9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

This exposure assessment aims to provide reliable estimates of current work place exposure level at the applicant's facility. Occupational work place exposure to hexavalent chromium [Cr(VI)] is regulated in most European countries. National Occupational Exposure Limits (OELs) across Europe respect a range of 8 hour *Time Weighted Average* (TWA) values between 1 µg/m^3 and 50 µg/m^3. The US *Occupational Safety and Health Administration* (OSHA) OEL is at 5 µg/m^3. In 2014, France introduced a new OEL of 1 µg/m^3. This is the most stringent OEL currently in place anywhere in the World and compliance requires substantial research and investment.

The Carcinogens and Mutagens Directive (2004/37/EC) requires each Member State to ensure employers reduce and replace use of hexavalent chromium substances, and the introduction of a new OEL in France provides one clear example of regulation by Member States to effect a reduction in workplace exposure to Cr(VI). Industry is proactively engaged in delivering continuous reduction through the development and implementation of appropriate RMMs.

Best practice across the industry is continually improving, driven by general awareness of workplace hygiene and increasingly stringent regulatory requirements. This commitment to reducing exposure also reflects the widespread recognition that surface treatment including coating with Cr(VI) is critical for several industries and that alternatives are not available in the near-term. Potential workplace exposure to Cr(VI) has progressively reduced in recent years as the effectiveness and implementation of risk management measures has improved, and this trend is clearly reflected in exposure measurement data available over the last 10 years or more.

9.0.1. Overview of uses and Exposure Scenarios

Tonnage information:

Assessed tonnage: 120.0 tonnes of chromium trioxide/year [containing approximately 60 tonnes of Cr(VI)].

The following table lists all the exposure scenarios (ES) assessed in this CSR.

Table 6. Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
ES1 – IW1		Use at industrial site – Functional chrome plating of piston rings for the use in diesel engines for large bore engines such as marine engines - Functional chrome plating of piston rings for the use in diesel engines for large bore engines such as marine engines (ERC 6b) - Delivery of raw material and decanting into dosing tanks (PROC 8b) - Functional chrome plating – automatic line (PROC 13) - Functional chrome plating – manual plating process (PROC 13) - Functional chrome plating - maintenance (PROC 8b) - Quality control of articles (PROC 8b) - Processing of the electrolyte (PROC 2) - Waste water management (PROC 2)	120.0 [approx.. 60 Cr(VI)]
Manufacture: M-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial site): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2. Introduction to the assessment

9.0.2.1. Environment

Scope and type of assessment

The current Chemical Safety Report (CSR) and the associated exposure scenarios are tailored to support the Application for Authorization (AfA) to continue use of chromium trioxide for use in functional chrome plating after the sunset date in September 2017.

Chromium trioxide has been included in Annex XIV to Regulation (EC) No 1907/2006 ('REACH') due to its intrinsic properties as being carcinogenic (Carc. 1A) and mutagenic (Mut. 1B)

Following 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. Accordingly, only the potential human health risks related to the classification of chromium trioxide as a carcinogenic and mutagenic toxicant are considered in the current CSR. The dominating health effect resulting from the intrinsic hazardous properties of chromium trioxide is lung cancer due to inhalation of dust and/or aerosols. Intestinal cancer following ingestion is also identified as a potential risk: however, the dose-response relationship is lower than that for lung cancer, and ingestion is generally not considered an important exposure route for workers.

Evaluation of any potential hazards to the environment is not required within the framework of this authorisation application. Health hazards may potentially relate to Cr(VI) exposure of the general population via the environment, and are considered accordingly.

Measures to prevent or limit release of Cr(VI) to the environment are provided as best practice at facilities carrying out operations using chromium trioxide. During industrial surface treatment operations, prevention of releases of substances to the aquatic environment is a matter of good practice. Treatment technology (on-site or off-site) to reduce Cr(VI) to trivalent chromium [Cr(III)] in wastewater is generally highly effective, such that residual concentrations of Cr(VI) in effluent are very low and often non-detectable, and may be considered negligible. Solid and liquid waste containing Cr(VI) is collected and treated as hazardous waste where residual Cr(VI) can be effectively safely treated. In view of the RMMs in place at the production facilities, emissions to the aquatic environment associated with surface treatment operations are effectively prevented.

Due to its low volatility, chromium trioxide will not normally be present in air. Nevertheless, energetic processes (e.g. plating, mixing) can release chromium trioxide into air. All workspaces with potential release to air are equipped with exhaust ventilation systems to remove residual particulates from workers breathing zone: exhaust air is passed through filters or wet scrubbers according to best available technique (minimum 99 % removal efficiency) before being released to atmosphere. While emissions to air are therefore very low, they have been considered in this assessment as a factor potentially contributing to Cr(VI) exposure of humans via the environment. The scope and type of the assessment of the pathway “man via the environment” is discussed in section 9.0.2.2 below.

Cr(VI) is neither directly nor indirectly released to soil due to adequate technical and organizational measures and therefore releases to soil are considered negligible.

Table 7. Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Freshwater	Not required	Not relevant
Sediment (freshwater)	Not required	Not relevant
Marine water	Not required	Not relevant
Sediment (marine water)	Not required	Not relevant
Sewage treatment plant	Not required	Not relevant
Air	Not required	Not relevant
Agricultural soil	Not required	Not relevant
Predator	Not required	Not relevant

Comments on assessment approach:

In accordance with REACH, Article 62(4)(d), potential risks to the environment need not be considered.

9.0.2.2. Man via environment

Scope and type of assessment

As discussed in 9.0.2.1., humans may potentially be exposed to chromium trioxide via the environment. Since strict emission control measures are implemented, releases to the aquatic environment (and also to soil), if any, are negligible, and the only relevant potential exposure path is inhalation of fine dust or particulates emitted from the facilities to air (see also “comments on assessment approach” below).

Within the current CSR, local concentration (Clocal) from emissions to air from industrial use is estimated based on available emission data from the company, and expressed as Cr(VI).

The regional concentrations are reported in section 10.2.1.1 (see Table 19, “Predicted regional exposure concentrations (Regional PEC)”) based on modeling with EUSES 2.1.2., and expressed as Cr(VI).

Table 8. Type of risk characterisation required for man via the environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (see RAC/27/2013/06 Rev.1)
Inhalation: Local long-term	Quantitative	Lung cancer: ELR = 2.9E−02 per µg Cr(VI)/m³ for 70 years
Oral: Local long-term	Not needed. Assume all inhaled material is respirable (worst case).	Intestinal cancer: ELR = 8.0E−04 per µg Cr(VI)/kg bw/d for 70 years

Comments on assessment approach:

The risk assessment for humans exposed via the environment is restricted to inhalation of airborne residues of chromium trioxide. The oral route (swallowing of the non-respirable fraction) does not need to be explicitly considered since:

(i) the exposure calculations (airborne concentrations) do not provide different particle size fractions (inhalable/thoracic/respirable);

(ii) the excess lifetime risk (ELR) for intestinal cancer is one order of magnitude lower than that for lung cancer. The assessment of health impacts is therefore dominated by the potential risk of lung cancer due to inhalation of Cr(VI);

(iii) the document on a reference dose-response relationship for Cr(VI) compounds (RAC/27/2013/06 Rev.1) states that “*in cases where the applicant only provides data for the exposure to the* *inhalable particulate fraction, as a default, it will be assumed that all particles were in the respirable size range.*"

Therefore, in accordance with the above findings and provisions on the risk assessment for humans exposed via the environment, since it is assumed that all particles are in the respirable size range, no exposure via the oral route needs to be considered.

This constitutes a worst case approach, since the potential lung cancer risk is an order of magnitude higher compared to the potential intestinal cancer risk, based on the dose-response relationships agreed by RAC.

9.0.2.3. Workers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table based on the hazard conclusions presented in section 5.11.

Table 9. Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see RAC/27/2013/06 Rev.1)
Inhalation	Systemic long-term	Not needed	
	Systemic acute	Not needed	Not relevant
	Local long term	Quantitative	Lung cancer ELR = 4.0E−03 per µg Cr(VI)/m³ for 40 years
	Local acute	Not needed	Not relevant
Dermal	Systemic long term	Not needed	Not relevant
	Systemic acute	Not needed	Not relevant
	Local long term	Not needed	Not relevant
	Local acute	Not needed	Not relevant
Eye	Local	Not needed	Not relevant

Comments on assessment approach related to toxicological hazard:

Chromium trioxide has been included into Annex XIV to REACH due to its intrinsic properties as being carcinogenic (Carc. 1A) and mutagenic (Mut. 1B).

Following 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 dominating health effect resulting from the intrinsic hazardous properties of chromium trioxide is lung cancer due to inhalation of dust and/or aerosols.

Exposure estimates generated by ART 1.5., or measured values are given in terms of Cr(VI).

The oral route (mucociliary clearance and swallowing of the non-respirable fractions) is not taken into account for the same reasons as already explained in the context of "man via environment" (section 9.0.2.1 above). In accordance with the RAC document on the dose-response relationship (RAC/27/2013/06 Rev.1), it has to be assumed that all particles are in the respirable size range. Hence no exposure via the oral route needs to be considered.

Comments on assessment approach related to physicochemical hazard:

Not relevant – physicochemical hazards are not subject of this CSR.

General information on risk management related to toxicological hazard:

Potential exposure of workers handling chromium trioxide is restricted to the lowest possible level.

Aqueous solutions of chromium trioxide are expected to entail only a low potential for generating mists, not requiring Respiratory Protective Equipment (RPE). Nevertheless, protective clothing, chemical-resistant gloves, and goggles are mandatory for those tasks involving handling of the aqueous solution.

General information on risk management related to physicochemical hazard:

Not relevant – physicochemical hazards are not the subject of this CSR.

9.0.2.4. Consumers

Exposure assessment is not applicable as there are no consumer-related uses for chromium trioxide.

9.1. Exposure scenario 1: Use at industrial site - Functional chrome plating of piston rings for the use in diesel engines for large bore engines such as marine engines

Functional chrome plating generally involves use of chromium trioxide in one or more of a series of pre-treatment steps and the plating step to deliver a surface coating that can be of unlimited thickness, but is typically between 2 µm and 5,000 µm thick.

At the site, piston rings with a diameter of 150 to 980 mm and a coating thickness of the flank between up to 250 µm and of the running surface up to 700 µm are produced. For piston rings at the upper end of the thickness range, dwell time in the chromium baths may be up to 14 hours.

Functional chrome plating enhances wear resistance, tribological properties, anti-stick properties and corrosion resistance of the treated part, in combination with other important functional characteristics.

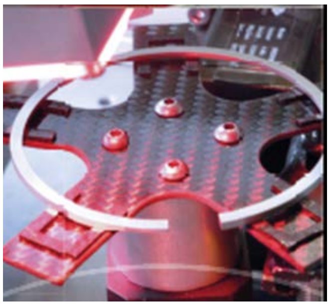

Figure 1: Example of a piston ring for large bore engines

Such secondary functional characteristics are chemical resistance, ability to strip, unlimited coating thickness, paramagnetic behaviour, a deposit that is non-toxic and anallergic, micro-cracked, and bright.Functional chrome plating provides substantial flexibility to treat parts with a broad range of sizes and geometries and the ability to plate inner surfaces of parts. The final surface coating does not contain any Cr(VI). Chrome plated surfaces are therefore safe to handle, and can be both machined and readily assembled.

For a more detailed description of the properties of functional chrome plating, see the AoA.

The form of application at the facility is immersion of parts through a series of baths containing solutions in a manual or automatic process.

The functional chrome plating process is characterised as a wet process within which treatment solutions and rinsate are recirculated in a closed loop and at increased process temperature.

Before the actual plating step, a number of pre-treatment steps is necessary to ensure that the surface to be plated is absolutely free of contaminants, corrosion and other residuals until the plating process is finished. All pre-treatment steps involve the use of chromium trioxide. It is advantageous to use chromium trioxide as a basis for the pre-treatment because any rinsing between pre-treatment steps can impair the surface activation and thus lead to faulty or badly adherent coatings. In addition, water consumption is reduced.

For a more detailed description of the process steps prior to chrome plating, see the AoA.

The metallic chrome coating is applied by electroplating based on the principle of electrolysis. Plating is performed by using the substrate as cathode and inducing an electrical current. The substrate is immersed in the electrolytic plating solution containing dissolved chromium trioxide and additives, the so-called electrolyte. During the electroplating process, the hexavalent chromium cations are reduced and build up a metallic chrome coating layer.

For chrome plating of piston rings, running surface plating has to be distinguished from side face plating. Plating of the running surface, i.e. the outer diameter of the piston ring, is much more common, as the running surface has the highest requirements in terms of wear resistance. Side face plating is performed additionally on piston rings where wear conditions are severest, for example on large bore engines.

The illustration below shows the principle of running surface plating of piston rings. The rings are stacked on top of each other and clamped together, forming a cylindrical mandrel. The side faces of the rings provide electrical contact over the whole length. Therefore it is not necessary to contact each single ring, nor must the inner diameter and side faces be protected from being plated. With this technique, that is very well suited to the special properties of both piston rings and the chromium trioxide functional chrome plating process, a large number of piston rings can be plated at once, making the process efficient.

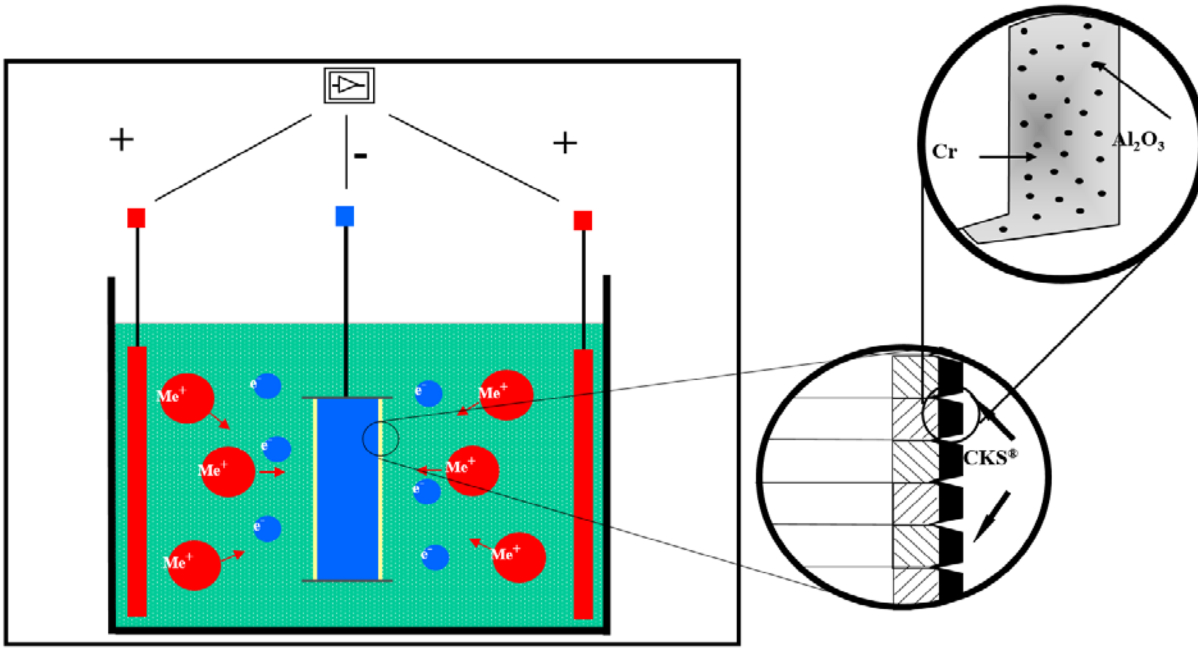

Figure 2: Principle of running surface plating of piston rings

In the plating process, solutions of chromium trioxide with concentrations between 80 g/l and 400 g/l are used. For functional chrome plating, common concentrations are around 250 g/l. Catalysts such as sulphuric acid are added in concentrations of 1 to 5 g/l. Additional catalysts contain mixed sulphate and fluoride ions and pre-prepared proprietary catalysts with each less than 2% of the content of chromium trioxide. The sulphate bath is a commonly used chromium trioxide bath and has an efficiency of approximately 15%. Although fluoride or mixed catalysts baths have a higher efficiency than the sulphate bath (25%), their use is limited due to the chemical activity of fluoride ions which can attack the uncoated surface. Organic, often proprietary, catalysts provide higher cathodic efficiencies of up to 25% and have the advantage not to attack the uncoated base material surface in those areas of the cathodes where the current density is too low for chromium to be deposited. The current density for chromium deposition is typically in the range of 20 A/dm² to 100 A/dm².

The main side reaction is hydrogen creation. In order to prevent the aerosols from entering the inhalable air, a suitable extraction unit is indispensable.

The bath temperature usually is between 40 and 70°C. High temperatures (70°C) and solution additives reduce the number of cracks or can even eliminate them but simultaneously make the coating softer.

The properties of electrodeposited coatings depend strongly on the type and exact chemical composition of the electrolyte, the current density and the electrolyte temperature. In the case of chromium deposition, the special advantageous properties of functional chrome coatings like high hardness can only be achieved within a certain working window of electrolyte composition, current density and electrolyte temperature. The chemical properties of chromium trioxide play a crucial role in the generation of those properties. However, the exact mechanism of chromium deposition from chromium trioxide solutions is still not completely understood.

There are four main groups of workers within the galvanic part of the plant with clearly separated responsibilities: two groups of workers taking care of all steps of the either automatic or manual plating process, maintenance workers responsible of regular maintenance and repair, but also for other activities, and finally workers for final quality control of the plated rings. A fifth group, personal from the general site service, is responsible for waste water management and deferrization.

Operating conditions and RMMs are specified to limit worker (inhalation and dermal) exposure to various components in the treatment solution and environmental exposure. LEV, coverage of baths during treatment are technical means to minimize concentrations of Cr(VI) and other components of treatment solutions in the workplace air. Personal Protective Equipment (PPE) like goggles, chemical resistant gloves and clothing s also specified to minimize potential dermal exposure. Equipment is maintained regularly.

Workers are skilled, and receive regular training with regards to chemical risk management and how to properly wear PPE. Regular housekeeping is also in place and generally speaking, management systems are in place ensuring high standards of operational procedure. The site is certified according to OSHAS 18001/ DIN ISO 14001.

Environment contributing scenario(s):	
Functional chrome plating of piston rings for the use in diesel engines for large bore engines such as marine engines	ERC6b
Worker contributing scenario(s):	
Delivery of raw material and decanting into dosing tanks	PROC 8b
Functional chrome plating – automatic line	PROC 13
Functional chrome plating – manual plating process	PROC 13
Functional chrome plating – maintenance	PROC 8b
Quality control of articles	PROC 8b
Processing of the electrolyte	PROC 2
Waste water management	PROC 2

Subsequent service life exposure scenario(s):

Not relevant.

Explanation on the approach taken for the ES

Occupational exposure estimates are based on measured data and/or on modelled data. Inhalation exposure has been estimated using the exposure model '*Advanced REACH Tool 1.5' or 'ART'*[4]. ART is a second tier model calibrated to assess exposure to inhalable dust, vapours, and mists; this Exposure Scenario is within the scope of ART. The figures obtained by modelling are considered to be worst-case estimates: supportive evidence for the conservative character of the modelled estimates is provided by comparison with relevant measured exposure data (measured concentrations of particulate residues of Cr(VI) in air), where available. Where the sample size and sampling strategy is adequate (i.e. personal sampling data), the risk characterisation relies on the measured exposure values; in other cases the results of the exposure modelling were used, as adequate measurement data was not available.

The detailed Exposure Scenario has been developed based on information provided by the site. The site provided details of the conditions under which the activity was carried out as well as the duration and frequency of each task. This information was verified during a site visit.

The frequency of a specific activity in the worker sub-scenarios is expressed as daily activity unless otherwise stated.

Any releases to the aquatic environment are essentially negligible. Chromium trioxide is contained within the preparation and the water used to rinse out the equipment is collected and recycled or disposed of in specialist facilities. Reductive treatment of any waste containing Cr(VI) additionally ensures negligible release of Cr(VI) to water. This is reflected in the environmental contributing scenario below.

[4] The use ART for workers exposure assessment under REACH is described in ECHA's updated Guidance on Information Requirements and chemical safety assessment R.14, Vers. 2, May 2010. Background information for ART are provided in: Fransman W., Cherrie J., van Tongeren M., Schneider T., Tischer M., Schinkel J., Marquart H., Warren, N.D., Spankie S., Kromhout H., Tielemans E. Development of a mechanistic model for the Advanced REACH Tool (ART). Version 1.5, January 2013.

9.1.1. Environmental contributing scenario 1: Functional chrome plating of piston rings for the use in diesel engines for large bore engines such as marine engines

Cr(VI) releases to the environment are carefully controlled by industry and monitored by regulators. The volume of Cr(VI) used depends on the scale of the functional chrome plating operations.

Air emissions relating to local exhaust ventilation (LEV) or extraction systems are filtered (HEPA filter) or passed through wet scrubbers to remove particulates prior to release to atmosphere. Information from facilities indicates that removal efficiency of at least 99% is typical for industry. The site regularly monitors and reports Cr(VI) emissions as part of permit conditions. Releases are often beneath detection limits and extended sampling times are necessary to quantify releases. These measured data have therefore been used, in line with the applicable models and guidance, to determine the local concentration of Cr(VI) in air, and exposure to man via the environment, as set out below.

There is only very low release of Cr(VI) to the aquatic environment, if any. Water from scrubbers or filters is recycled and occasionally replaced, with resulting material being treated as waste in accordance with relevant waste management regulations.

The facility has an on-site wastewater treatment facility that act to reduce the Cr(VI) to Cr(III). The solids are precipitated and the supernatant is discharged from the site. The treatment process is very efficient and concentrations of Cr(VI) are usually below detection limits.

Waste materials containing Cr(VI) are classified and treated as hazardous wastes according to EU and national regulations. Furthermore, reductive treatment of any liquid waste containing Cr(VI) additionally ensures that there is, if any, negligible release of Cr(VI) to waste water.

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ *See below*
Technical and organisational conditions and measures
▪ Air emission abatement: at least 99% efficiency ▪ Negligible discharge of Cr(VI) in wastewater from the site ▪ All solid and any liquid waste is collected and either the collected waste is directly forwarded to an external waste management company, or Cr(VI) in wastewater is reduced to Cr(III) on-site, and the treated waste is either recycled or forwarded to an external waste management company (licenced contractor) for disposal as hazardous waste
Conditions and measures related to sewage treatment plant
▪ Not applicable – negligible discharge of Cr(VI) in wastewater from the site
Conditions and measures related to treatment of waste (including article waste)
▪ Collection of all solid and liquid waste, reduction of Cr(VI) in wastewater to Cr(III), disposal as hazardous waste by an external waste management company (licenced contractor)
Other conditions affecting environmental exposure
▪ Exhaust air is passed through filters or wet scrubbers according to best available technique (minimum efficiency 99 %)

9.1.1.2. Releases

Point source emission data were provided for the site. These data were used to estimate $Clocal_{air,ann}$, the estimated annual average concentration in air, 100 m from point source, for the assessment of Man via Environment according to the Technical Guidance document R. 16, 2012.

Measured concentrations below the detection limit were used applying a factor of 0.5 to the reported values.

The $PECregional_{air,ann}$ was estimated in EUSES2.1.2. The following assumptions have been used for estimation:

Table 10. Parameters for estimating $PECregional_{air}$

Tonnage [as Cr(VI)]	Release factor* (%)	Regional fraction** (%)
60	0.004	100

* The release factor was estimated using tonnage and PEC_{local} information, provided by the site
** Percentage of tonnage used at regional scale

9.1.1.2. Exposure estimate for man via the environment - air

The air exposure concentrations are reported in the following table.

Table 11. Cr(VI) exposure concentrations in air, 100 meter from point source

No of Sites	Reporting Year	Exposure concentration (mg/m^3)
1	2014	1.96E-6

The exposure concentration of 1.96E-6 mg/m^3 is used as worst-case estimate of $Clocal_{air,ann.}$

The $PEClocal_{air,ann}$ of 1.96E-6 mg/m^3 is estimated as sum of $Clocal_{air,ann}$ and $PECregional_{air}$ and used as the basis for risk characterisation for man via the environment.

Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 70 year exposure time (24h/day, 7d/week), the following excess lifetime lung cancer mortality risk for the general population is derived based on the estimated exposure:

5.68E-02 per 1000 exposed.

As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m^3] might be an over-estimate.

9.1.2. Worker contributing scenario 1: Delivery of raw material and decanting into dosing tanks (PROC 8b)

Chromium trioxide is delivered as aqueous solution in IBC containers. Immediately after delivery, the aqueous solution is pumped over from the IBC containers to the dosing containers for re-filling of baths. Then the IBC's are cleaned.

9.1.2.1. Conditions of use

9.1.2.1.1. Delivery of raw material and decanting into dosing tanks

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Substantial (10 - 50%)	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low	ART 1.5
Activity emission potential	

	Method
▪ Duration of activity: < 3 h ▪ Frequency of activity: 1 d/week	ART 1.5 ART 1.5 (extended[5])
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Bottom loading	ART 1.5
▪ Situation: Transfer of liquid product with flow of 10–100 l/min	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: Large workrooms only	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: Medium level containment (99.00 % reduction) *The material transfer is enclosed with the receiving vessel being docked or sealed to the source vessel.*	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: 10 air changes per hour (ACH)	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.2.1.2. Cleaning of IBC containers

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Substantial (10 - 50%)	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low	ART 1.5
Activity emission potential	
▪ Duration of activity: < 1 h ▪ Frequency of activity: 1 d/week	ART 1.5 ART 1.5 (extended)
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Handling of contaminated objects	ART 1.5
▪ Situation: Activities with treated/contaminated objects (surface > 3 m²)	ART 1.5
▪ Contamination level: Contamination > 90 % of surface	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	

[5] The exposure model ART 1.5 does not include protection factors for the use of respiratory protection and no option to account for activities which do not take place every working day. Because these are important factors to be considered in the assessment of long-term exposure, we have extended the ART model by incorporating both parameters in the calculation of the final exposure estimate, where appropriate.

	Method
▪ Work area: Indoors	ART 1.5
▪ Room size: Large workrooms only	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: 10 air changes per hour (ACH)	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

In addition to the near-field exposure modelled above, far field exposure due to the influence of the manual plating activities has been assessed and added to the model estimate, using the estimated exposure based on measurement data in WCS 3 and applying a factor of 0.03 suggested by ART for low-volatile liquids.

9.1.2.2. Exposure and risks for workers

Table 12. Exposure concentrations and risks for worker

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation**
Inhalation, local, long-term	**0.21 µg/m³** (ART 1.5 prediction, 90th percentile value plus far-field exposure based on measured data)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.85 per 1000 exposed workers

<u>**Conclusion on risk characterisation**</u>

The modelled exposure estimate of 0.21 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.85 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

Functional chrome plating in baths or tanks

Functional chrome plating by dipping/immersion is conducted in sequential process steps within a series of tanks that contain treatment, cleaning and other related solutions. Tasks involved include the loading of jigs with the parts, pre-treatment with chromium trioxide in baths, plating treatment with chromium trioxide in baths, chemical post-treatment in baths, cleaning, rinsing, drying of the treated parts and finally the unloading of the parts from the jigs. The movement of parts through the different baths is either an automatic process in which the movement of the jigs is controlled electronically, a semi-automatic process in which the parts are moved by the operator between the baths using an overhead hoist in a predetermined sequence, or a manual process, in which the worker starts himself the process and moves the parts using hoists from tank to tank. All baths containing chromium trioxide or other hazardous substances are covered and equipped with extract ventilation during the treatment process.

9.1.3. Worker contributing scenario 2: Functional chrome plating – automatic line (PROC 13)

Tools containing the piston rings are manually prepared and then hanged to the jigs of the automatic, encapsulated line. Then the automatic process starts moving the parts in a predefined time through the different baths, controlled by the worker. Finally the treated piston rings are unloaded from the jigs and transported to the storage area. Apart from the operator loading, unloading, and electronically controlling the plating process, no other workers are present at the line during the process.

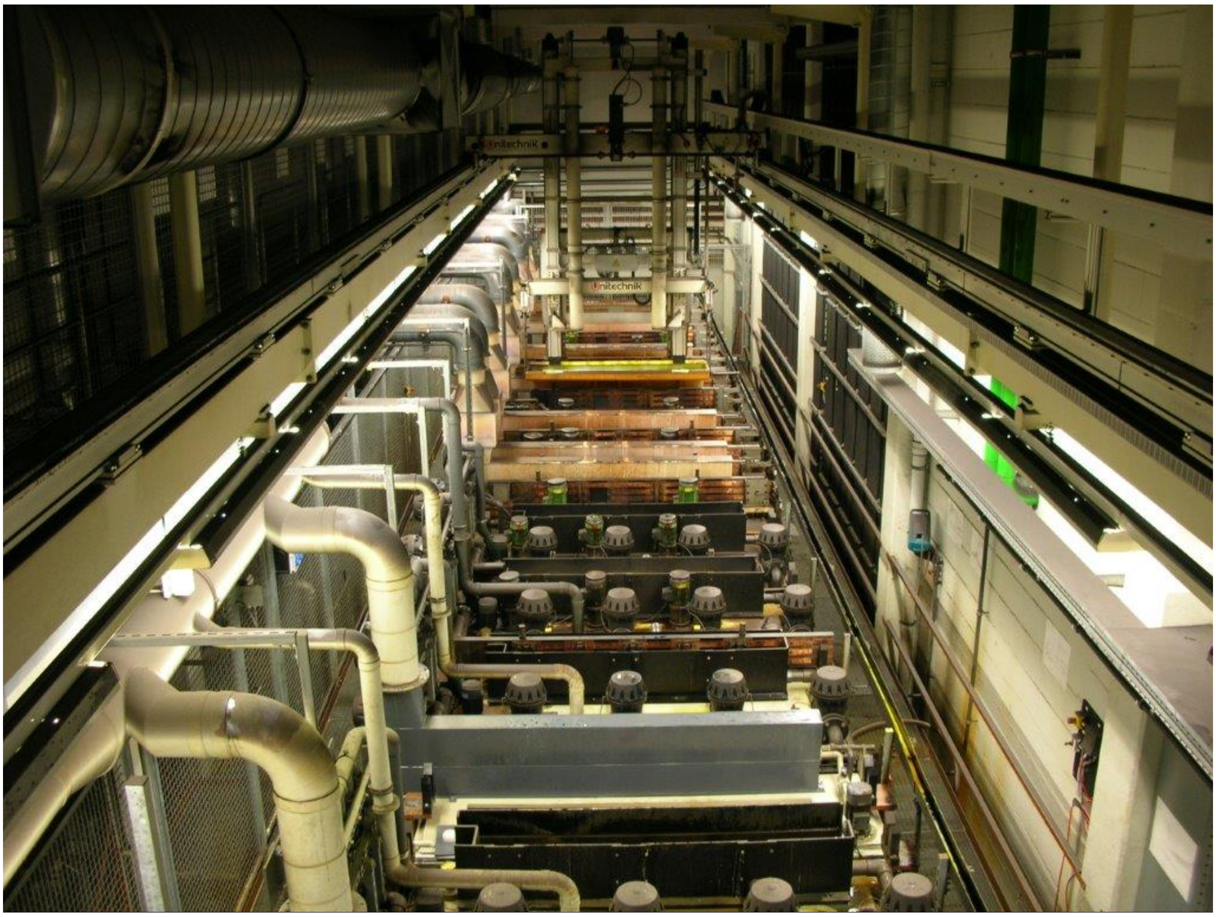

Figure 3: Example of automatic plating line

9.1.3.1. Conditions of use

	Method
Product (article) characteristics	
▪ Concentration of Cr(VI) in mixture:< 20%	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 8 hours	Measured data
Technical and organisational conditions and measures	
▪ General ventilation: 5-10 air changes per hour (ACH)	Measured data
▪ Local exhaust ventilation: Yes	Measured data
▪ Occupational Health and Safety Management System: Advanced	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	Measured data
Other conditions affecting workers exposure	

	Method
▪ Place of use: Indoor	Measured data
▪ Process temperature (for liquid): Above room temperature	Measured data

9.1.3.2. Exposure and risks for workers

Because this is a newly constructed line, an initial measurement according to the German Ordinance on Hazardous Substances and the Technical Rule for Hazardous Substances (TRGS) 402 in form of personal sampling was conducted beginning of 2015 followed by a control measurement mid of 2015.

The measured values below already consider the effectiveness of LEV (reflected by the measured values).

Table 13. Results of personal sampling, new automated line, in 2015

Sampling Date	No of samples	Result
Initial (2015)	**1**	**2.1 µg/m³**
Control (2015)	**1**	**0.9 µg/m³**

The reduced value in the control sampling is due to an improvement of the ventilation system after the initial measurement. While the result of the control sampling likely represent the current exposure situation the mean value of both results, **1.5 µg/m³** is used for risk assessment to account for remaining uncertainties.

Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 6.0 per 1000 exposed workers

Conclusion on risk characterisation

An excess lifetime lung cancer risk of 6.0 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.4. Worker contributing scenario 3: Functional chrome plating – manual plating process (PROC 13)

Piston rings are clamped on mandrels, hanged to the jigs and moved by the workers using a hoist through the different baths (i.e. rinsing, pre-passivation, etching, cleaning, plating, rinsing, and passivation). Finally the treated piston rings are unloaded from the jigs and transported to the storage area. Baths containing chromium trioxide are covered and equipped with extract ventilation during the treatment process.

Figure 4: Manual plating line

9.1.4.1. Conditions of use

	Method
Product (article) characteristics	
▪ Concentration of Cr(VI) in mixture: < 20%	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 8 hours	Measured data
Technical and organisational conditions and measures	
▪ General ventilation: 10 air changes per hour (ACH)	Measured data
▪ Containment: No	Measured data
▪ Local exhaust ventilation: Yes	Measured data
▪ Occupational Health and Safety Management System: Advanced	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	Measured data
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Measured data
▪ Process temperature (for liquid): Above room temperature	Measured data

9.1.4.2. Exposure and risks for workers

Recent measurement**)** according to the German Ordinance on Hazardous Substances and the Technical Rule for Hazardous Substances (TRGS) 402 in form of personal sampling and with an adequate LOD (< 1 µg/m³) are available since 2012.

The measured values below already considers the effectiveness of LEV (reflected by the measured values).

Table 14. Results of personal sampling 2012-2015, manual line

Sampling Time	N*	Arithmetic Mean	Geometric Mean	90^{th} Percentile	RCR
2012 - 2015	**6**	**1.11 µg/m³**	**0.93 µg/m³**	**1.99 µg/m³**	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 7.96 per 1000 exposed workers

Conclusion on risk characterisation

An excess lifetime lung cancer risk of 7.96 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.5. Worker contributing scenario 4: Functional chrome plating – Maintenance (PROC 8b)

Worker in the maintenance department are responsible for regular maintenance and repair but also for other tasks like transfer of newly delivered chromium trioxide to the dosing tanks, sampling and adjusting the automatic dosing based on the results of the laboratory analysis, dechroming of tools, draining of chromium trioxide for disposal, and cleaning of the baths areas.

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
▪ Concentration of Cr(VI) in mixture: < 20%	Measured data
Amount used (or contained in articles), frequency and duration of use/exposure	
▪ Duration of activity: < 8 hours	Measured data
Technical and organisational conditions and measures	
▪ General ventilation: 10 air changes per hour (ACH)	Measured data
▪ Containment: No	Measured data
▪ Local exhaust ventilation: Yes	Measured data
▪ Occupational Health and Safety Management System: Advanced	Measured data
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	Measured data
Other conditions affecting workers exposure	
▪ Place of use: Indoor	Measured data
▪ Process temperature (for liquid): Above room temperature	Measured data

9.1.5.2. Exposure and risks for workers

Recent measurement) according to the German Ordinance on Hazardous Substances and the Technical Rule for Hazardous Substances (TRGS) 402 in form of personal sampling are available in 2015. The measurements cover the tasks of the maintenance worker described above except the dosing of tanks after delivery of the chromium trioxide solution. This task was already modelled in WCS 1.

The measured values below already consider the effectiveness of LEV (reflected by the measured values).

Table 15. Results of personal sampling 2015, maintenance

Sampling Date	No of samples	Result
2015 - Person A	**1**	**2.0 µg/m³**
2015 – Person B	**1**	**1.2 µg/m³**

The 90th percentile value of both results, **1.92 µg/m³,** is used for risk assessment.

Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 7.68 per 1000 exposed workers

Conclusion on risk characterisation

An excess lifetime lung cancer risk of 7.68 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

9.1.6. Worker contributing scenario 5: Quality control of articles (PROC 8b)

Quality control of the finished articles is conducted in a room adjacent to the manual plating area. Because it seems to be possible that there are residual chrome particle on the finished article, all work places are equipped with a HEPA filtered down draft table.

9.1.6.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Powders, granules or pelletised material	ART 1.5
▪ Dustiness: Fine dust	ART 1.5
▪ Powder weight fraction [Cr(VI)]: Substantial (10 - 50%)	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Moisture content: Dry product (< 5 % moisture content)	ART 1.5
Activity emission potential	
▪ Duration of activity: < 480 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Handling of contaminated solid objects or paste formation)	ART 1.5
▪ Situation: Handling of slightly contaminated (layers of less than few grams) objects	ART 1.5
▪ 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	ART 1.5
Surface contamination	

	Method
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place?: Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: 300 m³	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: HEPA filter (99.0 % reduction)	ART 1.5 (extended)
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.6.2. Exposure and risks for workers

Table 16. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0.71 µg/m³** (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 2.84 per 1000 exposed workers

<u>**Conclusion on risk characterisation**</u>

The modelled exposure estimate of 0.71 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 2.84 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.7. Worker contributing scenario 6: Processing of the electrolyte (PROC 2)

The chromium trioxide containing electrolyte is processed for re-use in closed tanks in a separated room. Responsible for controlling the process operation is the central service department of the site.

9.1.7.1. Conditions of use

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: < 20%	ART 1.5

	Method
▪ Process temperature: Above room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low	ART 1.5
Activity emission potential	
▪ Duration of activity: < 1 h	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: No	ART 1.5
▪ Activity class: Bottom loading	ART 1.5
▪ Situation: Transfer of liquid product with flow of 10–100 l/min	ART 1.5
Surface contamination	
▪ Process fully enclosed? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: 100 m^3	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: High level containment (99.90 % reduction) *Physical containment or enclosure of the source of emission. The air within the enclosure is not actively ventilated or extracted. The enclosure is not opened during the activity.*	ART 1.5
▪ Secondary: Fixed capturing hood (90.00 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.7.2. Exposure and risks for workers

Table 17. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**1.0E-4 µg/m³** (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 4.0E-4per 1000 exposed workers

<u>**Conclusion on risk characterisation**</u>

The modelled exposure estimate of 1.0E-4 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 4.0E-4 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

9.1.8. Worker contributing scenario 7: Waste water management (PROC 2)

Very low amounts of Cr(VI), if at all, are released from waste water treatment systems, where residual Cr(VI) is reduced to Cr(III); the resulting Cr(III) is then precipitated and disposed to licensed landfills by licensed waste management companies. Responsible for controlling the waste water treatment is the central service department of the site. Treatment of chromium trioxide containing waste water is located in a separated room.

9.1.8.1. Conditions of use

9.1.8.1.1. Near field (volume of air within 1 metre in any direction of the worker's head) – waste water management

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Very small (0.5-1%)	ART 1.5
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low	ART 1.5
Activity emission potential	
▪ Duration of activity: < 15 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: Yes	ART 1.5
▪ Activity class: Activities with relatively undisturbed surfaces (no aerosol formation)	ART 1.5
▪ Situation: Open surface 0.3 - 1 m²	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: 300 m^3	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.8.1.2. Far field (volume of air outside 1 metre in any direction of the worker's head) – waste water management

	Method
Product (article) characteristics/substance emission potential	
▪ Substance product type: Liquid	ART 1.5
▪ Concentration of Cr(VI) in mixture: Very small (0.5-1%)	ART 1.5

	Method
▪ Process temperature: Room temperature	ART 1.5
▪ Vapour pressure of substance: < 0.01 Pa	ART 1.5
▪ Viscosity: Low	ART 1.5
Activity emission potential	
▪ Duration of activity: < 45 min	ART 1.5
▪ Primary emission source located in the breathing zone of the worker: No	ART 1.5
▪ Activity class: Activities with relatively undisturbed surfaces (no aerosol formation)	ART 1.5
▪ Situation: Open surface 0.3 - 1 m²	ART 1.5
Surface contamination	
▪ Process fully enclosed? No	ART 1.5
▪ Effective housekeeping practices in place? Yes	ART 1.5
Dispersion	
▪ Work area: Indoors	ART 1.5
▪ Room size: 300 m^3	ART 1.5
Technical and organisational conditions and measures – localised controls	
▪ Primary: No localized controls (0.0 % reduction)	ART 1.5
▪ Secondary: No localized controls (0.0 % reduction)	ART 1.5
▪ Ventilation rate: Only good natural ventilation	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
▪ Respiratory Protection: No	ART 1.5

9.1.8.2. Exposure and risks for workers

Table 18. Exposure concentrations and risks for worker

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0.039 µg/m³** (ART 1.5 prediction, 90th percentile value)	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 40 year working life (8h/day, 5d/week), the following excess lifetime lung cancer mortality risk up to age 89 is derived based on the estimated exposure: 0.16 per 1000 exposed workers

<u>Conclusion on risk characterisation</u>

The modelled exposure estimate of 0.039 µg Cr(VI)/m³ is used as the basis for risk characterisation (worst case). The estimate is based on several conservative assumptions regarding exposure.

An excess lifetime lung cancer risk of 0.16 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality. As the mechanistic evidence is suggestive of non-linearity, it is acknowledged by RAC that excess risks inferred in the low exposure range [i.e. below an exposure concentration of 1 µg Cr(VI)/m³] might be an over-estimate.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

Workers in the functional chrome plating process at the site are clearly assigned to specific tasks and no combination of tasks (sub-scenarios) can occur apart from operators of the central service department who could conduct the tasks described in WCS 6 and 7.

The highest exposure estimate at the site was for workers in the manual chrome plating area with an estimate of 1.99 µg Cr(VI)/m³ as the 90th percentile value. As a result and for use in the SEA, a maximum individual exposure value of 2 µg/m³ Cr(VI) is seen as a reasonable basis for calculation.

In this case, an excess lifetime lung cancer risk of 8 per 1000 exposed workers is estimated based on the above exposure estimate and the RAC dose-response relationship for lung cancer mortality.

10.1.2. Consumer

Not relevant as there is no consumer use.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Regional exposure

Environment

The regional predicted environmental concentration (PEC regional) and the related RCRs when a PNEC is available are presented in the table below.

The PEC regional have been estimated with EUSES.

Table 19. Predicted regional exposure concentrations (Regional PEC)

Protection target	Regional PEC	Risk characterisation
Freshwater	Not relevant	Not relevant
Sediment (freshwater)	Not relevant	Not relevant
Marine water	Not relevant	Not relevant
Sediment (marine water)	Not relevant	Not relevant
Air	1.53E-15 mg/m³	Not relevant
Agricultural soil	Not relevant	Not relevant

Man via environment

The exposure to man via the environment from regional exposure and the related RCRs are presented in the table below. The exposure concentration via inhalation is equal to the PEC air.

Table 20. Regional exposure to man via the environment

Route	Regional exposure	Risk characterisation
Inhalation	1.53E-15 mg/m³	Based on the dose-response relationship for lung cancer mortality derived by the RAC, considering a 70 year exposure time (24h/day, 7d/week), the following excess lifetime lung cancer mortality risk for the general population is derived based on the estimated exposure: 4.44E-11 per 1000 exposed.
Oral	Not relevant	Not relevant

10.2.2. Local exposure due to all wide dispersive uses

Not relevant as there are not several wide dispersive uses covered in this CSR.

10.2.3. Local exposure due to combined uses at a site

Not relevant as there are no combined uses at a site.