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CHEMICAL SAFETY REPORT

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Submitted by: Brenntag UK Ltd

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Uses applied for: Use 1: Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments

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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

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 (where applicable).

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

We declare that the risk management measures described in the exposure scenarios in Chapter 9 of this CSR are communicated via safety data sheets in the supply chain.

Part B

This review report uses the dose-response relationship established by 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 Structure of this dossier “Formulation” and uses covered in this dossier

The Aerospace and Defence Chromates Reauthorisation (ADCR) Consortium on behalf of the applicants has developed several review reports. These applications cover all uses of soluble chromates considered to be relevant by the ADCR consortium members. 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 the following dossiers with one use each:

- Anodise sealing
- Anodising
- Chemical conversion coating
- Chromate rinsing after phosphating
- Electroplating
- Formulation
- Inorganic finish stripping
- Passivation of (non-Al) metallic coatings
- Passivation of stainless steel
- Pre-treatments: deoxidising, pickling, etching and/or desmutting
- Slurry coating.

This dossier contains the use “Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments”. Formulation forms a first step in all supply chains relevant for the ADCR consortium.

9.1.2 Introduction to the assessment

9.1.2.1 Grouping approach for Cr(VI) compounds

The chromates shown in Table 9-1 have been included into Annex XIV of Regulation (EC) No 1907/2006 due to their intrinsic properties (mutagenic, carcinogenic, toxic for reproduction; depending on the chromate). 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 respective chromate(s) as mutagenic, carcinogenic and/or reproductive toxic substance(s) are addressed in this CSR. This requires investigating the potential exposure of workers as well as exposure of humans via the environment.

Chromium trioxide (CT) has been included in Annex XIV of REACH (Entry No. 16) due to its carcinogenic and mutagenic properties as it is classified as carcinogenic (Cat. 1A) and mutagenic (Cat. 1B). As CT is mainly used as aqueous solution in the processes described below, this Application for Authorisation

also covers Entry No. 17 of Annex XIV of REACH, which refers to acids generated from CT and their oligomers. **In the following, when referring to CT, this always also implies acids generated from CT and their oligomers.**

Sodium dichromate (SD; Entry No. 18) potassium dichromate (PD; Entry No. 19) and sodium chromate (SC; Entry No. 22) have been included in Annex XIV of REACH due to their CMR properties as they are all classified as carcinogenic (Cat. 1B), mutagenic (Cat. 1B) and reproductive toxicants (Cat. 1B).

For CT, and its acids, only carcinogenic and mutagenic properties must be considered for risk characterisation. Reproductive toxicity has also to be taken into account for Cr(VI) exposure related to SD, PD and SC as these chromates affect both fertility and development.

Table 9-1: Substances considered for the assessment

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
Chromium trioxide ^a (CT)	1333-82-0	215-607-8	16	Muta. 1B Carc. 1A	CrO ₃	99.99	0.52
Acids generated from chromium trioxide and their oligomers ^{a, b}	-	-	17	Carc. 1A			
Sodium dichromate ^c (SD)	10588-01-9	234-190-3	18	Muta. 1B Carc. 1B Repr. 1B	Na ₂ Cr ₂ O ₇	261.97	0.40
Potassium dichromate (PD)	7778-50-9	231-906-6	19	Muta. 1B Carc. 1B Repr. 1B	K ₂ Cr ₂ O ₇	294.19	0.35
Sodium chromate (SC) ^d	7775-11-3	231-889-5	22	Muta. 1B Carc. 1B Repr. 1B	Na ₂ CrO ₄	161.97	0.32

^a Chromium trioxide, when coming in contact with water forms chromic acid, dichromic acid and oligomers of chromic acid and dichromic acid, which are in the following referred as "Chromic acids and their oligomers". Chromium trioxide has been included in Annex XIV of REACH (Entry No. 16) due to its carcinogenic and mutagenic properties as it is classified as carcinogenic (Cat. 1A) and mutagenic (Cat. 1B). As chromium trioxide is mainly used as aqueous solution in the processes described below, this Application for Authorisation also covers Entry No. 17 of Annex XIV of REACH, which refers to "Acids generated from chromium trioxide and their oligomers". Differences between the substances (e.g., due to different forms: liquid, solid) with relevance to their hazards, exposure, alternatives etc. are considered in the assessment.

^b Including chromic acid (CAS No.: 7738-94-5 | EC No.: 231-801-5), dichromic acid (CAS No.: 13530-68-2 | EC No.: 236-881-5) and oligomers of chromic acid and dichromic acid.

^c This entry also covers sodium dichromate dihydrate (Formula: Cr₂H₄Na₂O₉ | CAS No.: 7789-12-0 | EC No.: 616-541-6), which is neither registered nor does it have a harmonised classification. Should it be used, we will treat it as if it were also classified

Formulation

SD

as mutagenic (Muta. 1B), carcinogenic (Carc. 1B) and reprotoxic (Repro. 1B), same as the anhydrous form. In this case, the molecular weight fraction of 0.4, as calculated for sodium dichromate, would be used, which is a conservative approach, because sodium dichromate dihydrate has a higher molecular weight (298 g/mol) with a lower Cr(VI) fraction (0.35) than sodium dichromate.

^d This entry also covers sodium chromate tetrahydrate (Formula: $\text{CrH}_8\text{Na}_2\text{O}_8$ | CAS No.: 10034-82-9 | EC No.: 600-068-7), which is neither registered nor does it have a harmonised hazard classification. Should it be used, we will treat it as if it were also classified as mutagenic (Muta. 1B), carcinogenic (Carc. 1B) and reprotoxic (Repro. 1B). In this case, the molecular weight fraction of 0.32, as calculated for sodium chromate, would be used, which is a conservative approach, because sodium chromate tetrahydrate has a higher molecular weight (234 g/mol) with a lower Cr(VI) molecular weight fraction (0.22) than sodium dichromate.

The carcinogenicity, mutagenicity and reproductive toxicities of CT, its acids, SD, PD, and SC are driven by the chromium VI (Cr(VI)) ion released when the substances solubilise and dissociate. Since Cr(VI) is the relevant and common molecular entity generated from all these substances, all exposure assessments are performed for Cr(VI). Also, the exposure-risk relationships and DNELs proposed by the Committee for Risk Assessment (RAC) express exposure as Cr(VI).

A grouping approach is used in this CSR, because

- All substances share this common toxic moiety (Cr(VI)), and are therefore expected to exert effects in an additive manner,
- At many sites various chromates are used in parallel, exposures of which are additive,
- For some uses, different chromates can be used interchangeably, as they provide the same performance properties and functionalities.

Human exposures (as well as environmental emissions) are expressed in units of Cr(VI) (converted by using substance-specific molecular weights) to allow for comparing and summing up of exposures and to support comparison with RAC's exposure-risk relationship and DNELs.

9.1.2.2 Exposure-risk relationships (ERRs) for carcinogenic effects and DNEL values for reproductive toxicity used for the assessment

The hazard evaluation follows recommendations given by RAC (ECHA, 2015)¹:

For assessing carcinogenic risk, exposure-risk relationships are used to calculate excess cancer risks.

As mutagenicity is a mode of action expected to contribute to carcinogenicity, the mutagenic risk is included in the assessment of carcinogenic risk, and low risks for mutagenicity are expected for exposures associated with low carcinogenic risks.

With respect to reproductive toxicity, DNELs for effects on fertility proposed by RAC are lower than DNELs derived for effects on developmental toxicity and, therefore, the RAC DNELs are used for the assessment of reproductive toxicity.

Sodium dichromate, sodium chromate and potassium dichromate are included in Annex XIV not only due to their carcinogenic and mutagenic properties but also because of their reproductive toxicities. Although the effects on reproduction only need to be assessed for Cr(VI) derived from these three substances, for reasons of simplification risk characterization ratios were calculated for total Cr(VI),

¹ ECHA Website: https://echa.europa.eu/documents/10162/21961120/rac_35_09_1_c_dnel_cr-vi_en.pdf/8964d39c-d94e-4abc-8c8e-4e2866041fc6; assessed in March 2021

regardless of the source (i.e., total Cr(VI)). Therefore, exposures resulting from all substances mentioned in Table 9-1 will be considered for each applicable exposure scenario relevant for uses of one or more of these three chromates. With respect to a possible risk to fertility, this represents a conservative estimate for sites which use CT in parallel with SD, SC and/or PD, because the contribution of CT does not have to be considered for effects on fertility.

A dermal DNEL for long-term systemic effects for workers is used in the risk characterization for dermal occupational exposures, because there is no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk in humans (ECHA, 2015).

9.1.2.2.1 Exposure risk relationships (ERRs) for carcinogenic effects

ECHA published on December 4, 2013 the document “*Application for Authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium*”² (ECHA, 2013), 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 (2013) 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, 2013): “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 (2013), 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 routes are 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).

Table 9-2: Exposure-risk relationships for inhalation exposure of workers used for calculating cancer risks due to Cr(VI) exposure (from ECHA, 2013)

TWA Cr(VI) inhalation exposure concentration [$\mu\text{g}/\text{m}^3$]*	Excess lung cancer risk in workers [$\times 10^{-3}$]
25	100
12.5	50
10	40

² ECHA Website: https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf; assessed in March 2021

TWA Cr(VI) inhalation exposure concentration [$\mu\text{g}/\text{m}^3$]*	Excess lung cancer risk in workers [$\times 10^{-3}$]
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 is presenting an exposure-risk relationship for lung cancer, whereas for oral exposure the focus is on an increased risk for tumours of the small intestine (ECHA, 2013). As with the assessment of worker exposure, for inhalation exposure of the general population, it is assumed that all particles are in the respirable size range.

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

Average Cr(VI) exposure concentration in ambient [$\mu\text{g}/\text{m}^3$]*	Excess lung cancer risk in the general population [$\times 10^{-3}$]
10	290
5	145
2.5	72
1	29
0.5	14
0.25	7
0.1	2.9
0.01	0.29

Average Cr(VI) exposure concentration in ambient [$\mu\text{g}/\text{m}^3$]*	Excess lung cancer risk in the general population [$\times 10^{-3}$]
0.001	0.029
0.0001	0.0029

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

Table 9-4: 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, 2013)

Constant average oral daily dose of Cr(VI) [$\mu\text{g}/\text{kg bw}/\text{day}$]*	Excess small intestine cancer risk in the general population [$\times 10^{-4}$]
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)

9.1.2.2.2 Derived no effect levels (DNELs) for the assessment of potential risks to reproduction

For the assessment of the potential risk to reproduction (fertility as the most sensitive endpoint), the risk characterisation ratios for inhalation exposure of **workers** are based on the DNEL inhalation for effects on fertility derived by RAC (ECHA, 2015):

- inhalation DNEL systemic long-term: $43 \mu\text{g Cr(VI)}/\text{m}^3$

The risk characterisation ratios for dermal exposure of **workers** are based on the DNEL dermal for effects on fertility derived by RAC (ECHA, 2015):

- dermal DNEL systemic long-term: $43 \mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$

The risk characterisation for oral and inhalation exposure of humans via the environment is based on the DNEL inhalation and the DNEL oral for the **general population** derived by RAC for effects on fertility (ECHA, 2015):

- inhalation DNEL systemic long-term: $11 \mu\text{g Cr(VI)}/\text{m}^3$
- oral DNEL systemic long-term: $17 \mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$.

Dermal exposure of humans via the environment is considered very unlikely (ECHA, 2016a).

9.1.2.3 Environment

Scope and type of assessment

The chromates in Table 9-1 are not listed in Annex XIV for endpoints related to concerns for the environment. Therefore, no environmental assessment has been performed.

9.1.2.4 Exposure of humans via the environment

9.1.2.4.1 Scope and type of assessment

The exposure of humans to Cr(VI) via the environment (HvE) as a result of wastewater and air emissions from the sites of the applicants and downstream users covered by this CSR is considered in sections 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 (K_{ow}) 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 the majority of 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 artifacts (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 humans via the environment 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 9-5.

In addition, risk characterisation ratios (RCRs) based on the DNELs derived by RAC (see also section 9.1.2.2) are calculated to take into account possible effects on reproduction for those chromates, which have been included in Annex XIV of the REACH Regulation due to their reproductive toxicity (in addition to their carcinogenic properties). Although in principle effects on reproduction only have to be evaluated for Cr(VI) originating from SD, SC and PD, RCRs have been calculated for total Cr(VI) exposure, irrespective from which of the chromates covered in this CSR it was released, following a conservative approach.

Table 9-5: 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 DNEL/dose – response relationship
Inhalation: Systemic Long Term	Carcinogenicity Quantitative	RAC dose-response relationship based on excess lung cancer risk (ECHA, 2013) 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 *
	Reproductive toxicity Quantitative	RAC DNEL for the general population, derived for effects on fertility (ECHA, 2015) 11 µg Cr(VI)/m ³
Oral: Systemic Long Term	Carcinogenicity Quantitative	RAC dose-response relationship based on excess cancer risk for tumours of the small intestine (ECHA, 2013) 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
	Reproductive toxicity Quantitative	RAC DNEL for the general population, derived for effects on fertility (ECHA, 2015) 17 µg Cr(VI)/kg bw/d

* The inhalation cancer risk characterisation 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).

9.1.2.4.2 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 industrial use of chromates covered in this CSR (see Table 9-1). 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, as described for example in the *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* (ID

0043-02). This states that regional exposure of the general population is not considered relevant by RAC³.

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, and distribution and exposure modelling are carried out with the European Union System for the Evaluation of Substances (EUSES) software (v. 2.2).

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 porewater 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)

³ 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”, consolidated version, 2016; <https://echa.europa.eu/documents/10162/658d42f4-93ac-b472-c721-ad5f0c22823c>

For sites where wastewater is led to a biological sewage treatment plant (STP), 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 specific reduction factors are therefore 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 taken into account 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 porewater 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. This is still 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*⁴ (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 day⁵. 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, 2016a).

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

⁴ 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 November 2020).

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>

⁵ 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).

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). 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 water and air are available from several sites in Europe. 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 from cleaning water and wash water from wet scrubbers. At all sites wastewater is collected and then treated by one or more of the following three options:

- Sending it to an external waste management company where it is treated as hazardous waste
- Recycling and evaporation in an on-site evaporation system; the residue is discharged as hazardous solid waste
- Discharge into a special treatment facility

The special treatment facility is in most cases located on-site but may also be external where the water is transferred via underground pipes. Typically, contaminated water is either disposed as hazardous waste by an external company or conveyed to the special treatment facility. Wastewater from the other sources listed above is usually either collected and mixed together for treatment at the treatment facility or recycled and then led to the evaporation system.

In the special treatment facility, the Cr(VI) in wastewater is reduced to Cr(III) by addition of a reducing agent (e.g., sodium metabisulphite, ferrous sulphate, or ferric chloride solutions) in excess of stoichiometry. Usually, reduction efficiency is measured by a redox probe. Following the reduction step, the wastewater pH is neutralized, and Cr(III) is precipitated. After monitoring of the Cr(VI)

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concentration in the reduced wastewater, usually the wastewater is mixed with other (non-Cr(VI) containing waste solutions. The wastewater is then discharged to an external municipal wastewater/sewage treatment plant for further treatment prior to discharge to receiving waters (river, canal, or sea).

Air

The exhaust air is released via stacks, and emitted air is treated in scrubbers or by air filters before being released to the ambient air.

Soil

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

Solid waste containing Cr(VI) may arise in the form of solid residue from the evaporation system for wastewater (at sites where this technique is performed), sludge from the reduction/neutralization process (at sites where this technique is performed), empty chemical containers, cleaning materials and disposable PPE. Waste materials containing Cr(VI) are classified and treated as hazardous wastes according to EU and national regulations. Any solid or liquid waste is collected and forwarded to an external waste management company (licenced contractor) for disposal as hazardous waste.

Substance-specific input values

We have used the properties of CT for the input of substance-specific physico-chemical properties to model the behaviour of Cr(VI) with EUSES. The parameters of CT were selected because a comparative EUSES assessment with an example scenario, in which only the substance-specific physico-chemical properties of the eight chromates covered by the ADCR consortium were used, yielded the most conservative result with the CT parameters. The exposure of HvE via the combined exposure via air, drinking water and fish was slightly higher when using the CT parameters than when using the parameters of the other chromates (the physico-chemical properties of the seven other chromates used for EUSES modelling and the outcome of the comparative EUSES assessment is provided in Annex I of the CSR). Accordingly, we have used the **parameters of CT for EUSES modelling of the environmental behaviour of Cr(VI) released from all source chromates and sites** (irrespective of the chromate used at a particular site) for reasons of conservatism and consistency. However, it must be noted that these physico-chemical properties are only used as a surrogate for those of Cr(VI), as no physical properties exist for the Cr(VI) ion. For the environmental fate properties, in contrast, data are available for Cr(VI). Table 9-6 shows the physico-chemical properties of CT and the environmental fate properties of Cr(VI) required for EUSES modelling, as given in the EU Risk Assessment Report (ECB, 2005).

Table 9-6: Physico-chemical properties of CT and environmental fate properties of Cr(VI) required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
Molecular weight	100 g/mol	100 g/mol	Refers to CT, value used in ECB (2005)
Melting /freezing point	196 °C	196 °C at 101.3 kPa	Refers to CT, value used in ECB (2005)
Boiling point	n/a decomposes at ~250 °C to Cr ₂ O ₃ and O ₂ (ECB, 2005)	250 °C	Refers to CT; value used in ECB (2005)
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	Completely soluble in water, 1667 g/L at 20 °C, a 1% solution has a pH <1.	1667 g/L at 20 °C	Refers to CT; value used in ECB (2005)
Kp <i>suspended matter</i>		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 <i>sediment</i>		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 <i>soil</i>		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 partition coefficients for Cr(VI) from Table 9-6 as follows (see Table 9-7). In the EU Risk Assessment Report (ECB, 2005), the Cr(VI) partition coefficients are given for suspended matter, sediment and soil under acidic and alkaline conditions. For EUSES modelling the mean value of the partition coefficients under acidic and alkaline conditions was used 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.

To assess the impact of the selected partition coefficients (under acidic or alkaline conditions), we conducted a sensitivity analysis with EUSES, where an exemplary exposure scenario (with no biological STP) was carried out using (a) the coefficients for acidic conditions, (b) the coefficients for alkaline conditions or (c) the calculated mean values. The outcome of the assessment was that the selected set of partition coefficients had close to no impact on the modelling result, as the variation of Cr(VI) exposure of HvE via the combined exposure routes air, drinking water and fish was lower than 2% (details are given in Annex II of this report).

Table 9-7: 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
<i>Kp suspended matter</i>	2 000 L/kg	200 L/kg	1 100 L/kg
<i>Kp sediment</i>	1 000 L/kg	100 L/kg	550 L/kg
<i>Kp soil</i>	50 L/kg	2 L/kg	26 L/kg

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

9.1.2.5 Workers

9.1.2.5.1 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).

All chromates considered in this CSR 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. Additionally, a quantitative exposure assessment and risk characterisation with respect to effects on reproduction considers both inhalation and dermal exposures.

For chromates classified as toxic for reproduction (SD, PD and SC, see section 9.1.2.1), dermal exposure must be assessed for possible effects on fertility. As explained above, the exposure assessment of this

CSR focuses on total Cr(VI) released from all assessed chromates combined. With respect to a possible risk on fertility this is a very conservative estimate for sites which use CT in parallel with SD, PD and/or SC (as the contribution of CT does not have to be considered for effects on fertility). The exposure-risk relationships and DNEL values used for risk characterisation are based on the RAC evaluation .

Table 9-8: 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 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 ^a
	Reproductive toxicity Quantitative	RAC DNEL for workers, derived for effects on fertility 43 µg Cr(VI)/m ³
Dermal: Systemic Long Term	Reproductive toxicity Quantitative	RAC DNEL for workers, derived for effects on fertility 43 µg Cr(VI)/kg bw/d ^b

^a The inhalation 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.

^b Only worker dermal DNEL long-term systemic fertility effects are applied for the risk characterization of dermal exposure, because there is no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans .

A qualitative risk characterisation with respect to the corrosive and skin sensitising properties of chromates such as CT is outside the scope of this CSR, as these chromates have been included in Annex XIV to Regulation (EC) No 1907/2006 (REACH) solely due to their carcinogenic and mutagenic properties, and reproductive toxicity (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 and/or communicate 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).

9.1.2.5.2 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). Potential dermal exposures arise from Cr(VI) dissolved in liquids, or from dusts of solid Cr(VI)-containing products.

Inhalation exposure of workers is assessed via reliable and representative workplace air measurements. We have assigned exposed workers to “Similar Exposure Groups” (SEGs), which are defined for each use and comprise groups of workers performing similar tasks and, hence, are assumed to experience similar exposures. Measured data from members of the same SEG are pooled. On several occasions, workers might be engaged in more than one use in parallel (e.g., an operator surveying a line of baths, where several surface treatments are done). The respective chapters on the use-specific exposure assessment explain how measured exposures are assigned to specific uses. As a general rule, the measured full-shift time-weighted average concentration is assigned to all uses for which tasks were performed at the day of the measurement.

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 $LOQ/\sqrt{2}$ 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 $LOQ/\sqrt{2}$ is preferred for data sets with a geometric standard deviation <3 . 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.

Personal monitoring, 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. In limited, specific circumstances, values from **stationary (static) measurements** are helpful: incidentally exposed workers, i.e., workers not directly engaged with Cr(VI) (also called bystanders), but spending 10% or more of their working time in the same work hall as operators handling Cr(VI), might experience inhalation exposure. Such exposures can be estimated from stationary measurements, representing concentrations at some distance from the primary sources.

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 adequate 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. 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 data are not used in the assessment. Indeed, as regards biological indicators:

- 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. The German method provides a correlation between biomonitoring in erythrocytes and inhalation exposures but only for CrO₃ concentrations above 30 µg/m³, which is above what is expected in these exposures. Additionally, it is expected that few sites apply biomonitoring in erythrocytes, as it is an invasive method using blood sampling and is thus difficult to apply to consistently use as a method of estimating exposure.
- Urinary biomonitoring does not allow a differentiation between Cr(III) and Cr(VI). France established a BLV (biological limit value) by ANSES (French evaluation Authorities) in 2017, which can be used for workers but only under the following conditions: when the use is electroplating AND when the chrome products used are exclusively Cr(VI) compounds. Indeed, in case of mixed exposure to both Cr(VI) and Cr(III) compounds, the urine measurements need to be interpreted in light of parallel respective atmosphere measurements of Cr(VI) and Cr(III) compounds (if available). According to ANSES, the literature data available does not allow establishing a dose-response relationship between the urine measurements and the health effects (lung cancer, kidney toxicity, immunotoxicity). These constraints do not facilitate the implementation of this biomonitoring.
- Finally, chromium levels in biomonitoring studies are influenced by factors other than occupational exposure (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, inhalation exposure measurements (ideally obtained by personal sampling) are preferred over biomonitoring in this case for exposure assessment.

Exposure modelling is applied for specific activities only, which cannot be adequately covered by measurements, such as:

- Activities of very short duration (e.g., laboratory workers handling Cr(VI) for a few minutes) might not allow direct measurements, taking into account the sensitivity of available methods.
- Infrequent activities, such as unscheduled maintenance activities, might not be included in occupational safety measurement programmes with the result that they are not covered by existing data.
- Activities using small amounts of mixtures with low concentrations of Cr(VI), such as use of touch-up pens.

Modelling is performed, where required, with Advanced REACH Tool (ART), version 1.5. Again, we have used the 90th percentile of the resulting distribution for risk assessment, according to .

Machining (e.g., drilling, grinding) of parts or blasting of surfaces, which were Cr(VI)-treated before might lead to Cr(VI) exposure via inhalation of fine dust particles that are generated. Such activities are included in the assessment if the surface treatment is expected to leave Cr(VI) on or near the surface.

Dermal exposure is considered for all activities related to a possible Cr(VI) exposure from using SD, PD or SC (to assess possible risks for reproductive toxicity). Minimisation of dermal exposure is required due to the corrosive and skin sensitising properties of the chromates. This is achieved by automating processes and, where manual handling cannot completely be avoided, by adequate personal protection equipment (for details on PPE see the respective exposure scenarios).

For processes for which dermal exposure cannot be excluded with certainty (e.g., sampling, cleaning, maintenance), the potential dermal exposure is modelled as the intensity of exposure is often difficult to accurately determine. However, modelling dermal exposure from the use of Cr(VI) substances as covered by this review report is difficult. The substances are mostly used as solids dissolved in a liquid, which is outside the applicability domain of the standard modelling tool ECETOC TRA. The Riskofderm model (v.2.1) does not contain adequate modules (DEO units) for several of the activities relevant here, e.g., handling contaminated objects, or cleaning activities. For all activities, including those outside the applicability domain of Riskofderm, we developed an Excel® spreadsheet-based model to estimate dermal exposure. This modelling approach uses dermal loads and assumption on contact areas depending on the tasks (PROCs) performed as proposed in the ECETOC TRA tool.

The following table lists the activities modelled (performed by various types of workers) and the approach used per activity.

Table 9-9: Activities with potential dermal exposure to SD, PD, or SC

Task	PROC
Weighing of solid chromates	PROC 8a, 8b
Charging mixing vessels	PROC 8a, 8b
Transfer of products	PROC 8b
Sampling	PROC 9
Cleaning of workplace	PROC 28
Maintenance and cleaning of equipment	PROC 28
Waste management – Handling of solid waste	PROC 8b
Filling of tank trucks	PROC 8b

The input data and the results of the modelling for the individual activities listed in Table 9-9 as well as the detailed Riskofderm protocols are given in Annex V. The 90th percentile exposure estimate from Riskofderm modelling are used for a plausibility check and are compared with the results of the Excel® spreadsheet-based model. The aggregated exposure estimates for the various worker contributing scenarios are also presented in Annex V.

Comments on assessment approach related to toxicological hazard:

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

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for risk characterisation. Further, in this review report reproductive toxicity is assessed using DNELs as proposed by RAC.

Comments on assessment approach related to physicochemical 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 previous applications for authorisation are provided in chapter 9.2.1.

General information on risk management related to physicochemical hazard:

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

9.1.2.6 Consumers

Consumer uses are not subject of this review report.

9.2 Use 1: “Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments”

9.2.1 Introduction

9.2.1.1 Relationship to previous application

This review report is for “**Use 1: Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments**”. 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. The review report is based on sector-specific knowledge provided by companies producing 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 and their often interchangeable roles in the supply chain, this chemical safety report covers formulation activities with soluble Cr(VI) compounds in a grouping approach (see section 9.1.2.1 for the justification). The following Table 9-10 shows the relevant substances and the initial applications to which this review report refers.

Table 9-10: Overview of initial applications

Application authorisation number	ID/	Substance	EC #	CAS #	Applicants	Use name
0032-01 REACH/20/18/0, REACH/20/18/2, REACH/20/18/4		Chromium trioxide	215-607-8	1333-82-0	Various applicants (CTAC consortium)	Formulation of mixtures exclusively for uses REACH/20/18/7 to REACH/20/18/34
0043-01 REACH/20/5/0, REACH/20/5/2		Sodium dichromate	234-190-3	7789-12-0; 10588-01-9	Various applicants (CCST consortium)	Use in formulation of mixtures intended exclusively for uses REACH/20/5/3, REACH/20/5/4, REACH/20/5/5, REACH/20/5/6, REACH/20/5/7 and REACH/20/5/8
0044-01 REACH/20/3/0		Potassium dichromate	231-906-6	7778-50-9	Various applicants (CCST consortium)	Formulation of mixtures intended exclusively for surface treatment of metals (such as aluminium, steel, zinc, magnesium, titanium,

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					alloys), composites and sealings of anodic films for the aerospace sector in the surface treatment processes in which any key functionalities listed in the Annex is required
0099-01 REACH/19/32/0, REACH/19/32/1	Sodium chromate	231-889-5	7775-11-3	Various applicants (GCCA consortium)	Formulation of mixtures of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by the aerospace sector

With the initial authorisation several obligations were issued by the European Commission on applications as listed above.

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: Obligations in EC Implementing decisions

Initial application	Current application
AH shall develop specific exposure scenarios for representative processes, operations and individual tasks, describing risk management measures and operational conditions applied and containing information on the exposure levels. This obligation applies to 0032-01, 0043-01, 0044-01, and 0099-01	Specific exposure scenarios were developed and made available to the DUs by the consortia responsible for the initial applications. Starting from that, the exposure scenarios provided in section 9.2.3 of this report, together with the risk management measures described there, were further developed and refined.
DUs shall implement best practices to reduce workplace exposure to the substances and its emissions to the environment to as low a level as technically and practically feasible, using closed systems and automation and local exhaust ventilation (LEV) systems, when possible. This obligation applies to 0032-01, 0043-01, 0044-01, and 0099-01	The exposure scenarios in section 9.2.3 describe the conditions of use including the technical and organisational measures to reduce and control workplace exposure.
AH and DUs shall restrict the area in which activities involving the use of solid chromates are conducted either physically by means of barriers or by means of a strict procedure during the activity and for a specified time thereafter. This obligation applies to 0099-01	Formulation activities with solid sodium chromate are conducted by experienced and well-informed operators at specific campaign days (few days per year). Access to respective area during these processes is restricted to these operators (see the exposure scenarios in section 9.2.3).

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<p>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.</p> <p>This obligation applies to 0043-01, 0044-01, and 0099-01</p>	<p>Organisational measures to control and maintain adequate functioning and use respiratory protective equipment (RPE) are described in section 9.2.2.3.1.2.</p>
<p>Appropriate standard operating procedures shall be developed and implemented 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 set out in Article 5 of Directive 2004/37/EC.</p> <p>This obligation applies to 0043-01 and 0044-01</p>	<p>The type of activities and the conditions of use relevant for handling solid waste are given in sections 9.2.3.2 to 0.</p>
<p>The AHs and DUs shall implement monitoring programmes for air monitoring of occupational exposure representative for the tasks undertaken and shall implement monitoring programmes for chromium (VI) emissions to wastewater and air from local exhaust ventilation.</p> <p>This obligation applies to 0032-01, 0043-01, 0044-01, and 0099-01</p>	<p>Monitoring programmes are implemented at the downstream users and data from these programmes were used for performing the exposure assessments of workers and of men via the environment.</p>
<p>The AHs and DUs shall regularly review the effectiveness of the risk management measures and operational conditions in place and to introduce measures to further reduce exposure and emissions.</p> <p>This obligation applies to 0032-01, 0043-01, 0044-01, and 0099-01</p>	<p>Sites regularly review the effectiveness of risk management measures and operational conditions in place</p>
<p>If an authorisation holder submits a review report, it shall include a detailed guidance on how to select and apply risk management measures and a refined assessment of the exposure to chromium (VI) of humans via the environment, 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 Information Requirements and Chemical Safety Assessment and of the European Union System for the Evaluation of Substances (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.</p> <p>This obligation applies to 0032-01, 0043-01, 0044-01 and 0099-01</p>	<p>Detailed information on the adequate RMMs for each activity are included in the exposure scenarios of this review report. The assessment of exposure of HvE is performed based on measured emission data from various sites. Inhalation exposure from emissions to air and oral exposure from emissions to wastewater is considered.</p>

Enforcement activities by Member State Enforcement Authorities

So far, we are not aware of any enforcement activity with relation to the uses 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 9.1.2.1). Typically, several chromates are used at one site in parallel to formulate a variety of products. In most cases, exposure of workers and of humans via the environment 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 (with the exemption of Task 1 of logistic operators: Filling of tank trucks (PROC 8b), which is modelled by ART, see 9.2.3.7.2). 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. For this, either Cr(VI) exposure was modelled for each task based on standard assumptions for the conditions of use, or, where available, monitoring data were considered for combinations of worker contributing scenarios.

- 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. Environmental monitoring data for releases to air and wastewater serve as a basis for EUSES modelling of human exposure via several environmental compartments (ambient air, drinking water, fish). 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.

Due to differences in the structure of the current and initial applications, in 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. Deviations between the consideration of PROCs are described in the third column.

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

Current application	Initial applications	Remarks
<u>ECS 1- Environmental contributing scenario</u> - ERC 2	Formulation into mixture (ERC 2)	
<u>WCS 1 – Operators – liquid mixtures</u> ^a PROC 5, PROC 8a, PROC 8b, PROC 9, PROC 28	Decanting and weighing of solids (PROC 8b) Transfer to vessel – aqueous solution (PROC 8a/8b) Transfer to vessel – solids (PROC 8b) Mixing by dilution, dispersion (closed or open process) (PROC 2-5) Transfer to small containers (including filtering) (PROC 9) Cleaning of equipment (PROC 8b) Maintenance of equipment (PROC 8a) Waste management (PROC 8b)	For cleaning PROC 28 is regarded more appropriate in the current application
<u>WCS 2 – Operators – solid mixtures</u> ^a PROC 5, PROC 8a, PROC 8b, PROC 9, PROC 28	Decanting and weighing of solids (PROC 8b) Transfer to vessel – solids (PROC 8b) Mixing by dilution, dispersion (closed or open process) (PROC 2-5) Transfer to small containers (including filtering) (PROC 9) Cleaning of equipment (PROC 8b) Maintenance of equipment (PROC 8a) Waste management (PROC 8b)	For cleaning PROC 28 is regarded more appropriate in the current application
<u>WCS 3 – Laboratory technicians</u> ^a - PROC 15	Quality Control – lab analysis (sampling, transfer, laboratory analysis) (PROC 15)	
<u>WCS 4 – Maintenance workers</u> ^a PROC 28	Maintenance of equipment (PROC 8a)	For maintenance and cleaning PROC 28 is regarded more appropriate in the current application
<u>WCS 5 – Logistics operators</u> ^a PROC 8b	Transfer to small containers (including filtering) (PROC 9)	As a main task of logistic operators truck loading is considered (PROC 8b)
<u>WCS 6 – Incidentally exposed workers</u> ^a PROC 0		Incidentally exposed workers were not considered in initial application
Not considered relevant in this review report, as these activities are not part of the use described in this review report or does not lead to Cr(V) exposure	Delivery and storage of raw material (PROC 1) Storage of formulation (PROC 1)	No exposure is expected from these processes in the current application

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^a For descriptions of tasks assigned to the individual PROCS see worker contributing scenarios in sections 9.2.3.2 to 0.

^b Since this application is based on several initial applications and the PROC descriptions sometimes vary between the different applications or are used in several variants in some cases the original PROC description is not given in this table but a summary description of the PROC(s) it is assigned to is.

The exposure scenarios and contributing scenario 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 mixtures containing CT, PD, SD and SC for being used in the aerospace and defence industry and its supply chains. This use is performed in the European Economic Area (EEA) in exclusively industrial settings at companies specialised in formulation activities. Their activities typically involve formulation of chromates for other supplies (in addition to the aerospace and defence supply chains) and formulation of mixtures not containing chromates. However, the respective portions vary from company to company.

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 sites producing liquid or solid mixtures, we prepared two separate workers exposure scenarios for the respective operators.

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 mixtures with soluble Cr(VI) compounds	
Environmental contributing scenario(s)		
ECS 1	Formulation into mixture	ERC2
Worker contributing scenario(s)		
WCS 1	Operators producing liquid mixtures	PROC 5, 8a, 8b, 9, 28
WCS 2	Operators producing solid mixtures	PROC 5, 8a, 8b, 9, 28
WCS 3	Laboratory technicians	PROC 15
WCS 4	Maintenance workers	PROC 28
WCS 5	Logistics operators	PROC 8b
WCS 6	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 mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments”. Mixtures (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 CT, SD, PD, and SC 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

Formulation of soluble chromates includes the preparation of aqueous solutions from the solid, neat substances or dilution of higher concentrated aqueous solutions (both processes with or without blending with additives). Further, solid mixtures are prepared by blending with additives.

Solid chromates are supplied in drums or bags as crystals, flakes, or powders. Formulators blend or dissolve the chromates in closed mixing vessel at ambient temperature. After mixing, the formulation is transferred to containers or other suitable packaging.

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.

Cr(VI)-containing mixtures are produced at industrial sites specialised in formulation activities. The way how Cr(VI)-containing mixtures are produced at the various companies vary substantially and includes companies

- producing continuously but batch-wise few special Cr(VI)-containing products in large amounts
- performing batchwise production of Cr(VI)-containing mixtures in low quantities.
- The share of the production of Cr(VI) products directed to the aerospace and defence supply chains also varies largely (3 to approx. 50% of the production at individual companies).

9.2.2.2 Teams and employees involved

Exposure groups (EGs) comprise the following groups:

- Operators manufacturing liquid mixtures
- Operators manufacturing solid mixtures
- Laboratory technicians
- Maintenance workers
- Logistics operators
- Incidentally exposed workers (without direct Cr(VI)-related activities).

Operators

Operators (for both liquid and solid mixtures) are typically performing the following tasks:

- Transportation of substances from the storage area to the mixing vessels in closed containers
- Filling solid or liquid substances into the mixing vessels, or,
- in the case of concentrated liquid solutions coupling and decoupling lines for feeding solutions into the mixing vessels by pumping systems

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- Surveying the mixing process
- Transfer of final products to storage tanks and/or (ADR approved) transport containers (drums, Intermediate Bulk Containers (IBC))
- Sampling
- Cleaning of workplaces and equipment
- Emptying of lines in case of repairs.

Typically, 1 to 3 operators oversee one mixing vessel. The same or other operators may be involved in filling products into containers.

Laboratory technicians

Laboratory technicians are responsible for quality control of raw materials and/or products. Typical tests comprise control of concentration of Cr(VI) substances. Handling of Cr(VI) containing materials comprises only (small) parts of shifts of the technicians.

Depending on company-internal organisation, on some occasions laboratory technicians may be engaged in taking samples.

Maintenance workers

Maintenance work in relation to facilities used for preparing mixtures is infrequent. It comprises repair of pumps, valves, 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.

Typically, there is a group of maintenance workers (1 to 5, depending on company size), who spend a small fraction of their time on activities with potential for Cr(VI)-exposure.

Logistics operators

Logistics operators are transporting raw materials and products to and from storage areas. In most cases this involves transport of closed drums, vessels, or containers, without the possibility of exposure. Where transport via tank trucks is involved, loading of tank trucks might be performed by logistic operators.

Typically, there is a group of logistics operators (2 to 10, depending on company size), who spend a small fraction of their time on activities with potential for Cr(VI)-exposure, if any.

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 are placed in a large hall and only one or few of these vessels is dedicated to the production of chromate containing mixtures.

9.2.2.3 Technical and organisational risk management measures

Formulators manufacturing products for use in ADCR supply chains are specialised industrial companies being active at few production sites in the EEA. They have rigorous internal safety health and the environment (SHE) organisational plans. The sites adhere to best practices to reduce workplace exposures and environmental emissions to as low as technically and practically feasible.

9.2.2.3.1 Workers

At all sites, risk management measures in accordance with Article 5 of Directive 2004/37/EC are implemented as appropriate. 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, e.g., according to the Control Of Substances Hazardous to Health (COSHH) Assessment rules in the UK or the Technical Rules for Hazardous Substances (TRGS) in Germany.

9.2.2.3.1.1 Technical measures

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

- Mixing vessels are closed systems, which are opened only 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
- LEV is provided at the point at which solid chromates are weighed as well as at points where they are added to the mixing vessel.

Efficiency of LEV

LEV systems are installed at the mixing vessels and are regularly inspected and controlled according to the specifications of the manufacturers. The efficiency of the installed LEV system depends on the exhaust air flow rate of the system per time unit. The sites follow the manufacturer requirements as well as recommendations from national guidelines, where applicable, and perform preventative maintenance of equipment to maintain the stated efficiencies of the LEV systems.

9.2.2.3.1.2 Organisational measures

All formulation sites are industrial sites with the relevant organisation structures for handling hazardous substances such as emergency plans. Some sites have their own firefighter brigade.

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

- Annual monitoring programmes are implemented for air monitoring of occupational exposure to chromium (VI), which are representative of the range of tasks undertaken where exposure to chromium (VI) is possible, including tasks involving process and maintenance operations (requirement for CT and SD).

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- The effectiveness of the risk management measures and operational conditions in place are regularly reviewed, and, as applicable, 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 or containers and other solid waste containing chromates (especially sodium and potassium dichromate), in accordance with the hierarchy of control provisions set out in Article 5 of Directive 2004/37/EC.
- Companies handling solid sodium chromate restrict access to the area on the days of production by adequate procedures, allowing only the operators involved in the production in the respective area.
- 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.

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 or aprons for specific tasks)
- Eye protection as per relevant risk assessment

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- 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.

Use of Assigned Protection Factors (APFs) throughout this CSR

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. RPE is described according to the types of devices that will be in use rather than APF values to be met. Since APFs vary numerically between countries and no generally accepted factors exist, a conservative approach is taken in this review report, when APFs are used to calculate workers exposure. Where an APF is cited for a type of RPE, this will correspond to the lowest APF value for that type of RPE over all countries listed in the Table to Annex V.

The specific PPE for each task is described in detail in the worker contributing scenarios in sections 9.2.3.2 to 9.2.3.7.

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 in wet scrubbers or 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 internally, and at most companies also by external services.

Wet scrubbers are controlled by measuring pH, conductivity or Cr(VI) concentration, ensuring proper function. 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

Cr(VI)-containing wastewater is gathered and either

- Sent directly to a waste management company (licensed contractor) for disposing it as hazardous waste or
- Recycled and evaporated in an on-site evaporation system (the residue is discharged by an external company certified for disposing of hazardous waste), or

- Treated onsite in a reduction facility: Cr(VI) in wastewater is reduced to Cr(III) by addition of a reducing agent (e.g., sodium bisulfite or ferrous sulfate). After the reduction process, Cr(III) is precipitated and separated from the wastewater by a filter press (the filter cake is disposed as waste), and the treated wastewater is typically discharged to an external wastewater treatment plant (WWTP) or municipal sewage treatment plant (STP).

For the reduction of environmental emissions to wastewater to the maximum extent possible, as organisational measures monitoring programmes for Cr(VI) emissions to wastewater are implemented and the effectiveness of the risk management measures and operational conditions in place are regularly reviewed.

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 may include the filter cake from the filter press (only contains Cr(III)), solid residues from the evaporation system for wastewater, and Cr(VI) contaminated waste from activities related to the formulation activities (e.g., empty chemical containers and bags, filters, waste from cleaning activities, contaminated PPE).

The filter cake containing Cr(III) is collected and stored in containers and forwarded to an external waste management company (licensed contractor) for disposal as waste.

The solid residues from the evaporation system for wastewater are collected and discharged as hazardous solid waste by an external waste management company (licensed contractor).

The Cr(VI)-contaminated solid waste such as contaminated wipes and PPE (gloves, coveralls, aprons, ...) or empty chemical containers (canisters, bags, drums) are usually disposed as hazardous waste unless they are cleaned prior to their disposal (if they are cleaned, they are disposed as non-hazardous solid waste). This hazardous solid waste is stored in closed drums and 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 mixtures at four sites in the EEA. The overall tonnage formulated in the EEA for manufacturing products used by the aerospace and defence industry and its supply chains is estimated as follows:

Up to 310 t Cr(VI)/year as CT (approx. 600 t/year CT)

Up to 40 t Cr(VI)/year as SD (approx. 100 t/year SD)

Up to 15 t Cr(VI)/year as PD (approx. 42 t/year PD)

Up to 0.35 t Cr(VI)/year as SC (approx. 1.1 t/year SC).

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.

Note that at some sites chromates are also used for other purposes, e.g. reduction to Cr(III) substances. For several formulators products for the aerospace and defence supply chains only is a part of their business with Cr(VI) substances.

Amount of Cr(VI) released to wastewater

Only a minor share of the total amount of Cr(VI) used at the site goes into wastewater, if any. The Cr(VI) concentration in wastewater prior to reduction is not measured at the sites. During the reduction step Cr(VI) is converted to Cr(III) and after precipitation collected in a filter press. As the concentration of Cr(III) in the filter cake is not measured, the amount of chromium leaving the process via the filter cake cannot be assessed.

At those sites, which sent Cr(VI) to wastewater, the residual Cr(VI) in wastewater after reduction, which is released to an external STP or WWTP, is between 0.004 and 0.32 kg per year (as described below in section 9.2.3.1.2).

Amount of Cr(VI) discharged as waste

Cr(VI) in solid waste occurs only in the form of solid residues from the wastewater evaporation systems (at sites where this technique is performed) and as contaminated cleaning materials, filters and PPE; the quantities are negligible and not quantifiable. Some sites discharge (part of) their Cr(VI) wastewater as liquid waste by sending it to an external company certified for disposing of liquid hazardous waste. These quantities are highly variable and not consistently quantifiable.

Cr(VI) captured from the LEV systems in wet scrubbers are sent to wastewater and are treated the same way as cleaning water. Where dry filters are used to capture aerosols, Cr(VI) is disposed of with the filters as hazardous waste, but no information is available for quantification.

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 exhaust air which is released via stacks is between 0.0012 and 0.056 kg per year (as described below in section 9.2.3.1.2). At the sites, the exhaust air is treated in wet scrubbers or by air filters before release (see above).

9.2.3 Exposure scenario 1 for Use 1: “Formulation of mixtures with soluble Cr(VI) compounds for use in aerospace and defence industry and its supply chains for surface treatments “

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 aqueous or solid mixtures containing water-soluble chromates from solid substances or liquid mixtures (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 companies performing these activities.

9.2.3.1 Environmental contributing scenario 1

As CT, SD, PD, and SC 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 CT (flakes), pure substance (100%); 52% Cr(VI)
Product B: Solid SD (powder), pure substance (100%); 40% Cr(VI)
Product C: Solid PD (powder), pure substance (100%); 35% Cr(VI)
Product D: Solid SC (powder), pure substance (100%); 32% Cr(VI)
Product E: Aqueous solution of CT as purchased (up to 50% CT (w/w)); max. 26% (w/w) Cr(VI)

Product F: Aqueous solution of SD as purchased (up to 70% SD (w/w)); max. 28% (w/w) Cr(VI)
Amount used, frequency and duration of use (or from service life)
<p>Product A: Solid CT (flakes), used to prepare mixtures</p> <ul style="list-style-type: none"> ▪ Total amount used annually in EEA: <ul style="list-style-type: none"> ▪ Up to 310 t Cr(VI)/year as CT ▪ Batch process ▪ Up to 365 days/year (see section 9.1.2.4.)
<p>Product B: Solid SD (flakes or powder), used to prepare mixtures</p> <ul style="list-style-type: none"> ▪ Total amount used annually in EEA: <ul style="list-style-type: none"> ▪ Up to 40 t Cr(VI)/year as SD ▪ Batch process ▪ Up to 10 days/year for aerospace and defence applications (see section 9.1.2.4.)
<p>Product C: Solid PD (flakes or powder), used to prepare mixtures</p> <ul style="list-style-type: none"> ▪ Total amount used annually in EEA: <ul style="list-style-type: none"> ▪ Up to 15 t Cr(VI)/year as PD ▪ Batch process ▪ Up to 10 days/year for aerospace and defence applications (see section 9.1.2.4.)
<p>Product D: Solid SC (flakes or powder), used to prepare mixtures</p> <ul style="list-style-type: none"> ▪ Total amount used annually in EEA: <ul style="list-style-type: none"> ▪ Up to 0.35 t Cr(VI)/year as SC ▪ Batch process ▪ Up to 10 days/year for aerospace and defence applications (see section 9.1.2.4.)
<p>Product E: Aqueous solution of CT as purchased, used to prepare mixtures</p> <ul style="list-style-type: none"> ▪ Total amount used annually in EEA: <ul style="list-style-type: none"> ▪ Included above ▪ Batch process ▪ Up to 50 days/year for aerospace and defence applications (see section 9.1.2.4.)
<p>Product F: Aqueous solution of SD as purchased, used to prepare mixtures</p> <ul style="list-style-type: none"> ▪ Total amount used annually in EEA: <ul style="list-style-type: none"> ▪ Included above ▪ Batch process ▪ Up to 10 days/year for aerospace and defence applications (see section 9.1.2.4.)
Technical and organisational conditions and measures

All products:

▪ **Technical measures**

- Air
 - Mixing vessels are equipped with LEV and
 - exhaust air is treated in wet scrubbers or by air filters before it is released via stack(s)
- Wastewater
 - Wastewater occurs from rinsing water, cleaning water, water from wet scrubbers, and liquid hazardous waste from the laboratory
 - Cr(VI)-containing wastewater is gathered and either sent directly to a certified external company for disposal or recycled and evaporated in an on-site evaporation system (and the residues sent to an external company certified for disposing of hazardous waste),
 - or treated onsite in a reduction facility, where Cr(VI) in wastewater is reduced to Cr(III) by addition of a reduction agent (e.g., sodium bisulfite or ferrous sulfate), followed by neutralisation and precipitation of Cr(III)
 - Reduced wastewater is sent to an external wastewater treatment plant (WWTP) or municipal sewage treatment plant (STP) (depending on local regulatory requirements).
- Soil
 - The indoor and outdoor surfaces where chemicals are handled are sealed and chemicals and solid waste containing Cr(VI) are stored in closed containers.
 - Mixing vessels and tanks are surrounded by tank pits, which collect splashes and wash water and direct it to the wastewater collection tank.

▪ **Organisational conditions and measures**

- Air
 - Cr(VI) air emission measurements are performed regularly at identified exhaust stack(s) where the process emissions are released
- Wastewater
 - Reduction of Cr(VI) in wastewater is controlled regularly by Cr(VI) measurements
 - Batches of reduced wastewater are discharged only after confirmation of Cr(VI) reduction to a concentration below the permitting limit (in accordance with the local regulatory requirements)

Conditions and measures related to sewage treatment plant

All products:

- Biological (municipal) STP: Standard STP (removal rate: 50% to sludge assumed, see description in section 9.1.2.4.)
- Sludge application to agricultural soil: in most cases not; however, as it is not ascertained in all cases, for a conservative assessment sludge application is assumed

<ul style="list-style-type: none"> ▪ Discharge rate STP: 2000 m³/day (by model default, if no site-specific data available) ▪ Dilution factor for receiving water body: 10 (by model default, if no site-specific data available)
Conditions and measures related to treatment of waste (including article waste)
<p>All products:</p> <ul style="list-style-type: none"> ▪ Filter cake from the wastewater reduction plant only contains Cr(III) (since, even if the reduction were incomplete, residual Cr(VI) is readily soluble in water and would be found in the water phase) and is forwarded to an external waste management company (licenced contractor) for disposal as waste. ▪ Other solid hazardous waste contaminated with Cr(VI) such as contaminated wipes and PPE or empty chemical containers (canisters, bags, drums) are usually also disposed as hazardous waste unless they are cleaned prior to their disposal (if they are cleaned, they are disposed as non-hazardous solid waste). This hazardous solid waste is stored in closed drums and containers and forwarded to an external waste management company (licensed contractor) for disposal as hazardous waste.
Other conditions affecting environmental exposure
<p>All products:</p> <ul style="list-style-type: none"> ▪ Processes are carried out at ambient temperature ▪ Mixing vessels are covered by lids (except during charging) ▪ Mixing vessels as well as tank truck filling stations are placed over tank pits to avoid environmental contamination (secondary containment pit)
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
<ul style="list-style-type: none"> ▪ None

Manufacture of chromate-containing mixtures for use in the aerospace and defence industry and its supply chains is carried out at few dedicated industrial formulation sites in the EEA. Production is batch-wise and, depending on the site conditions, substances, and products, occur from a few days per year to daily.

Air emissions

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

Contaminated water from wet scrubbers is treated as wastewater using the specific wastewater treatment technology at the site (see below).

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

Exhaust air from dedicated decanting and weighing stations (e.g., in the storage area), where the raw material is aliquoted, may also contribute to the air emissions of a site. However, due to the low frequency of such aliquoting processes, these emissions are negligible.

Wastewater emissions

Cr(VI) containing wastewater mainly arises from using water for cleaning purposes and from wet scrubbers. Wastewater is always treated by one of the following ways:

- Wastewater is collected and sent to an external waste management company (licensed contractor) for disposal
- (or) Wastewater is treated on-site in a reduction plant, where Cr(VI) in wastewater is reduced to Cr(III) by addition of a reduction agent (e.g., sodium bisulfite or ferrous sulfate, sodium dithionite in case of basic conditions)

In the former case external exposure is often preceded by a recycling step to regain purified water for production and to reduce the wastewater volume.

The wastewater typically is either led directly to large tanks or gathered in IBCs, the content of which is then pumped into the wastewater tanks for treatment. For the on-site reduction of Cr(VI) in wastewater the reducing agent is provided in excess, to ensure Cr(VI) reduction to a concentration below the permitting limit. Afterwards the wastewater is neutralised and Cr(III) is precipitated by addition of flocculant. The precipitated Cr(III) is then separated from the wastewater by a filter press and the filter cake is disposed by a certified waste handling company. In the reduced wastewater the Cr(VI) content is usually measured with a photometric method or atom absorption spectroscopy to confirm sufficient reduction in accordance with the permitted limit before the wastewater is released either to an external wastewater treatment plant (WWTP) or municipal sewage water treatment plant (STP). In addition to the photometric determination of Cr(VI) in wastewater on-site, the Cr(VI) concentration in reduced wastewater is at many sites also determined in regular intervals by external laboratories and/or the local authorities, whereby often more sensitive analytical methods are used, allowing the detection of very low Cr(VI) concentrations in wastewater (50 µg Cr(VI)/L or lower).

Soil emissions

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

9.2.3.1.2 Releases

There are four formulation companies with four sites in the EEA which produce formulations with the substances addressed here. Site-specific emission data are available for all four sites and were used for environmental emission modelling. Note that for some sites formulation of products intended for aerospace and defence supply chains comprise only part of their Cr(VI)-related activities (4 – 100%, depending on site) (at the site with 4% a larger part of the Cr(VI) is used for manufacturing Cr(III) products). Only the releases from formulating products for aerospace and defence supply chains are considered here.

The release fractions shown in Table 9-15 and presented as ranges served as input for EUSES modelling of human exposure via the environment. Note that the calculated releases to water refer to the emissions after the reduction step. Two out of the four sites don't release Cr(VI) to wastewater as all contaminated water is gathered and sent to a certified service provider for disposal.

Table 9-15: Local releases to the environment

Release route	Release fraction ^a	Release [kg/year] ^a	Explanation/Justification
Water ^b	7.5E-09 - 2.1E-06*	0 – 0.32	Measured release (site-specific data)
Air ^b	9.7E-08 - 1.9E-07**	0.0012 – 0.056	Measured release (site-specific data)
Soil ^b	0	0	No release to soil

^a The indicated ranges of release fractions to wastewater, air and soil are based on recent release data and tonnages provided by sites.

^b For values <LOQ a value corresponding to LOQ/2 was used, as described in ECHA's Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment (ECHA, 2016a). For wastewater emissions this is very likely an overestimation, since the upstream redox process leads to the almost complete conversion of Cr(VI) into Cr(III).

* Release fractions for water based on tonnage information from two sites (two sites don't release to wastewater)

** Release fractions for air based on tonnage information from three sites

For the sites of formulators covered in this CSR, the release fractions to wastewater range from 0 to 0.32 kg/year and the release fractions to air from 0.0012 to 0.056 kg/year. The release to soil is zero for all sites since there are no direct releases to soil.

A summary of the EUSES input data and release fractions derived from environmental monitoring data of representative sites is presented in Annex III of this report.

Releases to waste

Solid wastes are disposed of as described above by certified companies 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

The calculated exposure concentrations for humans via the environment (on a local scale) per site are shown in Annex III. The EUSES modelling protocols can be provided upon request.

The calculation of the share of exposure from formulation of products for aerospace and defence supply chains is shown below in Table 9-16.

Formulation

SD

Table 9-16: Exposure concentrations for humans via the environment – on local scale

	Inhalation			Oral			
Site	Local Cr(VI) PEC in air [$\mu\text{g}/\text{m}^3$]	Excess cancer lung risk [$1/(\mu\text{g}/\text{m}^3)$] ^a	Inhalation risk	Oral exposure (water and fish) [$\mu\text{g Cr(VI)}/\text{kg x d}$]	Excess cancer risk for tumours of the small intestine [$1/(\mu\text{g}/\text{kg bw}/\text{day})$] ^b	Oral risk	Combined risk
1	9.03E-07	2.90E-02	2.62E-08	7.55E-05	8.00E-04	6.04E-08	8.66E-08
2	3.17E-05	2.90E-02	9.19E-07	1.15E-06	8.00E-04	9.24E-10	9.20E-07
3	1.30E-06	2.90E-02	3.77E-08	1.32E-07	8.00E-04	1.06E-10	3.78E-08
4	4.28E-05	2.90E-02	1.24E-06	1.07E-06	8.00E-04	8.54E-10	1.24E-06
MIN	9.03E-07		2.62E-08	1.32E-07		1.06E-10	3.78E-08
MAX	4.28E-05		1.24E-06	7.55E-05		6.04E-08	1.24E-06

^a RAC dose-response relationship based on excess lifetime lung cancer risk (ECHA, 2013): Exposure to $1 \mu\text{g}/\text{m}^3$ Cr(VI) relates to an excess risk of 2.9×10^{-2} for the general population, based on 70 years of exposure; 24h/day.

^b RAC dose-response relationship based on excess cancer risk for tumours of the small intestine (ECHA, 2013): Exposure to $1 \mu\text{g}/\text{m}^3$ Cr(VI) relates to an excess risk of 8×10^{-4} for the general population, based on 70 years of exposure; 24h/day

Table 9-17: RCRs for reproductive toxicity for humans via the environment

	Inhalation			Oral		
Site	Inhalation exposure [$\mu\text{g}/\text{m}^3$]	DNEL inhalation systemic long-term [$\mu\text{g}/\text{m}^3$]	RCR inhalation	Oral exposure [$\mu\text{g}/\text{kg} \times \text{d}$]	DNEL oral systemic long-term [$\mu\text{g}/\text{kg} \times \text{d}$]	RCR oral
1	9.03E-07	11	8.21E-08	7.55E-05	17	4.44E-06
2	3.17E-05	11	2.88E-06	1.15E-06	17	6.79E-08
3	1.30E-06	11	1.18E-07	1.32E-07	17	7.78E-09
4	4.28E-05	11	3.89E-06	1.07E-06	17	6.28E-08
MIN	9.03E-07		8.21E-08	1.32E-07		7.78E-09
MAX	4.28E-05		3.89E-06	7.55E-05		4.44E-06

Conclusion on risk characterisation:Carcinogenicity

Combined risk of cancer by inhalation and by oral route from the local assessment result in excess cancer risks at the four sites of **3.78E-08 to 1.24E-06**. These theoretical cancer risks are low and 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.

Reproductive toxicity

Risks for reproductive toxicity are negligible as RCRs for inhalation and oral exposure are orders of magnitude below 1.

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 review report is based on measured emission data for emission to air and wastewater. 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 4.28E-05 to 9.03E-07 $\mu\text{g}/\text{m}^3$ (inhalation exposure) and 7.55E-05 to 1.32E-07 $\mu\text{g}/\text{kg} \times \text{d}$ (oral), resulting in an estimated excess cancer risk for both pathways combined of 3.78E-08 to 1.24E-06.

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

Application ID	90 th percentile of PEC _{local air} [$\mu\text{g}/\text{m}^3$]	Excess lung cancer risk
0032-01 (CT)	4.86E-5	1.41E-6
0043-01 (SD)	3.81E-02	1.10E-03
0044-01 (PD)	6.66E-03	1.93E-4
0099-01 (SC)	6.19E-5	1.80E-6

The assessments and consequently the excess lung cancer risk in the initial applications are for individual chromates. The risks calculated in this review report are based on measured emissions for various substances, as used at the sites.

Our risk estimates based on measured release data are lower than the risks calculated in the initial applications.

9.2.3.2 Worker contributing scenario 1 – Operators producing liquid mixtures

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 with solid or liquid material (PROC 8a, 8b) and surveying mixing process (PROC 5)
- Task 3: Transfer of liquid products to storage tanks or containers (PROC 8b)
- Task 4: Sampling (PROC 9)
- Task 5: Cleaning of workplaces and equipment (PROC 28)
- Task 6: Repair and maintenance activities (emptying lines in case of repairs) (PROC 28).
- Task 7: 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.

9.2.3.2.1 Conditions of use

Table 9-18 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

Table 9-18: Conditions of use – worker contributing scenario 1 – Operators (liquid mixtures)

Product (article) characteristics
<p>Product 1: Solid CT, SD, PD or SC (flakes or powder) for Tasks 1, 2, and 7</p> <ul style="list-style-type: none"> ▪ Substance product type: Powders, granules or pelletised material ▪ Dustiness: Flakes or powder ▪ Moisture content: Dry product (< 5 % moisture content) ▪ Weight fraction: Pure material (100%) ▪ Concentration in pure substance: 52% Cr(VI) for CT, 40% Cr(VI) for SD, 35% Cr(VI) for PD, 32% Cr(VI) for SC
<p>Product 2: Aqueous solutions of CT or SD for Tasks 1, 2, and 7</p> <ul style="list-style-type: none"> ▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix ▪ Viscosity: Liquids with low viscosity (like water) ▪ Concentration of substance in mixture: = max. 50% CT or 70% SD (w/w)); max. 28% (w/w) Cr(VI)
<p>Product 3: Liquid mixture of CT, SD, PD or SC for Tasks 3-6</p> <ul style="list-style-type: none"> ▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix ▪ Viscosity: Liquids with low viscosity (like water) ▪ Concentration of substance in mixture: max. 28% (w/w) Cr(VI) (based on up to 50% CT or 70% SD (w/w) in liquid products)

Amount used (or contained in articles), frequency and duration of use/exposure
<p>Task 1: Weighing of solid material</p> <ul style="list-style-type: none"> ▪ Duration of activity 8-15 min/batch, 1 – 2 batches/shift ▪ Frequency of task: approx. 20 batches per year, 1 – 2 batches/shift
<p>Task 2: Charging mixing vessels and surveying the mixing process</p> <ul style="list-style-type: none"> ▪ Duration of activity 60 -300 min/batch, 1 – 2 batches/shift ▪ Frequency of task: 10 to 400 batches per year, 1 – 2 batches/shift
<p>Task 3: Transfer of liquid products to storage tanks or containers</p> <ul style="list-style-type: none"> ▪ Duration of activity: 60 to 480 min/batch ▪ Frequency of task: 10 to 400 batches per year, 1 – 2 batches/shift
<p>Task 4: Sampling</p> <ul style="list-style-type: none"> ▪ Amount: 100-1000 mL ▪ Duration of activity: 5 min ▪ Frequency of task: once per batch, up to 400 batches per year, 1 – 2 batches/shift
<p>Task 5: Cleaning of workplaces and equipment</p> <ul style="list-style-type: none"> ▪ Duration of activity: up to 45 min/day ▪ Frequency of task: approx. 240 days per year
<p>Task 6: Repair and maintenance activities</p> <ul style="list-style-type: none"> ▪ Duration of activity: 15 - 60 min/day ▪ Frequency of task: approx. 48 days per year
<p>Task 7: Waste management – disposal of solid waste</p> <ul style="list-style-type: none"> ▪ Duration of activity: 5 - 10 min ▪ Frequency of task: approx. 240 days per year
Technical and organisational conditions and measures
Companies handling solid sodium chromate restrict access to the area on the days of production
<p>Task 1: Weighing of solid material</p> <ul style="list-style-type: none"> ▪ LEV: No ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
Task 2: Charging mixing vessels and surveying the mixing process

<ul style="list-style-type: none"> ▪ LEV: yes ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 3: Transfer of liquid products to storage tanks or containers</p> <ul style="list-style-type: none"> ▪ LEV: Yes ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 4: Sampling</p> <ul style="list-style-type: none"> ▪ LEV: No ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 5: Cleaning of workplaces and equipment</p> <ul style="list-style-type: none"> ▪ LEV: No ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 6: Repair and maintenance activities</p> <ul style="list-style-type: none"> ▪ LEV: No ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 7: Waste management – cleaning of containers, disposal of solid waste</p> <ul style="list-style-type: none"> ▪ LEV: situation-dependent ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Conditions and measures related to personal protection, hygiene, and health evaluation</p>
<p>Gloves</p> <p>Chemical resistant gloves are worn during all tasks (Task 1 to 7).</p> <p>All gloves used for the handling of chemicals are tested according to EN 374. A variety of materials are suited for protection against chromates.</p> <p>The following materials have a breakthrough time ≥ 8h for aqueous CT solutions (10% CT) and saturated aqueous SD solutions ^a:</p> <ul style="list-style-type: none"> ○ Natural rubber/Natural latex (0.5 mm) ○ Polychloroprene (0.5 mm)

- Nitrile rubber/Nitrile latex (0.35 mm)
- Butyl rubber (0.5 mm)
- Fluorocarbon rubber (0.4 mm)
- Polyvinyl chloride (0.5 mm)

The following materials have a breakthrough time ≥ 8 h for aqueous CT solutions (50% CT) ^a:

- Fluorocarbon rubber (0.4 mm)

The following materials have a breakthrough time ≥ 2 h for aqueous CT solutions (50% CT) ^a:

- Polychloroprene (0.5 mm)
- Butyl rubber (0.5 mm)
- Polyvinyl chloride (0.5 mm)

The following material is assumed to have a breakthrough time ≥ 4 h for solid CT and SD:

- Butyl rubber (0.7 mm)

Type of gloves to be used for specific tasks is laid down in work instructions for the tasks.

For shorter exposure periods and low concentrations material thickness can be adapted according to rules provided by glove suppliers.

Respiratory protection equipment

RPE is worn during all tasks involving solid chromates (Tasks 1, 2 and 7).

The following types of RPE are used according to EN 529:2005 ^b:

- Full mask with P3 filter or P3 combination filter (APF 20)
- Powered filtering device incorporating a hood, helmet or a full mask (APF 40)

Type of RPE to be used for specific tasks is laid down in work instructions for the tasks.

Protective clothes

Chemical protective clothes or a protective suit or apron must be worn during tasks 1 to 7. Coveralls are worn during handling solid chromates (Task 1 and 2) and during cleaning of workplaces with water hoses (Task 5). For all cleaning activities performed with a hose the workers wear waterproof boots (Task 5).

Type of protective clothes to be used for specific tasks is laid down in work instructions for the tasks.

Eye protection

Eye protection as per relevant risk assessment is worn during all tasks (Task 1 to 7).

Type of eye protection to be used for specific tasks is laid down in work instructions for the tasks.

Other conditions affecting workers' exposure

Task 1: Weighing of solid material

- Place of use: indoors – large size workroom
- Temperature: room temperature
- Activity class: Movement and agitation of powders, granules or pelletised material

<ul style="list-style-type: none"> ▪ Situation: Handling with low level of agitation ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 2: Charging mixing vessels and surveying the mixing process</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: a) Falling of powders, granules or pelletised material; b) Transfer of liquid products ▪ Situation: a) Transferring 1 – 10 kg/minute; b) Transferring 10 – 100 L/minute ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 3: Transfer of liquid products to storage tanks or containers</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: Transfer of liquid products ▪ Situation: Transferring 10 – 100 L/minute ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 4: Sampling of preparations</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: Transfer of liquid products ▪ Situation: Transferring 0.1 – 1 L/minute ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 5: Cleaning of workplace and equipment</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – any size workroom ▪ Temperature: room temperature ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 6: Repair and maintenance activities</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – any size workroom ▪ Temperature: room temperature

<ul style="list-style-type: none"> ▪ Activity class: Handling of contaminated solid objects or paste ▪ Situation: Handling of slightly contaminated (layers of less than few grams) objects ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 7: Waste management – cleaning of containers, disposal of solid waste</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – any size workroom ▪ Temperature: room temperature ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m) ▪ Activity class: Handling of contaminated solid objects or paste (worst case assumption, see details in section 9.2.3.2.2) ▪ Handling type: Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.
<p>Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply</p>
<ul style="list-style-type: none"> ▪ None

^a <https://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index.jsp> ; accessed 8 December 2020

^b For selection of APF see Annex VI of this report.

9.2.3.2.2 Exposure and risks for workers

Depending on the nature and amount of the mixtures produced, the situation at the formulators varies largely. At some sites, chromate-containing products are manufactured only a few days per year (batch-wise production in campaigns upon demand) and these products make only a small part of their portfolio. Other companies are highly specialised on (few) Cr(VI) containing products which are produced for the larger part of the year. The latter one is relevant only for mixtures containing CT. Products of all formulators are only partly destined for the aerospace and defence industry and its supply chains.

Increasingly, solid chromates are replaced at some sites by use of liquid master batches (concentrated aqueous solutions) to reduce exposure to chromate dust. In this case Task 1 is not relevant.

Typically, 1 to 3 operators oversee mixing operations. At most sites, during these production campaigns no other personnel is allowed in the respective working area. Filling of containers is either performed by the same individuals after mixing is complete or by other operators (1 to 2).

Companies typically operate in a 1-shift system. The size of batches varies largely, between 50 L and 9000 L (9 m³). On some occasions, large batches of diluted chromium trioxide with volumes up to 30 m³ are produced.

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

Decanting and weighing is required only for some recipes, especially those requiring smaller amounts of chromates. For larger batches, typically, total content of (several) containers is used for production.

Weighing of solid material (flakes) (up to 100 kg) is performed on a floor mounted weighing scale. Typically, weighing and aliquoting the required amounts takes 8 to 15 min per batch. Weighed material is transported in a container with closed lid to the mixing area. When possible, premixes of solid material in water are prepared at the weighing station, to avoid dust exposure during filling the mixing vessels.

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

If not weighed before (see above), raw materials are transported from the storage area in closed containers (drums or bags, from 20 to 250 kg) by forklift or jack lift to the mixing (or weighing) area. In most cases, the operators are responsible for the transport, but, depending on the company-internal organisation, also logistic operators may be performing it. However, logistic operators never open the containers. Typically, the containers (20 to 50 kg) are lifted to the level of the opening hole of the mixing vessel and emptied manually into the vessel, which already contains water and other mixture components. The lid of the mixing vessel is closed immediately after introducing the material. All mixing vessels are equipped with LEV, producing negative pressure at the opening. Only complete drums (or aliquoted amounts, see above, weighing) of solid material are poured into the mixing vessels. Therefore, no solid material remains in the used containers.

Companies using high quantities of solid materials use drum grappler for lifting and emptying drums in the mixing vessel. Such devices can also be used to clean the drums in situ: empty drums are automatically turned upside-down by the grappler and cleaned by a water jet. The water used for cleaning is fed into the mixing vessel and used for production.

The company handling the largest amounts of chromium trioxide per batch developed a semi-automatic device for lifting large drums (250 kg) by a drum grappler. The device works with a top part with an automatic lid, which impedes that air from the mixing vessel escapes during pouring the material into the vessel. Thereby dust generation is reduced to a minimum. The grappler takes drums from the palette and places it close to the LEV located sidewise. An operator opens the drum and places the top part on top of the drum. The grappler takes the drum, turns it upside-down and the content is poured into the vessel. An operator pounds on the drum from the outside to allow for complete emptying of the drum. The grappler then turns the empty drum again (with the opening closed by the top part), places it on the palette again, where the drum is closed again by the operator, after removal of the top part.

Liquid stock solutions are typically delivered in IBCs by forklift or jack lift, which can be closed and transported back to the storage area, if not consumed completely. The liquid material is pumped into the mixing vessels. Jack lifts are equipped with a scale, allowing to monitor the amount of material pumped into the mixing vessel. Equipment is either used continuously without cleaning or flushed with water and the wash water used for production. After use, suction lances are safely stored in containers adjacent to the mixing vessels to avoid contamination with droplets.

Mixing vessels (from 1 to 9 m³) are equipped with exhaust ventilation and internal automatic stirrers. One or two batches are typically produced on a production day. Filling raw materials into the vessel requires 60 to 120 min per batch, the whole mixing process up to 5 hours.

Task 3: Transfer of liquid products to storage tanks or containers (PROC 8b)

At some sites separate groups of workers (all belonging to the SEG of formulation operators) are responsible for surveying the mixing operations and for filling the containers but at other sites it is the same workers during a specific shift, or they are alternating their activities (one shift mixing, next shift filling of containers).

The final liquid mixtures are either pumped to storage tanks (typically of up to 1 m³, e.g., IBC, up to 16 m³ max) or directly to product containers (via filters) through closed lines. Typically, sizes of containers vary between 25 and 1000 L. Containers are placed on a scale and filled by the line from the storage tank until the correct weight is achieved. A mobile LEV is placed on top of the opening of the container. The line and the valve are flushed with water, which is gathered in a separate IBC (the wash water is either used as process water to produce the formulations or sent to wastewater). Finally, the container is closed. Filled and closed containers are stored in the storage area awaiting transport to the users.

Some sites are equipped with automated filling lines, allowing the operator to survey the process from a larger distance. The filling line automatically is equipped with exhaust ventilation. It provides containers (up to 25 L) with labels, and controls the amount filled. It also allows for automatic cleaning of the lines before filling the next batch and for taking samples. The operator, apart from surveying the process, only needs to close the containers.

Semi-automated IBC filling takes place in a stand with integrated scale. IBCs are filled by closed lines from the mixing vessel and also allow to take samples. Access to the stand is restricted and not allowed when lines are open.

Water from cleaning lines is either gathered in IBCs and transported to the wastewater treatment facility or directed immediately to wastewater.

Task 4: Sampling (PROC 9)

Typically, one sample (up to three in rare occasions, in case of quality problems) is taken per produced batch for quality control. Samples can be taken from the mixing or storage tank, e.g., by means of a pump with valve. The sampling bottle is filled via a funnel or directly by introducing a flexible tube into the sampling bottle. Sample sizes vary between 100 mL and 1 L. Bottles are closed and transported to the lab by the operator. Samples are taken from the mixing vessel, while LEV is running.

Automated lines for filling containers or semi-automated filling of IBCs have automated sampling procedures included, as described above, which avoid contact of the operator with the products.

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

The mixing vessels are placed over tank pits (secondary containment pit) to avoid any release of contaminated water.

Formulation

SD

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, some companies use plastic foil or a temporary peelable coating 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.

At the site where large batches with CT are produced, at the end of the shift splashes or contamination with solid material is hosed down with water and contaminated equipment is also cleaned with a hose. The cleaning water is either used as process water or led to the wastewater gathering points.

Depending on the situation, cleaning activities take 30 to 60 minutes per day.

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

Repairs are infrequent and concern, e.g., broken pumps or similar equipment. In case of repairs lines are emptied and flushed with water by operators. Where there is visible contamination, flushing is repeated with bisulfite solution to reduce Cr(VI). After these cleaning steps, cleaned parts can be removed by maintenance workers.

Repairs requiring opening of the lines is infrequent. A conservative estimate is once per week at some sites, other report less activities. A frequency of once per week, with a duration of up to 1 hour is assumed here. As operators are mainly involved by operating the lines, exposure from this activity is considered to be low.

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

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

Empty bags are carefully and slowly folded (to avoid emission of contaminated dust). Where possible a mobile LEV is applied. Folded bags are put into a closed drum or a sealed big bag, adequately labelled and disposed of as hazardous waste by an external waste management company (licenced contractor). Empty drums are either discharged without cleaning as hazardous waste or returned to their supplier for disposal. At one site, drums are cleaned in situ above the mixing vessel (see above): drums are places upside down and the inside of the drums is rinsed with a low-pressure water jet; the rinsing water is led to the mixing vessel. At another site, processing large amounts of CT, empty drums are cleaned in semi-automatic “washing machines”. For machine washing drums are opened under LEV and placed manually upside down in the washing machine. Up to 5 large or 12 small drums can be placed simultaneously, plus smaller contaminated equipment, e.g., the top part (see above). Cleaning water again is gathered and either used as process water (yes, in case of the washing machine) or sent to wastewater treatment. Cleaned drums are disposed of as waste.

Some formulators take back empty IBCs from their clients. Empty plastic IBCs are sent back to the IBC producer without prior cleaning for disposal. Steel IBCs are used in a recycling system and refilled

9.2.3.2.2.1 Inhalation exposure

Measured inhalation exposure concentrations

Twenty-one longer-term (>2h), shift-representative personal measurements are available, which were taken at operators manufacturing liquid chromate mixtures containing CT, SD or SC. RPE is worn by the operators during the periods with potential exposure, especially during filling the mixing vessels with solid or liquid raw materials. Further, 15 stationary measurements close to the mixing vessels are available, which support the personal measurements (3 additional measurements were dismissed as the distance to the workplaces was unclear). The summary statistics of these values, obtained from three sites located in the EU, are given in the following table (measurements from the fourth site, producing mainly solid mixtures, are presented in section 9.2.3.3.2). All measurements are from the period 2017 to 2021. The majority of values (n=15) is for formulating CT and no differences between substances can be discerned. Therefore, combined datasets are evaluated.

A file with the individual measurements can be provided upon request. Information on the analytical methods used is provided in Annex IV.

Table 9-19: Summary statistics of workplace measurements for WCS 1 – Mixing operators

Type of measurement	Number of measurements	Values >LOQ	AM [$\mu\text{g}/\text{m}^3$]	Median [$\mu\text{g}/\text{m}^3$]	90 th percentile [$\mu\text{g}/\text{m}^3$]
Personal	21	21	3.3	3.5	8.4
Stationary	15	15	0.5	0.22	1.9

Stationary measurements show exposures with an arithmetic mean and 90th percentile value lower by a factor of 4 – 7 (median is lower by one order of magnitude) compared to values obtained from personal sampling. The measurements are representative for the main activities of filling the mixing containers with liquid or solid material and filling product containers (Tasks 1 to 3). As several of the measurements are covering the total shift sampling can also be considered to be included (Task 4) as well as workplace cleaning and handling of waste (Tasks 5 and 7). The only activity potentially not covered is preparing equipment for maintenance (Task 6). However, as emptying and flushing lines is done only infrequently, over short periods only and involves handling of diluted liquid mixtures only, often in closed lines, the impact on long-term average exposure levels is expected to be negligible.

Table 9-20 shows the resulting long-term inhalation exposure concentration for formulation operators used for risk assessment, based on the 90th percentile of personal sampling values. As RPE (at least full mask with P3 filter, some sites apply powered filtering devices with a hood) is worn during all critical exposure periods, an adequate APF is used for calculating exposure.

Table 9-20: Inhalation exposure assessment for WCS 1 – Mixing operators

Type of measurement	Number of measurements	Exposure value (8h TWA) ^a [$\mu\text{g}/\text{m}^3$]	Assigned protection factor (APF) for RPE ^b	Exposure value corrected for RPE [$\mu\text{g}/\text{m}^3$]	Long-term exposure [$\mu\text{g}/\text{m}^3$] ^c
Personal	21	8.4	20	0.42	0.42

^a Based on 90th percentile of measurements.

^b Minimum: Full mask with P3 filter or P3 combination filter; according to EN 529:2005 (BSI), see Annex VI of this report.

^c As exposure can be daily at some sites, no correction for frequency is applied

9.2.3.2.2.2 Dermal exposure

In Table 9-21 the task-specific dermal exposures for operators producing liquid mixtures are shown, based on modelling of the activities with Cr(VI) exposure. The parameters considered for dermal exposure modelling are described in detail in Annex V of this report.

Table 9-21: Dermal exposure modelling for WCS 1 –Operators producing liquid mixtures

Task	PROC(s)	Cr(VI) concentration* [%]	Annual average dermal exposure value [$\mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$]
Task 1: Weighing of solid material	PROC 8a, 8b	Max. 40	0.857
Task 2: Charging the mixing vessels with solid or liquid material and surveying mixing process	PROC 8a, 8b, 5	Max. 40	6.86
Task 3: Transfer of liquid products to storage tanks or containers	PROC 8b	Max. 26	4.46
Task 4: Sampling of products	PROC 9	Max. 26	2.67
Task 5: Cleaning of workplaces and equipment	PROC 28	Max. 2.6**	3.87
Task 6: Repair and maintenance activities	PROC 28	Max. 2.6**	0.178
Task 7: Waste management – cleaning of containers, disposal of solid waste	PROC 8b	Max. 40	13.7
Combination of all tasks			32.6

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

* Highest concentration of SD, PD, or SC

** 10-fold dilution assumed due to cleaning activity; for details see Annex V.

Although in a very conservative approach it was assumed that exposure from each activity adds to exposures from other activities (including secondary ones, often performed by other SEGs), the combined dermal exposures from all tasks does not exceed the DNEL.

9.2.3.2.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-22 shows the risk characterisation for carcinogenicity for operators manufacturing liquid mixtures. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure data for mixing operators and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013).

Table 9-22: Risk characterisation for carcinogenicity for WCS 1 – Operators producing liquid mixtures

Route of exposure and type of effects	Long-term exposure [$\mu\text{g}/\text{m}^3$]	Risk characterisation: Excess lifetime lung cancer risk * [$1/\mu\text{g}/\text{m}^3$]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.42 [$\mu\text{g}/\text{m}^3$]	4.00E-03	1.74E-03

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

Risk for reproductive toxicity

Table 9-23 shows the risk characterisation for reproductive toxicity for operators producing liquid mixtures. The risk characterisation for reproductive toxicity is based on measured Cr(VI) inhalation exposure data for the operators and modelled dermal Cr(VI) exposure values which are compared to the RAC DNELs for workers, derived for effects on fertility (ECHA, 2015).

Table 9-23: Risk characterisation for reproductive toxicity for WCS 1 – Operators producing liquid mixtures

Route of exposure and type of effects	Long-term exposure	Risk characterisation: RAC DNEL *	Risk characterisation ratio (RCR)
Inhalation: Systemic Long Term	0.42 $\mu\text{g}/\text{m}^3$	43 $\mu\text{g Cr(VI)}/\text{m}^3$	0.01
Dermal: Systemic Long Term	32.6 $\mu\text{g}/\text{kg bw}/\text{d}$	43 $\mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$	0.76
Combination of inhalation and dermal exposure			0.77

* RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Conclusion on risk characterisation:Carcinogenicity:

The excess life-time cancer risk for operators producing liquid mixtures containing CT, SD, PD or SC is **1.74E-03**.

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 values

As explained above, 1 to 5 mixing operators (including workers engaged in filling containers) are estimated to work at a site in parallel per shift performing this use. For all three sites considered here, in total **9 workers** are estimated to be engaged full-time at the three sites, although the total workforce sharing this work may be higher (a fourth site is mainly engaged in producing solid mixtures, which is discussed in WCS2, section 9.2.3.3).

Reproductive toxicity:

The RCR for the endpoint reproductive toxicity based on a conservative assessment is well below 1 (0.77).

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 producing liquid mixtures in the present assessment is **1.74E-03**.

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0032-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.27 µg Cr(VI)/m	1.08E-03
	Waste management (modelled)	0.22 µg Cr(VI)/m ³	0.88E-03
0043-01, 0044-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.26 µg Cr(VI)/m ³	1.04E-03
	Waste management (modelled)	0.22 µg Cr(VI)/m ³	0.88E-03

0099-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.26 µg Cr(VI)/m ³	1.04E-03
	Sampling (modelled)	0.0014 µg Cr(VI)/m ³	5.6E-6
	Waste management (modelled)	0.00147 µg Cr(VI)/m ³	5.88E-6

Exposure and risk based on measured data is slightly lower in the initial applications. However, risks in the current and initial applications are practically identical if risks from different tasks in the initial applications are combined.

9.2.3.3 Worker contributing scenario 2 – Operators producing solid mixtures

Production of solid mixtures is restricted to a few specialised sites. Operators are typically performing the following tasks:

- Task 1: Charging the mixing vessels (PROC 8a, 8b)
- Task 2: Surveyance of mixing process, transfer of solid products to storage containers (drums, bags) and closure of containers (PROC 5, 8b)
- Task 3: Sampling (PROC 9)
- Task 4: Cleaning of workplaces (PROC 28)
- Task 5: Repair and maintenance activities (PROC 28).
- Task 6: Waste management - disposal of solid waste (PROC 8b).

Typically, 1 operator (out of a team of up to 7 operators) oversees a mixing vessel containing (up to 500 kg formulated product per batch).

9.2.3.3.1 Conditions of use

Table 9-24 summarises the conditions of use for the activities with direct Cr(VI) exposure related to production of solid mixtures by operators.

Table 9-24: Conditions of use – worker contributing scenario 2 – Operators (solid mixtures)

Product (article) characteristics
Product 1: Solid CT, SD, PD or SC (flakes or powder) for Task 1 and Task 6 <ul style="list-style-type: none"> ▪ Substance product type: Powders, granules or pelletised material ▪ Dustiness: Flakes or granules ▪ Moisture content: Dry product (< 5 % moisture content) ▪ Weight fraction: Pure material (100%) ▪ Concentration in pure substance: 52% Cr(VI) for CT, 40% Cr(VI) for SD, 35% Cr(VI) for PD, 32% Cr(VI) for SC
Product 2: Solid mixture of CT, SD, PD or SC for Tasks 2-5

Formulation

SD

<ul style="list-style-type: none"> ▪ Concentration of substance in mixture: max. 32% (w/w) Cr(VI) (based on up to 80% SD in solid products) ▪ Product type: Solid mixture ▪ Dustiness Granules or powder
Amount used (or contained in articles), frequency and duration of use/exposure
<p>Task 1: Charging mixing vessels</p> <ul style="list-style-type: none"> ▪ Duration of activity 8-15 min/batch, 1 – 4 batches/shift ▪ Frequency of task: approx. 160 batches per year, 1 – 4 batches/shift
<p>Task 2: Mixing process and filling containers</p> <ul style="list-style-type: none"> ▪ Duration of activity: 50 - 110 min ▪ Frequency of task: approx. 160 batches per year, 1 – 4 batches/shift
<p>Task 3: Sampling of preparations</p> <ul style="list-style-type: none"> ▪ Amount: approx. 250 g per sample ▪ Duration of activity: < 5 min ▪ Frequency of task: once per batch, approx. 160 batches per year, 1 – 4 batches/shift
<p>Task 4: Cleaning of workplace</p> <ul style="list-style-type: none"> ▪ Duration of activity: 60 - 90 min/shift ▪ Frequency of task: approx. 80 days per year (two batches per shift, on average)
<p>Task 5: Repair and maintenance</p> <p>A: Cleaning of equipment for external repair</p> <ul style="list-style-type: none"> ▪ Duration of activity: 30 min ▪ Frequency of task: once every 2 years <p>B: Exchange of dust filters of air exhaust system</p> <ul style="list-style-type: none"> ▪ Duration of activity: 180 min ▪ Frequency of task: up to once every 4 years
<p>Task 6: Waste management – Handling of solid waste</p> <ul style="list-style-type: none"> ▪ Duration of activity: 10 min/shift ▪ Frequency of task: approx. 80 days per year (two batches per shift, on average)
Technical and organisational conditions and measures
Companies handling solid sodium chromate restrict access to the area on the days of production
Task 1: Charging mixing vessels

<ul style="list-style-type: none"> ▪ LEV: yes ▪ Ventilation rate of general ventilation system: mechanical ventilation (at least 3 ACH) ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 2: Mixing preparations in closed mixing vessels and filling containers</p> <ul style="list-style-type: none"> ▪ LEV: yes ▪ Ventilation rate of general ventilation system: mechanical ventilation (at least 3 ACH) ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 3: Sampling of preparations</p> <ul style="list-style-type: none"> ▪ LEV: yes ▪ Ventilation rate of general ventilation system: mechanical ventilation (at least 3 ACH) ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 4: Cleaning of workplace</p> <ul style="list-style-type: none"> ▪ LEV: No ▪ Vacuum cleaner with wet filter ▪ Ventilation rate of general ventilation system: mechanical ventilation (at least 3 ACH) ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 5: Repair and maintenance</p> <ul style="list-style-type: none"> ▪ LEV: no ▪ Ventilation rate of general ventilation system: mechanical ventilation (at least 3 ACH) ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Task 6: Waste management – Handling of solid waste</p> <ul style="list-style-type: none"> ▪ LEV: no ▪ Ventilation rate of general ventilation system: mechanical ventilation (at least 3 ACH) ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
<p>Conditions and measures related to personal protection, hygiene, and health evaluation</p>
<p>Gloves</p> <p>Chemical resistant gloves are worn during all tasks (Task 1 to 7).</p> <p>All gloves used for the handling of chemicals are tested according to EN 374. A variety of materials are suited for protection against chromates.</p> <p>The following materials have a breakthrough time ≥ 8h for aqueous CT solutions (10% CT) and saturated aqueous SD solutions ^a:</p> <ul style="list-style-type: none"> ○ Natural rubber/Natural latex (0.5 mm)

- Polychloroprene (0.5 mm)
- Nitrile rubber/Nitrile latex (0.35 mm)
- Butyl rubber (0.5 mm)
- Fluorocarbon rubber (0.4 mm)
- Polyvinyl chloride (0.5 mm)

The following materials have a breakthrough time ≥ 8 h for aqueous CT solutions (50% CT) ^a:

- Fluorocarbon rubber (0.4 mm)

The following materials have a breakthrough time ≥ 2 h for aqueous CT solutions (50% CT) ^a:

- Polychloroprene (0.5 mm)
- Butyl rubber (0.5 mm)
- Polyvinyl chloride (0.5 mm)

The following material is assumed to have a breakthrough time ≥ 4 h for solid CT and SD:

- Butyl rubber (0.7 mm)

Type of gloves to be used for specific tasks is laid down in work instructions for the tasks.

Respiratory protection equipment

RPE is worn during Tasks 1 - 3 and 5 - 6, except for Task 2, when the mixing process in closed vessels takes place.

The following types of RPE are used according to EN 529:2005 ^b:

- Full mask with P3 filter or P3 combination filter (APF 20)

Type of RPE to be used for specific tasks is laid down in work instructions for the tasks.

Protective clothes

In addition to chemical protective clothes disposable coveralls (Tyvek 500 XL) are worn during all tasks.

Type of protective clothes to be used for specific tasks is laid down in work instructions for the tasks.

Eye protection

Eye protection as per relevant risk assessment is worn during all tasks (Task 1 to 6).

Type of eye protection to be used for specific tasks is laid down in work instructions for the tasks.

Other conditions affecting workers' exposure

Task 1: Charging mixing vessels

- Place of use: indoors – large size workroom
- Temperature: room temperature
- Activity class: Falling of powders, granules or pelletised material
- Situation: Transferring 10 – 100 kg/minute

<ul style="list-style-type: none"> ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 2: Mixing preparations in closed mixing vessels and filling containers</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: Falling of powders, granules or pelletised material ▪ Situation: Transferring 10 – 100 kg/minute ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 3: Sampling of preparations</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: Movement of powders, granules or pelletised material ▪ Situation: Transferring 0.1 – 1 kg/minute ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 4: Cleaning of workplace</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: Movement of powders, granules or pelletised material ▪ Situation: Movement and agitation of < 10 gram ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 5: Repair and maintenance</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature ▪ Activity class: Handling of contaminated solid objects or paste ▪ Situation: Handling of slightly contaminated (layers of less than few grams) objects ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m)
<p>Task 6: Waste management – Handling of solid waste</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – large size workroom ▪ Temperature: room temperature

<ul style="list-style-type: none"> ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m) ▪ Activity class: Handling of contaminated solid objects or paste ▪ Handling type: Careful handling, involves workers showing attention to potential danger, error or harm and carrying out the activity in a very exact and thorough (or cautious) manner.
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
<ul style="list-style-type: none"> ▪ None

^a <https://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index.jsp> ; accessed 8 December 2020

^b For selection of APF see Annex VI of this report.

9.2.3.3.2 Exposure and risks for workers

The relevant activities with direct Cr(VI) exposure for operators and the working conditions are described below in detail. The whole activity takes place in a separate work area exclusively dedicated to handling chromates. During campaigns involving chromates only the operators responsible for performing the tasks described below are allowed to be present in this area. The production of solid mixtures is restricted to approx. 80 days per year.

Task 1: Charging of mixing vessels

Manufacture of solid mixtures is performed by filling the various components into a mixing vessel. The operators transport the closed containers (25 kg bags) with the neat chromates from the storage by a forklift to the hall with the mixing vessels. In rare occasions, this activity can also be done by other workers (e.g., logistics operators), who leave the area before the bags are opened. Bags are lifted with the forklift to the height of the mixing vessel opening, opened manually and the material poured into the mixing vessel. LEV is installed at the vessel opening, in addition the operator wears respiratory protection during the period with potential dust exposure. Only one operator is performing all activities.

In the Implementing Decisions for Authorisation of sodium and potassium dichromate (see Table 9-10) use of closed systems and automation is suggested, or, where this is not possible, local LEV must be used. As currently no automation system is available for the procedure of filling the mixing vessels under the specific conditions relevant for this WCS (small amounts delivered in bags), vessels are equipped with local LEV, accompanied by use of respiratory protection for the critical period, minimising workers exposure.

Task 2: Mixing preparations in closed mixing vessels and filling containers

For the mixing process the vessel is closed and mixing is achieved by a stirring device in the vessel. No exposure is expected during this period. The final product is filled into polyethylene bags of (up to) 25 kg via a semi-automated filling device (conveyer belt) with integrated scales, equipped with LEV. The filling process is stopped once the intended weight is achieved. Full bags are closed manually using a plastic zip tie (see photo below). Polyethylene bags are placed in a second plastic bag for transport,

which is sewn close by a machine. Typically, one operator is performing this activity. The filling process takes about 30 minutes. During this activity operators wear Tyvek coveralls and respiratory protection.



Figure 1: Packaging of solid mixtures

Task 3: Sampling of preparations

After completion of the mixing procedure, the operator takes one sample of approx. 250 g per batch with a sampling spoon via the vessel opening and fills it in a brown plastic flask. The flask is tightly closed, and the operator takes it to the laboratory for quality control. The whole procedure takes a few seconds only, during which the LEV is on, and the operator wears respiratory protection.

Task 4: Cleaning of workplace

The mixing vessels are placed over tank pits (secondary containment pit) to avoid any release of contaminated water. For cleaning of small spills of solid (and also liquid) material outside the mixing vessel the operator uses a vacuum cleaner (Kärcher with wet filter, NT 35/1 TACT TE H; air flow 74 L/s, 254 mbar). Remains are hosed with water. Mixing vessels are also hosed with water. All cleaning water is led to a collecting tank for reduction of Cr(VI).

Task 5: Repair and maintenance

Repair of parts on mixing vessels are extremely rare. The estimated frequency is once every two years. If parts potentially contaminated with Cr(VI) are concerned, the parts are carefully cleaned by the operator by rinsing it with water. Cleaned parts are sent to an external repair shop.

Particle filters in the exhaust air system are regularly automatically cleaned by mechanical movement. Used filters are changed approx. every 4 years. During such a filter change the filters are mechanically moved in the closed system to allow particles from the filters to sediment. Then filters are removed, packaged, and sent to an external service company. All settled dust is collected in a waste bag and sent off for disposal as hazardous waste. During this activity the operator wears respiratory protection.

Task 6: Waste management – Handling of solid waste

Empty bags are carefully folded to avoid dust generation and are placed in a closed big bag. This task is conducted in the work hall where the mixing process is performed. During this activity the operator wears respiratory protection. Also other solid waste with Cr(VI) contamination (e.g., gloves, coveralls) is gathered in the big bag, which is sealed, adequately labelled and sent to an external waste management company (licenced contractor) for disposal as hazardous waste.

9.2.3.3.2.1 Inhalation exposure

Measured inhalation exposure concentrations

Solid mixtures for the aerospace and defence supply chains are manufactured at one site in the EEA only. Production is batch-wise at certain production days only (approx. 80 days/year, as explained above).

Measurement data are available from campaigns in 2018 and 2020. In a measurement campaign in 2018, the concentration measured during producing a batch of solid CT-containing product was below the limit of quantification ($<0.3 \mu\text{g}/\text{m}^3$).

In 2020 exposure during manufacture of solid formulations with sodium dichromate or sodium chromate was measured. Loading of vessels (short-term activity, up to 27 min) and the mixing, sampling and deloading activity (up to 115 min) were measured separately and combined for a time-weighted representative measurement per batch. Table 9-25 shows these time-weighted inhalation exposure concentrations for workers producing solid mixtures, based on personal monitoring measurements. The individual measurements are provided in Annex IV of this report. RPE is worn during all exposure-relevant periods during production. Shift-average TWA values are calculated from these values, taking into consideration that two batches are produced per day and that the remaining time of the shift are free of exposure

The values provided in the table present the individual measurements obtained from the 2020 measurement campaign performed at this site.

Table 9-25: Measured inhalation exposure concentrations for WCS 2 – Operators producing solid mixtures

Year of measurement/ substance	Duration	Measured concentration ($\mu\text{g}/\text{m}^3$)	Exposure value (8h TWA) [$\mu\text{g}/\text{m}^3$]	Assigned protection factor (APF) for RPE ^b	Exposure value corrected for RPE [$\mu\text{g}/\text{m}^3$]	Long-term exposure [$\mu\text{g}/\text{m}^3$] ^c
2018/CT	80	<0.3	0.05	20	0.003	
2020/SD	132	60.1	33.1 ^a	20	1.65	0.14
2020/SC	58	41.4	10.0	20	0.5	
2020/SC	131	24.8	13.5	20	0.68	

Formulation

SD

^a Two batches are produced on a typical production day – the remainder of the workday is free from Cr(VI)-related activities; calculation example (for second row): $60.1 \mu\text{g}/\text{m}^3 \times 2 \times 132 \text{ min}/480 \text{ min} = 33.1 \mu\text{g}/\text{m}^3$ (1 batch = 132 minutes), TWAs in all rows were calculated accordingly

^b Full mask with P3 filter or P3 combination filter; according to EN 529:2005 (BSI), see Annex VI of this report.

^c The frequency correction factor of 20/240 was applied: approx. 160 batches are produced in total at the site, with 2 batches per day on average (80 production days). Up to 7 operators are instructed to perform this activity. If all batches in a specific year are produced by 4 different operators (average assumption), then each individual operator is exposed at 20 days per year.

Although there are few measurements for this specific activity of manufacturing solid mixtures only, these measurements are supported by the broader database on liquid mixture manufacture (see 9.2.3.2.2.1). As expected, solid mixtures can give rise to higher exposures (although one measurement, in 2018, yielded a very low concentration) during the activity. To account for the limited database, the highest shift-average concentration ($33.1 \mu\text{g}/\text{m}^3$) is used for risk characterisation.

9.2.3.3.2.2 Dermal exposure

In Table 9-26 the dermal exposure concentrations for operators producing solid mixtures are shown, based on modelling of the activities with Cr(VI) exposure. The parameters considered for dermal exposure modelling are described in detail in Annex V of this report.

- Task 1: Charging the mixing vessels (PROC 8a, 8b)
- Task 2: Surveyance of mixing process, transfer of solid products to storage containers (drums, bags) and closure of containers (PROC 5, 8b)
- Task 3: Sampling (PROC 9)
- Task 4: Cleaning of workplaces (PROC 28)
- Task 5: Repair and maintenance activities (PROC 28).
- Task 6: Waste management - disposal of solid waste (PROC 8b).

Table 9-26: Dermal exposure modelling for WCS 2 – Operators producing solid mixtures

Task	PROC(s)	Cr(VI) concentration* [%]	Annual average dermal exposure value [$\mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$]
Task 1: Charging the mixing vessels with solid material	PROC 8a, 8b	Max. 40	4.57
Task 2: Surveyance of mixing process, transfer of solid products to storage containers (drums, bags) and closure of containers	PROC 5, 8b	Max. 32	3.66
Task 3: Sampling of products	PROC 9	Max. 32	3.66
Task 4: Cleaning of workplaces and equipment	PROC 28	Max. 3.2**	1.59

Task 5: Repair and maintenance activities	PROC 28	Max. 3.2**	0.046
Task 6: Waste management – cleaning of containers, disposal of solid waste	PROC 8b	Max. 40	4.57
Combination of all tasks			18.1

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

* Highest concentration of SD, PD, or SC

** 10-fold dilution assumed due to cleaning activity; for details see Annex V.

Although in a very conservative approach it was assumed that all tasks are performed during the same shift and that exposure from each activity adds to previous exposures, the combined dermal exposures from all tasks does not exceed the DNEL.

9.2.3.3.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-27 shows the risk characterisation for carcinogenicity for operators producing solid mixtures. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure data and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013).

Table 9-27: Risk characterisation for carcinogenicity for WCS 2 – Operators producing solid mixtures

Route of exposure and type of effects	Long-term exposure [$\mu\text{g}/\text{m}^3$]	Risk characterisation: Excess lifetime lung cancer risk * [$1/\mu\text{g}/\text{m}^3$]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.14	4E-03	5.6E-4

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

As explained above, 4 operators are assumed to produce 160 batches per year (if more workers are assumed to be involved (up to seven), their relative shares of exposure time would decrease). There is only one site in the EEA performing this activity.

Risk for reproductive toxicity

Table 9-28 shows the risk characterisation for reproductive toxicity for operators producing solid mixtures. The risk characterisation for reproductive toxicity is based on measured Cr(VI) inhalation exposure data and modelled dermal Cr(VI) exposure values which are compared to the RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Table 9-28: Risk characterisation for reproductive toxicity for WCS 2 – Operators producing solid mixtures

Route of exposure and type of effects	Long-term exposure	Risk characterisation: RAC DNEL *	Risk characterisation ratio (RCR)
Inhalation: Systemic Long Term	0.14 [$\mu\text{g}/\text{m}^3$]	43 $\mu\text{g Cr(VI)}/\text{m}^3$	0.003
Dermal: Systemic Long Term	18.1 [$\mu\text{g}/\text{kg bw}/\text{d}$]	43 $\mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$	0.42
Combination of inhalation and dermal exposure			0.42

* RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for operators producing solid mixtures containing CT, SD, PD or SC is **5.6E-4**. **Four operators** are assumed to produce 160 batches per year at the one site in the EEA performing this activity.

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 values.

Reproductive toxicity:

- The RCR for the endpoint reproductive toxicity based on a conservative assessment is well below 1 (0.42).

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

Comparison of outcome with initial application:

The excess life-time cancer risk for operators producing solid mixtures is **5.6E-4**.

Risk estimates in initial applications:

No specific assessment for manufacture of solid mixtures was made in initial applications. Exposure and risk for formulation tasks in initial applications are:

Application	Activity	Exposure estimate	Risk

0032-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.27 µg Cr(VI)/m	1.08E-03
	Waste management (modelled)	0.22 µg Cr(VI)/m ³	0.88E-03
0043-01, 0044-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.26 µg Cr(VI)/m ³	1.04E-03
	Waste management (modelled)	0.22 µg Cr(VI)/m ³	0.88E-03
0099-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.26 µg Cr(VI)/m ³	1.04E-03
	Sampling (modelled)	0.0014 µg Cr(VI)/m ³	5.60E-06
	Waste management (modelled)	0.00147 µg Cr(VI)/m ³	5.88E-06

Estimated exposure and risk, which are based on measured data and which consider the frequency of activities, are lower by a factor of 2 in the current assessment compared to the initial applications.

9.2.3.4 Worker contributing scenario 3 – Laboratory technicians

Usually, there is a group of 1 to 6 laboratory technicians per site (depending, e.g., on the size of the site). Although all laboratory technicians may be involved in activities with potential for Cr(VI)-exposure, 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:

Main task

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

Secondary task

- Task 2: Sampling of material (raw materials or products) (PROC 9)

Typical activities in the laboratory are determination of the chromate concentration in samples, determination of density, chloride concentration and other parameters.

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 development⁶ according to REACH Art. 56(3), no exposure assessment is performed for the laboratory work such as quality control of samples.

⁶ 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

The activity of sampling the mixing vessel typically consumes a small fraction of the lab technician's time. This task is described in detail in the worker contributing scenario for operators (see section 9.2.3.2.2 and 9.2.3.3.2).

9.2.3.5 Worker contributing scenario 4 – Maintenance workers

A group of approximately 2 to 5 maintenance workers is engaged per site (depending, e.g., on the size of the site). All maintenance workers may be involved in activities related to formulation of chromates, but these tasks constitute only a small fraction of their time and most of their work is not related to activities related to Cr(VI) exposure. Although it is hard to estimate this fraction due to the infrequency of Cr(VI)-related maintenance activities, it can be considered a conservative estimate if a maintenance worker spends on average a maximum of 10% of his working time on such activities.

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

- Task 1: Maintenance of equipment (PROC 28)

The activity of maintenance of equipment 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 9-29 summarises the conditions of use for maintenance with Cr(VI) exposure related to formulation of chromates carried out by maintenance workers.

Table 9-29: Conditions of use – worker contributing scenario 4 – Maintenance workers

Product (article) characteristics
Product 1: Liquid mixture of CT, SD, PD or SC <ul style="list-style-type: none"> ▪ Concentration of substance in mixture: max. 26% (w/w) Cr(VI) (based on up to 50% CT or 70% SD (w/w) in liquid products); <<1% (w/w) Cr(VI) after cleaning of equipment ▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix ▪ Viscosity: Liquids with low viscosity (like water)
Amount used (or contained in articles), frequency and duration of use/exposure
Task 1: Maintenance and cleaning of equipment <ul style="list-style-type: none"> ▪ Duration of activity: 30-120 min ▪ Frequency of task: once per week, 48 weeks per year
Technical and organisational conditions and measures
Task 1: Maintenance and cleaning of equipment <ul style="list-style-type: none"> ▪ LEV: No ▪ Ventilation rate of general ventilation system: natural ventilation

<ul style="list-style-type: none"> ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
Conditions and measures related to personal protection, hygiene, and health evaluation
<p>Gloves</p> <p>All gloves used for the handling of chemicals are tested according to EN 374. A variety of materials are suited for protection against chromates.</p> <p>The following materials have a breakthrough time ≥ 8h for aqueous CT solutions (10% CT) and saturated aqueous SD solutions ^a:</p> <ul style="list-style-type: none"> ○ Natural rubber/Natural latex (0.5 mm) ○ Polychloroprene (0.5 mm) ○ Nitrile rubber/Nitrile latex (0.35 mm) ○ Butyl rubber (0.5 mm) ○ Fluorocarbon rubber (0.4 mm) ○ Polyvinyl chloride (0.5 mm) <p>Type of gloves to be used for specific tasks is laid down in work instructions for the tasks.</p>
Respiratory protection equipment
<p>No RPE is worn during maintenance activities performed on pre-cleaned equipment.</p>
Protective clothes
<p>Chemical protective clothes are worn during activities with possible Cr(VI) exposure.</p> <p>Type of protective clothes to be used for specific activities is laid down in work instructions for the activities.</p>
Eye protection
<p>Eye protection as per relevant risk assessment is worn during Task 1.</p> <p>Type of eye protection to be used for specific activities is laid down in work instructions for the activities.</p>
Other conditions affecting workers' exposure
<p>Task 1: Maintenance and cleaning of equipment</p> <ul style="list-style-type: none"> ▪ Place of use: indoors – any size workroom ▪ Temperature: room temperature ▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, <1 m) ▪ Activity class and subclass: Handling of contaminated objects
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
<ul style="list-style-type: none"> ▪ None

^a <https://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index.jsp>; accessed 8 December 2020.

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 workers and the working conditions.

Task 1: Maintenance of equipment

Maintenance workers are responsible for various tasks in a company and may comprise electricians, fitters, and other types of workers. Only 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.

Typical maintenance tasks comprise checking connections and thickness of piping and vessels to avoid leakages and to attend to pumps or mixers not working properly. Further activities include change of filters, e.g., at exhaust ventilation devices.

In case equipment needs to be dismantled for repair the formulation operator is responsible for emptying and cleaning lines and equipment by flushing with water and air. Depending on the contamination, this may also include a step for reducing Cr(VI) with bisulfite. Only after careful control (visual inspection of the conditions and absence of contamination with chromates or clearance given by the laboratory after having analysed remaining Cr(VI) concentrations), the maintenance worker is allowed to remove the parts. Responsibilities and procedures are laid down in standard operating procedures, which also include specifications on PPE.

Repair usually takes place in companies' own workshops and – in rare occasions - at a specialized external company. At most companies, spare parts are available for critical components, allowing immediate replacement and continuation of the production and repair of dysfunctional parts without time pressure.

Reports on frequencies of repair interventions vary considerably. Conservatively estimated, maintenance tasks require between 30 and 120 min of working time and are performed once per week, by a single maintenance worker. Maintenance activities are performed at ambient temperature (15-25°C). The level of contamination on parts is considered to be very low, due to the preceding cleaning process.

9.2.3.5.2.1 Inhalation exposure

Measured inhalation exposure concentrations

There are only two measurements (personal sampling) from maintenance workers in formulation companies available. Activities during the measurement period included presence in the hall where the formulation vessels are located. Formulation activities with chromium trioxide were carried out during the measurement period. However, no Cr(VI)-related specific maintenance activities were performed during this period:

- Measurement 1: Electrician; presence during measurement period (approx. 240 min): in various areas of the company; measured value: 0.08 µg Cr(VI)/m³
- Measurement 2: Fitter; presence during measurement period (148 min): formulation area; measured value: 1.01 µg Cr(VI)/m³

As this database is not sufficient to perform the assessment, additional values measured for maintenance workers in the aerospace and defence supply chains is used. These measurements are taken at companies engaged in various uses of chromates. However, typical maintenance activities such as removal and repair of broken equipment is common to all uses. Therefore, these data are considered a suitable surrogate for assessing exposure of maintenance workers also in formulation companies. Some of these measurements cover maintenance activities not only related to galvanic but also to spraying uses (i.e., slurry coating and/or use of primer), as multiple tasks including maintenance on galvanic- and spraying-related equipment were performed during some measurements.

In total, 36 personal monitoring values are available, but two values were excluded from the analysis: one value was below an unreasonably high LOQ (i.e., $<2 \mu\text{g}/\text{m}^3$) and a second values was excluded because the worker experienced high exposure ($6.94 \mu\text{g}/\text{m}^3$) due to inappropriate individual behaviour. Of the remaining 34 personal measurements, 19 are long-term, shift-representative (including the two measurements on maintenance workers in formulation companies above) and 15 short-term personal measurements are available.

The pooled personal monitoring data come from 14 sites in four countries in the EEA (29 measurements) and from three sites in the UK (five measurements). About 41% of the data (14 values, including seven short-term measurements) are $<\text{LOQ}$ and 59% (208 values, including eight short-term measurements) are $>\text{LOQ}$. A summary on the analytical methods for inhalation exposure monitoring and information on their LOQs is given in Annex IV of this report. The individual measurements can be provided upon request.

Personal measurements – related to Cr(VI)-related maintenance activities in aerospace and defence supply chains (long-term measurements)

The AM of the total long-term measurements is $0.702 \mu\text{g}/\text{m}^3$ and the 90th percentile is $1.47 \mu\text{g}/\text{m}^3$ for the pooled personal monitoring data. The exposure values cover general inspections, maintenance and cleaning throughout the site and specific activities such as replacement of heaters, repair of pipes, pumps, or dampers in the baths, cleaning, and replacement of demisters of the air purification systems, cleaning and repair of wet scrubbers, removal of anodes from treatment baths or refilling of chemicals for the wastewater treatment plant. The activities reported for the pooled long-term measurements show a large overlap with the activities reported for the monitoring data covering maintenance activities related to passivation of (non-Al) metallic coatings, which further supports the total long-term measurements to be considered for the assessment.

Beside the one measurement mentioned above, during which anodes were removed from a treatment bath, use of RPE (reusable half mask – particle filter) was documented for three additional measurements (“infrequent maintenance activities” were performed in one case, no details available for the other two measurements).

Personal measurements – related to Cr(VI)-related maintenance activities in aerospace and defence supply chains (short-term measurements)

For the total of 15 short-term measurements the AM is $0.325 \mu\text{g}/\text{m}^3$ and the 90th percentile is $0.870 \mu\text{g}/\text{m}^3$. During these measurements the workers performed regular maintenance of the baths and related equipment such as LEV, rectifier, pumps, panels and sensors, inspection and cleaning of wet scrubbers, or aspiration of extraction filters above treatment baths with a vacuum cleaner.

Formulation

SD

For all short-term measurements it is documented that RPE (e.g., reusable half mask – particle filter, or half mask 3M 42795 (FFABEK1P3RD)) is used, e.g., during line breakdowns or during maintenance of equipment.

Table 9-30 shows the summary statistics of workplace measurements for maintenance and/or cleaning workers in the aerospace and defence industry and its supply chains. For values <LOQ, half of the LOQ (LOQ/2) was considered for statistical evaluation. All measurements are from the period 2018-2021.

Table 9-30: Summary statistics of inhalation exposure measurements (personal monitoring) for WCS 4 – Maintenance workers

	N	<LOQ	AM [$\mu\text{g}/\text{m}^3$]	SD [$\mu\text{g}/\text{m}^3$]	Median [$\mu\text{g}/\text{m}^3$]	90 th Perc. [$\mu\text{g}/\text{m}^3$]
Long-term	19	7	0.702	1.21	0.240	1.47
Short-term	15	7	0.325	0.399	0.170	0.870

Despite the broad range of sites and activities covered, the data show only small variation. Median and 90th percentile of the long-term values differ by a factor of 6, but between AM and the 90th percentile there is only a factor of 2. A relevant portion of the measurement resulted in values below LOQ.

More than one chromate is used at many of the sites providing these measurements and measurements are often not assignable to a single chromate. Therefore, stratification according to substance is not reasonable.

In Table 9-31 the long-term inhalation exposure concentration for maintenance workers in formulation companies as used for risk characterisation, is shown. Frequencies of chromate-related activities as well as residence times in areas handling chromates vary largely from site to site. Therefore, in a conservative way, only frequency but not duration of the activity is considered for calculating the long-term average exposure (based on the 90th percentile of the measurements). It is assumed that on average, maintenance activities are divided between two workers per site.

RPE may be worn during specific maintenance and/or cleaning activities as its use was documented for all short-term measurements. However, it is assumed that RPE was worn during certain short periods of the shift average measurements. Therefore, no RPE is considered in the exposure assessment, which constitutes a further conservative element of the assessment.

Table 9-31: Measured inhalation exposure concentrations for WCS 4 – Maintenance workers

Activity	Measured exposure concentration (8h TWA) [$\mu\text{g}/\text{m}^3$]	Assigned protection factor (APF) for RPE ^b	Exposure value corrected for RPE [$\mu\text{g}/\text{m}^3$]	Long-term exposure ^c [$\mu\text{g}/\text{m}^3$]
Maintenance	1.47	1	1.47	0.147

^a Based on 90th percentile of measurements.

^b No RPE is considered, see text above.

Formulation

SD

^c The frequency/duration correction factor of $48/(2*240) = 0.1$ was applied, assuming that each activity is carried out by a single maintenance worker

9.2.3.5.2.2 Dermal exposure

In Table 9-32 the dermal exposure concentrations for maintenance workers are shown, based on modelling of the activities with Cr(VI) exposure. The parameters considered for dermal exposure modelling are described in detail in Annex V of this report.

Table 9-32: Dermal exposure modelling for WCS 4 – Maintenance workers

Task	PROC(s)	Cr(VI) concentration* [%]	Annual average dermal exposure value [$\mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$]
Task 1: Maintenance and cleaning of equipment	PROC 28	2.6*	0.18

*Highest concentration of SD, PD, or SC

** 10-fold dilution assumed due to cleaning activity; for details see Annex V.

The dermal exposure value ($0.18 \mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$) is well below the DNEL of $43 \mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$.

9.2.3.5.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-33 shows the risk characterisation for carcinogenicity for maintenance workers. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure data for maintenance workers and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013).

Table 9-33: Risk characterisation for carcinogenicity for WCS 4 – Maintenance workers

Route of exposure and type of effects	Long-term exposure [$\mu\text{g}/\text{m}^3$]	Risk characterisation: Excess lifetime lung cancer risk * [$1/\mu\text{g}/\text{m}^3$]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.147	4E-03	5.88E-4

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

As explained above, 2 maintenance workers are assumed to work at a formulation. This number might differ between sites. However, if the work is distributed between more than two workers, the individual risk would be lower, but the number of exposed workers would be higher.

Risk for reproductive toxicity

Table 9-34 shows the risk characterisation for reproductive toxicity for maintenance workers. The risk characterisation for reproductive toxicity is based on measured Cr(VI) inhalation exposure data for maintenance and/or cleaning workers and modelled dermal Cr(VI) exposure values which are compared to the RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Table 9-34: Risk characterisation for reproductive toxicity for WCS 4 – Maintenance workers

Route of exposure and type of effects	Long-term exposure	Risk characterisation: RAC DNEL *	Risk characterisation ratio (RCR)
Inhalation: Systemic Long Term	0.147 µg Cr(VI)/m ³	43 µg Cr(VI)/m ³	0.00342
Dermal: Systemic Long Term	0.178 µg/kg bw/d	43 µg Cr(VI)/kg bw/d	0.00414
Combination of inhalation and dermal exposure			0.0076

* RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Conclusion on risk characterisation:Carcinogenicity

The excess life-time cancer risk for maintenance workers is 5.88E-04.

This risk estimate can be considered as conservative, because:

- it is based on a conservative 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 values, and
- no correction for wearing RPE was applied although workers may wear RPE under certain conditions for some activities.

As described above, it is considered for the assessment that **two maintenance workers** per site perform all maintenance activities related to the formulation use.

Reproductive toxicity

The RCR for the endpoint reproductive toxicity based on a conservative assessment is well below 1 (0.076).

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

Comparison of outcome with initial application:

The excess life-time cancer risk for maintenance workers in the present assessment is **5.88E-4**.

No separate group of maintenance workers were distinguished in the initial applications. Exposure during maintenance of equipment was covered by measurements during formulation activities.

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0032-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.27 µg Cr(VI)/m	1.08E-03
0043-01, 0044-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.26 µg Cr(VI)/m ³	1.04E-03
0099-01	Formulation (measured) (including cleaning and maintenance of equipment)	0.26 µg Cr(VI)/m ³	1.04E-03

Exposure and risk based on personal measurements of maintenance workers in the present assessment leads to slightly lower values compared to the outcome for formulation activities, including cleaning and maintenance of equipment in the initial assessments.

9.2.3.6 Worker contributing scenario 5 – Logistics operators

At some sites a special group of workers is responsible for filling product containers and tank trucks with liquid products. At other sites no tank trucks are used and filling operations are done by the operators engaged in producing the mixtures.

Main task

- Task 1: Filling of tank trucks (PROC 8b)

Secondary task

- Task 2: Transfer of liquid products to storage tanks or containers (PROC 8b)

As Task 2 is a main task performed by operators producing mixtures, it has already been described in detail in the worker contributing scenario for the operators (see section 9.2.3.2.1).

The activities related to Task 1 are described below in detail.

9.2.3.6.1 Conditions of use

Table 9-35 summarises the conditions of use for the activities with Cr(VI) exposure related to formulation of mixtures carried out by logistics workers.

Table 9-35: Conditions of use – worker contributing scenario 5 – Logistics workers

Product (article) characteristics
<p>Product 1: Liquid mixture of CT, SD, PD or SC</p> <ul style="list-style-type: none"> ▪ Concentration of substance in mixture: max. 26% (w/w) Cr(VI) (based on up to 50% CT in liquid products) ▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix ▪ Viscosity: Liquids with low viscosity (like water)
Amount used (or contained in articles), frequency and duration of use/exposure
<p>Task 1: Filling of tank trucks (PROC 8b)</p> <ul style="list-style-type: none"> ▪ Amount: up to 40 m³ product (10 400 kg Cr(VI)) ▪ Duration of activity: 120 min ▪ Frequency of task: up to 36 days per year
Technical and organisational conditions and measures
<p>Task 1: Filling of tank trucks (PROC 8b)</p> <ul style="list-style-type: none"> ▪ LEV: No ▪ Transfer via semi-closed lines ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
Conditions and measures related to personal protection, hygiene, and health evaluation
<p>Gloves</p> <p>All gloves used for the handling of chemicals are tested according to EN 374. A variety of materials are suited for protection against chromates.</p> <p>The following materials have a breakthrough time ≥ 8h for aqueous CT solutions (10% CT) and saturated aqueous SD solutions ^a:</p> <ul style="list-style-type: none"> ○ Natural rubber/Natural latex (0.5 mm) ○ Polychloroprene (0.5 mm) ○ Nitrile rubber/Nitrile latex (0.35 mm) ○ Butyl rubber (0.5 mm) ○ Fluorocarbon rubber (0.4 mm) ○ Polyvinyl chloride (0.5 mm) <p>The following materials have a breakthrough time ≥ 8h for aqueous CT solutions (50% CT) ^a:</p> <ul style="list-style-type: none"> ○ Fluorocarbon rubber (0.4 mm) <p>The following materials have a breakthrough time ≥ 2h for aqueous CT solutions (50% CT) ^a:</p> <ul style="list-style-type: none"> ○ Polychloroprene (0.5 mm) ○ Butyl rubber (0.5 mm)

<ul style="list-style-type: none"> ○ Polyvinyl chloride (0.5 mm) <p>Type of gloves to be used for specific activities is laid down in work instructions for the activities.</p>
<p>Respiratory protection equipment</p> <p>No RPE is worn during Task 1.</p>
<p>Protective clothes</p> <p>Chemical protective clothes or a protective suit are worn during this task.</p> <p>Type of protective clothes to be used for specific tasks is laid down in work instructions for the tasks.</p>
<p>Eye protection</p> <p>Eye protection as per relevant risk assessment is worn during this task.</p> <p>Type of eye protection to be used for specific tasks is laid down in work instructions for the tasks.</p>
<p>Other conditions affecting workers' exposure</p> <p>Task 1: Filling of tank trucks (PROC 8b)</p> <ul style="list-style-type: none"> ▪ Place of use: Outdoors ▪ Temperature: ambient temperature (15-25°C) ▪ Primary emission source proximity: The primary emission source is not in the breathing zone of the worker (far field, >1 m) ▪ Activity class: Transfer of liquid products ▪ Situation: Transferring >1000 L/min ▪ Containment of the process: Handling that reduces contact between product and adjacent air
<p>Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply</p> <ul style="list-style-type: none"> ▪ None

<https://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index.jsp> ; accessed 8 December 2020

9.2.3.6.2 Exposure and risks for workers

Task 1: Tank truck loading

The main activity of logistics operators at some sites (apart from filling product containers, as described under 9.2.3.2) is the filling of tank trucks with ready formulated product.

At few sites handling larger amounts of product, tank trucks are loaded with product. Trucks are located above a concrete area with rinse water gathering (secondary containment pit). The product is pumped via semi-closed lines from storage tanks to the tank truck. The hose is introduced in the manhole from above and the manhole covered by the lid during filling. After filling the truck lines are emptied by flushing with air. The end of the hose is placed on an open container to avoid spilling of any remaining droplets at the outlet. Any spills or splashes at the outside of the truck (which do not

occur under normal circumstances) are washed down with a hose and the wash water is gathered and led to the wastewater treatment.



Figure 2: Loading of a tank truck

9.2.3.6.2.1 Inhalation exposure

Measured inhalation exposure concentrations

Only one measurement is available for filling a tank truck with an aqueous solution of chromate (in this case low-concentrated sodium chromate solution). The personal monitoring measurement (duration 110 min) of the logistics operator was below the limit of quantification of $0.316 \mu\text{g}/\text{m}^3$.

Inhalation exposure concentrations obtained with modelling

Only one workplace measurement is available for this infrequent activity. Therefore, the activity was modelled with ART (Advanced REACH Tool, version 1.5). The total loading process (2 hours duration) is separated in two activity phases:

- Nearfield exposure during coupling and decoupling lines (10 min)
- Far field exposure during loading of the tank truck (110 min, no active involvement of the logistics worker, who is surveying the process in $> 4 \text{ m}$ distance).

The remaining of the shift is dedicated to other activities, not related to chromates. The modelling was performed for loading a concentrated chromium trioxide solution (26% Cr(VI)). The ART protocol with the input parameters used for modelling is given in Annex IV of this report.

In Table 9-36 the inhalation exposure concentrations for logistics workers during tank truck loading, as modelled with ART, are shown.

Table 9-36: Inhalation exposure modelling with ART – tank truck loading

Activity phase	Type of exposure	Duration	Modelled exposure concentration 90 th percentile [$\mu\text{g}/\text{m}^3$]	Shift-average exposure concentration [$\mu\text{g}/\text{m}^3$]
Near field – introducing and removing of lines	Near field	10 min	1.7	
Far field – surveying loading process	Far field	110 min	1.4	
				0.356

In Table 9-37 the long-term inhalation exposure concentrations for logistics workers during tank truck loading, is calculated.

Table 9-37: Inhalation exposure concentrations for WCS 5 – logistics workers

Activity	Exposure value (8h TWA) [$\mu\text{g}/\text{m}^3$]	Assigned protection factor (APF) for RPE ^a	Exposure value corrected for RPE [$\mu\text{g}/\text{m}^3$]	Long-term exposure ^b [$\mu\text{g}/\text{m}^3$]
Task 1 – tank truck loading	0.356	1	0.356	0.0534

^a No RPE is considered.

^b The frequency/duration correction factor of 0.15, as the activity is performed up to 36 times per year ($36/240 = 0.15$).

9.2.3.6.2.2 Dermal exposure

Table 9-38 shows the dermal exposure concentrations for logistics workers, based on modelling of the activities with Cr(VI) exposure. The parameters considered for dermal exposure modelling are described in detail in Annex V of this report.

Table 9-38: Dermal exposure modelling for WCS 5 – logistics operators

Task	PROC(s)	Cr(VI) concentration [%]	Annual average dermal exposure value [$\mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$]
Task 1: Filling of tank trucks	PROC 8b	Max. 26	0.669
Task 2: Transfer of liquid products to storage tanks or containers	PROC 8b	Max. 26	4.46
Combination of all tasks			5.13

*Highest concentration of SD, PD, or SC

9.2.3.6.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-39 shows the risk characterisation for carcinogenicity for logistics operators. The risk for carcinogenicity is based on the modelled Cr(VI) inhalation exposure during tank truck loading and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013).

Table 9-39: Risk characterisation for carcinogenicity for WCS 5 – logistics operators

Route of exposure and type of effects	Long-term exposure [$\mu\text{g}/\text{m}^3$]	Risk characterisation: Excess lifetime lung cancer risk * [$1/\mu\text{g}/\text{m}^3$]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.0534	4E-03	2.14E-04

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

The same worker is assumed to be engaged in up to 36 loading activities per year.

Risk for reproductive toxicity

Table 9-40 shows the risk characterisation for reproductive toxicity for logistics operators. The risk characterisation for reproductive toxicity is based on the modelled Cr(VI) inhalation exposure during tank truck loading and modelled dermal Cr(VI) exposure values which are compared to the RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Table 9-40: Risk characterisation for reproductive toxicity for WCS 5 – logistics operators

Route of exposure and type of effects	Long-term exposure	Risk characterisation: RAC DNEL *	Risk characterisation ratio (RCR)
Inhalation: Systemic Long Term	$0.0534 \mu\text{g}/\text{m}^3$	$43 \mu\text{g Cr(VI)}/\text{m}^3$	0.0012
Dermal: Systemic Long Term	$5.13 \mu\text{g}/\text{kg bw}/\text{d}$	$43 \mu\text{g Cr(VI)}/\text{kg bw}/\text{d}$	0.119
Combination of inhalation and dermal exposure			0.120

* RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Conclusion on risk characterisation:

Carcinogenicity:

The excess life-time cancer risk for a logistics operator engaged in tank truck loading is estimated to be **2.14E-04**.

This calculation assumes that all loading activities are done by the same worker at a site. This activity is performed at two sites only. So, two logistics workers are considered in total.

This risk estimate can be considered as conservative, because:

- it is based on a conservative exposure-risk relationship (ERR),
- it uses a conservative modelling approach.

Reproductive toxicity:

The RCR for the endpoint reproductive toxicity based on a conservative assessment is well below 1 (0.12).

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

Comparison of outcome with initial application:

The excess life-time cancer risk for a logistics operator engaged in tank truck loading is estimated to be **2.14E-04**.

The risk characterisation of workers engaged in formulation activities in the initial assessment included tasks such as filling the products into containers (“Transfer to small containers (including filtering) (PROC 9)”). However, the rare activity of truck loading was not addressed specifically. The risk estimates in the initial application are given below.

Risk estimates in initial applications:

Application	Activity	Exposure estimate	Risk
0032-01	Formulation (measured) (including transfer to small containers)	0.27 µg Cr(VI)/m	1.08E-03
0043-01, 0044-01	Formulation (measured) (including transfer to small containers)	0.26 µg Cr(VI)/m ³	1.04E-03
0099-01	Formulation (measured) (including transfer to small containers)	0.26 µg Cr(VI)/m ³	1.04E-03

The risk estimated (based on a conservative modelling approach) in the current assessment is lower by a factor of 5 compared to formulation operators in the initial assessments.

9.2.3.7 Worker contributing scenario 6 – 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 most formulation sites there are no incidentally exposed workers, but at few sites, mixing vessels for other (non-Cr-VI) products are placed in the same working hall, requiring attendance by those workers. These workers may incidentally be exposed due to inhalation background exposure in the work area. 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.

9.2.3.7.1 Conditions of use

Table 9-41 summarises the conditions of use for various tasks performed by incidentally exposed workers working in the hall and in the vicinity of the mixing vessels where formulation of chromates is carried out, from which the workers are incidentally exposed.

Table 9-41: Conditions of use – worker contributing scenario 5 – Incidentally exposed workers

Product (article) characteristics
Product 1: Liquid mixture of CT, SD, PD or SC for Task 1 <ul style="list-style-type: none"> ▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix ▪ Viscosity: Liquids with low viscosity (like water) ▪ Concentration of substance in mixture: max. 26% (w/w) Cr(VI) (based on up to 50% CT in liquid products)
Amount used (or contained in articles), frequency and duration of use/exposure
Task 1: Activities with indirect Cr(VI) exposure <ul style="list-style-type: none"> ▪ Duration of activity: up to 480 min ▪ Frequency of task: 240 days/year
Technical and organisational conditions and measures
Task 1: Activities with indirect Cr(VI) exposure <ul style="list-style-type: none"> ▪ Ventilation rate of general ventilation system: natural ventilation ▪ Process temperature: room temperature ▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)
Conditions and measures related to personal protection, hygiene, and health evaluation
Task 1: Activities with indirect Cr(VI) exposure <ul style="list-style-type: none"> ▪ Standard PPE (not intended for protection against chromates) as described in work instructions for the tasks
Other conditions affecting workers exposure
Task 1: Activities with indirect Cr(VI) exposure <ul style="list-style-type: none"> ▪ Place of use: indoors – any size workroom

<ul style="list-style-type: none"> ▪ Primary emission source proximity: The primary emission source is usually in the far field (>1 m)
<p>Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply</p>
<ul style="list-style-type: none"> ▪ None

9.2.3.7.2 Exposure and risks for workers

Task 1: Activities without direct Cr(VI) exposure

The number of incidentally exposed workers at industrial sites engaged in formulation is low:

- At some sites production of products containing Cr(VI) is organised batch-wise and is concentrated on a number of days per year, with access to the relevant areas only for the personnel involved in the production.
- At other sites the area for producing mixtures containing Cr(VI) is dedicated to these activities only, with only involved staff having access.

However, at few sites with various formulation activities, mixing vessels dedicated to producing non-chromate products are 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 exposure from solid chromates is possible for incidentally exposed workers.

Further, at few sites, staff responsible for wastewater management and similar activities may be required to perform part of their activities in the production areas. The portion of their time spent in the relevant area is well below 50%.

Overall, the number of incidentally exposed workers per site is estimated to be 0 to 2 per site. We conservatively estimate that two incidentally exposed workers (being indirectly exposed during 50% of their working time to Cr(VI) from formulation) has to be considered per site..

9.2.3.7.2.1 Inhalation exposure

As described in section 9.2.3.5.2.1 there are two measurements (personal sampling) from maintenance workers in formulation companies, which did not carry out specific maintenance activities during the measurement period. Activities during the measurement included presence in the hall where the formulation vessels are located. Formulation activities with chromium trioxide were carried out during the measurement period.

- Measurement 1: Electrician; presence during measurement period (approx. 240 min): in various areas of the company; measured value: 0.08 µg Cr(VI)/m³
- Measurement 2: Fitter; presence during measurement period (148 min): formulation area; measured value: 1.01 µg Cr(VI)/m³

Therefore, we consider these measurements as indicative for background exposure during formulation. As there are only few measurements available for incidentally exposed workers from formulation companies, in addition we discuss here exposure data from incidentally exposed workers

from other companies in the aerospace and defence industry and its supply chains, mainly people working in halls where chromates are handled in galvanic baths. Activities of these workers include, e.g., logistic operations (without direct contact to chromates), jiggling and masking. Various soluble chromates are handled in these surroundings.

Measured inhalation exposure concentration

In total, 18 personal and eight stationary measurements are available for incidentally exposed workers in galvanic departments. Two personal long-term measurements were excluded from further analysis due to unreasonably high LOQs (i.e., above 1 µg/m³).

Of the remaining 16 personal monitoring data, 15 are long-term (≥2h)⁷, shift-representative and one is a short-term (<2h) measurement.

The personal monitoring data come from five sites in five countries in the EEA (eight measurements) and from two sites in the UK (eight measurements). Approximately 63% of the data (ten values, including the one short-term measurement) are <LOQ and 37% (six values) are >LOQ. A summary on the analytical methods for inhalation exposure monitoring and information on their LOQs is given in Annex IV of this report. The individual measurements can be provided upon request. An overview of the available data for line operators is given in Table 9-42.

Table 9-42: Overview of available inhalation exposure measurements for WCS 6 – Incidentally exposed workers

	n	>LOQ	<LOQ
Personal			
- Long-term (≥2h)	15	6	9
- Short-term (<2h)	1	0	1

Personal measurements – long-term

Long-term personal measurements were taken in galvanic halls. The arithmetic mean (AM) over the total of long-term personal measurements is 0.316 µg/m³, the median is 0.290 µg/m³ and the 90th percentile is 0.500 µg/m³.

Personal measurements – short term

The short-term measurement has an exposure value of 1.0 µg/m³.

Stationary measurements

The eight stationary monitoring data are long-term measurements. The arithmetic mean (AM) over of these measurements is 0.0564 µg/m³. The measurements were taken in halls with multiple immersion uses.

⁷ All long-term measurements (≥2h) are considered as shift-representative measurements and used as such as 8h TWA exposure values; no recalculation has been performed.

Formulation

SD

Table 9-43 shows the summary statistics of workplace measurements for incidentally exposed workers. For values <LOQ, half of the LOQ (LOQ/2) was considered for statistical evaluation. All measurements are from 2018-2021.

Table 9-43: Summary statistics of inhalation exposure measurements for WCS 6 – Incidentally exposed workers

Personal (measurement period 2018-2021)						
	N	% of total	AM [$\mu\text{g}/\text{m}^3$]	SD [$\mu\text{g}/\text{m}^3$]	Median [$\mu\text{g}/\text{m}^3$]	90 th Perc. [$\mu\text{g}/\text{m}^3$]
Long-term	15	94	0.316	0.254	0.290	0.500
Short-term	1	6	n.a. ^a			
Stationary – (measurement period 2018-2021)						
	N	% of total	AM [$\mu\text{g}/\text{m}^3$]	SD [$\mu\text{g}/\text{m}^3$]	Median [$\mu\text{g}/\text{m}^3$]	90 th Perc. [$\mu\text{g}/\text{m}^3$]
Long-term - total	8	100	0.0564	n.a.	n.a.	n.a.

n.a. = not assessed; the statistical parameter was only determined if at least three (for AM) or ten (for SD, Median and 90th percentile) values were available.

^a The value is 1.0 $\mu\text{g}/\text{m}^3$

The exposure data for incidentally exposed workers from galvanic uses are in the same range as the two measurements from maintenance workers in formulation company described above. In a conservative approach we take the higher of the two measurements as indicative for inhalation exposure of incidentally exposed workers in formulation companies. This value is higher than the 90th percentile of the data described above by a factor of 2. Table 9-44 shows the resulting long-term inhalation exposure concentration for incidentally exposed workers used for risk assessment, based on this maximum value.

Table 9-44: Measured inhalation exposure concentration for WCS 6 – Incidentally exposed workers

Type of measurement	Number of measurements	Exposure value (8h TWA) ^a [$\mu\text{g}/\text{m}^3$]	Assigned protection factor (APF) for RPE ^b	Exposure value corrected for RPE [$\mu\text{g}/\text{m}^3$]	Long-term exposure ^c [$\mu\text{g}/\text{m}^3$]
Personal	15 plus 2	1.01	1	1.01	0.501

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

^a Based on maximum observed in formulation company.

^b No RPE is considered.

^c Workers are assumed to be exposed during 50% of their shift: factor 2.

Formulation

SD

9.2.3.7.2.2 Dermal exposure

No dermal exposure is considered for incidentally exposed workers, as they are not in direct contact with Cr(VI).

9.2.3.7.2.3 Risk characterisation

Risk for carcinogenicity

Table 9-45 shows the risk characterisation for carcinogenicity for incidentally exposed workers. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure data and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013).

Table 9-45: Risk characterisation for carcinogenicity for WCS 6 – Incidentally exposed workers

Route of exposure and type of effects	Long-term exposure [$\mu\text{g}/\text{m}^3$]	Risk characterisation: Excess lifetime lung cancer risk * [$1/\mu\text{g}/\text{m}^3$]	Excess lifetime cancer risk (ELCR)
Inhalation: Systemic Long Term	0.501	4.00E-03	2.00E-03

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

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

Risk for reproductive toxicity

Table 9-46 shows the risk characterisation for reproductive toxicity for incidentally exposed workers. The risk characterisation for reproductive toxicity is based on measured Cr(VI) inhalation exposure data, as no dermal exposure is considered for these workers. The exposure values are compared to the RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Table 9-46: Risk characterisation for reproductive toxicity for WCS 6 – Incidentally exposed workers

Route of exposure and type of effects	Long-term exposure	Risk characterisation: RAC DNEL *	Risk characterisation ratio (RCR)
Inhalation: Systemic Long Term	$0.501 \mu\text{g}/\text{m}^3$	$43 \mu\text{g}/\text{m}^3$	0.0117

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

* RAC DNEL for workers, derived for effects on fertility (ECHA, 2015).

Conclusion on risk characterisation:

Carcinogenicity

The Excess life-time cancer risk for incidentally exposed workers is **2.00E-03**.

This risk estimate can be considered as conservative, because:

- it is based on a conservative 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 values.

As described above, it is considered for the assessment that **two incidentally exposed workers** (, being indirectly exposed during 50% of their working time to Cr(VI) from formulation) has to be considered per site.

Reproductive toxicity

The RCR for the endpoint reproductive toxicity based on the assessment of inhalation exposure is well below 1 (0.0117).

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

Comparison of outcome with initial application

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.

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)

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"⁸), 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 and wastewater are assessed (see section 9.2.3.1).

10.2.2 Local exposure due to all wide dispersive uses

There are no wide dispersive uses covered in this CSR.

10.2.3 Local exposure due to combined uses at a site

Only one use is covered by this CSR.

However, formulation activities for manufacturing products destined for other supply chains than aerospace and defence may occur and contribute to local emissions.

⁸ RAC/SEAC, consolidated version, 2016; <https://echa.europa.eu/documents/10162/658d42f4-93ac-b472-c721-ad5f0c22823c>

Formulation

SD

For the site with the highest combined risk ($1.24E-6$) 100% of the releases were attributed to aerospace and defence uses. This risk level would only marginally be exceeded by one site ($2.1E-6$), if the total tonnages are used for calculation. Note that at this site a larger part of the Cr(VI) is used as an intermediate to produce products containing Cr(III).

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 four chromates covered by the ADCR consortium other than chromium trioxide (CT) is shown. The physico-chemical properties of CT are given in section 9.1.2.4.

With these physico-chemical properties as input parameters we carried out a comparative EUSES assessment with an example scenario in which only the substance-specific physico-chemical properties of the five chromates covered by the ADCR consortium were exchanged.

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

Physico-chemical properties of sodium dichromate (SD), required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	10588-01-9		
Molecular weight	262 g/mol	262 g/mol	Refers to SD; value used in ECB (2005)
Melting/freezing point	Becomes anhydrous at 100 °C (ECB, 2005), salt melts at ca. 357 °C	357 °C at 101.3 kPa	Refers to SD; value used in ECB (2005)
Boiling point	decomposes above 400 °C (ECB, 2005)	400 °C	Refers to SD; value used in ECB (2005)
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	2355 g/L at 20°C; (a 1% solution has a pH ~4)	2355 g/L at 20°C	Refers to SD; value used in ECB (2005)

Physico-chemical properties of sodium chromate (SC), required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	7775-11-3		
Molecular weight	161.99 g/mol	161.99 g/mol	Refers to SC, value used in ECB (2005); Registration dossier
Melting/freezing point	decahydrate loses H ₂ O and melts at ~20°C; anhydrous salt melts at ~762°C (acc. to ECB, 2005); 792°C (acc. to registration dossier)	500°C (highest value possible for EUSES)	Refers to SC, value used in ECB (2005); Registration dossier
Boiling point	n/a; inorganic compound	500°C (highest value possible for EUSES)	
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	~530 g/l at 20°C (the aqueous solution is alkaline (pH 9))	530 g/L at 20°C	Refers to SC, value used in ECB (2005)

Physico-chemical properties of potassium dichromate (PD) required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	7778-50-9		
Molecular weight	294.22 g/mol	294.22 g/mol	Refers to PD, value used in ECB (2005)
Melting/freezing point	~398°C	398	Refers to PD, value used in ECB (2005)
Boiling point	n/a decomposes above 500°C	500	Refers to PD, value used in ECB (2005)
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	~115 g/L at 20°C (a 10% solution has a pH ~3.5)	115 g/L at 20°C	Refers to PD, value used in ECB (2005)

Physico-chemical properties of dichromium trischromate (DtC) required for EUSES modelling

Property	Description of key information	Value selected for EUSES modelling	Comment
CAS	24613-89-6		
Molecular weight	451.97 g/mol	451.97 g/mol	Refers to DtC, value used in SVHC support document (ECHA, 2011)
Melting/freezing point	The substance melts above 300°C	300	Refers to DtC, value used in SVHC support document (ECHA, 2011)
Boiling point	n/a	300	Refers to DtC, value used in SVHC support document (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	96.6 g/L at 20°C	96.6 g/L	Refers to DtC, value used in SVHC support document (ECHA, 2011)

Comparative EUSES assessment with an example scenario

The outcome of the comparative EUSES assessment is shown in the Table below. The test was carried out using the partition coefficients determined under alkaline conditions and no use of a biological STP was assumed. 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 slightly higher based on CT data. Although the difference is very small, we used CT data for EUSES modelling of Cr(VI) exposure for all sites for reasons of conservatism.

Outcome of the comparative EUSES assessment of the impact of the physico-chemical properties of the five different chromates on the concentrations in the considered Cr(VI) uptake media 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]
SD	1.77E-07	1.02E-08	1.74E-07	3.61E-07
CT	3.41E-07	1.02E-08	1.74E-07	5.25E-07
SC	1.77E-07	1.02E-08	1.74E-07	3.61E-07
PD	1.77E-07	1.02E-08	1.74E-07	3.61E-07
DtC	1.77E-07	1.02E-08	1.74E-07	3.61E-07

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

We assessed the impact of the selected partition coefficients (under acidic or alkaline conditions) in a sensitivity analysis with EUSES. We carried out an exemplary exposure scenario (with no biological STP) using (a) the coefficients for acidic conditions, (b) the coefficients for alkaline conditions or (c) the calculated mean values. The outcome of the assessment is shown in the table below. From the table it becomes obvious that the variation of Cr(VI) exposure of HvE via the combined exposure routes air, drinking water and fish was lower than 2%. Accordingly, it can be concluded that the selected set of partition coefficients had close to no impact on the modelling result.

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	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]	Variation of sum of daily dose through intake of drinking water, fish, and air from calculation with mean partition coefficients [%]
Mean values	1.74E-07	1.00E-08	1.74E-07	3.58E-07	0%
Acid	1.72E-07	9.89E-09	1.74E-07	3.56E-07	0.59%
Alkaline	1.77E-07	1.02E-08	1.74E-07	3.61E-07	- 0.89%

11.3 Annex III – EUSES input data and release fractions derived from environmental monitoring data of representative sites

Table Annex III-1: EUSES input data and release fractions derived from environmental monitoring data of representative sites

Site	Fraction of tonnage released to air	Release to air [kg/year]	Fraction of tonnage released to water	Release to water [kg/year]	STP discharge rate [m3/day]	Application of sewage sludge to agricultural soil/grassland	Dilution factor receiving water
1	1.90E-07	0.00118	2.12E-06	0.320	2000 ^a	assume yes ^b	10 ^c
2	8.89E-08	0.0416	7.47E-09	0.00389	110000		10 ^c
3	9.72E-08	0.00170	no water emission	0.00	-	-	-
4	-	0.0562	no water emission	0.00	-	-	-
MIN	8.89E-08	0.0012	7.47E-09	0.00			
MAX	1.90E-07	0.0562	2.12E-06	0.320			

^a No site-specific information available for the STP discharge rate and thus, the EUSES default of 2000 m3/day was used.

^b Application of STP sludge to agricultural soil is considered since no information to the contrary is available.

^c No site-specific information available for the flow rate of the receiving water, the EUSES default of 18 000 m3/day was used.

Table Annex III-2: Exposure concentrations for humans via the environment – on local scale

Site	Inhalation		Oral (drinking water and fish)	
	Local Cr(VI) PEC in air [$\mu\text{g}/\text{m}^3$]	Drinking water * [$\mu\text{g Cr(VI)}/\text{kg x d}$]	Fish * [$\mu\text{g Cr(VI)}/\text{kg x d}$]	Oral exposure (water and fish) [$\mu\text{g Cr(VI)}/\text{kg x d}$]
1	9.03E-07	7.52E-05	3.00E-07	7.55E-05
2	3.17E-05	1.15E-06	8.80E-09	1.15E-06
3	1.30E-06	1.25E-07	7.18E-09	1.32E-07
4	4.28E-05	1.06E-06	7.46E-09	1.07E-06
MIN	9.03E-07	1.25E-07	7.18E-09	1.32E-07
MAX	4.28E-05	7.52E-05	3.00E-07	7.55E-05

* See explanations on oral uptake via drinking water and fish in CSR section 9.1.2.4.2.

Remarks on measured exposure:

The local exposure concentrations reported in the table above are based on the **releases of the sites related to products intended for aerospace and defence supply chains**. Note that 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.

11.4 Annex IV – Inhalation exposure measurements for workers

11.4.1 WCS 1 - Operators producing liquid mixtures

For inhalation exposure measurements for this SEG, the following analytical methods were used:

- spectrophotometric according to NIOSH 7600
- IFA 6666 (sampling), ISO 16740 (Analysis)
- UV spectroscopy after filter elution, BGI 505-5-2

Reported LOQs ranged from 0.02 to 0.6 µg/sample. Available Information on methods and LOQs for individual measurements are documented in a separate excel file.

11.4.2 WCS 2 - Operators producing solid mixtures

For inhalation exposure measurements for this SEG, the following analytical methods was used:

IOM filters (PVC), MSHA, “SCORT ELF Pump” ID-33, UV-VIS spectrophotometric determination NIOSH 7600/IFA 6666 (sampling), ISO 16740 (Analysis).

A LOQ of 0.3 µg/m³ was reported for the 2018 measurement. No LOQ was reported for the other data, but all values could be quantified (see below). Available Information on methods and LOQs for individual measurements are documented in a separate excel file.

Individual measurements for WCS 2 – Operators producing solid mixtures

Data from measurement campaigns in 2018 and 2020 (personal monitoring of mixing operators) with chromium trioxide (CT), sodium dichromate (SD) and sodium chromate (SC).

Measurements in 2020 were performed as two separate measurements for loading the vessels and the remaining activities (mixing, loading of product containers). Time-weighted average concentrations were calculated from these two measurements as shown in the table below for the duration of production of the batch.

Year of measurement/ substance	Duration	Measured concentration (µg/m ³)	Total duration	Time-weighted exposure value per batch (µg/m ³)
2018/CT	80	<0.3	80	0.15
2020/SD-loading	17	132.4		
2020/SD-mixing, filling product containers	115	50.0		
			132	60.61
2020/SC-loading	8	37.5		

Formulation

SD

2020/SC-mixing, filling product containers	50	42.0		
			58	41.38
2020/SC-loading	27	11.1		
2020/SC-mixing, filling product containers	104	28.4		
			131	24.8

11.4.3 WCS 4 to 6 - Analytical methods

For inhalation exposure measurements, diverse analytical methods were used. Frequently reported analytical methods are NIOSH 7600 (VIS), NIOSH 7605 2003, ion chromatography, OSHA 215, UV/VIS spectrometry, IFA 6665: 2014-10 with ion chromatography or UV/VIS Spectroscopy, ISO 16740 PN-87/Z-04126/03.

According to the diversity of analytical methods used, the reported LOQs are heterogenous, ranging from 0.01 µg/m³ to 10 µg/m³.

Available Information on methods and LOQs for individual measurements are documented in a separate excel file.

11.4.4 WCS 5 – Inhalation exposure for WCS 5 – Logistics workers - ART protocols

a) ART Input parameters used and output for exposure modelling of workers during tank truck loading – near field

ART REPORT – Chromium trioxide - Logistic operators - tank truck loading

PROC 8b

Chemical details

Chemical	chromium trioxide
CAS No.	1333-82-0

Scenario details

Number of activities	1
Total duration (mins)	10
Nonexposure period (mins)	0

Metadata

ART version	1.5
Creator	
Date created	01-Dec-21
Date last edited	18-Dec-21

Details for Activity Connecting and disconnecting lines

Emission sources:	Near field 	Duration (mins):	10 
	Far field		

Near-field exposure

Operational Conditions

Substance emission potential

Substance product type	Liquids
Process temperature	298 K
Vapour pressure	0 Pa
Liquid weight fraction	0.26
Viscosity	Low

Activity emission potential

Activity class	Handling of contaminated objects
Situation	Activities with treated/contaminated objects (surface 0.3-1 m ²)
Contamination level	Contamination 10-90 % of surface

Surface contamination

Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion

Work area	Outdoors
Source located close to buildings?	No

Risk Management Measures

Localised controls

Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)

Formulation

SD

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0017 mg/m³.

The inter-quartile confidence interval is 0.00064 mg/m³ to 0.0048 mg/m³.

b) ART Input parameters used and output for exposure modelling of workers during tank truck loading – far field

ART REPORT – Chromium trioxide - Logistic operators - tank truck loading

PROC 8b

Chemical details

Chemical	chromium trioxide
CAS No.	1333-82-0


Scenario details

Number of activities	1
Total duration (mins)	110
Nonexposure period (mins)	0

Metadata

ART version	1.5
Creator	
Date created	01-Dec-21
Date last edited	18-Dec-21

Details for Activity Loading phase

Emission sources:	Near field	Duration (mins):	110
	Far field 		

Far-field exposure

Operational Conditions

Substance emission potential

Substance product type	Liquids
Process temperature	298 K
Vapour pressure	0 Pa
Liquid weight fraction	0.26
Viscosity	Low

Activity emission potential

Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 100 - 1000 l/minute
Containment level	Handling that reduces contact between product and adjacent air. <i>Note: This does not include processes that are fully</i>
Loading type	Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely

Surface contamination

Process fully enclosed?	No
Effective housekeeping practices in place?	Yes

Dispersion

Work area	Outdoors
Source located close to buildings?	No
Worker distance	> 4 m

Risk Management Measures

Localised controls

Primary	No localized controls (0.00 % reduction)
Secondary	No localized controls (0.00 % reduction)
Segregation	No segregation (0.00 % reduction)
Personal enclosure	No personal enclosure (0.00 % reduction)

Formulation

SD

Predicted exposure levels

ART predicts air concentrations in a worker's personal breathing zone outside of any Respiratory Protection Equipment (RPE). The use of RPE must be considered separately.

Mechanistic model results

The predicted 90th percentile full-shift exposure is 0.0014 mg/m³.

The inter-quartile confidence interval is 0.00054 mg/m³ to 0.0041 mg/m³.

11.5 Annex V – Dermal exposure modelling

11.5.1 EXCEL-based exposure assessment

Table Annex V-1 shows a generic, Excel-based exposure assessment developed for the purpose of this review report. It is based on the upper end of the range for the dermal load (0.1 mg/cm²/d) as provided in the EU RAR (ECB, 2005), which was based on EASE for non-dispersive use with direct handling with incidental contact, which is similar to the situation relevant here. The rationale for the selection of the parameters used is provided in the table below.

As a conservative assumption exposure of one side of both hands (480 cm²) is assumed for activities such as weighing solids, maintenance activities, handling of solid waste and cleaning small spills with wipes. Handling highly concentrated liquid chromate solutions require special care and education, due to its skin corrosive properties (see below). Larger contamination needs to be avoided under all circumstances and the (lack of) history of incidences in the companies confirms this. Therefore, for tasks involving highly concentrated chromate solutions (e.g. charging the mixing vessels with liquid concentrates, transfer of product to storage vessels or containers, sampling and connecting lines for tank truck filling) only occasional small-scale contact with skin is assumed (e.g. by droplets). A skin contact area of 240 cm² is used here.

For those activities with possible exposure to splash water (i.e. cleaning with a water hose, Task 5 in WCS1, section 9.2.3.2 and Task 4 in WCS2, section 9.2.3.3) exposure of larger parts of the body is assumed. The consumer module of ECETOC TRA (ECETOC, 2009; 2012) assumes exposure of half of the surface of the body (corresponding to 8750 cm²). However, this approach seems overly conservative taking into consideration that whole body personal protection equipment (coverall) and waterproof boots are mandatory for such cleaning activities. Therefore, for cleaning activities with a hose (Task 5 in WCS1) a skin contact area of 2083 cm² has been assumed, which corresponds to the surface of both hands and forearms, i.e. ca. ¼ of the front of the body. As use of impermeable coveralls is required for cleaning with a hose, 95% protection efficiency is assumed according to HEEG opinion (EC, 2010).

The actual dermal exposure to the product is calculated under consideration of body weight (ECHA, 2012) and PPE efficiency (EC, 2010). For the calculation of the dermal exposure to Cr(VI) the concentration of Cr(VI) in the solid or liquid substance or product is considered. In general, in case more than one substance is used only the molecular weight fraction of Cr(VI) for the substance with the highest molecular weight fraction is considered to calculate the Cr(VI) exposure concentration in a conservative manner (molecular weight fraction of Cr(VI) for SD, PD and SC: 0.40, 0.35, and 0.32, respectively). For cleaning spills a rapid dilution (at least 10-fold) of the Cr(VI) containing product or solution is assumed, because small spills are taken up with wet wipes and larger contaminations are reduced by a suitable reduction agent (e.g. ascorbic acid) before wiping it up or taking up with absorbent. A high dilution can also be assumed when remaining contaminants are hosed down with a water hose.

It should be noted that SD, PD and SC are classified for skin corrosion. As a consequence, dermal exposure to any neat substance has to be prevented. The assumption of permeation of gloves by 5 % of the potential dermal dose is a purely hypothetical assumption since dermal exposure has to be prevented due to local effects alone. The same is essentially true for other tasks, since e.g., SD concentrations ≥0.1 % require labelling as Skin Sens. 1 (H317) according to the CLP Regulation, implying that such low concentrations may be sensitising to the skin.

Formulation

SD

The following table shows the calculations for WCS1 and WCS 4 to 6. As different frequencies apply for the manufacture of solid mixtures, the dermal assessment for WCS 2 is presented in a separate table.

Formulation

SD

Table Annex V-1: Modelled Exposure for Workers in WCS 1, 4 and 5 (main tasks and secondary tasks; Excel-based approach)

Parameter	Unit	weighing of solid chromates	Charging mixing vessels	Transfer of products	Sampling	Cleaning of workplace, equipment with hose	Cleaning of workplace with wipes etc.	Maintenance of equipment	Waste management – Handling of solid waste	Filling of tank trucks	Aggregated total exposure per WCS ($\mu\text{g}/\text{kg bw}/\text{d}$)
PROC		8a, 8b	8a, 8b	8b	9	28	28	28	8b	8b	
Exposed part of the body		hand	hand	hand	hand	hands and forearms	hand	hand	hand	hand	
EU RAR modelling assumption (0-0.1 mg/cm ²)	mg/cm ²	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Skin contact area (see text)	cm ²	480	240	240	240	2083	480	480	480	240	
Dermal load	mg	48	24	24	24	208.3	48	48	48	24	
Body weight	kg	70	70	70	70	70	70	70	70	70	

2022

Formulation

SD

Parameter	Unit	weighing of solid chromates	Charging mixing vessels	Transfer of products	Sampling	Cleaning of workplace, equipment with hose	Cleaning of workplace with wipes etc.	Maintenance of equipment	Waste management – Handling of solid waste	Filling of tank trucks	Aggregated total exposure per WCS ($\mu\text{g}/\text{kg bw}/\text{d}$)
Potential dermal exposure to product	mg/kg bw	0.686	0.343	0.343	0.343	2.98	0.69	0.686	0.686	0.343	
PPE efficiency (coverall and/or gloves), see text	%	95	95	95	95	95	95	95	95	95	
Actual dermal exposure to product	mg/kg bw	0.0343	0.0171	0.0171	0.0171	0.149	0.0343	0.0343	0.0343	0.0171	
Cr(VI) concentration in product	%	40.0 (WCS1 Product 1)	40.0 (WCS1 Product 1)	26.0 (WCS1 Product 3)	26.0 (WCS1 Product 3)	2.60 (WCS1 Product 3 diluted)	2.60 (WCS1 Product 3 diluted)	2.60 (WCS1 Product 3 diluted)	40.0 (WCS1 Product 1)	26.0 (WCS1 Product 3)	
Task specific dermal exposure to Cr(VI)	$\mu\text{g}/\text{kg bw}$	13.7	6.99	4.46	4.46	3.87	0.891	0.891	13.7	4.46	

2022

Formulation

SD

Parameter	Unit	weighing of solid chromates	Charging mixing vessels	Transfer of products	Sampling	Cleaning of workplace, equipment with hose	Cleaning of workplace with wipes etc.	Maintenance of equipment	Waste management – Handling of solid waste	Filling of tank trucks	Aggregated total exposure per WCS ($\mu\text{g}/\text{kg bw}/\text{d}$)
Frequency	d/year	15	240	240	144	240	240	48	240	36	
Annual average dermal exposure to Cr(VI)	$\mu\text{g}/\text{kg bw}/\text{d}$	0.857	6.86	4.46	2.67	3.87	0.891*	0.178	13.71	0.669	
Tasks for WCS 1 – Operators liquid mixtures		X	X	X	X	X		X	X		32.61
Tasks for WCS 2 – Operators solid mixtures											See separate table
Tasks for WCS 4 – Maintenance workers								X			0.178

2022

Formulation

SD

Parameter	Unit	weighing of solid chromates	Charging mixing vessels	Transfer of products	Sampling	Cleaning of workplace, equipment with hose	Cleaning of workplace with wipes etc.	Maintenance of equipment	Waste management – Handling of solid waste	Filling of tank trucks	Aggregated total exposure per WCS ($\mu\text{g}/\text{kg bw}/\text{d}$)
Tasks for WCS 5 – Logistics operators				X						x	5.13
Tasks for WCS 6 – Incidentally exposed workers											0.00

*not considered in total, as cleaning with hose leads to higher exposure (it is assumed that only the one or the other method is applied)

All values rounded to three significant figures, but unrounded values used in calculation

Formulation

SD

Table Annex V-2: Modelled Exposure for Workers in WCS 2 (main tasks and secondary tasks; Excel-based approach)

Parameter	Unit	Charging mixing vessels	Transfer of products	Sampling	Cleaning of workplace with hose	Cleaning of workplace with wipes	Maintenance of equipment	Waste management – Handling of solid waste	Aggregated total exposure per WCS ($\mu\text{g}/\text{kg bw}/\text{d}$)
PROC		8a, 8b	8b	9	28	28	28	8b	
Exposed part of the body		hand	hand	hand	hands and forearms	hand	hand	hand	
EU RAR modelling assumption (0-0.1 mg/cm ²)	mg/cm ²	0.1	0.1	0.1	0.1	0.1	0.1	0.1	
Skin contact area (see text)	cm ²	480	480	480	2083	480	480	480	
Dermal load	mg	48	48	48	208.3	48	48	48	
Body weight	kg	70	70	70	70	70	70	70	
Potential dermal exposure to product	mg/kg bw	0.686	0.686	0.686	2.98	0.69	0.686	0.686	

2022

Formulation

SD

Parameter	Unit	Charging mixing vessels	Transfer of products	Sampling	Cleaning of workplace with hose	Cleaning of workplace with wipes	Maintenance of equipment	Waste management – Handling of solid waste	Aggregated total exposure per WCS (µg/kg bw/d)
PPE efficiency (overall and/or gloves), see text	%	95	95	95	95	95	95	95	
Actual dermal exposure to product	mg/kg bw	0.0343	0.0343	0.0343	0.1488	0.0343	0.0343	0.0343	
Cr(VI) concentration in product	%	40.0 (WCS2 Product 1)	32.0 (WCS2 Product 2)	32.0 (WCS2 Product 2)	3.20 (WCS1 Product 2 diluted)	3.20 (WCS1 Product 2 diluted)	32.0 (WCS2 Product 2)	40.00 (WCS2 Product 1)	
Task specific dermal exposure to Cr(VI)	µg/kg bw	13.7	11.0	10.97	4.76	1.10	10.97	13.7	
Frequency	d/year	80	80	80	80	80	1	80	
Annual average dermal exposure to Cr(VI)	µg/kg bw/d	4.57	3.66	3.66	1.59	0.366*	0.0457	4.57	18.09

*not considered in total, as cleaning with hose leads to higher exposure (it is assumed that only the one or the other method is applied)

All values rounded to three significant figures, but unrounded values used in calculation.

Discussion and conclusions

Table Annex V-1 summarises the results of the dermal exposure assessment for WCS1, 4 and 5. In a conservative manner all tasks possibly performed by one SEG are considered in the aggregated dermal exposure assessment. There are slight organisational differences between the sites, regarding assignment of certain tasks. To cover the situation of all sites, dermal exposure from any activity possibly related to a certain SEG (including secondary tasks) is considered for all SEGs that could perform this activity. The exposure estimate for operators producing solid mixtures is presented in a separate table (Table Annex V-2), because frequency of activities differ here and require separate calculations.

The highest exposure was calculated for WCS 1 (32 µg Cr(VI)/kg bw/d), which includes seven main and secondary tasks, the contributions of which are summed up. Despite this conservative approach applied exposure estimates for all tasks are below the DNEL of 43 µg Cr(VI)/kg bw/d.

The possibilities and limitations of modelling these activities with Riskofderm are explained in section 11.5.2.

11.5.2 Riskofderm modelling

The Riskofderm model (v.2.1) only contains a limited number of modules (DEO units), which are applicable to the worker activities described in sections 9.2.3.2 to 0. The only DEO for activities relating to the tasks relevant for this use is DEO 1 (filling, mixing, loading; only hand, not body exposure covered by the model), like filling mixing vessels and sampling. No valid DEO unit is available for handling contaminated objects, which actually is the most relevant type of contact for weighing of solids, cleaning and maintenance activities, handling of contaminated waste, and connecting lines of tank trucks. Handling of contaminated objects would also be the best description of filling mixing vessels with liquid concentrates, as this activity is performed by pumping the liquids through closed lines: exposure is restricted to the activities of connecting and disconnecting the lines between the containers containing the concentrates (e.g. IBCs) and the mixing vessels.

In the following we present the results from Riskofderm modelling of filling mixing vessels with neat chromates or with highly concentrated aqueous solutions of chromates (DEO 1). The relevance of these predictions for the situation at formulators is discussed afterwards.

The conditions of use applied for the Riskofderm model are described in the following table Annex V-3 (for details see in sections 9.2.3.2 to 0). Table Annex V-4 uses the outcome of the Riskofderm modelling (see the protocols in sections 11.5.2.1 and 11.5.2.2) to calculate the daily dermal exposure.

Table Annex V-3: Conditions of use (Riskofderm modelling, DEO 1, realistic input parameters)

	Method
Product (article) characteristics	
<ul style="list-style-type: none"> Physical form of the used product: <ul style="list-style-type: none"> Charging mixing vessels: liquid Charging mixing vessels: solid 	Riskofderm 2.1
Amount used (or contained in articles), frequency and duration of use/exposure	
<ul style="list-style-type: none"> Duration of dermal exposure: <ul style="list-style-type: none"> Liquid: Charging mixing vessels (30-60 min) Solid: Charging mixing vessels (30-60 min) 	Riskofderm 2.1
<ul style="list-style-type: none"> Frequency of skin contact: Rare contact 	Riskofderm 2.1
<ul style="list-style-type: none"> Use rate of the product: <ul style="list-style-type: none"> Liquid: Charging mixing vessels (1000 L/60 min) Solid: Charging mixing vessels (100 kg/20 min) 	Riskofderm 2.1
Technical and organisational conditions and measures	
<ul style="list-style-type: none"> Level of automation of the task: Liquid: Semi-automated (transfer via closed lines with pumps); solid: Manual task 	Riskofderm 2.1
Conditions and measures related to personal protection, hygiene, and health evaluation	
<ul style="list-style-type: none"> Dermal protection: Yes (Chemically resistant gloves conforming to EN374 with specific activity training) and (other) appropriate dermal protection [Effectiveness Dermal: 95%] 	Riskofderm 2.1
Other conditions affecting workers exposure	
<ul style="list-style-type: none"> Generation of aerosols or splashes during task: No 	Riskofderm 2.1
<ul style="list-style-type: none"> Type of skin contact: Light skin contact 	Riskofderm 2.1

The 90th percentile exposure estimate from Riskofderm modelling was used for an estimate of potential dermal exposure. The results of the Riskofderm model are documented in the table below.

Modelling results

The exposure estimates modelled with Riskofderm are shown in the following table.

Table Annex V-4: Modelled Exposure for workers based on Riskofderm results

Parameter	Unit	Charging mixing vessels (solids)	Charging mixing vessels (liquids)	Rationale (Reference)
		(hands)	(hands)	
Potential dermal exposure to product per event	mg/μL	26.7 mg	891 μL	Riskofderm result, 90 th percentile
Density	g/cm ³	-	Approx. 1.5	
Potential dermal exposure to product per event	mg	26.7	1336.5*	
Body weight	kg	70	70	Body weight for workers (Guidance IR & CSA, R.8 (ECHA, 2012))
Potential dermal exposure to product	mg/kg bw/d	0.381	19.1	Calculated
PPE efficiency (gloves, protective clothing, or apron)	%	95	95	see (EC, 2010)
Actual dermal exposure to product	μg/kg bw/d	19.1	954.6	Calculated
Cr(VI) concentration in product	%	40	28	See WCS specific conditions of use as described in 9.2.3.2 sections to 0
Actual dermal exposure to Cr(VI)	μg/kg bw/d	7.63	267.3	Calculated
Frequency	d/year	240	240	
Annual average dermal exposure to Cr(VI)	μg/kg bw/d	7.63	267.3	Calculated

*calculated from the volume of liquid product (891 μL) predicted by Riskofderm and an assumed density of 1.5 g/cm³.

For filling liquid concentrates the Riskofderm modelling predicts an exposure concentration of 267 μg/kg bw/day, which is above the DNEL by a factor of 6. The exposure predicted for filling solid neat substances is lower than that for liquids by a factor of 35 (7.6 μg/kg bw/day). This difference indicates substantial uncertainties in the exposure predictions: actually, many user companies change their procedures and use concentrated liquid chromates instead of neat solids, as dermal exposure during these transfers is clearly less likely to occur than during handling of solids. Solids can give rise to dust exposure and are more difficult to handle. In contrast, liquid concentrations are transferred via closed lines and are pumped from container to container. As outlined above, this activity of transferring

liquids via closed lines actually would be better modelled as “Handling contaminated objects”. No respective DEO is available in Riskofderm.

In order to interpret the results from the Riskofderm model, considering the underlying data is helpful. Warren et al. (2006) lists the studies, which were used to establish DEO1 of the Riskofderm model. Two of the studies (Lansink et al. 1996, RISKOFDERM, 2003a, as cited in Warren et al. (2006); studies on loading solids: calcium carbonate, zinc oxide) are not available. The others are discussed here:

Fransman et al. (2004) investigated the dermal exposure to cyclophosphamide of hospital personnel. The data used by Warren et al. (2006) were hand exposure from pouring urine of patients. From the reported concentration of cyclophosphamide in urine (16.7 µg/mL), the median contamination rate of gloves (0.0006 ng/cm²/min) a contamination rate for the “product” (urine) of 3.6 µg/cm²/min can be calculated. With a duration of the activity of 6.5 min the dermal load is 0.0023 mg urine/cm² or 1.12 mg urine per individual and activity (with a surface area of hands of 480 cm²).

Warren et al. (2006) further used data from mixing anti-fouling agents as reported by . These authors measured exposure of hands of workers mixing paints at a dockyard. The geometric mean exposure rate during mixing was 31.2 mg/cm²/hour. It is stated that “large quantities of paints were being used and depending on the situation up to 200 L could be processed during a 2h period”. Further the authors state that “worker’s hands were often contaminated from splashes and from contact with containers or the painting equipment”. This gives a dermal load of 62.4 mg x 480 cm² per activity (2 hours).

Delgado et al. (2004) investigated dermal exposure in car repair shops. Workers filled spray guns manually by pouring the liquid products into the spray guns. The geometric mean of the contamination rate was 24.4 µg/cm²/min, with an average duration of 2.56 min per activity. This leads to a dermal load per activity (with surface area 480 cm² for hands) of 30 mg product per activity.

Gijsbers et al. (2004) performed dermal exposure measurements in companies producing mixtures containing 2-(2- butoxyethoxy)ethanol (DEGBE), a glycol ether used in paints and other products. The loading activities involved handling of packages with pure DEGBE and manual adding them to a production process. This included sometimes filling the substance from larger containers, such as drums, into cans. The measurements showed that 217 mg substance (geometric mean) landed on the hands of the workers. However, exposure varied largely, with a range up to 28000 mg per individual and activity. The arithmetic mean is given as 3215 mg per individual and activity.

Source	Activity	Dermal load per activity
Fransman et al. (2004)	Decanting of urine (hospital)	1.12 mg (over 6.5 min)
Hughson and Aitken (2004)	Manual mixing anti-fouling paints (with visible large contaminations of hands) (dockyards)	29952 mg (over 2 hours)
Delgado et al. (2004)	Manual filling of spray guns (car repair shops)	30 mg (over 2.56 min)

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Gijsbers et al. (2004)	Industrial production of mixtures containing DEGBE	217 mg (over 1 – 15 min)
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Two of the reported studies conclude that several grams of substance end on the surface of the hands only. In case of chromates this would be considered a severe contamination and a health threat. Due to the corrosive properties of the substances, even small-scale contaminations of gloves need to be avoided. A photo in the publication by Gijsbers et al. (2004) shows how a worker wrings out a bag into a mixing vessel. report severe contaminations of the hands from the mixing of anti-fouling paints. Such activities leading to direct contact are unthinkable for handling corrosive chromates, for which special care is required to avoid immediate and severe consequences (burns).

Our situation of handling highly corrosive liquids (concentrated solutions of chromates) requires special care in handling. Formulation workers are instructed to perform all activities following high hygiene standards. Liquids are transferred via lines with pumps, which is different to the activities described by (Gijsbers et al., 2004), where bags with the liquid substance are poured into vessels. Also, the other studies address manual activities with intimate contact to the materials, which is different to handling of chromates. We therefore consider the exposure Riskofderm predictions for DEO1 not suitable to describe exposure during the mixing processes for producing chromate mixtures.

11.5.2.1 Riskofderm protocol: Filling of liquid raw materials into mixing vessels

Filling, mixing or loading (DEO unit 1)		Aliquot chemicals, decanting of liquid	
<i>You can move the input messages with the input fields by dragging and dropping</i>		<i>Scroll down to see the remainder!</i>	
Question	Answer	Additional explanation	Measured range as basis for model
What is the quality of the ventilation related to the task done?	Normal or good ventilation	Good (mechanical) ventilation and/or proper local exhaust ventilation	0,56-225 kg/min for powders; 0,008-257 L/min for liquids
What is the frequency of (skin) contact with the contaminant?	Rare contact	It happens sometimes, but on average less than once per scenario	
What kind of (skin) contact with the contaminant occurs?	Light contact	Touching of contaminated surfaces and/or limited deposition of dust or aerosols	
What type of product is handled?	Liquid	The product handled is a liquid	
Are significant amounts of aerosols or splashes generated in the task?	No	Task does not lead to substantial interaction between product and air, nor to dropping of product on a hard surface	
What is the level of automation of the task done by the worker?	Automated or semi-automated task	The task is largely done by a machine and the interaction of the worker with either package, contaminated installation or product is limited	
What is the use rate of the product?	16,67	L/min	
Percentile for the exposure rate distribution to be assessed	90	percentile	Scroll up or down The sheet "Fillmixload_results" provides an overview of the results of this assessment
		Overview results Back	
		median percentile distribution	
Resulting exposure rate hands	1,71	14,9	µL/min or mg/min
Resulting exposure rate body	only hand exposure is estimated with this model		µL/min or mg/min
What is the cumulative duration of the scenario during a shift?	60	minutes	1-20 min for powders; 0,33-125 for liquids
		median percentile distribution	
Exposure loading per shift hands	103,000	891,000	µL or mg
Exposure loading per shift body	only hand exposure is estimated with this model		µL or mg
See the guidance for some remarks on different criteria for the performance of the model.			

11.5.2.2 Riskofderm protocol: Filling of solid raw materials into mixing vessels




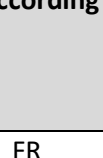
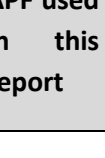
Filling, mixing or loading (DEO unit 1)		Aliquot chemicals, decanting of liquid		
<i>You can move the input messages with the input fields by dragging and dropping</i>		<i>Scroll down to see the remainder!</i>		
Question	Answer	Additional explanation	Measured range as basis for model	
What is the quality of the ventilation related to the task done?	Normal or good ventilation	Good (mechanical) ventilation and/or proper local exhaust ventilation	for powders: always Manual task 0,56-225 kg/min for powders; 0,008-257 L/min for liquids <i>Scroll up or down The sheet "Fillmixload_results" provides an overview of the results of this assessment</i>	
What is the frequency of (skin) contact with the contaminant?	Rare contact	It happens sometimes, but on average less than once per scenario		
What kind of (skin) contact with the contaminant occurs?	Light contact	Touching of contaminated surfaces and/or limited deposition of dust or aerosols		
What type of product is handled?	Low or moderately dusty solid	A low or moderately dusty solid either does not		
Are significant amounts of aerosols or splashes generated in the task?	No	Task does not lead to substantial interaction between product and air, nor to dropping of product on a hard surface		
What is the level of automation of the task done by the worker?	Manual task	The task is largely done manually with substantial interaction between worker and package, contaminated installation or product		
What is the use rate of the product?	5 kg/min			
Percentile for the exposure rate distribution to be assessed	90 percentile			
		median		percentile distribution
Resulting exposure rate hands	,154			1,34
Resulting exposure rate body	only hand exposure is estimated with this model			
What is the cumulative duration of the scenario during a shift?	20 minutes		1-20 min for powders; 0,33-125 for liquids	
		median	percentile distribution	
Exposure loading per shift hands	3,080		26,700	
Exposure loading per shift body	only hand exposure is estimated with this model			
			µL or mg µL or mg	

See the guidance for some remarks on different criteria for the performance of the model.

11.6 Annex VI – 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. As can be seen in the Table below, APFs vary numerically between countries and no generally accepted factors exist. In a conservative approach in this review report we use the lowest value per device over all countries listed in the Table. As it is not always possible to differentiate between companies using combined gas-particle or pure particle filters P3, the same APF (20) is used for full masks with combined gas particle filter Gas X P3 and with particle filter P3.

Table Annex VI-1: Assigned protection factors according to EN 529 and APFs 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	
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
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

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Powered filtering device incorporating a hood or a helmet (PAPR, powered & supplied air respiratory protection) TH3			200	100	200	200	40	40	40
Powered filtering device incorporating a full mask TM3	EN 12942		100 0	500	400	100 0	40	60 (120 L/min) 100 (160 L/min)	40
fresh air hose breathing apparatus - full mask or hood or helmet	EN 138		500	100 0	400	500	40	-	40
Supplied-air respirator (SAR) Continuous flow compressed airline breathing apparatus 4A/4B	EN 14594		-	-	-	-	-	250	40
Compressed air line breathing apparatus with demand valve - Apparatus with a full face mask	EN 14593-1		100 0	100 0	400	100 0	40	-	40

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