

# CHEMICAL SAFETY REPORT

<b>Legal name of applicant(s):</b>	Indestructible Paint Ltd.		
<b>Submitted by:</b>	Indestructible Paint Ltd.		
<b>Substances:</b>	Chromium trioxide (CT) (includes "Acids generated from chromium trioxide and their oligomers", when used in aqueous solutions)	EC 215-607-8	CAS 1333-82-0
<b>Uses applied for:</b>	Use 1: Use of chromium trioxide in the formulation of mixtures intended for supply to authorised industrial gas turbine uses		

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### **Preliminary Remark**

Indestructible Paint Ltd's slurry coating products are also used in the aerospace and defence sector for protecting vital components. The use and application of the products is very similar for the protection of industrial gas turbine and related components as it is for the aerospace and defence sector. Indestructible Paint Ltd is part of the Aerospace and Defence Chromate Reauthorisation (ADCR) consortium. As a consortium member and as the uses of their products in both sectors is the same, Indestructible Paint Ltd made a request to the ADCR consortium to allow relevant occupational and environmental exposure data and information to be used to support the industrial turbine use application. The consortium members reviewed the request and agreed that relevant information could be accessed and used in the industrial turbine use application as part of a letter of access agreement.

## **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.

### **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 site of the applicant.

### **3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED**

Not applicable - as the application is for the applicant's use at his own site only.

## Part B

This 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.

## 9 EXPOSURE ASSESSMENT (AND RELATED RISK CHARACTERISATION)

### 9.1 Introduction to the assessment

#### 9.1.1 Classification

As shown in Table 9-1 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 process 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.

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 CT as mutagenic and carcinogenic substance are addressed in this CSR. This requires investigating the potential exposure of workers as well as exposure of humans via the environment.

**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 <sup>6+</sup>	52.00	1
Chromium trioxide <sup>a</sup> (CT)	1333-82-0	215-607-8	16	Muta. 1B Carc. 1A	CrO <sub>3</sub>	99.99	0.52
Acids generated from chromium trioxide and their oligomers <sup>a, b</sup>	-	-	17	Carc. 1A			

<sup>a</sup> 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.

<sup>b</sup> 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.

The carcinogenicity and mutagenicity of CT and its acids 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 proposed by the Committee for Risk Assessment (RAC) express exposure as Cr(VI).

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.

### 9.1.2 Exposure-risk relationships (ERRs) for carcinogenic effects

The hazard evaluation follows recommendations given by RAC (ECHA, 2015)<sup>1</sup>:

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.

ECHA published on December 4, 2013 the document "*Application for Authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium*"<sup>2</sup> (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):

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<sup>1</sup> ECHA Website: [https://echa.europa.eu/documents/10162/21961120/rac\\_35\\_09\\_1\\_c\\_dnel\\_cr-vi\\_en.pdf/8964d39c-d94e-4abc-8c8e-4e2866041fc6](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

<sup>2</sup> ECHA Website: [https://echa.europa.eu/documents/10162/13579/rac\\_carcinogenicity\\_dose\\_response\\_crvi\\_en.pdf](https://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf); assessed in March 2021

Formulation

Chromium trioxide

**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
2.5	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
0.1	2.9
0.01	0.29
0.001	0.029
0.0001	0.0029

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

Formulation

Chromium trioxide

**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)

### 9.1.3 Environment

#### Scope and type of assessment

CT is not listed in Annex XIV for endpoints related to concerns for the environment. Therefore, no environmental assessment has been performed.

### 9.1.4 Exposure of humans via the environment

#### 9.1.4.1 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

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Chromium trioxide

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 chromium trioxide 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.

**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 <sup>3</sup> Cr(VI) relates to an excess risk of 2.9x10 <sup>-2</sup> *
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 <sup>-4</sup>

\* 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).

#### 9.1.4.2 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 chromium trioxide 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

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Chromium trioxide

relevant by RAC<sup>3</sup>.**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. 2.1.2).

Release days

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

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

For sites where wastewater is sent 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

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<sup>3</sup> 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>

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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*<sup>4</sup> (v.3.1) of the European Food Safety Authority (EFSA), the maximum of the mean consumption of fish (and fish- and marine-/freshwater-products) is 29.3 g per day<sup>5</sup>. 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 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

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<sup>4</sup> 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>

<sup>5</sup> 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).

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## Chromium trioxide

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 chromium trioxide. These releases are generally governed by, and comply with, local worker and environmental regulatory requirements.

Wastewater

There is no emission to wastewater from the production of CT containing products at the applicant's site. All wastewater is gathered in an IBC and sent to a certified external service provider for disposal as hazardous waste.

Air

Mixing vessels are equipped with local exhaust ventilation. Exhaust air is purified with dry filters before being released via stacks.

Soil

No direct release to soil is possible.

Solid waste containing Cr(VI) may arise in the form empty chemical containers, cleaning materials (e.g. rags, wipes), 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 (licensed contractor) for disposal as hazardous waste.



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**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. 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 <sub>2</sub> O <sub>3</sub> and O <sub>2</sub> (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)
<i>K<sub>p</sub> 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
<i>K<sub>p</sub> 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

Property	Description of key information	Value selected for EUSES modelling	Comment
Kp soil		26 L/kg	Refers to Cr(VI); value for acidic and alkaline conditions given in ECB (2005), mean value is used; see text below for details
Bioconcentration factor fish	1 L/kg	1 L/kg	Refers to Cr(VI); value used in ECB (2005)

We derived the 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 I 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
Kp suspended matter	2 000 L/kg	200 L/kg	1 100 L/kg
Kp sediment	1 000 L/kg	100 L/kg	550 L/kg
Kp soil	50 L/kg	2 L/kg	26 L/kg

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

## 9.1.5 Workers

### 9.1.5.1 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).

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

**Table 9-8: 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 (ECHA, 2013)  For workers; based on 40 years of exposure; 8h/day; 5 days/week  Exposure to 1 µg/m <sup>3</sup> Cr(VI) relates to an excess risk of 4x10 <sup>-3 a</sup>

<sup>a</sup> 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.

A qualitative risk characterisation with respect to the corrosive and skin sensitising properties of CT is outside the scope of this CSR, as CT has been included in Annex XIV to Regulation (EC) No 1907/2006 (REACH) solely due to its carcinogenic and mutagenic properties. 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 communicate risk management measures derived by the registrants of CT due to other substance properties related to human health concerns, which they communicated via the Safety Data Sheets (SDS).

#### 9.1.5.2 Comments on assessment approach

##### General approach

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

**Inhalation exposure** of workers is assessed via reliable and representative workplace air measurements. We have assigned exposed workers to “Similar Exposure Groups” (SEGs), which 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 other activities with potential Cr(VI) exposure in parallel (e.g., spraying or brush/touch-up activities with other chromates).

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

**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. Values from **stationary (static) measurements** are also helpful for evaluating background exposures and longer-term room-representative concentrations.

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 90<sup>th</sup> percentile, without differentiating between health endpoints (ECHA, 2016b). We have followed the recommendation in the ECHA guidance to use the 90<sup>th</sup> 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 used in the assessment as supporting information only. Use for risk characterisation is limited as:

- The measure of chromium in erythrocytes is the only one which is specific to Cr(VI). However, the available literature data on the general population and on workers are insufficient to determine reference values and limit values for this indicator (ANSES, 2017). The German method provides a correlation between biomonitoring in erythrocytes and inhalation exposures but only for  $CrO_3$  concentrations above  $30 \mu g/m^3$ , which is above what is expected in these exposures (Greim, 2000). 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) (Drexler and Hartwig, 2009). 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) (ANSES, 2017). These constraints do not facilitate the implementation of this biomonitoring.

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- 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 are preferred over biomonitoring in this case for quantifying exposure and risk.

**Comments on assessment approach related to toxicological hazard:**

Dose-response relationships for carcinogenic effects as proposed by RAC are used for risk characterisation.

**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 are provided in chapters 9.2.2.3 and 9.2.3.1 to 9.2.3.4.

**General information on risk management related to physicochemical hazard:**

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

### **9.1.6 Consumers**

Consumer uses are not subject of this dossier.

## 9.2 Use 1: “Use of chromium trioxide in the formulation of mixtures intended for supply to authorised industrial gas turbine uses”

### 9.2.1 Introduction

Table 9-9 lists the exposure scenario (ES) and contributing scenarios assessed in this chapter.

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

ES number	ES Title	Environmental release category (ERC)/ Process category (PROC)
ES1-IW1	Formulation of mixtures with chromium trioxide	
Environmental contributing scenario(s)		
ECS 1	Formulation into mixture	ERC 2
Worker contributing scenario(s)		
WCS 1	Mixing operators	PROC 5, 8a, 8b, 9, 28
WCS 2	Laboratory technicians	PROC 15
WCS 3	Maintenance and/or cleaning workers	PROC 28
Exposure scenario for industrial end use at site: ES1-IW1		

### 9.2.2 Detailed information on use

#### 9.2.2.1 Process description

Formulation of products with chromium trioxide consists of the preparation of aqueous solutions from the solid, neat substance (including blending with additives).

Solid chromates are supplied in drums as flakes. Dissolution of the chromium trioxide occurs in mixing vessel at ambient temperature. After mixing, the formulation is transferred via closed lines to product containers.

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.

#### 9.2.2.2 Teams and employees involved

Exposure groups (EGs) comprise the following groups:

- Mixing operators
- Laboratory technicians
- Maintenance workers

### 9.2.2.3 Technical and organisational risk management measures

The applicant is an industrial company specialised in formulation activities since many years. The company operates at one site in the United Kingdom (UK). It has rigorous internal safety, health and the environment (SHE) organisational plans.

#### 9.2.2.3.1 Workers

Only well-trained personnel are allowed to handle chromates. Workplaces are assessed regularly regarding the handling of hazardous substances according to the Control Of Substances Hazardous to Health (COSHH) Assessment rules.

##### 9.2.2.3.1.1 Technical measures

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

- Mixing vessels have a lid, which is opened only for adding raw materials
- Mixing vessels have local exhaust ventilation (LEV) and automated stirrers
- 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.

##### 9.2.2.3.1.2 Organisational measures

The formulation site is an industrial site with the relevant organisation structures for handling hazardous substances such as emergency plans.

The following organisational measures to reduce workplace exposure are implemented:

- Regular monitoring programmes are implemented for monitoring of occupational exposure to chromium (VI).
- 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.
- 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).

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- 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.
- 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.
- Chemical products are stored in a designated area.
- Effective cleaning practices are implemented to prevent surface contamination in the vicinity of the vessels.

## 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 risk assessment and in accordance with the exposure scenarios). The following PPE is applied for activities where exposure to Cr(VI) is possible, in order to control Cr(VI) exposures:

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

The specific PPE for each task is described in detail in the worker contributing scenarios in sections 9.2.3.2 to 9.2.3.4.

**9.2.2.3.2 Environment**

## 9.2.2.3.2.1 Emissions to air

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

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

**Efficiency of air emission abatement technology**

Efficiency of air abatement technology is regularly controlled internally.



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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 Emissions to wastewater**

There is no emission to wastewater from the production of CT containing products. All wastewater (e.g., from rinsing equipment used for production, see photo in Figure 9-5) is gathered in an IBC and sent to a certified external service provider for disposal as hazardous waste.

**9.2.2.3.3 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**

The Cr(VI)-contaminated solid waste such as contaminated wipes and PPE (gloves, overalls, foils) or empty chemical containers (canisters, 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**

Assessed tonnage: Up to ■ (0.2 - 5) tonnes CT/year  
Up to ■ (0.1 – 2.6) tonnes Cr(VI)/year

**9.2.2.4.2 Mass balance considerations****Consumption during process**

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

**Amount of Cr(VI) released to wastewater**

There is no emission to wastewater from the production site.

**Amount of Cr(VI) discharged as waste**

Cr(VI) in solid waste occurs in the form of contaminated wipes and PPE (gloves, overalls, foils) or empty chemical containers (canisters, 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); the quantities are low and not quantifiable.

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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 up to 0.004 kg per year (as described in section 9.2.3.1.2). At the site, the exhaust air is treated by air filters before release (see above).

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### 9.2.3 Exposure scenario 1 for Use 1: “Use of chromium trioxide in the formulation of mixtures intended for supply to authorised industrial gas turbine uses”

**Market sector:** -

**Sector of use:** SU 9

**Article categories:** not relevant

**Environment contributing scenario(s):** ERC 2

**Worker 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

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

Manufacture of aqueous mixtures containing water-soluble chromates from solid substances (see detailed use information in section 9.2.2.1).

#### Explanation on the approach taken for the ES:

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

#### 9.2.3.1 Environmental contributing scenario 1

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

##### 9.2.3.1.1 Conditions of use

**Table 9-10: Conditions of use – environmental contributing scenario 1**

<b>Product (article) characteristics</b>
Product A: Solid CT (flakes), pure substance (100%); <b>52% Cr(VI)</b>
<b>Amount used, frequency and duration of use (or from service life)</b>
Product A: Solid CT (flakes), used to prepare mixtures <ul style="list-style-type: none"> <li>▪ Annual used amount at a site: 0.2 – 5 (■) t CT/a</li> <li>▪ Batch process</li> <li>▪ Approx. 50 days/year</li> </ul>
<b>Technical and organisational conditions and measures</b>

<p><b>Technical measures</b></p> <p>Air</p> <ul style="list-style-type: none"> <li>- Mixing vessels are equipped with LEV and</li> <li>- exhaust air is treated by air filters before it is released via stack(s)</li> </ul> <p>Wastewater</p> <ul style="list-style-type: none"> <li>- Wastewater occurs from rinsing water, cleaning water, and liquid hazardous waste from the laboratory</li> <li>- Cr(VI)-containing wastewater is gathered and sent directly to an certified external company for disposal</li> </ul> <p>Soil</p> <ul style="list-style-type: none"> <li>- The indoor surfaces where chemicals are handled are sealed and chemicals and solid waste containing Cr(VI) are stored in closed containers.</li> </ul> <p><b>Organisational conditions and measures</b></p> <p>Air</p> <ul style="list-style-type: none"> <li>- Cr(VI) air emission measurements are performed at identified exhaust stack(s) where the process emissions are released</li> </ul> <p>Wastewater</p> <ul style="list-style-type: none"> <li>- Cr(VI)-containing wastewater is gathered and sent directly to an certified external company for disposal</li> </ul>
<p><b>Conditions and measures related to sewage treatment plant</b></p> <ul style="list-style-type: none"> <li>▪ Not applicable as no emission to wastewater occurs</li> </ul>
<p><b>Conditions and measures related to treatment of waste (including article waste)</b></p> <p>All products:</p> <ul style="list-style-type: none"> <li>▪ Solid hazardous waste contaminated with Cr(VI) such as contaminated wipes and PPE or empty chemical containers (canisters, bags, drums) are disposed as hazardous waste This hazardous solid waste is forwarded to an external waste management company (licensed contractor) for disposal as hazardous waste.</li> </ul>
<p><b>Other conditions affecting environmental exposure</b></p> <p>All products:</p> <ul style="list-style-type: none"> <li>▪ Processes are carried out at ambient temperature (higher temperatures may occur due to exothermic blending)</li> <li>▪ Mixing vessels are covered by lids (except during charging)</li> </ul>
<p><b>Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply</b></p> <ul style="list-style-type: none"> <li>▪ None</li> </ul>

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Manufacture of chromate-containing mixtures for use in the gas turbine sector is carried out at a dedicated industrial formulation site in United Kingdom. Production is batch-wise.

#### Air emissions

The production facility is equipped with local exhaust ventilation (where solid CT is weighed and at the mixing vessels). Emissions are treated by abatement technology, consisting of dry particle filters.

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

#### Wastewater emissions

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

#### Soil emissions

There is no direct release to soil.

#### 9.2.3.1.2 Releases

The release fraction from the production site are shown in Table 9-11. They are calculated from the annual amount of Cr(VI) used at the site and the amounts of Cr(VI) emitted to water and air. The site-specific release fractions are used as input for EUSES modelling of the environmental concentrations. As the site doesn't release Cr(VI) to wastewater (all contaminated water is gathered and sent to a certified service provider for disposal) the respective release fraction is zero. Air emissions are based on measurements in 2021, where a maximum concentration of 2 µg/m<sup>3</sup> was measured. Further measurements in 2022 confirmed the low emissions (with all measurements being below the LoQ).

**Table 9-11: Local releases to the environment**

Release route	Release fraction <sup>a</sup>	Release [kg/year] <sup>a</sup>	Explanation/Justification
Water	0	0	No release to wastewater
Air	1.0E-6 – 2.0E-5 (■)	0.004	Measured release (site-specific data)
Soil <sup>b</sup>	0	0	No release to soil is possible

<sup>a</sup> Releases and release fractions to wastewater, air and soil are based on recent release data and tonnages provided by the site.

#### 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

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

These releases resulted in modelled (EUSES) environmental concentrations and human exposures as shown in the following table. The resulting estimated overall risk from exposure of humans via the environment is 8.77E-08, which is very low (Table 9-12).

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

**Table 9-12: Exposure concentrations and excess cancer risk estimates for humans via the environment – on local scale (applicant's site)**

Inhalation			Oral			
Local Cr(VI) PEC in air [ $\mu\text{g}/\text{m}^3$ ]	Excess lung cancer risk [ $1/(\mu\text{g}/\text{m}^3)$ ] <sup>a</sup>	Inhalation risk	Oral exposure (water and fish) [ $\mu\text{g Cr(VI)}/\text{kg} \times \text{d}$ ] <sup>b</sup>	Excess cancer risk for tumours of the small intestine [ $1/(\mu\text{g}/\text{kg bw}/\text{day})$ ] <sup>c</sup>	Oral risk	Combined risk
3.02E-6	2.90E-02	8.76E-08	1.32E-07	8.00E-04	1.06E-10	<b>8.77E-08</b>

<sup>a</sup> 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  $2.9 \times 10^{-2}$  for the general population, based on 70 years of exposure; 24h/day.

<sup>b</sup> combined exposure from drinking water ( $1.25 \times 10^{-7} \mu\text{g Cr(VI)}/\text{kg} \times \text{d}$ ) and fish consumption ( $7.2 \times 10^{-9} \mu\text{g Cr(VI)}/\text{kg} \times \text{d}$ )

<sup>c</sup> 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  $8 \times 10^{-4}$  for the general population, based on 70 years of exposure; 24h/day.

Note that the modelling of local air concentrations with EUSES is generally acknowledged as being overly conservative, as described in detail in section 9.1.4.2.

#### Conclusion on risk characterisation:

##### Carcinogenicity

Combined risks of cancer by inhalation and by the oral route from the local assessment result in a combined excess cancer risk of 8.77E-8. This theoretical cancer risks is based on a conservative, linear ERR. Further, due to the overly conservative nature of the predictions of the EUSES model for the local air concentrations the risk level can be considered an overestimation.

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

### 9.2.3.2 Worker contributing scenario 1 – Mixing operators

Operators are typically performing the following tasks:

- Task 1: Weighing of solid material in dedicated area (PROC 8a, 8b)
- Task 2: Charging the mixing vessels (PROC 8a, 8b) and surveying mixing process (PROC 5)

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- 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 9-13 summarises the conditions of use for the activities with direct Cr(VI) exposure related to formulation of liquid mixtures carried out by operators.

**Table 9-13: Conditions of use – worker contributing scenario 1 – Mixing operators**

<b>Product (article) characteristics</b>
Product 1: Solid CT (flakes) for Tasks 1, 2, and 7 <ul style="list-style-type: none"> <li>▪ Substance product type: Granules or pelletised material</li> <li>▪ Dustiness: Flakes</li> <li>▪ Moisture content: Dry product (&lt; 5% moisture content)</li> <li>▪ Weight fraction: Pure material (100%)</li> <li>▪ Concentration in pure substance: 52% Cr(VI) for CT</li> </ul>
Product 2: Liquid mixture of CT for Tasks 3-6 <ul style="list-style-type: none"> <li>▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix</li> <li>▪ Viscosity: Liquids with low viscosity (like water)</li> <li>▪ Concentration of substance in mixture: = max. 6% CT; max. 3% (w/w) Cr(VI)</li> </ul>
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>
Task 1: Weighing of solid material <ul style="list-style-type: none"> <li>▪ Duration of activity 3-15 min/batch, 1 – 5 batches/shift</li> <li>▪ Frequency of task: approx. 150 batches per year, 1 – 5 batches/shift</li> </ul>
Task 2: Charging mixing vessels and surveying the mixing process <ul style="list-style-type: none"> <li>▪ Duration of activity 30 - 60 min/batch</li> <li>▪ Batch size: 1 to 1000 L</li> <li>▪ Frequency of task: approx. 50 days/year (150 batches per year, 1 – 5 batches/shift)</li> </ul>
Task 3: Transfer of liquid products to storage tanks or containers <ul style="list-style-type: none"> <li>▪ Duration of activity: 60 to 240 min/batch</li> <li>▪ Batch size: 1 to 1000 L</li> <li>▪ Frequency of task: approx. 50 days/year (150 batches per year, 1 – 5 batches/shift)</li> </ul>
Task 4: Sampling <ul style="list-style-type: none"> <li>▪ Amount: 100-1000 mL</li> <li>▪ Duration of activity: 5 min</li> <li>▪ Frequency of task: 50 days/year (once per batch, 150 batches per year, 1 – 5 batches/shift)</li> </ul>

<p>Task 5: Cleaning of workplaces and equipment</p> <ul style="list-style-type: none"> <li>▪ Duration of activity: up to 45 min/day</li> <li>▪ Frequency of task: approx. 50 days per year</li> </ul>
<p>Task 6: Repair and maintenance activities</p> <ul style="list-style-type: none"> <li>▪ Duration of activity: 15 - 60 min/day</li> <li>▪ Frequency of task: approx. 48 days per year</li> </ul>
<p>Task 7: Waste management – disposal of solid waste</p> <ul style="list-style-type: none"> <li>▪ Duration of activity: 5 - 10 min</li> <li>▪ Frequency of task: approx. 50 days per year</li> </ul>
<p><b>Technical and organisational conditions and measures</b></p>
<p>Tasks 1: Weighing of solid material</p> <ul style="list-style-type: none"> <li>▪ LEV: Yes</li> <li>▪ Ventilation rate of general ventilation system: mechanical ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p>Task 2: Charging mixing vessels and surveying the mixing process</p> <ul style="list-style-type: none"> <li>▪ LEV: Yes</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p>Task 3: Transfer of liquid products to storage tanks or containers</p> <ul style="list-style-type: none"> <li>▪ LEV: Yes</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p>Task 4: Sampling</p> <ul style="list-style-type: none"> <li>▪ LEV: No</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p>Task 5: Cleaning of workplaces and equipment</p> <ul style="list-style-type: none"> <li>▪ LEV: No</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p>Task 6: Repair and maintenance activities</p> <ul style="list-style-type: none"> <li>▪ LEV: No</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p>Task 7: Waste management – cleaning of containers, disposal of solid waste</p> <ul style="list-style-type: none"> <li>▪ LEV: situation-dependent</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<p><b>Conditions and measures related to personal protection, hygiene, and health evaluation</b></p>



**Gloves**

Chemical resistant gloves are worn during all tasks (Task 1 to 7).

All gloves used for the handling of chemicals are tested according to EN 374. A variety of materials are suited for protection against chromates.

The following materials have a breakthrough time  $\geq 8$ h for aqueous CT solutions (10% CT) and saturated aqueous SD solutions <sup>a</sup>:

- 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  $\geq 8$ h for aqueous CT solutions (50% CT) <sup>a</sup>:

- Fluorocarbon rubber (0.4 mm)

The following materials have a breakthrough time  $\geq 2$ h for aqueous CT solutions (50% CT) <sup>a</sup>:

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

The following material is assumed to have a breakthrough time  $\geq 4$ 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. (SEA (2018) explains that for tasks where “dexterity is required ... a single use splash resistant nitrile glove (BS EN 374) are suitable. These gloves should be replaced every time they are removed”).

**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 <sup>b</sup>:

- Powered filtering device incorporating a hood or helmet (APF 40)

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

**Protective clothes**

Coveralls are worn during all task (1 to 7).

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.

<b>Other conditions affecting workers' exposure</b>
<p>Task 1: Weighing of solid material</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – large size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Activity class: Movement and agitation of powders, granules or pelletised material</li> <li>▪ Situation: Handling with low level of agitation</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> </ul>
<p>Task 2: Charging mixing vessels and surveying the mixing process</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – large size workroom</li> <li>▪ Temperature: room temperature (elevated temperatures might occur due to exothermic nature of blending process)</li> <li>▪ Activity class: Falling of powders, granules or pelletised material</li> <li>▪ Situation: a) Transferring 1 – 10 kg/minute</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> </ul>
<p>Task 3: Transfer of liquid products to containers</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – large size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Activity class: Transfer of liquid products</li> <li>▪ Situation: Transferring 10 – 100 L/minute</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> </ul>
<p>Task 4: Sampling of preparations</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – large size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Activity class: Transfer of liquid products</li> <li>▪ Situation: Transferring 0.1 – 1 L/minute</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> </ul>
<p>Task 5: Cleaning of workplace and equipment</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – any size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> </ul>
<p>Task 6: Repair and maintenance activities</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – any size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Activity class: Handling of contaminated solid objects or paste</li> <li>▪ Situation: Handling of slightly contaminated (layers of less than few grams) objects</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> </ul>

<p>Task 7: Waste management – cleaning of containers, disposal of solid waste</p> <ul style="list-style-type: none"> <li>▪ Place of use: indoors – any size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> <li>▪ Activity class: Handling of contaminated solid objects or paste (worst case assumption, see section details in 9.2.3.2.2)</li> <li>▪ 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.</li> </ul>
<p><b>Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply</b></p>
<ul style="list-style-type: none"> <li>▪ <i>None</i></li> </ul>

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

<sup>b</sup> For selection of APF see Annex II of this report.

### 9.2.3.2.2 Exposure and risks for workers

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

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

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

The CT is filled into the mixing vessel with the scoop and by pouring the remaining material (Figure 9-1). The mixing vessel (batch volume up to 1 m<sup>3</sup>) is equipped with an internal automatic stirrer and LEV which produces negative pressure at the opening. The LEV is running during this process. Feeding the vessel takes up to 1 hour per batch, the whole mixing process may take up to 3 days (no manual intervention necessary during this time).



**Figure 9-1: Filling the mixing vessel**

#### Task 3: Sampling (PROC 9)

Typically, one sample is taken per produced batch for quality control. The sample is taken from the mixing vessel. The size of the sample bottle is up to 1000 mL. Samples are taken from the mixing vessel, while LEV is running.

#### Task 4: Transfer of liquid products to storage tanks or containers (PROC 8b)

Afterwards, the final product is pumped via closed lines to a storage vessel, from which it is decanted into product containers (1 or 5 L) by gravity, with a tap at the bottom of the storage vessel. A mobile LEV is located above the container. Filling of container, performed by two operators, may take 1 to 4 hours per batch. Operators wear eye protection, coveralls, and gloves during filling of containers.

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

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

Small splashes or amounts are taken up with wipes (Figure 9-2). Wipes are disposed of as solid waste.

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**Figure 9-2: Wiping up solid material from the vessel top**

Around vessels where solid chromates are used, a plastic foil is used to line the workplace surfaces. After filling all raw materials, the foil is folded and disposed of as solid waste (Figure 9-3), thus reducing any possibility to spread the solid material to a minimum.



**Figure 9-3: Folding the foil around the vessel after the filling process is complete**

Filters of the LEV systems are changed after completion of the filling process (Figure 9-4). This material, together with other solid waste (wipes, emptied and rinsed drums, filters), is disposed of as solid waste by an external company certified for disposing hazardous waste. After filling of the vessel is complete the equipment (scoop, drums) is rinsed with water (Figure 9-5) and the contaminated rinsing water is

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gathered in an IBC for disposal as hazardous waste by an external certified company. During all these activities the operator wears a coverall, gloves, and respiratory protection.



**Figure 9-4: Changing LEV filters**



**Figure 9-5: Cleaning equipment**

Depending on the situation, cleaning activities take up to 45 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. After these cleaning steps, cleaned parts can be removed by maintenance workers. A conservative estimate is 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, foils, etc.) occurring during production is gathered in closed bags and transported to tightly closed drums in the storage area awaiting disposal by an external certified company as hazardous waste.

#### 9.2.3.2.2.1 Inhalation exposure

A workplace measurement campaign was conducted in 2021. Static sampling was applied, following “HSG173 Monitoring strategies for toxic substances” (airflow 2 l/min) and hexavalent chromium was analysed by spectrophotometry (MDHS 52/4, alkaline-treated PVDF Filters).

The following results were obtained.

**Table 9-14: Results of static workplace measurements**

Task performed	Duration of measurement	LoQ ( $\mu\text{g Cr(VI)}/\text{m}^3$ )	Measured concentration ( $\mu\text{g Cr(VI)}/\text{m}^3$ )
Workers transfer material from original container to mixing vessel	79 min	0.3	<0.3
Surveying mixing process	248 min	0.3	<0.3
Product filtering and filling of containers	244 min	0.3	<0.3
Filtered product decanted into product containers	Not given	0.3	<0.3

Further, for the activity in the lowest row an additional personal monitoring measurement is available, confirming the low exposure (value below LoQ of  $0.3 \mu\text{g Cr(VI)}/\text{m}^3$ ).

#### 9.2.3.2.2.2 Biomonitoring

In a campaign performed in 2022 chromium in urine was determined for 21 workers of the company. Fifteen values were below the limit of detection. Of the remaining 5 ranged from 0.8 to 2.1  $\mu\text{mol}/\text{mol}$

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creatinine and only one value (61  $\mu\text{mol/mol}$  creatinine) was above the UK BMGV of 10  $\mu\text{mol/mol}$  creatinine. Follow-up activities included check of the conditions and retesting of the worker. Retesting yielded a result well below the BMGV, therefore the initial value was considered spurious.

**Table 9-15: Biomonitoring data per individual**

No.	SEG	Year	Cr exposure value as measured [ $\mu\text{mol/mol}$ creatinine]
1	Laboratory	2022	Not detected
2	Manufacturing	2022	Not detected
3	Laboratory	2022	Not detected
4	Applications/others	2022	0.8
5	Laboratory	2022	Not detected
6	Laboratory	2022	Not detected
7	Laboratory	2022	Not detected
8	Manufacturing	2022	61
9	Manufacturing	2022	Not detected
10	Applications/others	2022	1.3
11	Manufacturing	2022	Not detected
12	Laboratory	2022	Not detected
13	Manufacturing	2022	1.0
14	Applications/others	2022	Not detected
15	Applications/others	2022	Not detected
16	Manufacturing	2022	1.0
17	Applications/others	2022	Not detected
18	Applications/others	2022	Not detected
19	Applications/others	2022	1.3
20	Applications/others	2022	Not detected
21	Laboratory	2022	Not detected



**Table 9-16: Measured inhalation exposure concentrations for WCS 1 – Mixing operators**

Type of measurement	Number of measurements	Exposure value (8h TWA) <sup>a</sup> [ $\mu\text{g}/\text{m}^3$ ]	Assigned protection factor (APF) for RPE <sup>b</sup>	Exposure value corrected for RPE [ $\mu\text{g}/\text{m}^3$ ]	Long-term exposure <sup>c</sup> [ $\mu\text{g}/\text{m}^3$ ]
Personal/static	5	0.15	40	0.00375	0.0016

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

<sup>a</sup> 50% of LOQ

<sup>b</sup> According to EN 529:2005 (BSI), see Annex II of this report.

<sup>c</sup> Frequency factor 0.42 (exposure at up to 100 days per year (for filling vessels and product containers) (=100/240).

#### 9.2.3.2.2.3 Risk characterisation

##### Risk for carcinogenicity

Table 9-17 shows the risk characterisation for carcinogenicity for mixing operators. 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 9-17: Risk characterisation for carcinogenicity for WCS 1 – Mixing 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	0.0016	4.00E-03	6.4E-06

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  $4 \times 10^{-3}$  for workers, based on 40 years of exposure; 8h/day; 5 days/week.

##### Conclusion on risk characterisation:

The Excess lifetime cancer risk for mixing operators is 6.4E-06. One to two operators are involved in production of a batch.

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

### 9.2.3.3 Worker contributing scenario 2 – Laboratory technicians

#### Main task

- Task 1: Quality control of samples (PROC 15)

At the site, laboratory technicians are responsible for quality control, including spraying the products (check of performance of products by spraying small panels in a spray booth; positive pressure spray booth, fed by air in a laminar flow). 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.

Existing monitoring results confirm low exposures during quality control activities in the laboratory as well as for quality control spraying. These measurements (2 static, 1 personal sampling) demonstrate low exposure in the laboratory (all values below LoQ of 0.3 µg Cr(VI)/m<sup>3</sup>). Levels below the limit of quantification in biomonitoring measurements confirm the low level of exposure (Table 9-15).

As the handling of substances in laboratories for quality control purposes under controlled conditions and in amounts below 1 t/year falls under the exemption for authorisation for the use of substances in scientific research and development<sup>6</sup> according to REACH Art. 56(3), no exposure assessment is performed for the laboratory analysis of treatment bath samples.

### 9.2.3.4 Worker contributing scenario 3 – Maintenance workers

A group of approximately 1 to 2 maintenance workers is engaged at the site. Chromates-related 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 5% of his working time (up to 2 hours per day, 1 day per week) 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.

#### 9.2.3.4.1 Conditions of use

Table 9-18 summarises the conditions of use for maintenance and cleaning activities with Cr(VI) exposure related to formulation of chromates carried out by maintenance workers.

**Table 9-18: Conditions of use – worker contributing scenario 3 – Maintenance workers**

Product (article) characteristics
Product 1: Liquid mixture of CT <ul style="list-style-type: none"> <li>▪ Concentration of substance in mixture: max. 3% (w/w) Cr(VI) (based on up to 6% CT in liquid products); &lt;&lt;1% (w/w) Cr(VI) after cleaning of equipment</li> </ul>

<sup>6</sup> Q&A Reference number: ID 0585; <https://echa.europa.eu/de/support/gas-support/browse/-/qa/70Qx/view/ids/585-1442-1443-1498-1565>; assessed in March 2021

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<ul style="list-style-type: none"> <li>▪ Product type: Solids dissolved in a liquid or incorporated in a liquid matrix</li> <li>▪ Viscosity: Liquids with low viscosity (like water)</li> </ul>
<b>Amount used (or contained in articles), frequency and duration of use/exposure</b>
<p>Task 1: Maintenance and cleaning of equipment</p> <ul style="list-style-type: none"> <li>▪ Duration of activity: 30-120 min</li> <li>▪ Frequency of task: once per week, 48 weeks per year</li> </ul>
<b>Technical and organisational conditions and measures</b>
<p>Task 1: Maintenance and cleaning of equipment</p> <ul style="list-style-type: none"> <li>▪ LEV: No</li> <li>▪ Ventilation rate of general ventilation system: natural ventilation</li> <li>▪ Occupational health and safety management system: advanced (see section 9.2.2.3.1.2)</li> </ul>
<b>Conditions and measures related to personal protection, hygiene, and health evaluation</b>
<p><b>Gloves</b></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 <math>\geq 8</math>h for aqueous CT solutions (10% CT) <sup>a</sup>:</p> <ul style="list-style-type: none"> <li>○ Natural rubber/Natural latex (0.5 mm)</li> <li>○ Polychloroprene (0.5 mm)</li> <li>○ Nitrile rubber/Nitrile latex (0.35 mm)</li> <li>○ Butyl rubber (0.5 mm)</li> <li>○ Fluorocarbon rubber (0.4 mm)</li> <li>○ Polyvinyl chloride (0.5 mm)</li> </ul> <p>Type of gloves to be used for specific tasks is laid down in work instructions for the tasks.</p>
<b>Respiratory protection equipment</b>
No RPE is worn during maintenance activities performed on pre-cleaned equipment.
<b>Protective clothes</b>
<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>
<b>Eye protection</b>
<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>
<b>Other conditions affecting workers' exposure</b>
Task 1: Maintenance and cleaning of equipment

<ul style="list-style-type: none"> <li>▪ Place of use: indoors – any size workroom</li> <li>▪ Temperature: room temperature</li> <li>▪ Primary emission source proximity: The primary emission source is in the breathing zone of the worker (near field, &lt;1 m)</li> <li>▪ Activity class and subclass: Handling of contaminated objects</li> </ul>
<b>Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply</b>
<ul style="list-style-type: none"> <li>▪ None</li> </ul>

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

#### 9.2.3.4.2 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 at the company and may comprise electricians, fitters, and other types of workers. Only fitters are expected to come into contact with CT 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.

In case equipment needs to be dismantled for repair the mixing operator is responsible for emptying and cleaning lines and equipment by flushing with water and air. 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. Spare parts are available for critical components, allowing immediate replacement and continuation of the production and repair of dysfunctional parts without time pressure.

As frequencies of repair interventions vary considerably, conservatively it is 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 very low, due to the preceding cleaning process.

##### 9.2.3.4.2.1 Inhalation exposure

No Cr(VI) measurements are available for maintenance workers at the site. Therefore, risk characterisation is based on measured data from maintenance workers from other companies using chromates. These data were gathered by the ADCR consortium for the purpose of describing exposure of maintenance workers at sites down the aerospace and defence supply chain using various soluble chromates including chromium trioxide for surface treatments.

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Although these uses are different, 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 this formulation company.

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 value 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  $>\text{LOQ}$ . Reported LOQs ranged from 0.02 to  $0.6 \mu\text{g}/\text{sample}$ . 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.

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 90<sup>th</sup> 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 90<sup>th</sup> 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.

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.

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Table 9-19 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 9-19: Summary statistics of inhalation exposure measurements (personal monitoring) for WCS 3 – 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 <sup>th</sup> 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 90<sup>th</sup> percentile of the long-term values differ by a factor of 6, but between AM and the 90<sup>th</sup> percentile there is only a factor of 2. A relevant portion of the measurement resulted in values below LOQ.

In Table 9-20 the long-term inhalation exposure concentration for maintenance workers as used for risk characterisation, is shown.

**Table 9-20: Measured inhalation exposure concentrations for WCS 3 – Maintenance workers**

Activity	Measured exposure concentration (8h TWA) <sup>a</sup> [ $\mu\text{g}/\text{m}^3$ ]	Assigned protection factor (APF) for RPE <sup>b</sup>	Exposure value corrected for RPE [ $\mu\text{g}/\text{m}^3$ ]	Long-term exposure <sup>c</sup> [ $\mu\text{g}/\text{m}^3$ ]
Maintenance	1.47	1	1.47	0.074

<sup>a</sup> Based on 90<sup>th</sup> percentile of measurements.

<sup>b</sup> No RPE is considered, see text above.

<sup>c</sup> The frequency/duration correction factor of =005 was applied (once per week, up to 2 hours: =1/5 x 2/8), assuming that each activity is carried out by a single maintenance worker

#### 9.2.3.4.2.2 Risk characterisation

##### Risk for carcinogenicity

Table 9-21 shows the risk characterisation for carcinogenicity for maintenance and/or cleaning workers. The risk for carcinogenicity is based on measured Cr(VI) inhalation exposure data for maintenance and/or cleaning workers and the RAC dose-response relationship for the excess lifetime cancer risk for lung cancer (ECHA, 2013).

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**Table 9-21: Risk characterisation for carcinogenicity for WCS 3 – 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	0.074	4.00E-03	3.0E-04

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  $4 \times 10^{-3}$  for workers, based on 40 years of exposure; 8h/day; 5 days/week.

**Remarks on exposure data:**

The excess life-time cancer risk for maintenance workers is 3.0E-04. This risk is higher than the one determined for mixing operators, who are more intensely handling and are longer exposed to chromates. This points towards a conservative assessment for maintenance workers

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

## **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 chromium trioxide. 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) - regional assessment**

In accordance with RAC's conclusions (see e.g. the RAC/SEAC "Opinion on an Application for Authorisation for Use of Sodium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites and sealings of anodic films"<sup>7</sup>), 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**

The assessment of exposure of humans via the environment was performed using site-specific emission data for chromium trioxide used for this use at one single site. At that site CT is used for formulating slurry coating products destined for aerospace and defence industry and gas turbine

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<sup>7</sup> RAC/SEAC, consolidated version, 2016; <https://echa.europa.eu/documents/10162/658d42f4-93ac-b472-c721-ad5f0c22823c>



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industry and their supply chains. As the amounts used for both industries are approximately equal, the total local emissions and PECs are expected to be two times the figures reported for this use.

## 11 Annexes

### 11.1 Annex I – 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%

## 11.2 Annex II – 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 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.

### 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	<b>10</b>
Half mask with particle filter P3	EN 140 (mask) EN 143 (filter)		-	30	30	-	20	10	<b>10</b>
Half mask with combined gas-particle filter Gas X P3	EN 405		-	30	-	-	10	-	<b>10</b>
Full mask (all types) with particle filter P3	EN 136 (mask) EN 143 (filter)		500	400	400	500	40	30	<b>20</b>
Full mask (all types) with combined gas-particle filter Gas X P3	EN 136 (mask) EN 143 (filter)		-	400	-	-	20	-	<b>20</b>

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Powered filtering device incorporating a hood or a helmet (PAPR, powered & supplied air respiratory protection) TH3	EN 12941		200	100	200	200	40	40	<b>40</b>
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)	<b>40</b>
fresh air hose breathing apparatus - full mask or hood or helmet	EN 138		500	100 0	400	500	40	-	<b>40</b>
Supplied-air respirator (SAR) Continuous flow compressed airline breathing apparatus 4A/4B	EN 14594		-	-	-	-	-	250	<b>40</b>
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	-	<b>40</b>

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