus reducing any possibility to spread the solid material to a minimum.

Filters of the LEV systems are changed after completion of the filling process. This material, together with other solid waste (wipes, emptied and rinsed drums, filters), is disposed of as solid waste by an external company certified for disposing hazardous waste. After filling of the vessel is complete the equipment (scoop, drums) is rinsed with water and the contaminated rinsing water is gathered in an IBC for disposal as hazardous waste by an external certified company. During all these activities the operator wears a coverall, gloves, and respiratory protection.

Depending on the situation, cleaning activities and filter changes take up to 45 minutes per day.

Task 5: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)

Solid waste (wipes, contaminated PPE, foils, etc.) occurring during production is gathered in closed bags and transported to tightly closed drums in the storage area awaiting disposal by an external certified company as hazardous waste.

9.2.4.2.2.1 Inhalation exposure

At Company B regular and extensive workers exposure monitoring programmes were carried out in the years 2021 to 2023 comprising

- Personal sampling
- Static measurements and
- Biomonitoring.

In total, 52 air measurements were performed. The monitoring comprised manufacture of products (WCS 1), filling of product containers (WCS 2) and change of the main filters (WCS 4).

Table 9-44: Workplace measurements performed at Company B (2021-2023)

	Production	Filling containers (see WCS 2)	Main filter change (see WCS 4)
Personal	13	9	2
Static	25	3	-

The production workers perform various activities during one production campaign, including weighing of solid chromate, filling chromates into mixing vessels, addition of other components, mixing, milling, sampling of liquid product, cleaning of workplaces, and filter changes of the LEV system at the tanks.

Besides products with strontium chromate at the site products containing pentazinc chromate octahydroxide (PCO) or chromium trioxide are produced (use of these latter two substances fall under other authorisations). As the measurement reports not always clearly identify the products manufactured during the measurement campaign and/or the chromate used, and the conditions of use are essentially the same for the different products, all measurements of Cr(VI) available for workers manufacturing chromate-containing mixtures at Company B are used in the assessment.

Personal sampling

Personal sampling measurements on production operators from the years 2021 to 2023 are provided in the following table. These measurements include all activities as described above (tasks 1 to 5). As the production is batchwise (with different batch sizes requiring different durations for producing the batches) and the time after batch production is dedicated to activities without chromate exposure time weighted average (TWA) exposure concentrations are calculated from these data. During production mixing workers wear a powered filtering device with hood.

Table 9-45: Personal sampling measurements from mixing operators at Company B

Date of measurement	**Substance**	**Measurement duration (min)**	**Concentration (µg/m3)**	**TWA (µg/m^3) (without considering RPE)**
06.05.2021	CT	45	7.9	0.658
06.05.2021	StC	25	34	2.833
06.05.2021	PCO	60	1.7	0.213
25.01.2022	CT, StC, PCO	240	<0.63*	0.156
25.01.2022	CT, StC, PCO	158	<1.9*	0.313
25.01.2022	CT, StC, PCO	204	<0.74*	0.156
26.01.2022	CT, StC, PCO	305	<0.49*	0.156
26.01.2022	CT, StC, PCO	306	<0.49*	0.156
27.01.2022	CT, StC, PCO	325	<0.46*	0.156
22.09.2022	StC, CT	148	5.4	1.665
22.09.2022	StC, CT	250	<0.05	0.013
12.09.2023	CT	67	0.45	0.063
20.09.2023	StC	27	85.6	4.815
			90th percentile	**2.60**

*LOQ calculated by dividing the LOQ for amount detectable by sampling volume

In the report of the 2022 measurement campaign the limit of quantification was given as amount per sampling filter. The LOQ in air was calculated by dividing this amount by the air volume sucked per sample.

In addition to personal sampling data static measurements exist. Twenty-two static measurements were performed in the production area during a production campaign. Two values reported in 2021 were below the LOQ, without a LOQ given in the report of the laboratory having performed the measurements. In total, only 4 out 22 static measurements in the production area were above the respective LOQ. Three values from the 2022 report are not listed in the table below as the devices were located directly at the opening of the mixing vessel, yielding high, not meaningful values.

Table 9-46: Static measurements in the production area

Date	Location	Substance	Measurement duration (min)	Concentration measured (µg/m3)	Concentration including values <LOQ (µg/m3)
05.06.2021	Production hall	StC	25	<LOD*	
05.06.2021	Production hall	PCO	60	<LOD*	
05.06.2021	Production hall	CT	45	4	4
25.01.2022	Production hall	PCO	245	0.1	0.1
25.01.2022	Production hall	CT	252	<0.6	0.3
25.01.2022	Production hall	Not reported	250	<0.6	0.3
26.01.2022	Production hall	Not reported	248	<0.6	0.3
26.01.2022	Production hall	CT	246	<0.61	0.305
26.01.2022	Production hall	CT	241	<0.62	0.31
26.01.2022	Production hall	CT	240	<0.62	0.31
26.01.2022	Production hall	StC	238	<0.63	0.315
26.01.2022	Production hall	PCO	240	<0.63	0.315
27.01.2022	Production hall	Not reported	247	<0.6	0.3
27.01.2022	Production hall	CT	244	<0.61	0.305
27.01.2022	Production hall	CT	247	<0.61	0.305
27.01.2022	Production hall	CT	251	<0.6	0.3
27.01.2022	Production hall	StC	257	<0.58	0.29
27.01.2022	Production hall	PCO	252	<0.6	0.3
12.09.2023	Production hall	CT	67	<0.07	0.035
20.09.2023	Production hall	Not reported	256	0.7	0.7
20.09.2023	Production hall	Not reported	254	<0.02	0.01
20.09.2023	Production hall	Not reported	160	0.06	0.06
90th percentile					0.354

*Neither LOQ on sampling filter nor in air given

The 90th percentile of these static measurements of 0.354 µg/m^3 is largely determined by the LOQs of the measurements around 0.6 µg/m^3: only two concentrations above LOQ (4 and 0.7 µg/m^3, from the 2021 and 2023 campaign, resp.) are higher than 0.3 µg/m^3. Therefore, the real 90th percentile of concentrations can be assumed to be lower. The reason for the single high value of 4 µg/m^3 is unknown and the measurement report does not provide explanations. Monitoring devices were placed in various areas around the production and filling areas. A site map with the exact locations can be provided upon request.

The following methods were applied in the various campaigns (as given in reports):

2021: NIOSH 7600, IOM sampling head, VIS absorption/spectrophotometry

Jan 2022: MDHS 52/4 – Alkaline-treated PCDF filters - spectrophotometry

Sept 2022: ISO 16740 (sampling) – Quartz filters – Ion Chromatography and Spectrophotometric measurement using Diphenyl Carbazide

2023: NIOSH 7600, Quartz filters – ISO 16740:2005 - Ion Chromatography and Spectrophotometric measurement using Diphenyl Carbazide

Upon request of the company, in the two most recent campaigns the sensitive ISO 16740 method was applied, yielding low LOQs, as can be seen in the tables above.

9.2.4.2.2.2 Biomonitoring

Biomonitoring is performed regularly with all staff members volunteering to participate. The results from the campaigns performed from 2018 to 2023 are reported in Annex V. Overall, apart from two values measured in 2022, all values are well below the BMGV of 10 µmol/mol creatinine.

9.2.4.2.2.3 Risk characterisation

The risk characterisation is based on 90th percentile of TWAs calculated from personal sampling measurements from mixing operators (see Table 9-45). The static measurements in the production area, which with the exemption of 4 values, were all below the LOQ, confirm the low exposure levels.

Respiratory protection (Powered filtering device with hood, TH3) is worn by workers during production campaigns. As products with strontium chromate are produced batchwise at only up to 8 days per year, the frequency is considered in calculating long-term exposure and cancer risks.

Table 9-47: Inhalation exposure assessment for WCS 1 –Operators handling solid chromates

Type of measurement	Number of measurements	Exposure value [a] [µg/m^3]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m^3]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [µg/m^3]
Personal	13	2.60	40	0.0650	0.0333	0.00217

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on 90th percentile of measurements.

[b] RPE is used, see above.

[c] See explanations for the time correction factor in text: 8d/240d.

Risk for carcinogenicity

Table 9-48 shows the risk characterisation for carcinogenicity for operators handling solid chromates at company B handling solid chromates during manufacture of primer products. The risk for carcinogenicity is calculated using the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-48: Risk characterisation for carcinogenicity for WCS 1 – Operators handling solid chromates

Route of exposure and type of effects	Long-term exposure [µg/m^3]	Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m^3]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.00217	4.00E-03	8.67E-06

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 4x10^{-3} for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for operators handling solid chromates is **8.67E-06.**

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the 90th percentile of the reported long-term measurements,

As explained above, up to two mixing operators are involved in these activities per day.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The excess life-time cancer risk for operators handling solid chromates in the present assessment is **8.67E-06.**

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0046-01 (StC)	Formulation (measured) (all activities including mixing, grinding and maintenance)	0.26 µg Cr(VI)/m^3	1.04E-03

Exposure and risk based on site-specific measured data in this assessment is two orders of magnitude below the one calculated in the initial application.

9.2.4.3 Worker contributing scenario 2 –Operators handling liquid products

Filling operators are typically performing the following tasks:

- Task 1: Transfer of liquid products to containers (PROC 8b)
- Task 2: Cleaning of workplaces and equipment (PROC 28)
- Task 3: Waste management – cleaning of containers, disposal of solid waste (PROC 8b).

Filling operators are not in contact with solid chromates but handle the final liquid products only. In the following sections, the conditions of use for each task with potential direct Cr(VI) exposure are specified and the individual activities are described in more detail.

9.2.4.3.1 Conditions of use

Table 9-49 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

Table 9-49: Conditions of use – worker contributing scenario 2 – Operators handling liquid products

Product (article) characteristics	
Task 1: Transfer of liquid products to containers (PROC 8b)	
Maximum Cr(VI) concentration in product [%]	20% StC: up to 5.2% Cr(VI)
Product type and dustiness	Liquid dispersion
Task 2: Cleaning of workplaces and equipment (PROC 28)	
Maximum Cr(VI) concentration in product [%]	20% StC: up to 5.2% Cr(VI)
Product type and dustiness	Low amounts of dust or liquid spills
Task 3: Waste management – disposal of solid waste (PROC 8b)	
Maximum Cr(VI) concentration in product [%]	20% StC: up to 5.2% Cr(VI)
Product type and dustiness	Residues of liquid dispersion, solid waste
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Transfer of liquid products to containers (PROC 8b)	
Amount [L]:	up to 500 kg/d liquid product
Duration of activity [min/event]:	up to 240 min/d
Frequency of task [1/shift]	up to 8 days/year
Task 2: Cleaning of workplaces and equipment (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	up to 60 min/d
Frequency of task [1/shift]	up to 8 days/year
Task 3: Waste management – disposal of solid waste (PROC 8b)	
Amount [L]:	n.a.
Duration of activity [min/event]:	Up to 10 min/d
Frequency of task [1/shift]	up to 8 days/year
Technical and organisational conditions and measures	

Task 1: Transfer of liquid products to containers (PROC 8b)	
LEV:	yes
Type of LEV	Capturing hood
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 2: Cleaning of workplaces and equipment (PROC 28)	
LEV:	no
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Task 3: Waste management – disposal of solid waste (PROC 8b)	
LEV:	no
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task !: Transfer of liquid products to containers (PROC 8b)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	no
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 2: Cleaning of workplaces and equipment (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	no
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Task 3: Waste management – disposal of solid waste (PROC 8b)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	no
Protection clothes	Disposable protective clothes (coverall)
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Tasks 1 to 3:	
Place of use	Indoors
Temperature	Ambient temperature

Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
None

[a] For selection of APF see Annex IV of this report.

9.2.4.3.2 Exposure and risks for workers

Task 1: Transfer of liquid products to containers (PROC 8b)

This task is typically performed by filling operators at the day after the production campaign. The final product is decanted from the storage vessel into product containers (1 or 5 L) by gravity, with a tap at the bottom of the storage vessel. A mobile LEV is located above the container. Filling of product containers, performed by two operators, may take 1 to 4 hours per batch. Operators wear eye protection, coveralls, and gloves during filling of containers.

Task 2: Cleaning of workplaces and equipment (PROC 28)

Little contamination occurs from filling product containers. Small splashes or contaminations, if they occur, are taken up with wipes. Empty storage tanks are cleaned with solvent, using long brushes.

Task 3: Waste management – cleaning of containers, disposal of solid waste (PROC 8b)

Solid waste (wipes, contaminated PPE, etc.) occurring during production is gathered in closed bags and transported to tightly closed drums in the storage area awaiting disposal by an external certified company as hazardous waste.

9.2.4.3.2.1 Inhalation exposure

As described above (section 9.2.4.2.2.1) nine personal sampling and 3 static measurements are available for filling operations.

Personal sampling

Personal sampling measurements on filling operators from the years 2022 to 2023 are provided in the following table. As the operations are performed batchwise (with different batch sizes requiring different time for filling containers) and the time after this task is dedicated to activities without chromate exposure time weighted average (TWA) exposure concentrations are calculated from these data.

Table 9-50: Personal sampling measurements on operators filling product containers

Date of measurement	Substance	Measurement duration (min)	Concentration (µg/m3)	TWA (µg/m3)
27.01.2022	CT	323	<0.46*	0.156
27.01.2022	CT	321	<0.47*	0.157
27.01.2022	CT	248	<0.60*	0.156
22.09.2022	CT	263	<0.05	0.014
22.09.2022	CT	273	<0.05	0.014
14.09.2023	Not reported	82	<0.06	0.005
14.09.2023	Not reported	79	<0.06	0.005

Date of measurement	Substance	Measurement duration (min)	Concentration (µg/m3)	TWA (µg/m3)
22.09.2023	StC	41	0.25	0.250
22.09.2023	StC	43	<0.12	0.005
			90th percentile	**0.176**

*LOQ calculated by dividing the LOQ for amount detectable by sampling volume

All but one value measured in 2023 (0.25 µg/m^3) were below the LOQ. The 90th percentile of the TWAs calculated is 0.176 µg/m^3.

In addition to personal sampling data three static measurements from the filling area exist. Two were below the LOQ, and one concentration measured in 2023 was at 0.06 µg/m^3.

Table 9-51: Static measurements in the filling area

Date	Location	Measurement duration (min)	Concentration measured (µg/m3)
14.09.2023	Filling area	78	0.06
22.09.2023	Filling area	36	<0.14
22.09.2023	Filling area	33	<0.15

Monitoring devices were placed in various areas around the production and filling areas. A site map with the exact locations can be provided upon request.

9.2.4.3.2.2 Biomonitoring

As explained in section 9.2.4.2.2.2, biomonitoring is performed regularly with all staff members volunteering to participate. The results from the campaigns performed from 2018 to 2023 are reported in Annex V. Overall, apart from two values measured in 2022, all values are well below the BMGV of 10 µmol/mol creatinine.

9.2.4.3.2.3 Risk characterisation

The risk characterisation is based on the 90th percentile of TWAs calculated from personal sampling measurements from filling operators (see Table 9-52). Only one of the values measured was above the limit of quantification. The static measurements in the production area confirm the low exposure levels.

As products with strontium chromate are filled batchwise at only up to 8 days per year, the frequency is considered in calculating long-term exposure and cancer risks.

Table 9-52: Inhalation exposure assessment for WCS 2 – Operators handling liquid products

Type of measure-ment	Number of measure-ments	Exposure value [a] [µg/m^3]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m^3]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [µg/m^3]
Personal	9	0.176	1	0.176	0.0333	0.00586

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on 90th percentile of measurements.

[b] no RPE is used.

[c] See explanations for the time correction factor in text: 8d/240d.

Risk for carcinogenicity

Table 9-53 shows the risk characterisation for carcinogenicity for operators handling liquid products at company B. The risk for carcinogenicity is calculated using the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-53: Risk characterisation for carcinogenicity for WCS 1 – Operators handling liquid products

Route of exposure and type of effects	Long-term exposure [µg/m^3]	Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m^3]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.00586	4.00E-03	2.34E-05

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 4x10^{-3} for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for operators handling liquid products is **2.34E-05.**

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the 90th percentile of the reported long-term measurements,

As explained above, up to two filling operators are involved in these activities per day.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The excess life-time cancer risk for operators handling liquid products in the present assessment is **2.34E-05.**

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0046-01 (StC)	Formulation (measured) (all activities including mixing, grinding and maintenance)	0.26 µg Cr(VI)/m^3	1.04E-03

Exposure and risk based on site-specific measured data in this assessment is well below the one calculated in the initial application.

9.2.4.4 Worker contributing scenario 3 – Laboratory technicians

Laboratory technicians may be involved in activities with potential for Cr(VI)-exposure during their handling of samples for quality control purposes (analysis and quality control by spraying of small panels). These tasks only account for a small fraction of their time and most of their work is not related to handling Cr(VI) containing materials.

Laboratory technicians are not engaged in taking samples in the production area. Sampling is performed by mixing operators.

As the handling of substances in laboratories for quality control purposes under controlled conditions and in amounts below 1 t/year falls under the exemption for authorisation for the use of substances in scientific research and development[12] according to EU REACH Art. 56(3), no exposure assessment is performed for the laboratory work such as quality control of samples.

9.2.4.5 Worker contributing scenario 4 – Maintenance workers

Activities with potential Cr(VI) exposure related to maintenance are restricted to the following task:

- Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters of LEV systems (PROC 28)

9.2.4.5.1 Conditions of use

Table 9-54 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

Table 9-54: Conditions of use – worker contributing scenario 4 – Maintenance workers

Product (article) characteristics
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)

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[12] Q&A Reference number: ID 0585; https://echa.europa.eu/de/support/qas-support/browse/-/qa/70Qx/view/ids/585-1442-1443-1498-1565; assessed in March 2021

Maximum Cr(VI) concentration in product [%]	100% StC: up to 26% Cr(VI)
Product type and dustiness	Solid, powder - fine dust
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Amount [L]:	n.a.
Duration of activity [min/event]:	up to 40 min/day
Frequency of task [1/shift]	up to 24 days/year
Technical and organisational conditions and measures	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Gloves	Chemical resistant gloves according to EN 374 as per relevant risk assessment
RPE	Powered filtering device with hood, helmet or full mask (TH3, TM3) (APF 40)
Protection clothes	Chemical protective coverall
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Cleaning and maintenance tasks with potential exposure to chromate dust, including change of dust filters (PROC 28)	
Place of use	Indoors
Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

9.2.4.5.2 Exposure and risks for workers

Main filters of the air exhaust system need to be changed regularly (typically once per month or, in addition, in case the magnehelic pressure gauge indicates reduced air flow). One person is involved only, and the activity takes approximately 30 minutes. PPE consists of nitrile gloves, coverall and respiratory protection (air fed battery powered filtering device).

Before commencing, all production machines that have LEV attached are shut down as well as the main LEV system. The worker uses a scissor lift to reach the ceiling of the production area where the enclosed main filters are located. The worker removes four filters, which are placed individually into polyethylene bags. New filters are inserted, and the system is closed. Used filters are disposed of in the closed polyethylene bags as hazardous waste, as well as used PPE (gloves, coverall).

Other maintenance activities on various types of equipment are performed on clean and chromate-free parts and machines only. No exposure of maintenance workers is expected from this.

9.2.4.5.2.1 Inhalation exposure

Two personal exposure measurements for this activity are available from the campaigns 2022 and 2023.

Table 9-55: Personal sampling measurements from operators changing filters of LEV system

Date of measurement	Measurement duration (min)	Concentration (µg/m3)	TWA (µg/m3)
22.09.2022	38	<0.4	0.016
21.09.2023	18	1.94	0.073

These values are further supported by nine measurements at EEA formulation sites for similar activities, which yielded concentrations ranging from 0.2 to 9.60 µg/m^3 (reported in section 9.2.3.5.2.1). We use the maximum concentration measured at the site for risk characterisation.

9.2.4.5.2.2 Biomonitoring

As explained in section 9.2.4.2.2.2, biomonitoring is performed regularly with all staff members volunteering to participate. The results from the campaigns performed from 2018 to 2023 are reported in Annex V. Overall, apart from two values measured in 2022, all values are well below the BMGV of 10 µmol/mol creatinine.

9.2.4.5.2.3 Risk characterisation

The risk assessment is based on the maximum value measured at the site. With a frequency of up to twice per month and a maximum duration of the activity of 40 min, a time correction factor of 0.00833 results.

Table 9-56: Inhalation exposure assessment for WCS 4 – Maintenance workers

Type of measure-ment	Number of measure-ments	Exposure value [a] [µg/m^3]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m^3]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [e] [µg/m^3]
Personal	2	1.94	40	0.0485	0.00833	0.000404

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on maximum of Task 1 measurements.

[b] RPE is used, see above.

[c] See explanations for the time correction factor of 0.00833 in text (above table).

Risk for carcinogenicity

Table 9-57 shows the risk characterisation for carcinogenicity for maintenance workers. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-57: Risk characterisation for carcinogenicity for WCS 4 – Maintenance workers

Route of exposure and type of effects	**Long-term exposure [µg/m^3]**	**Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m^3]**	**Excess lifetime cancer risk (ELCR)**
Inhalation: Systemic Long Term	0.000404	4.00E-03	1.62E-06

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m^3 Cr(VI) relates to an excess risk of 4x10^{-3} for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for maintenance workers is **1.62E-06**.

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the maximum value reported as well as the 90th percentile of the reported long-term measurements.

As explained above, one maintenance worker is involved in these activities per day.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

The excess life-time cancer risk for maintenance workers in the present assessment is **1.62E-06.**

Risk estimates in initial applications (maintenance was assessed as part of regular activities of formulation workers):

Application	Activity	Exposure estimate	Risk
0046-01 (StC)	Formulation (measured) (all activities including mixing, grinding and maintenance) (combined assessment for WCS 2- 7)	0.26 µg Cr(VI)/m^3	1.04E-03

The excess cancer risk calculated in this assessment is significantly lower.

9.2.4.6 Worker contributing scenario 5 – Incidentally exposed workers

Incidentally exposed workers are defined as workers who spend a relevant part (10% or more) of their working time in the work area where chromates are handled, but do not carry out tasks with direct Cr(VI) exposure potential themselves. At the formulation site relevant here, the number of incidentally exposed workers is low. The activities performed by incidentally exposed workers are summarized for the present assessment as the following task:

- Task 1: Activities with indirect Cr(VI) exposure (PROC 0)

9.2.4.6.1 Conditions of use

Table 9-36 summarises the conditions of use for various tasks performed by incidentally exposed workers.

Table 9-58: Conditions of use – worker contributing scenario 5 – Incidentally exposed workers

Product (article) characteristics	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Maximum Cr(VI) concentration in product [%]	up 30% StC: up to 8% Cr(VI)
Product type and viscosity	liquid, low viscosity
Amount used (or contained in articles), frequency and duration of use/exposure	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Amount [kg]:	n.a.
Duration of activity [min/event]:	up to 240 min/d
Frequency of task [1/shift]	up to 8 days/year
Technical and organisational conditions and measures	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
LEV:	No
Type of LEV	n.a.
Type of general ventilation in working hall:	Natural ventilation
Air changes per hour (ACH) of general ventilation:	n.a.
Occupational health and safety management system:	Advanced (see section 9.2.2.3.1)
Conditions and measures related to personal protection, hygiene, and health evaluation	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Gloves	Standard PPE (not intended for protection against chromates) as described in work instructions for the tasks
RPE	No
Protection clothes	Chemical protective clothes
Eye protection	Eye protection as per relevant risk assessment
Other conditions affecting workers' exposure	
Task 1: Activities with indirect Cr(VI) exposure (PROC 0)	
Place of use	Indoors

Temperature	Ambient temperature
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
None	

9.2.4.6.2 Exposure and risks for workers

At Company B the production of chromate-containing products is performed batchwise. During production, the area is closed to all workers but the staff responsible for and engaged with the production campaign.

9.2.4.6.2.1 Inhalation exposure

Potential for incidental exposure is limited to the task of filling product containers. During this activity up to four other workers might be present in the same working hall. However, exposure of operators from this task is low: only one out of 9 personal measurements for filling operators yielded a concentration above the limit of quantification (see section 9.2.4.3.2.1). Static measurements in the filling area show that concentrations in the work area are <0.1 µg/m^3 (Table 9-51). Exposure of incidentally exposed workers with workplaces at some distance to the liquid products are expected to have even less exposure at the eight days per year during which this task is performed. With consideration to the frequency (exposure at 8 days per year) the average long-term is estimated to be well below 0.0059 µg/m^3 (exposure estimate for filling operators). For risk characterisation we assume the exposure concentration to be 50% of that of filling operators.

Low background exposure at the premises is confirmed by static measurements with devices located in the office rooms farther away from the emission sources (see Table 9-59).

Table 9-59: Static measurements of background exposure

Date	Location	Measurement duration (min)	Concentration measured (µg/m3)
25.01.2022	Sales office	295	<0.51
26.01.2022	Sales office	247	<0.61
27.01.2022	Sales office	253	<0.59

9.2.4.6.2.2 Biomonitoring

As explained in section 9.2.4.2.2.2, biomonitoring is performed regularly with all staff members volunteering to participate. The results from the campaigns performed from 2018 to 2023 are reported in Annex V. Overall, apart from two values measured in 2022, all values are well below the BMGV of 10 µmol/mol creatinine.

9.2.4.6.2.3 Risk characterisation

Exposure of incidentally exposed workers is estimated from exposures measured during filling of product containers: it is assumed to be 50% of the exposure level of filling operators (see above). As products with strontium chromate are filled batchwise at only up to 8 days per year, the frequency is considered in calculating long-term exposure and cancer risks.

Table 9-60: Inhalation exposure assessment for WCS 5 – Incidentally exposed workers

Type of measurement	Number of measurements	Exposure value [a] [µg/m³]	Assigned protection factor (APF) for RPE [b]	Exposure value corrected for RPE [µg/m³]	Time correction factor for Cr(VI) tasks [c]	Long-term exposure [µg/m³]
Personal	9	50% of 0.176	1	0.0880	0.0333	0.00293

All exposure values rounded to three significant figures for presentation, but unrounded values were used for calculation of exposure.

[a] Based on 90th percentile of measurements.

[b] no RPE is used.

[c] See explanations for the time correction factor in text: 8d/240d.

Risk for carcinogenicity

Table 9-53 shows the risk characterisation for carcinogenicity for operators handling liquid products at company B. The risk for carcinogenicity is calculated using the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013c).

Table 9-61: Risk characterisation for carcinogenicity for WCS 5 – Incidentally exposed workers

Route of exposure and type of effects	Long-term exposure [µg/m³]	Risk characterisation: Excess lifetime lung cancer risk * [1/µg/m³]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.00293	4.00E-03	1.17E-05

* RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013c): Exposure to 1 µg/m³ Cr(VI) relates to an excess risk of 4×10^{-3} for workers, based on 40 years of exposure; 8h/day; 5 days/week.

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for operators handling liquid products is **1.17E-05.**

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses the 90th percentile of the reported long-term measurements,

As explained above, up to four workers may be incidentally exposed during filling of product containers.

Based on the gathered information and considering the implemented RMM we conclude that risk of exposure is minimised.

Comparison of outcome with initial applications:

Exposure of incidentally exposed workers was not considered in previous applications.

10 RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1 Human health (related to combined, shift-long exposure)

10.1.1 Workers

Efforts were undertaken to clearly identify and describe groups of workers exposed to chromates. These SEGs (similar exposure groups) typically perform more than one task. Exposure data provided cover the various activities performed during the work routine of these workers and are used to describe long-term exposure. Therefore, the combined exposure from performing several tasks is already covered in the exposure assessment.

In Exposure Scenario No. 1 (Company A), for WCS 1 and 2 there is the possibility that the same operators who handle the solid chromates are further engaged in processing the liquid primer product in their remaining time. If the same worker would perform all tasks in WCS 1 and WCS 2, a combined theoretical excess cancer risk of 2.3E-04 would result.

10.1.2 Consumers

No consumer uses are addressed in this CSR.

10.2 Environment (combined for all emission sources)

10.2.1 All uses (regional scale) – regional assessment

In accordance with RAC's conclusions (see e.g., the RAC/SEAC "Opinion on an Application for Authorisation for Use of Sodium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites and sealings of anodic films"[13]), no regional assessment has been carried out as it can be assumed that Cr(VI) from any source will be reduced to Cr(III) in most environmental situations and therefore the effects of Cr(VI) as such are likely to be limited to the area around the source, as described in the EU Risk Assessment Report for chromates (ECB, 2005). Therefore, combined exposures from various sources on the regional scale do not need to be considered.

On the local scale all relevant exposures from the emission source to air are assessed (see section 9.2.3.1). No emission to wastewater occurs at the sites.

10.2.2 Local exposure due to all wide dispersive uses

There are no wide dispersive uses covered in this CSR.

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[13] RAC/SEAC, consolidated version, 2016; https://echa.europa.eu/documents/10162/658d42f4-93ac-b472-c721-ad5f0c22823c

10.2.3 Local exposure due to combined uses at a site

The assessment of exposure of humans via the environment was performed using site-specific emission data for all substances used for this use “Formulation”. At the production sites of the formulating companies, no other uses are relevant.

11 Annexes

11.1 Annex I – Comparative assessment of physico-chemical input parameters for EUSES modelling

In the following tables the physico-chemical properties of the two other chromates, PCO and PHD, as well as of barium chromate[14], a substance not covered under ADCR but being present in several primer products covered by the present use, are shown. The physico-chemical properties of StC are given in section 9.1.2.5.

We carried out a comparative EUSES assessment, where an identical example exposure scenario was calculated with the different substance-specific physico-chemical properties of StC, PHD, PCO and barium chromate.

Physico-chemical properties of the other chromates covered by the ADCR consortium

Table Annex I-1: Physico-chemical properties of potassium hydroxyoctaoxodizincate-dichromate (PHD), required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	11103-86-9		
Molecular weight	418.9 g/mol	418.9 g/mol	Refers to PHD; in the Annex XV dossier for PHD (ECHA, 2011)
Melting/freezing point	n/a; decomposes above 500°C	500°C	Refers to PHD; in the Annex XV dossier for PHD (ECHA, 2011)
Boiling point	n/a; decomposes above 500°C	500°C	Refers to PHD; in the Annex XV dossier for PHD (ECHA, 2011)
Vapour pressure	n/a: inorganic ionic compound	0.00001 Pa	n/a; dummy value entered
Log Kow	n/a: inorganic ionic compound	0	n/a; dummy value entered
Water solubility	0.5-1.5 g/L at 20°C	1.5 g/L at 20°C	Refers to PHD; in the Annex XV dossier for PHD (ECHA, 2011)

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[14] Barium chromate is not subject to authorisation but is present in some primer products in combination with at least one ADCR chromate and thus contributes to Cr(VI) exposure.

Table Annex I-2: Physico-chemical properties of pentazinc chromate octahydroxide (PCO), required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	49663-84-5		
Molecular weight	579 g/mol	579 g/mol	Refers to PCO; value used in the Annex XV dossier for PCO (ECHA, 2013a)
Melting/freezing point	n/a; decomposes above 300°C	300°C	Refers to PCO; value used in the Annex XV dossier for PCO (ECHA, 2013a)
Boiling point	n/a; decomposes above 300°C	300°C	Refers to PCO; value used in the Annex XV dossier for PCO (ECHA, 2013a)
Vapour pressure	n/a: inorganic ionic compound	0.00001 Pa	n/a; dummy value entered
Log Kow	n/a: inorganic ionic compound	0	n/a; dummy value entered
Water solubility	< 0.02 g/L at 20°C	0.02 g/L at 20°C	Refers to PCO; value used in the Annex XV dossier for PCO (ECHA, 2013a)

Table Annex I-3: Physico-chemical properties of barium chromate (BaCr), required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	10294-40-3		
Molecular weight	253 g/mol	253 g/mol	Refers to BaCr; value used in Registration Dossier of BaCr[15]
Melting/freezing point	n/a; decomposes at 1400°C	500°C (highest value possible for EUSES)	Refers to BaCr; value used in Registration Dossier of BaCr[18]
Boiling point	n/a; decomposes at 1400°C	500°C (highest value possible for EUSES)	Refers to BaCr; value used in Registration Dossier of BaCr[18]
Vapour pressure	n/a: inorganic ionic compound	0.00001 Pa	n/a; dummy value entered
Log Kow	n/a: inorganic ionic compound	0	n/a; dummy value entered
Water solubility	0.0026 g/L at 20°C	0.0026 g/L at 20°C	Refers to BaCr; value used in Registration Dossier of BaCr[18]

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[15] Registration Dossier of barium chromate, as published on ECHA´s dissemination website; https://echa.europa.eu/de/registration-dossier/-/registered-dossier/25071; assessed in November 2022

Comparative EUSES assessment with an example scenario

The Table below shows the outcome of the comparative EUSES assessment. We carried out the comparative assessment using mean partition coefficients. The scenario considers that a company uses 3000 kg Cr(VI) per year and releases of 0.9 kg/year to water and 0.8 kg/year to air. Wastewater is treated in a biological STP, with an adjusted Cr(VI) distribution in the STP of 50% to water and 50% to sludge (as described in section 9.1.2.4.2). Application of STP sludge to agricultural soil and grassland is considered.

As can be seen from the table, the modelling results are largely identical, except for the daily dose through intake of drinking water, which is marginally lower for BaCr, having the lowest water solubility out of the four chromates.

Table Annex I-4: Outcome of the comparative EUSES assessment of the impact of the physico-chemical properties of the four different chromates on the Cr(VI) concentrations in drinking water, fish, and air

Chromate	Daily dose through intake of drinking water [mg/kg/day]	Daily dose through intake of fish [mg/kg/day]	Daily dose through intake of air [mg/kg/day]	Sum of daily dose through intake of drinking water, fish, and air [mg/kg/day]
StC	2.56E-05	9.97E-08	1.74E-07	2.59E-05
PHD	2.56E-05	9.97E-08	1.74E-07	2.59E-05
PCO	2.56E-05	9.97E-08	1.74E-07	2.59E-05
BaCr	2.55E-05	9.97E-08	1.74E-07	2.58E-05

11.2 Annex II – EUSES sensitivity analysis of impact of partition coefficients

We assessed the impact of the selected partition coefficients (mean value of partition coefficients determined for acidic and alkaline conditions) in a sensitivity analysis with EUSES. We carried out the same exemplary exposure scenario as described in Annex I, using (a) the lowest coefficients, determined for alkaline conditions, (b) the calculated mean values, or (c) the highest coefficients, determined for acidic conditions. The outcome of the assessment is shown in the table below. Use of the lowest partition coefficients lead to the highest oral exposure, while use of the highest partition coefficient leads to the lowest oral exposure.

Table Annex II-1: Outcome of the comparative EUSES assessment of the impact of the partition coefficients on the concentrations in the considered Cr(VI) uptake media drinking water, fish, and air

Set of partition coefficients used	Annual average local PEC in air (total) [mg/m³]	Local PEC in groundwater under agricultural soil [mg/L]	Local concentration in drinking water [mg/L]	Local PEC in surface water during emission episode (dissolved) [mg/L]	Daily dose through intake of drinking water [mg/kg/day]	Daily dose through intake of fish [mg/kg/day]	Daily dose through intake of air [mg/kg/day]	Sum of dose from drinking water and fish and air
Alkaline	6.10E-07	4.46E-03	4.46E-03	6.15E-05	1.27E-04	1.01E-07	1.74E-07	1.27E-04
Mean	6.10E-07	8.97E-04	8.97E-04	6.07E-05	2.56E-05	9.97E-08	1.74E-07	2.59E-05
Acidic	6.10E-07	4.91E-04	4.91E-04	5.99E-05	1.40E-05	9.84E-08	1.74E-07	1.43E-05

11.3 Annex III – Analytical methods

Analytical methods used for measurements at Company B are reported in section 9.2.4.

11.3.1 Workplace exposure measurements used at EEA sites

In general, the methods used followed the national recommendations. Various types of dust samplers were used for the personal and stationary (static) sampling.

In most cases, analysis was performed with sensitive methods applying ion chromatography followed by UV detection (Metropol M-43) or spectrometric detection (ISO 16740).

Also at a German site, in a campaign in 2019, a photometric method was used, whereas in more recent years atom absorption spectrometry was applied. LOQs below 0.2 µg/m^3 were achieved in all these measurements at the site.

11.4 Annex IV – Respiratory protection – Assigned protection factors (APF)

The European Standard EN 529 – "Respiratory protective devices. Recommendations for selection, use, care and maintenance" provides guidance on the selection and use of RPE. It also lists "Assigned protection factors" as recommended in various European countries. Further, factors used in France are given in INRS guidance ED6106 and APFs used in UK are laid down in HSG 53.

As can be seen in the Table below, APFs vary numerically between countries and no generally accepted factors exist. As it is not always possible to differentiate between companies using combined gas-particle or pure particle filters P3, the same APF (10 resp. 20) is used for half masks resp. full masks with combined gas particle filter Gas X P3 and with particle filter P3. For all ambient-air independent devices an APF of 250 is used.

We noted that large differences exist in the APFs ambient air-independent breathing apparatuses in the UK and in EEA countries. HSG 53 gives APFs ranging from 40 to 2000, whereas much larger APFs are used in several EEA countries. Examples:

- fresh air hose breathing apparatus (EN 138): UK: APF 40, Germany: APF 1000, Sweden: APF 500
- constant flow airline breathing apparatus with full mask (EN 14594): UK: APF 40, France: APF 250.

We asked HSE for assistance in choosing adequate APFs and were referred to the British Standards Institutions (BSI). BSI explained that these APFs were discussed many years ago and cited recent publications (Connell and Lynch, 2023). These authors describe some potential reasons for the differences, among them different types of data used (data from compliant and non-compliant programs were used according to Connell and Lynch (2023) in the UK) and the use of a safety factor. Considering these uncertainties and for the sake of a harmonised assessment of risks in the UK and the EEA based on the same type of data (an APF of 250 is used in respective ADCR EU applications for chromates in primer products, this being the lowest APF reported in an EEA country) in this report for various types of ambient air-independent breathing apparatuses (e.g. fresh air hose breathing apparatus, constant flow airline breathing apparatus with full mask or hoods/helmet demand valve compressed air breathing apparatus), an APF of 250 is used for calculating exposure concentrations.

Table Annex IV-1: Assigned protection factors used for assessment

Type	Specific EU norm	Example	APFs as used in some countries according to EN 529						APF used in this report
			Fin	D	I	S	UK	FR[1]	
Filtering half mask FFP3 (non-reusable)	EN 149		20	30	30	20	20	10	**10**
Half mask with particle filter P3	EN 140 (mask) EN 143 (filter)		-	30	30	-	20	10	**10**

Type	**Specific EU norm**	**Example**	**APFs as used in some countries according to EN 529**						**APF used in this report**
			Fin	D	I	S	UK	FR[1]	
Half mask with combined gas-particle filter Gas X P3	EN 405		-	30	-	-	10	-	**10**
Full mask (all types) with particle filter P3	EN 136 (mask) EN 143 (filter)		500	400	400	500	40	30	**20**
Full mask (all types) with combined gas-particle filter Gas X P3	EN 136 (mask) EN 143 (filter)		-	400	-	-	20	-	**20**
Powered filtering device incorporating a hood or a helmet (PAPR, powered & supplied air respiratory protection) TH3	EN 12941		200	100	200	200	40	40	**40**
Powered filtering device incorporating a full mask TM3	EN 12942		1000	500	400	1000	40	60 (120 L/min) 100 (160 L/min)	**40**
fresh air hose breathing apparatus - full mask or hood or helmet	EN 138		500	1000	400	500	40	-	**250**
Supplied-air respirator (SAR) Continuous flow compressed airline breathing apparatus 4A/4B	EN 14594		-	-	-	-	40 [2]	250	**250**

Type	**Specific EU norm**	**Example**	**APFs as used in some countries according to EN 529**						**APF used in this report**
			Fin	D	I	S	UK	FR[1]	
Compressed air line breathing apparatus with demand valve - Apparatus with a full face mask	EN 14593-1		1000	1000	400	1000	2000 [2]	-	**250**

[1] Source: INRS guidance ED6106

[2] Source: HSG 53

11.5 Annex V - Biomonitoring Company B

Biomonitoring is regularly performed by the company and offered to all staff members. In the table below, results from 2018 to 2023 are presented. From this large number of values, only two exceeded the UK BMGV of 10 µmol/mol creatinine (one from 2022, one from 2019). Follow-up activities included check of the conditions and retesting of the workers. Retesting yielded results well below the BMGV.

Table Annex V-1: Biomonitoring data per individual

Date of Test	Result (µmol Cr/mol creatinine)
03.10.2023	0.33
29.09.2023	1.41
29.09.2023	0.54
22.09.2023	1.20
22.09.2023	0.54
22.09.2023	1.20
22.09.2023	0.54
22.09.2023	0.44
22.09.2023	1.20
22.09.2023	0.33
22.09.2023	1.41
22.09.2023	0.65
22.09.2023	0.33
22.09.2023	0.76
22.09.2023	0.65
22.09.2023	**
22.09.2023	1.31
22.09.2023	0.44
22.09.2023	**
08.03.2023	**
08.03.2023	0.44
08.03.2023	1.52
08.03.2023	1.31
08.03.2023	0.44
08.03.2023	0.87
08.03.2023	5.87
08.03.2023	0.54
08.03.2023	0.54

08.03.2023	0.44
08.03.2023	0.87
08.03.2023	1.09
08.03.2023	0.33
08.03.2023	0.98
08.03.2023	0.54
08.03.2023	0.33
08.03.2023	1.20
08.03.2023	0.54
08.03.2023	**
08.03.2023	0.65
08.03.2023	0.65
08.03.2023	1.09
23.09.2022	ND
23.09.2022	21.00
23.09.2022	**
23.09.2022	1.80
23.09.2022	ND
23.09.2022	0.80
27.01.2022	ND
27.01.2022	ND
27.01.2022	ND
27.01.2022	0.80
27.01.2022	ND
27.01.2022	ND
27.01.2022	ND
27.01.2022	61.00
27.01.2022	ND
27.01.2022	1.30
27.01.2022	ND
27.01.2022	ND
27.01.2022	1.00
27.01.2022	ND
27.01.2022	ND
27.01.2022	2.10

27.01.2022	ND
27.01.2022	ND
27.01.2022	1.30
27.01.2022	ND
27.01.2022	ND
28.07.2021	0.65
17.07.2021	0.54
15.06.2021	0.33
14.06.2021	1.41
06.05.2021	0.87
29.04.2021	1.20
19.04.2021	0.44
13.04.2021	0.44
13.04.2021	0.44
17.03.2021	**
17.03.2021	0.44
10.03.2021	0.33
08.03.2021	0.44
22.02.2021	0.44
09.02.2021	0.33
03.02.2021	0.54
28.01.2021	0.54
21.01.2021	1.31
05.01.2021	0.44
03.12.2020	0.33
27.11.2020	0.65
24.11.2020	1.09
24.11.2020	1.96
13.10.2020	1.09
13.10.2020	0.87
13.10.2020	2.83
07.10.2020	0.87
07.10.2020	1.52
01.10.2020	0.87
22.09.2020	0.65

19.08.2020	0.87
17.08.2020	1.52
12.08.2020	0.87
05.08.2020	0.33
29.07.2020	0.65
27.07.2020	0.54
21.07.2020	0.44
07.07.2020	1.52
04.07.2020	**
02.07.2020	0.54
16.06.2020	0.33
16.06.2020	0.65
20.05.2020	0.33
30.04.2020	0.33
15.04.2020	0.65
07.04.2020	0.33
31.03.2020	0.65
30.03.2020	0.54
24.03.2020	0.44
20.03.2020	0.33
18.03.2020	0.54
17.03.2020	0.54
17.03.2020	0.22
26.02.2020	0.33
25.02.2020	0.87
25.02.2020	0.33
22.02.2020	0.65
13.02.2020	0.33
08.02.2020	5.66
29.01.2020	0.87
28.01.2020	0.44
28.01.2020	2.18
25.01.2020	0.87
20.01.2020	1.41
14.01.2020	0.33

08.01.2020	0.44
08.01.2020	1.09
07.01.2020	1.20
06.01.2020	0.98
03.01.2020	0.44
23.12.2019	2.61
17.12.2019	1.52
17.12.2019	0.33
13.12.2019	0.76
12.12.2019	1.63
06.12.2019	0.44
06.12.2019	0.33
03.12.2019	0.44
03.12.2019	0.22
29.11.2019	0.54
21.11.2019	0.33
18.11.2019	0.54
18.11.2019	0.54
18.11.2019	0.44
16.11.2019	0.22
31.10.2019	0.87
31.10.2019	0.44
17.10.2019	0.33
15.10.2019	1.09
15.10.2019	*
08.10.2019	0.65
08.10.2019	0.44
04.10.2019	0.44
04.10.2019	0.22
03.10.2019	1.31
30.09.2019	0.76
30.09.2019	0.65
25.09.2019	0.44
21.09.2019	0.33
11.09.2019	0.33

06.09.2019	0.65
29.08.2019	0.33
13.08.2019	ND
30.07.2019	2.90
30.07.2019	ND
24.07.2019	ND
23.07.2019	ND
17.07.2019	ND
09.07.2019	ND
09.07.2019	ND
02.07.2019	ND
25.06.2019	ND
24.06.2019	ND
18.06.2019	ND
18.06.2019	ND
18.06.2019	ND
18.06.2019	ND
12.06.2019	ND
12.06.2019	ND
11.06.2019	ND
11.06.2019	ND
05.06.2019	ND
28.05.2019	ND
21.05.2019	ND
13.05.2019	ND
13.05.2019	ND
03.05.2019	ND
01.05.2019	ND
30.04.2019	2.0
30.04.2019	ND
30.04.2019	ND
10.04.2019	ND
02.04.2019	ND
02.04.2019	ND
27.03.2019	ND

26.03.2019	ND
26.03.2019	2.0
26.03.2019	ND
23.03.2019	ND
20.03.2019	ND
20.03.2019	ND
14.03.2019	ND
12.03.2019	ND
12.03.2019	ND
05.02.2019	ND
05.02.2019	ND
05.02.2019	ND
05.02.2019	ND
30.01.2019	ND
29.01.2019	1.60
29.01.2019	13.00
21.01.2019	1.30
21.01.2019	ND
18.01.2019	ND
08.01.2019	ND
07.01.2019	ND
07.01.2019	ND
07.01.2019	ND
07.01.2019	ND
12.12.2018	8.00
11.12.2018	8.50
14.11.2018	ND
27.10.2018	ND
26.10.2018	ND
24.10.2018	ND
24.10.2018	ND
22.10.2018	ND
22.10.2018	ND
22.10.2018	ND
16.10.2018	ND

16.10.2018	ND
16.10.2018	ND
11.10.2018	ND
11.10.2018	ND
09.10.2018	ND
09.10.2018	ND
09.10.2018	ND
09.10.2018	ND
01.10.2018	ND
12.09.2018	ND
12.09.2018	ND
12.09.2018	ND
12.09.2018	ND
04.09.2018	ND
04.09.2018	ND
04.09.2018	ND
04.09.2018	ND
20.08.2018	ND
20.08.2018	ND
20.08.2018	ND
09.08.2018	ND
06.08.2018	ND
31.07.2018	ND
31.07.2018	ND
17.07.2018	ND
17.07.2018	ND
10.07.2018	ND
10.07.2018	ND
02.07.2018	ND
02.07.2018	ND
02.07.2018	ND
25.06.2018	ND
20.06.2018	ND
19.06.2018	ND
15.06.2018	ND

15.06.2018	ND
15.05.2018	ND
15.05.2018	ND
14.05.2018	ND
09.05.2018	ND
08.05.2018	ND
08.05.2018	ND
01.05.2018	ND
24.04.2018	ND
20.04.2018	ND
12.04.2018	ND
12.04.2018	ND
09.04.2018	ND
04.04.2018	ND
04.04.2018	ND
04.04.2018	2.70
04.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
03.04.2018	ND
27.03.2018	ND
27.03.2018	ND
27.03.2018	ND
26.03.2018	ND
15.03.2018	ND
15.03.2018	ND

07.03.2018	ND
06.03.2018	ND
06.03.2018	ND
06.03.2018	ND
26.02.2018	ND
26.02.2018	2.40
26.02.2018	ND
26.02.2018	ND
14.02.2018	ND
13.02.2018	ND
13.02.2018	ND
13.02.2018	2
13.02.2018	ND
29.01.2018	ND
29.01.2018	ND
29.01.2018	ND
29.01.2018	ND
26.01.2018	ND
24.01.2018	ND

ND	not detected
*	Sample bottle not labelled
**	Concentrated Urine

If results were given in µg Cr/l urine or µg Cr/g creatinine values were recalculated to µmol Cr/mol creatinine with the following parameters:

Molecular weight CrO_3:	99.9	g/mol
atom weight Cr:	52	g/mol
molecular weight creatinine:	113.12	g/mol
concentration creatinine in urine:	12	mmol/L.

12 References

ANSES, Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (2017). COLLECTIVE EXPERT APPRAISAL: SUMMARY AND CONCLUSIONS. Regarding the expert appraisal on setting occupational exposure limits for chemical agents. Evaluation of biomarkers of exposure and recommendations for biological limit values and biological reference values for hexavalent chromium and its compounds.

Connell, S.,Lynch, S. (2023). Demystifying APFs for RPE: Attempting the impossible. *Journal of the International Society for Respiratory Protection;* 40(2):

de Bruin, Y. B., de Knecht, J., Hollander, A., Bakker, J., van Jaarsveld, H.,Hogendoorn, E. (2010). Risk assessment using EUSES; Refinement options to estimate atmospheric transportation by its Operational Priority Substances Model (OPS). *Human and Ecological Risk Assessment: An International Journal;* 16(5): 945-961.

Drexler, H.,Hartwig, A. (2009). Biologische Arbeitsstoff-Toleranz-Werte (BAT-Werte), Expositionsäquivalente für krebserzeugende Arbeitsstoffe (EKA), Biologische Leitwerte (BLW) und Biologische Arbeitsstoff-Referenzwerte (BAR). Arbeitsmedizinisch-toxikologische Begründungen. 16. Lfg., DFG Deutsche Forschungsgemeinschaft, WILEY-VCH Weinheim.

ECB, European Chemicals Bureau (2005). European Union Risk Assessment Report: Chromium Trioxide, Sodium Chromate, Sodium Dichromate, Ammonium Dichromate, Potassium Dichromate. 3rd Priority List, Vol. 53. EUR 21508 EN. European Commission. Joint Research Centre.

ECHA, European Chemicals Agency (2011). Annex XV Dossier. Proposal for Identification of a Substance as a Category 1A or 1B CMR, PBT, vPvB or a Substance of an Equivalent Level of Concern. Potassium hydroxyoctaoxodizincatedichromate(1-). Submitted by France, https://echa.europa.eu.

ECHA, European Chemicals Agency (2013a). Annex XV Dossier. Proposal for Identification of a Substance as a Category 1A or 1B CMR, PBT, vPvB or a Substance of an Equivalent Level of Concern. Pentazinc chromate octahydroxide. Submitted by France, https://echa.europa.eu.

ECHA, European Chemicals Agency (2013b). Annex XV Dossier. Proposal for Identification of a Substance as a Category 1A or 1B CMR, PBT, vPvB or a Substance of an Equivalent Level of Concern. Strontium chromate. Submitted by France, https://echa.europa.eu.

ECHA, European Chemicals Agency (2013c). Application for Authorisation: Establishing a Reference Dose Response Relationship for Carcinogenicity of Hexavalent Chromium. Helsinki, 04 December 2013. RAC/27/2013/06 Rev.1. (Agreed at RAC-27). http://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf.

ECHA, European Chemicals Agency (2015). Amendment of the RAC note "Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent chromium" to include the intrinsic property “Toxic to reproduction” of the Cr(VI) compounds (RAC/27/2013/06 Rev.1 agreed on 4 December 2013 at RAC-27). 35th Meeting of the Committee for Risk Assessment 24-27 November _ 1-4 December 2015, Helsinki, Finland. https://echa.europa.eu/documents/10162/21961120/rac_35_09_1_c_dnel_cr-vi-_en.pdf/8964d39c-d94e-4abc-8c8e-4e2866041fc6.

ECHA, European Chemicals Agency (2016a). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.14: Occupational exposure assessment. Version 3.0, August 2016. Helsinki, Finland. https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

ECHA, European Chemicals Agency (2016b). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment. Version 3.0, February 2016. Helsinki, Finland. https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

ECHA, European Chemicals Agency (2021). How to apply for authorisation. Version 1.2, February 2021. ECHA-21-G-01-EN. http://echa.europa.eu/.

EFSA, European Food Safety Authority (2014). Scientific Opinion on the risks to public health related to the presence of chromium in food and drinking water. EFSA Panel on Contaminants in the Food Chain (CONTAM). *The EFSA Journal;* 12(3):3595http://www.efsa.europa.eu/de/efsajournal/doc/3595.pdf.

FIOH, Finish Institute of Occupational Health (2012). Biomonitoring of exposure to chemicals – Guideline for specimen collection 2011-2012. Finnish Institute of Occupational Health: Helsinki, Finland.

Greim, H. (2000). Analytische Methoden zur Prüfung gesundheitsschädlicher Arbeitsstoffe. Band 2: Analysen in biologischem Material. Deutsche Forschungsgemeinschaft, Arbeitsgruppe "Analytische Chemie" der Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe

14. Lfg., Wiley-VCH, Weinheim.

Morton, M.,Lion, K. (2016). Estimation with Values Below the Limit of Quantitation. Presented at CORESTA Congress - Berlin, Germany - 9-13 October 2016.

RIVM, National Institute of Public Health and the Environment (2004). European Union System for the Evaluation of Substances 2.0 (EUSES 2.0). Background report. RIVM Report no. 601900005/2004. RIVM, Bilthoven, The Netherlands Prepared for the European Chemicals Bureau.

Succop, P. A., Clark, S., Chen, M.,Galke, W. (2004). Imputation of data values that are less than a detection limit. *Journal of Occupational and Environmental Hygiene;* 1(7): 436-441.

Toet, C.,de Leeuw, F. A. A. M. (1992). Risk Assessment System for New Chemical Substances: Implementation of atmospheric transport of organic compounds. RIVM Rapport 679102008. RIVM, National Institute for Public Health and the Environment, Bilthoven, The Netherlands.

U.S. EPA, Environmental Protection Agency (2019). Guidelines for Human Exposure Assessment. EPA/100/B-19/001. Washington, D.C.: Risk Assessment Forum, U.S. EPA. https://www.epa.gov/sites/production/files/2020-01/documents/guidelines_for_human_exposure_assessment_final2019.pdf