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The update of the CSR by the applicant(s) may be necessary to ensure that any additional information provided by the applicant(s) to ECHA Committees (Committees for Risk Assessment and Socio-economic Analysis) during the evaluation of their application for authorisation on basis of which the authorisation was considered is reflected in the CSR.

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CHEMICAL SAFETY REPORT

Substance Name: Chromium trioxide

EC Number: 215-607-8

CAS Number: 1333-82-0

Registrant's Identity: Volta Energy Solutions Hungary Kft

Authorisation number: REACH/20/13/0 – REACH/20/13/1

Notice:
The applicant for this review report for Authorisation is part of the same group as Circuit Foil SARL – Luxembourg – (CFL SARL). CFL SARL has applied for a similar authorisation (submission on 7th November 2015) and that was the subject of a positive recommendation by ECHA committees (RAC/SEAC opinion published on 16th March 2017[1]) and a decision by the European Commission (REACH18/17/0) for the same use. The applicant makes reference to all the elements of the CFL application with permission of the latter and confirms that at the minimum the safety measures included in the CFL application will be implemented.
The Review Report is intended to describe the Operational Conditions (OC), the Risk Management Measures (RMM), the anticipated exposure levels and the estimated excess of risk following a substantial increase in tonnage. It has to be noted that based on the initial Authorisation granted to the applicant, the plant has been built and is operational since March 2020. Because it is a brand-new plant not having reached its full production capacity as initially granted, the review report relies on:

- *The conditions as initially Authorised, including RAC and SEAC comments and opinions,*
- *The implementation of these conditions in the new plant, when more stringent (e.g. air exhaust ratios),*
- *The initial monitoring program ran 6 months after the plant opening,*
- *The state-of-the-art section of the CFL factory in Luxembourg and the output (copper foil for use in electronic applications) is practically identical.*

Part of the OC/RMM are already in place in the new plant and relevant for the new conditions, and part of them need to be adapted due to the production increase and the consequences in terms of work management. Therefore, the CSR combines the dual use of "past continuous" and "future", to make the distinction between what is operational and relevant and what will be implemented.

It is important to insist on the fact that Volta and CFL group works on the basis of the reference fab concept. This means that all innovations, safety and HSE practices from CFL are implemented also in the new site. The same practices are applied:

- *The high level risk management policy implemented,*
- *The implementation of adequate solutions to manage the risks, in line with the hierarchy of controls principles. Including process and engineering improvements that can be made only at the new site;*
- *A continuous effort to prevent and control exposure of workers, the general public and the environment to Chromium VI (including successful efforts to reduce Cr(VI) usage in process since the CFL application)*

The design of the new plant is managed by competent persons from CFL SARL, the current standard of quality is similarly applied, and the organisational and risk management policies implemented at the Wiltz site is the gold-standard. From an exposure and environmental emission perspective the highest standards are applied.

Key modifications are highlighted in green.

This CSR is an updated version compiled following request for additional information from ECHA.

December 2021

[1] ECHA/RAC/SEAC: AFA-O-0000006555-69-01/D

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Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

A succinct summary of representatives risk management measures (RMM) and operational conditions (OC) is given here below. The RMMs and OCs applicable to Volta Energy Solutions Hungary Kft for the chromium trioxide uses are described in more details in Section 9.

[ES1 - IW1 – Formulation of CrO_3]

ECS and WCS	Task (ERC/spERC or PROC)	Annual amount per site (tonnes/year)	Technical RMMs, including: *Containment, *Ventilation (general, LEV…) *customized technical installation, etc	Organisational RMMs, including: *Duration and Frequency of exposure *OSH management system *Supervision *Monitoring arrangements *Training, etc	PPE (characteristics)	Other conditions	Effectiveness of waste water and waste air treatment (for ERC)	Release factors: water, air and soil (for ERC)	Detailed info. in CSR (section)
ECS 1	Formulation (ERC 2, spERC eurometaux 2.2c.v2.1 for air releases)	100 t/year	Wet scrubber to prevent release to the atmosphere, On-site waste water treatment plant.	ISO 14001	-	-	Waste water treatment: reduction, neutralization, decantation leading (reduction of Cr(VI) to Cr(III) Air treatment: wet scrubbers with waste water treated as detailed above.	Water: 0.01 % (waste water concentration <0.1ppm) Air: 0.01% Soil: 0%	9.0.2.1 9.1.1
WCS 1	Storage and handling (PROC 1)	100 t/year	Closed system General ventilation: 8 to 12 ACH	ISO 45001, Safety training, specific medical trimestral survey, specific hygiene and safety instructions. Exposure monitoring related to Cr(VI) OEL. Closed and locked area, restriction of access. <1h per shift, 1 operation per week.	Nitrile gloves, Safety Googles, Protective suit.	Ambient temperature, Indoor, purity ≥ 99.5%.	-	-	9.1.2
WCS 2	Dissolution of CrO3 flakes into water (PROC 4)	100 t/year	Open system General ventilation: 35 ACH Semi-automated process Filler funnel fitted with a fixed capturing hood and enclosed in a fume cupboard like device. Operator in the far field.	ISO 45001, Safety training, specific medical trimestral survey, specific hygiene and safety instructions. Exposure monitoring related to Cr(VI) OEL. Restricted access when operating. 12-h per shift, 365 days a year.	Nitrile gloves, Full face respirator, Disposable all-in-one suit.	Ambiant temperature, Indoor, purity ≥ 99.5%.	-	-	9.1.3
WCS 3	Manual maintenance (repair) of machinery (PROC 28)	100 t/year	Open system General ventilation: 8 to 12 ACH	ISO 45001, Safety training, specific medical trimestral survey, specific hygiene and safety instructions. Exposure monitoring related to Cr(VI) OEL. Device of concern is abundantly washed with clean water prior to intervention. 2 hours per shift, twice a month.	Nitrile gloves, Full face respirator, Disposable all-in-one suit.	Ambiant temperature, Indoor, Conc. in mixture: extremely small	-	-	9.1.4

Abbreviations: WCS=Worker contributing scenario, ECS=Environmental Contributing Scenario,* ERC=Environmental Release Category (or spERC if available) , PROC= Process category, LEV=Local Exhaust Ventilation, PPE=Personal Protective Equipment

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

Volta Energy Solutions Hungary Kft declares hereby that risk management measures as described in this Exposure Scenario are implemented.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

Volta Energy Solutions Hungary Kft declares hereby that risk management measures as described in this Exposure Scenario are communicated to industrial workers.

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

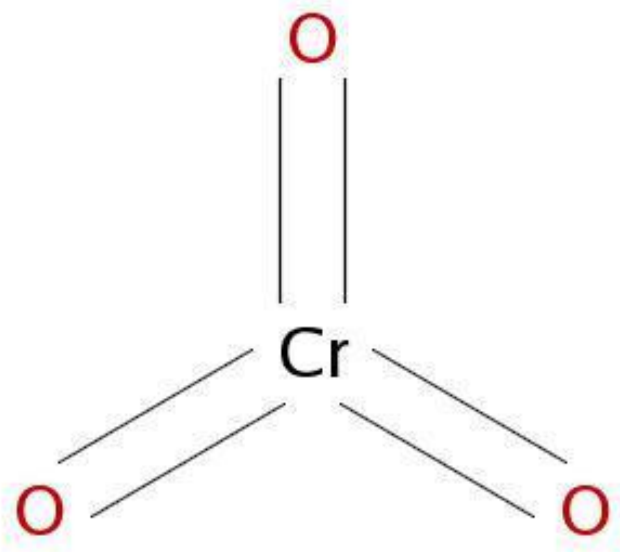
1.1. Name and other identifiers of the substance

The substance **Chromium trioxide** is a mono constituent substance (origin: inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

Picture 1. Substance identity

EC number:	215-607-8
EC name:	chromium trioxide
CAS number (EC inventory):	1333-82-0
CAS name:	Chromium trioxide
IUPAC name:	Trioxochromium
Molecular formula:	CrO3
Molecular weight range:	= 99.99

Structural formula:



1.2. Composition of the substance

Name: Chromium trioxide

Degree of purity: >= 99.5 % (w/w)

Picture 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
Chromium trioxide EC no.: 215-607-8	>= 99.5 % (w/w)		

1.3. Physicochemical properties

No relevant information available

2. MANUFACTURE AND USES

No information available on quantities

2.1. Manufacture

No information available on manufacture

No information available on manufacturing process related to the specified manufacture(s)

No information available on production of articles covered by the specified use(s)

2.2. Identified uses

To ensure Lithium-Ion batteries' performance, safety and long-term capacity, copper anodes need to be protected against oxidation. To that end, copper foils are treated with a chemical conversion coating with chromium trioxide. During this a chemical and electro-chemical processing step, also called passivation, Cr(VI) is converted into Cr(III).
The passivation bath is prepared from CrO_3 flakes, dissolved in water to formulate a concentrated solution and then diluted to the appropriate concentration (0.075% w/w of CrO_3). All the tasks likely to lead to worker exposure will be automated (dissolution of CrO_3, preparation and supply of the passivation medium…). Passivation baths will be continuously filled-in with passivation medium which will be recirculated to the storage tank (Picture 4). Form time to time, the storage tank will be drained and filled-in with fresh preparation. Waste waters will be treated (reduction to Cr(III), decantation of sludges…) before release into a municipal waste water treatment plant. Air extracted from the installations and workshops will go through wet-scrubbers; the related waste water will be collected by the waste water network for treatment.

Picture 3. Uses at industrial sites

Identifiers	Use descriptors	Other information
IW-1: Industrial formulation of a chromium trioxide solution below 0.1% w/w concentration for the passivation of copper foil used in the manufacture of Lithium Ion Batteries (LiB) for motorised vehicles	**Environmental release category (ERC):** ERC 2: Industrial use of reactive processing aids **Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure (WCS 1 - Storage and handling) PROC 4: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) (WCS 2 – Dissolution of CrO_3 flakes into water) PROC 28: Manual maintenance (cleaning and repair) of machinery (WCS 3 - Maintenance (repairing) of machinery) **Product Category used:** PC 14: Metal surface treatment products, including galvanic and electroplating products **Sector of end use:** SU 16: Manufacture of computer, electronic and optical products, electrical equipment **Technical function of the substance during formulation:** Surface active agents	Tonnage of substance: 100.0 Number of sites: 1 Substance supplied to that use: As a substance Subsequent service life relevant for that use: no

2.3. Uses advised against

No information available

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

Chromium trioxide is applied to provide protective chemical conversion coatings used to prevent corrosion/oxidation to copper foils. To that end, CrO_3 flakes are dissolved into water to obtain a concentrated Cr(VI) solution at [redacted] g/L. This concentrated solution is subsequently diluted to less than [redacted]% CrO_3 w/w and used for the passivation.
Picture 4 gives an overview of the life cycle of CrO_3 in the production plant. The starting material is solid CrO_3 (flakes – 25 kg barrels) stored and handled without any direct contact to workers (WCS 1) or leading to environmental emissions (air, water). To produce the concentrated Cr(VI) solution ([redacted] g/L), CrO_3 flakes are transferred into a tank for the dissolution with water. Each barrel is opened, emptied, rinsed and closed automatically (WCS 2) in a safe area. This concentrated solution is automatically transferred, diluted to [redacted]% CrO_3 w/w and stored in dedicated tanks. As shown under WCS 4 (out of the scope of the present authorisation), passivation tanks are automatically filled-in with fresh solution. Weary solutions are drained and replaced y fresh ones. The industrial process can be subject of maintenance work in case of installation malfunction (WCS 3, not shown in Picture 4). The plant will operate 365 days per year.

Emission to the environment can occur during the dissolution stage (air) and passivation (air, water). All the venting systems (general ventilation, Local Exhaust Ventilation – LEV) are connected to wet scrubbers transferring the potential CrO_3 airborne particles into a water phase. This water phase, as well as the used chromium solution from the passivation baths are treated (reduction, pH neutralisation, settlement) before release into a municipal sewage treatment plant (ECS 1).

[redacted]

Picture 4. Life-cycle of CrO_3 at the future plant *(ECS: Environmental Contributing Scenario, WCS: Worker*

Contributing Scenario, WCS 3 (Maintenance) not shown).

The reference site for the Applicant (Wiltz, Luxembourg) is certified ISO 9001, ISO 14001 and BS-OHSAS 18001. Audits on the quality, safety and environments are done on parts (yearly) or on the entire (every three years) of the processes. Non major non-conformity has been identified since the certifications.

The plant is certified ISO 14001 and ISO 45001 as well. Every quality, safety, environmental processes are managed and monitored by both competent personnel from CFL SARL (Wiltz, Luxembourg) and trained / competent personnel from the new plant. This new plant benefits from the high safety policy already implemented at Wiltz site, based on continual improvement of their procedures, workers sensitization and safety equipment (collective and individual).

9.0.1. Overview of uses and Exposure Scenarios

Tonnage information:

Assessed tonnage: 100 tonnes/year.

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

Picture 5. 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 - Formulation	-	Use at industrial site - Formulation, dissolution of CrO_3 into water (ERC 2) - Delivery and storage (PROC 1) - Dilution of the substance into a large container (PROC 4) - Maintenance (repairing) of machinery (PROC28)	100.0

9.0.2. Introduction to the assessment

9.0.2.1. Environment

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

Regarding the intrinsic hazardous properties of the substance (carcinogenic 1A and Mutagenic 1B) and in accordance with article 62-4. d) of the REACH regulation (EC) No 1907/2006, potential risks to the environment do not need to be considered. The environmental exposure to Cr(VI) due to the use described in the present document has been estimated to determine the man *via* environment exposure.

Environmental exposure assessment has been performed in accordance with the dedicated guidance documents [1,2], and the EU-RAR (2005) [3]. It concerns the following use of chromium trioxide:

- Formulation of the chromium trioxide solution at [redacted] g/L (*c.f.* section 9.0 for more details on this step).

The relevant direct releases to the environment are:

- Wastewater releases based on the threshold limit 0.1 ppm of Cr(VI) measured "at the end of the pipe", *i.e.* after on-site treatment and before releases to sewage network. It should be noted that if formulation of the chromium trioxide solution at [redacted] g/L is the only use falling into the scope of the authorisation, the integrative approach applied to assess waste water releases takes also into account potential aqueous releases due to other step use of Chromium trioxide solution at concentration below [redacted] g/L during

[1] ECHA Guidance R.16 (2016) - https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf.
[2] ECHA Guidance Appendix R.7.13-2 (2008): Environmental risk assessment for metals and metal compounds - https://echa.europa.eu/documents/10162/13632/information_requirements_r7_13_2_en.pdf/0497e68d-4bb5-4b12-a4db-52ce0c1bc237.
[3] EU-RAR (2005) - https://echa.europa.eu/documents/10162/3be377f2-cb05-455f-b620-af3cbe2d570b.

passivation step of copper foil.
- Releases to air due to emission as aerosol and/or particulate during the formulation of the chromium trioxide solution at [redacted] g/L, taken into account efficient RMMs.

Effluent on-site treatment and release

Before to be released in the environment, chromium trioxide effluents flow goes through an on-site sewage treatment plant where chromium trioxide is reduced to trivalent chromium using bisulfite. Efficiency of the process is continuously checked based to the continuous measurements of the pH and redox potential of the treated solution, in order to be in conditions guaranteeing the whole Cr(VI) reduction to Cr(III).

After the on-site treatment, the company measures continuously the concentration in chromium trioxide of its effluent. Effluent release to the sewage network is conditioned by the measurement of the chromium trioxide (automatized process).

The facility is currently not sized to use 100 tonnes CrO_3/year. The current maximum effluent flow rate is 48 m^3/day. In the next years, and in order to take into account the sizable increase of the facility (using 100 tonnes CrO3/year), the maximum effluent flow rate will be 145 m^3/day.

In case of Cr(VI) above the limit of 0.1 ppm, redox potential and pH outside the optimum treatment conditions, or malfunctioning of the measurements system, the effluent is automatically sent to safety tanks with a volume capacity enabling to store 0.78 days of effluent flowing (maximum effluent daily flow rate: 145 m^3/day). The contaminated effluent is retreated in the on-site sewage treatment plant, until the Cr(VI) concentration falls below 0.1 ppm.

The measures of all parameters mentioned above are recoded, and kept at the disposal to the authorities.

In addition, the on-site treatment of effluent containing Cr(VI) involves the production of sludge which contains chromium only as Cr(III). The sludge is pumped from the decantation tank, and sent to be treated by a dedicated company to recover the heavy metals.

Releases to air

Considering the low volatility of the substance, and in accordance with the EU-RAR (2005), releases to air of chromium trioxide is expected to be negligible. However, by applying a conservative approach, relevant releases could be associated with the particulate or aerosol phases.

Such releases are prevented during the whole process where Chromium trioxide is used by using wet scrubber. The generated waste water is collected by the waste water network and sent to the on-site sewage treatment plant.

Releases to soil

Direct release to soil is strictly excluded as the basements is on retention. Therefore, direct releases to soil is considered as negligible.

Picture 6. Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion
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

9.0.2.2. Man *via* environment

As there is no threshold for effect, conclusions of RAC report RAC/27/2013/06 Rev.1 were used to conclude on the hazardous of the exposure.

Picture 7. 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	ELR for lung cancer mortality: 2.9E-2 per µg Cr(VI)/m^3 for 70 years 24h/day, every day (general population)
Oral: local, long-term	Quantitative	ELR for intestinal cancer mortality: 8.0E-4 per µg Cr(VI)/kg bw/day for 70 years 24h/day, every day (general population)

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 RAC/27/2013/06 Rev.1 document. RAC linear dose-response relationships were used as there is no threshold for chromium trioxide.

Picture 8. 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	Not relevant
	Systemic, acute	Not needed	Not relevant
	Local, long-term	Quantitative	ELR lung cancer mortality: 4.0E-3 per µg Cr(VI)/m^3 for 40 years 8h/day, 5 days/week (workers)
	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

Considering the RAC report RAC/27/2013/Rev. 1, the only relevant route to consider is the inhalation route. Regarding the oral route, it is not taken into account (assuming that all particulate fractions are in the respirable range).

9.0.2.4. Consumers

Exposure assessment is not applicable as there are no consumer-related uses for the substance.

9.1. Exposure scenario 1: Use at industrial site – Formulation

Sector of use:

SU 16, Manufacture of computer, electronic and optical products, electrical equipment

Environment contributing scenario(s):	
Formulation into a mixture	ERC 2
Worker contributing scenario(s):	
WCS 1 - Storage and handling	PROC 1
WCS 2 – Dissolution of CrO_3 flakes into water	PROC 4
WCS 3 - Maintenance (repairing) of machinery	PROC 28

Hierarchy of control principles.
Because the plant has been created from scratch, under the latest Health and Safety regulations and standards, the hierarchy of control principles are strictly followed. Because the use of CrO_3 cannot be avoided or substituted, the first step is to minimise the exposure. All the tasks related to the use of CrO_3 are automated. Involvement of workers is limited to surveillance of industrial processes or handling of sealed containers. In order to ensure a high level of protection of workers, the three lower levels of the hierarchy are implemented.

- **Engineering controls**

All the workshops are equipped with a mechanical ventilation leading to an 8 to 12 Air Change per Hour (ACH), except in the dissolution cabinet with a ventilation rate of around 35 ACH (WSC 2, see section 9.1.3). The design of the ventilation takes into consideration the shape of the workshops as well as the presence of installations that could interfere with the air renewal efficiency. On-line measurement of the air velocity, as well as the pressure differential at the filters, are a continuous monitoring of the system. In case of malfunction, the maintenance team is automatically alerted and a visual alarm informs the bystanders. In addition, all the installation is annually checked by external contractors to ensure a proper efficiency.

At some specific points, Local Exhaust Ventilations (capturing hood, fume cupboard) are implemented at the exposure source points (WCS 2). They are designed to reach the required technical specifications (90 to 99% emission reduction). Once installed, the aspiration velocity (anemometers) is continuously monitored as well as the pressure differential between the interior (depression) and the exterior (atmospheric pressure) of the dissolution cabinet (see section 9.1.3. for more details). LEVs are regularly (monthly) rinsed with water suction pipes to remove any potential dust. The contaminated water goes directly into the WWT system (treatment by Na-bisulfite), where the waste water is treated by effluent on-site treatment. In case of malfunction of one of the LEVs installed in the cabinet, the maintenance team and the on-call dissolution-production engineer is automatically alerted. In addition, a visual alarm is activated at the entrance of the cabinet and the installation is locked. No further intervention by workers is allowed prior an action from the maintenance team.

- **Administrative controls**

On top of the implemented administrative controls, the plant will be certified ISO 9001, ISO 14001 and ISO 45001. These standards imply a high level of organisational and risk management policies. At the date of drafting this CSR, the Applicant has published tenders to hire contractors to implement these management systems. The Applicant is waiting for quotations and expected obtain the certifications in 2021.
More precisely, and according to the current legislation a workplace assessment is performed, with an annual revision. According to a specific procedure, every worker regularly involved in tasks with the presence of Cr(VI) follows:

- Two full-days training for new comers subject to a final examination,
- A monthly safety-sensitisation and an annual sensitisation dedicated to chemical safety,
- Specific medical trimestral survey:
  - Based on the Hungarian laws biological monitor (urine test) need to be performed once a year. The Applicant applies it on a quarterly basis.
  - Due to the potential tissue effects related to high exposure to Cr(VI), special attention is given to skin and mucosal, during the periodic occupational health check. This is intended to detect the first signs of skin or mucosal ulcer, characteristic of Cr(VI) exposure.
  - Contrary to what was stated in the initial dossier, no generalised biomonitoring program will be implemented; the main reasons are addressed in Annex 3,
- The instructions related to hygiene and safety rules, e.g. appropriate behaviour in case of malfunctions, PPEs to wear and how to wear them…,
- Shift supervisor responsible of the control and operator's adherence to the PPE requirements,
- The internal organisational procedures allow to an equal share of the roles between the workers for a dedicated WCS. This conducts the tasks will be equally distributed in duration and nature among workers.

CrO_3 barrels are stored in locked room with access restricted to authorised worker only (see 9.1.2. for more details). Dissolution operation takes place in a dedicated room, with restricted access. No other workers except those involved in the dissolution operation are allowed to enter (see 9.1.3. for more details).

- **Personal protective equipment (PPE) management process**

The PPE is part of the individual allocation of each worker of the company. Table 8 lists the PPE types related to the WCS. Workers likely to be involved in WCS 2 or WCS 3 wear the PPE as shown in **Erreur ! Source du**

renvoi introuvable..

The main drivers for the selection of the implemented PPE are:

- To reduce at max the exposure in case of accidental contact which is very unlikely due to the design of the installation and the organisation,
- To maintain the operator awareness at the highest level. They have to keep in mind that they handle very hazardous chemicals. This strategy is complementary to the frequent communication around the hazard of CrO_3.

The workers who may be exposed to substances such as chromium trioxide (preparation of the dilution, maintenance task) have disposable overall chemical types, full face masks, disposable gloves, closed goggles, face shield, boots. According to the manufacturer instructions, respiratory equipment is visually checked to detect any damages, scratches or visual distortion of the masks or the cartridges. The frequency of replacement of the filters is according to the manufacturer instructions. Replacement of PPE is done by the workers or their supervisors by visiting the company's shop where is made a standard and immediate exchange of the PPE.

Each operator likely to use RPE follows a dedicated training specifying, amongst other, how to check the adequacy of the used cartridge, how to fit the mask on, the facial hairstyle restrictions, how to clean the mask and change the filters, and how to check the sealing once put on. A dedicated documentation is made available to the operators. A sealing test is performed by each worker before each intervention needing to wear a full-face mask. The procedure is:

- After properly put on the full-face mask, cover the filters of the mask with the palm of the hands and try to take a breath.
- If one cannot take a breath, the full-face mask is properly fitted. If one can take a breath the mask is not sealed properly. In this case, make sure that the filters are inserted correctly and that the belts are tightened properly.

Regular field audits are planned well as spot checks permitting to ensure PPE performances. These integrated quality, safety and environment audits will be integrated in the management systems once the plant will be certified according to ISO 9001, ISO 14001 and BS-OHSAS 18001 (expected date end of 2021). Moreover, training and sensitisation for safety will be performed (bimonthly 1/4 hour security). High security policy based on continual improvement of the procedures, training and information on the risks and the importance of wearing the PPE is conducted.
The non-wearing of the PPE will be systematically notified by supervisors who will give written warnings for repeated offenses. Repeated offenses can lead to dismissal for serious misconduct.

It has to be noted that the protection factor of the RPE was not taken into account in the exposure assessment. Administrative controls as well as engineering controls are designed to minimise the exposure to CrO_3. RPE is the ultimate barrier of protection in case of unexpected event. Therefore, it is anticipated that the risk should be properly managed without RPE, keeping the personal protection only as a last resort in case of breaching of protective barriers. Therefore, it’s a worst-case situation.

Table 8. List of PPE according to the WCS

PPE Type	PPE supplier	Used for WCSs
Tychem overall (EN 340 Cat III, EN13034 Type 6, EN 13982 Type 5, EN14605 Type 4 & Type 3, EN1073, EN14126 Type 4B, EN1149) TYCHEM C	Dupont	WCS 2 / WCS 3
Full Face Mask with ABEK2 filter (EN 136) 3M 6700-6800-6900 & 3M 6099 ABEK2P3	3m	WCS 2 / WCS 3
Nitril gloves (EN 374 JKL, EN 374, EN 388 X131 Cat III) Alphatec 58-270	Ansell	WCS 1 / WCS 2 / WCS 3
Chemical resistant safety boots (EN ISO 20345 S5 SRC) Sicherheitsstiefel S5 SRC	Nora	All WCS
Safety Goggles (EN 166, EN 170) Pheos Guard Spectacles	Uvex	WCS1
Working Clothes (EN 1149, EN ISO 13688, EN ISO 11611 Cat I, EN ISO 11612, EN 61482-1-2)	Vektor	WCS1

Picture 1: Illustrative full equipment of a worker intended to operate on WCS 2 and WCS 3.

The nature of the tasks as described in the CSR reflects the ramp-up of the plant and expansion in production capacity foreseen (100 t/year).

It should be recalled that the plant has been built and is operational only since March 2020. It is a brand-new plant not having reached its full production capacity even under the original authorisation. The ramp-up as well as the expansion plans are being executed during this same start-up period. Because of the experience gained by the management team, a better understanding of the foreseen needs in terms of organisational conditions has been gained in the past months. Since the drafting of the CSR, these conditions have been refined and optimised to fit the industrial and management capabilities of the plant. In addition, especially for WCS2 (dissolution of the CrO3), the whole team as gained in experience and improved their working methods.

Therefore, the task duration and frequency, and the work organisation were revised during the review of the submitted dossier. Based on the feed-back of the first year of partial functioning of the plant, a new and more definitive organization has been defined:
The plant will function in continuous operations, 365 days a year, and 24h a day. The number of annual working days per operator is 180 days, excluding holidays. It has to be noted that the number of days of holidays depends on the age and the time-on-the-job. In the table below is described the frequency per worker involved in each WCS.

Table 9. Description of the frequency of exposition to each WCS

WCS	Frequency per worker involved in the WCS.	Comments	Number of exposed workers
WCS 1	<1h/day, 1 day/month	Chromium trioxide stock are very low, at least once a month there is a delivery.	number of workers/task: 1 number of workers/team: 12
WCS 2	3h/day, 365 days/year	maximum total amount of 11 barrels per day, a rotation between operators is established	number of workers/task: 2 number of workers/team: 12
WCS 3	Repairing: 2 hours/day, 2 days/month	Repairing: only when suspected defective devices are identified.	number of workers/task: 2 number of workers/team: 16.

9.1.1. Environmental contributing scenario 1: Formulation

9.1.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily use at site: <= 0.274 tonnes /day of CrO_3, eq. to 0.142 tonnes /day of Cr
• Annual use at a site: <= 100.0 tonnes/year of CrO_3, eq. to 52 tonnes /year of Cr

• Percentage of EU tonnage used at regional scale: = 100 %
Conditions and measures related to the on-site sewage treatment plant
• On-site treatment: Cr(VI) reduction to Cr(III), followed by neutralization and decantation
• Discharge rate of effluent in sewage network: 145 m^3/day
• Threshold limit of Cr(VI) in effluent: < 0.1 ppm
• Application of sludge on agricultural soil: No
Conditions and measures related to sewage treatment plant
• Municipal STP: Yes o Fstp(air) = 0% [EU-RAR, 2005] o Fstp(effluent) = 50% [EU-RAR, 2005] o Fstp(sludge) = 50% [EU-RAR, 2005]
• Discharge rate of STP: >= 16000 m3/d (*i.e.* STP capacity of 80000 eq. of inhabitants)
• Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: No (Waste disposal according to national/local legislation)
Other conditions affecting environmental exposure
• Receiving surface water flow rate: = 86400 m3/d (Altal-Er river)

9.1.1.2. Releases

The local releases to the environment are reported in the following table.

Table 10. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Measured release	**Final release factor:** 0.01 % **Local release rate:** 0.0145 kg/day of Cr(VI) **Explanation / Justification:** see below
Air	Based on spERC eurometaux 2.2c.v2.1 [4]	**Final release factor:** 0.01% **Local release rate:** 0.0142 kg/day of Cr(VI) **Explanation / Justification**: see below
Soil	Release factor	**Final release factor:** 0% **Explanation / Justification**: see section 9.0.2.1.

As mentioned in section 9.0.2.1, the limit of release of chromium trioxide in effluent is fixed by the company on 0.1 ppm of Cr(VI). The company measures continually the concentration in Cr(VI) of their effluents. To calculate the measured release, a worst case was applied considering the maximal of 0.1 mg/l. With a rate flow of 145 m^3/day, the local release rate is 0.0145 kg/day of Cr(VI).

Concerning the local air release, the factor of 0.01% is from the spERC eurometaux 2.2c.v2.1. This air release factor is applicable for formulation of metal compounds in other than plastics and paint sectors when specific RMMs are applied (see the spERC factsheet for more details). As described in section 9.0.2.1, during the formulation of the chromium trioxide solution, wet scrubbers are in place to prevent potential release to the air. As web scrubber is listed as applicable RMM in the spERC factsheet, the air release factor of 0.01% from the spERC eurometaux 2.2c.v2.1 is considered relevant.

The abatement efficiency of the wet scrubber is nearly 100%. Efficiency of gas washing is constant: refreshing limit in the washing water for H_2CrO_4 is 3000 µS/cm. When the rinsing water conductivity reaches the limit,

[4] http://www.reach-metals.eu/force-download.php?file=/images/SPERCsFactSheets/02eannex7_eurometaux%202.2a-c.v2.1.pdf

system start the contaminated water to WWTP, and change it to fresh clear RO water. The limit conductivity (= proportional to Cr(VI) concentration), is so far from saturation concentration therefore the efficiency of the dissolution of CrO3 is constant as the concentration gradient is high.

9.1.1.3. Exposure and risks for man *via* the environment

The exposure and risks for man via the environment has been calculated with EUSES 2.1.2, in accordance with the assumptions of the EU-RAR (2005):

- As releases of Cr(VI) from any sources are expected to be reduced to Cr(III) in the environment, the impact of Cr(VI) as such is therefore likely to be limited to the area around the source (*c.f.* section 3.1.1 of the EU-RAR(2005) for more details). As a consequence, **the risk assessment has been focused only on the local impact of emission form the use of Cr(VI) presented in this dossier**.
- The removal of Cr(VI) during the waste water treatment in municipal STP used for the risk assessment was as followed: 50% adsorbed onto sewage sludge, 50% in effluent.
- **For all relevant compartment of the environment, it was assumed that 3% of the estimated Cr(VI) concentration will remain as Cr(VI), and 97% converted to Cr(III)** (*c.f.* section 3.1.1.2.1 of the EU-RAR(2005) for more details).
- For calculation of the local water concentration, only dilution and adsorption are taken into account, considering both acidic (*i.e.* pH < 6) and neutral-alkaline (*i.e.* pH > 6) environments. The adsorption coefficient fo Cr(VI) described in section 3.1.1.2.2 of the EU-RAR (2005) has been taken into account.
- As Cr(VI) released to soil or sediment is rapidly converted into Cr(III), the exposure of man *via* the environment from these sources has been considered as limited. As a consequence, **only drinking water and fish consumption has been taken into account for the oral route of man via the environment**.

The exposure concentrations (using EUSES) and risk characterization are reported in the following table. Only the exposure concentrations for neutral/alkaline environment are mentioned, considered as worst-case compared to acidic environment (*i.e.* higher exposure concentrations for the compartments relevant for the man via environment risk assessment).

Table 11. Cr(VI) exposure concentrations and risks for the environment

Protection target	Exposure concentration – Local PEC	Risk characterisation
Freshwater	2.13E-06 mg/L	Not relevant*
Sediment (freshwater)	9.43E-04 mg/kg_{ww}	Not relevant*
Marine water	Not relevant#	Not relevant*
Sediment (marine water)	Not relevant#	Not relevant*
Sewage treatment plant	4.54E-04 mg/L	Not relevant*
Air	7.62E-06 mg/m^3	Not relevant*
Agricultural soil	2.19E-04 mg/kg ww	Not relevant*
Man *via* environment - Inhalation	2.28E-07 mg/m^3	ELR= 6.61E-06
Man *via* environment - Oral	6.44E-08 mg/kg dw/day	ESIR= 5.15E-08

* Not relevant as the scope of the authorization is limited to human health.
# Not relevant as the risk assessment has been focused only on the local impact of emission form the use of Cr(VI) presented in this dossier (*i.e.* no seawater environment around the industrial site).
ELR: Excess of Lung cancer Risk
ESIR: Excess of Small Intestine cancer Risk

Picture 9. Contribution to oral intake for man *via* the environment from local contribution

Type of food	Estimated daily dose in Cr(VI)	Concentration in food in Cr(VI)
Drinking water	6.09E-08 mg/kg bw/day	2.13E-06 mg/L
Fish	3.5E-09 mg/kg bw/day	2.13E-06 mg/kg ww
Leaf crops	Not relevant	Not relevant
Root crops	Not relevant	Not relevant
Meat	Not relevant	Not relevant
Milk	Not relevant	Not relevant

The excess of cancer risk for lung or small intestine, respectively ELR and ESIR, are calculated according to the linear regression depicted in RAC document RAC/27/2013/06 Rev.1. It has to be noted that “*[a]s the mechanistic evidence is suggestive of non-linearity, it is acknowledged that the excess risks in the low exposure range might be overestimated*” (RAC, 2013).

9.1.2. Worker contributing scenario 1: Delivery and storage (PROC 1)

9.1.2.1. Conditions of use

Chromium trioxide are delivered as flakes in 25 kg sealed drums. The drums are stored near the location of the preparation of chromium trioxide solutions (see WCS 2, 9.1.3.) to limit the transfer of drums. Moreover, the drums are stored in a locked cabinet with restricted access. As the drums are sealed, there is no potential for exposure.
The 5 workers involved in this contribution scenario are regularly trained for safety and ensure the general housekeeping of the storage area. The physical integrity of each barrel (e.g. absence of deformation, leakage) are visually checked after each shipping, before storage and before delivery for the dissolution.
The delivery of the barrels from the storage area to the dissolution box is covered by WCS 2, happening every day/365. The same workers are involved in both WCS 1 and WCS 2.

	Method
Product (article) characteristics	
• Dustiness of material: Medium (flakes)	Qualitative assessment
• Concentration of substance in mixture: 99,7%	Qualitative assessment
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	Qualitative assessment
Technical and organisational conditions and measures	
• General ventilation: Enhanced general ventilation (5-10 air changes per hour)	Qualitative assessment
• Containment: Closed system (minimal contact during routine operations)	Qualitative assessment
• Local exhaust ventilation: no [Effectiveness Inhal: 0%]	Qualitative assessment
• Occupational Health and Safety Management System: Advanced	Qualitative assessment
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	Qualitative assessment
• Gloves (according to EN 374), safety googles (according to EN 166) and protective suite.	Qualitative assessment
Other conditions affecting workers exposure	
• Place of use: Indoor	Qualitative assessment
• Process temperature (for solid): Ambient	Qualitative assessment

9.1.2.2. Exposure and risks for workers

As formally reported in the following table, no exposure is expected during WSC1.

Table 12. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, local, long-term	**0 µg/m³**	ELR = 0

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

Based on the a 40 year working life (8h/day, 5 days/week) the ELR for lung cancer mortality is equal to 0 (regarding the ELR per µg Cr(VI)/m^3 given by the report RAC/27/2013/06 Rev.1).

9.1.3. Worker contributing scenario 2: Dilution of the substance into a large container

(PROC 4)

9.1.3.1. Conditions of use

Chromium trioxide flakes are dissolved in a concentrated solution ([redacted] g/L). The transfer of CrO_3 flakes take place in a dedicated room, the dissolution cabinet, with mechanical ventilation (c.a. 35 ACH). In this dedicated room, with restricted access, only dissolution operation occurs. More precisely, the transfer of the flakes into the concentrated solution tank is done in a device called “Barrel reverser” (Picture 10 (1)). This reverser is composed of a filler funnel where the barrels are emptied (drop height of 40 cm). The filler funnel is connected to the dissolution tank. This tank is filled in with water and continuously stirred to get a homogenous solution at [redacted] g CrO_3/L. The dissolution cabinet is maintained closed with a shutter.

[redacted]

Picture 10: Barrel reverser. Schematic description, functioning, monitoring panel, and visual representation. (1) Schematic parts of the Barrel reverser. (2) to (7) dissolution steps (2-barrel entry, 3- automatic cover removal, 4- automatic barrel toggling, 5- barrel washing, 6- barrel closing, 7- barrel exit). (8) overview of the barrel reverser in the dissolution cabinet with the 3 LEVs. N*ote that each air extraction system is directed to a single scrubber*. (9) Picture of the dissolution cabinet taken from the workshop.

The operator in charge of the dissolution task takes out full barrels from warehouse storage area to the dissolution cabinet. Before opening the dissolution cabinet to start the task, the operator turns the exhaust system on to create a depression. After having checked the conformity of the installation (cleaning status, traces of contamination, functioning of the LEVs…), the operator puts the barrel on the trail, using a leverage device. Then the barrel transfer sequence is launched. Once the door of the barrel reverser is opened, the barrel is automatically transferred inside it. Once the door tightly closed, the barrel is automatically opened and slowly and carefully toggled to transfer the flakes into the filler funnel. Once empty, the barrel is inserted into the funnel to be rinsed with water, automatically closed and put out of the box. Then a new cycle can be launched by the operator. All the emptied and sealed barrels are stored in a special container for contaminated products. These containers are treated by a chemical waste processing company according to law.

It is important to note that the operator never enter into the barrel reverser. Only maintenance operators are allowed to intervene inside this area, under exceptional conditions only and after thorough cleaning procedures.

The plant will have 3 dissolution boxes in operation. The organizational conditions will be: 2 shifts per day (12 h each), with 3 workers per shift. In the morning-shift, two workers will be in charge of the dissolution task, and the third one to the monitoring of the waste water treatment plant (WWTP). The three workers of the afternoon-shift will be affected to the (WWTP).
The 2 workers in charge of the dissolution (morning-shift) will operate the three dissolution boxes in sequence. Dissolving 3 to 4 barrels per dissolution box, taking not more than 3h in total (1 hour per box, not more than 16 minutes per barrel). The total amount of CrO3 dissolved per day will be around 275 kg/day, that is 11 barrels, and not more than 100 t/year in total. This amount will be equally split amongst the three dissolution boxes.

It has to be noted that the operators involved in WCS operate the WWTP as well. The tasks related to the monitoring of the WWTP are: samples collection (treated effluent, sludges) for lab analyses, lab measurements, process control System monitoring, intervention (e.g.: liquid transfer from storage vessels to waste water treating Lines Cu and Cr with valves and vacuums, cleaning, minor maintenance, press filter cleaning, physical observation in every 2 hours on site, etc...). None of these tasks may lead to exposure to Cr(VI) as it is after the reduction by sodium bisulfite.

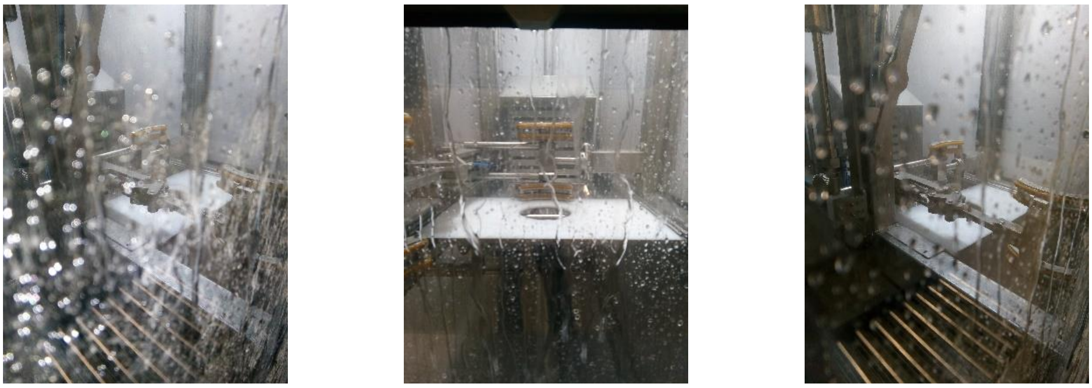
Engineering controls to prevent worker exposure are:

- The operation takes place in an isolated room without other source of exposure,
- A fully automated process; operator only has to insert the fresh barrel and remove the empty one; he is at more than 1 m from the filler funnel,
- Airtight barrel reverser, with depression compared with the external medium,
- The dissolution cabinet is fitted with air extraction allowing 35 ACH. Inside the barrel reverser, the air exhaust rate is around 50 ACH.
- The upper part of the filler funnel is a dust aspiration system, aiming to capture all the CrO_3 dusts potentially emitted during the emptying. The dust is instantly flushed with water into the dissolution tank. The mixing tank is equipped of an air extractor (10 ACH) to remove the particles still in suspension in the tank,
- As described in Section 9.1. in case of malfunction of one of the LEVs, an alert is sent to the maintenance team, a visual alarm informs the operator, and the dissolution cycle is blocked until intervention of the competent personnel,
- As shown in Picture 11, CrO_3 flakes are of a deep red. Before, during and after each dissolution operation, the operator checks the presence of red dust deposited of any surface of the barrel reverser. The material used to build the barrel reverser is white to allow detection of such a deposit.

Picture 11: General aspects of CrO_3 flakes.

This cleaning cycle is automatically performed at the end of every dissolution sequence, once a day. Indeed, once all the barrels have been emptied, water is flushed into the entire box to remove chromium residues from the air space and surfaces. The waste water is then neutralised with sodium bisulfite and transferred to the WWTP. In case of detection of red dust, the operator stops any on-going process and ask the maintenance team to intervene. Before any direct intervention, a new cleaning cycle is launched.

Pictures taken from outside the dissolution box illustrating the effectiveness of the cleaning system:



Picture 12: Illustration of the effectiveness of the cleaning system displayed in the dissolution box.

In addition to the generic administrative controls detailed in Section 9.1. and the frequent trainings related to the safety policies, workers involved in this task are specifically trained for the use of the dissolution box and for the proper behaviour in case of abnormal situation. During the transfer only authorised workers are allowed to be present.

Workers wear the PPEs as detailed in Section 9.1. and illustrated by Picture 10.

The conditions of this task are described in the below table.

	Method
Product (article) characteristics	
• Dustiness of material: Medium (flakes)	ART 1.5
• Concentration of substance in mixture: 99,5%	ART 1.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: 3 hours Duration of the emission phase: 2 minutes Calculations: Duration of the emission phase: 10 seconds per barrel, 11 barrels a day (110 seconds rounded to 120 seconds/2 min). Total duration of the task per barrel, including emission phase: 16 minutes Total duration of the task per day, including emission phase: 3 hours (11 barrels a day)	ART 1.5
• One worker per operation, height people skilled and instructed in total. Frequency: about 200 operation per year, about 25 / year / worker.	For information
Technical and organisational conditions and measures	
• Activity emission potential: transfer of flakes (one 25 kg barrel in around 10 seconds) by gravimetry (drop height < 0.5 m) with a very exact and cautious manner (automated) at a transferring rate between 100 to 1000 kg/minutes. The remaining time is devoted to the handling of the barrel, the rinsing and the transfer between every step of the task.	ART 1.5
• Containment: Open process fitted with: - a fume cupboard (Wet scrubber 1 – 99% reduction) - a fixed capturing hood (dust aspiration ring – 90% reduction) - Dust aspiration in the dissolution tank not considered for this assessment.	ART 1.5
• No segregation. Even if the operator is segregated from the barrel reverser, there is a breach of the containment during the transfer of the full/empty barrels. Therefore, even if the emission phase (dropping off the power) is performed in full containment (dissolution box tightly closed), a worst-case situation has been preferred. This approach is also illustrated by the use of PROC4.	ART 1.5
No personal enclosure, but worker far from the source (> 1m, far field).	ART 1.5
• General ventilation: Enhanced general ventilation (35 air changes per hour)	ART 1.5

	Method
Note that 30 ACH is the maximum air exhaust rate available in ART 1.5	
• Occupational Health and Safety Management System: only four people are authorized for doing this work, they are regularly made aware about the extremely hazardous of chromium trioxide.	ART 1.5
• Restricted area, with limited access. No secondary source of exposure.	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with at least 20 regarding the supplier specification) [Effectiveness Inhal: 95%]	Not taken into account in the exposure prediction.
• The employee has to put in addition of the respiratory mask, protective rubber gloves, rubber boots and a disposable all-in-one suit.	For information.
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.5
• Process temperature (for solid): Ambient	ART 1.5
• Room volume: 100 m^3	ART 1.5

9.1.3.2. Exposure and risks for workers

The exposure concentrations and risk characterization are reported in the following table.

Table 13. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration (90th percentile)	Risk characterisation
Inhalation, local, long-term	**0.003 µg/m³ (ART 1.5)**	ELR = 6.2E-06

Conclusion on risk characterisation

Based on a 40 year working life (8h/day, 5 days/week) the ELR for lung cancer mortality is equal to 1.5E-4 (regarding the ELR per µg Cr(VI)/m^3 given by the report RAC/27/2013/06 Rev.1 and a conversion factor of 0.52 for CrO_3).

For this WCS, 8 workers are exposed, one at a time. That corresponds to 365 days per year dispatched to the 12 workers, for a task lasting a full 8-hour shift. A time factor correction should also be applied. Considering an average of 365 workings day in a year, the factor correction will be:

6 [(365 working days/60 operating days)].

The corrected ELR per operator is then 1.0E-6.

Note that no correction regarding the shift duration (12h vs 8h) is proposed as the emission phase is not related to the shift duration. A longer shift leads to exposure "dilution" instead. The proposed calculation is considered as a conservative approach.

Supporting information based on measured data:

As presented in Annex I of the CSR, a monitoring program has been launched in August 2020. For the WCS2, only 2 samples from the same operator have been generated, as well as 2 static samples located close to the barrel reverser door and to the control panel (Picture 10). The measured concentrations are either close to the limit of detection (3 out of the 4 measures) or below the limit of detection. The measured concentrations, when higher the LOQ are 0.030 µgCrO_3/m^3 on average, knowing that the LOQ is around 0.030 µg CrO_3/m^3.

This supporting value should be compared to the modelled value at 0.072 µgCrO_3/m^3.

Remark 1: the worker exposure concentration of 0.003 µg/m³ does not take into account the correction of RPE. We could divide this concentration by the APF factor of the RPE (APF = at least 20 regarding the supplier specification).

Remark 2: as it is explained by the RAC this ELR might be an overestimate. In fact, extrapolating outside the range of observation inevitably introduces uncertainties. 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.

Remark 3: Acknowledging the limits of the measured values (e.g. limited number of data points, limited number of operators, reduced duration of the task compared to a normal shift…), these supporting data tend to demonstrate appropriateness of the modelling.

9.1.4. Worker contributing scenario 3: Manual maintenance (repair) of machinery (PROC 28)

9.1.4.1. Conditions of use

This contributing scenario is limited to one type of intervention: repairing of malfunctioning devices (e.g. tanks, pumps, pipes, passivation installations).

Cleaning steps are included in the operating WCS (WCS 1 and WCS2); that means operators dealing with these WCSs are requested to apply high level housekeeping practices. No preventive maintenance is done. Intervention on the installations is driven by detection of malfunctions (observation from workers, alerts, monitoring of integrated measures…). A team of 16 people might be involved in this WCS3, in order to always have at least 4 maintenance operators per 12h shifts fully authorised to intervene on the Chromium devices. Based on the feedback from the first months of plant operation and the historical data from the reference site of Wiltz (Luxembourg), not more than 2 interventions per month on devices likely to be in contact with Cr(VI) are expected. These operations require 2 workers for around a two-hour period.

Before any intervention, the device of concern is abundantly washed with clean hot water, to optimise dissolution of any trace of CrO_3, and every surface is visually checked before intervention (CrO_3 stains in red contaminated surfaces). The waste water is then directed to the water treatment system. Operators wear full PPEs as illustrated in **Erreur ! Source du renvoi introuvable.**. Operators are instructed to not use abrasive technics in order to avoid a formation of contaminated particles. After intervention, the watertightness of the installation is checked before starting again the production.
As explained in Section 9.1. workers from the maintenance team are regularly trained on the risk related to CrO_3 exposure and on the appropriate behaviour to reduce exposure.

Picture 13: Maintenance operator simulating an intervention on the piping system.

The conditions of this task are described in the below table.

	Method
Product (article) characteristics	
• Considered liquid after extensive rinsing with clean water (low viscosity)	ART 1.5
• The vapour pressure of Cr(VI) is very low, arbitrary set at 0.0001 Pa	
• Concentration of substance in mixture: extremely small, as CrO_3 is very soluble and the contaminated devices will be extensively rinsed.	ART 1.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: 120 minutes	ART 1.5
• Twice a month. Two workers per operation, 15 people skilled and instructed in total. Frequency: about 24 operation per year, about 3.2 / year / worker.	For information
Technical and organisational conditions and measures	
• Activity emission potential: handling of contaminated objects of a surface between 1 to 3 m², with 10 to 90% contaminated.	ART 1.5
• Process considered as open	ART 1.5
• No localised controls	
• General ventilation: Enhanced general ventilation (5-10 air changes per hour)	ART 1.5
• Occupational Health and Safety Management System: only four people are authorised for doing this work, they are regularly made aware about the extremely hazardous of chromium trioxide.	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: Yes (Respirator with at least 20 regarding the supplier specification) [Effectiveness Inhal: 95%]	Not taken into account in the exposure prediction.
• The employee has to put in addition of the respiratory mask, protective rubber gloves, rubber boots and a disposable all-in-one suit.	For information.
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.5
• Process temperature (for solid): Ambient	ART 1.5
• Room volume: >3000 m^3	ART 1.5

9.1.4.2. Exposure and risks for workers

The exposure concentrations and risk characterization are reported in the following table.

Table 14. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration (90^{th} percentile)	Risk characterisation
Inhalation, local, long-term	**0.0058 µg/m³ (ART 1.5)**	ELR = 1.2E-05

<u>Conclusion on risk characterisation</u>

Based on the a 40 year working life (8h/day, 5 days/week) the ELR for lung cancer mortality is equal to 1.2E-5 (regarding the ELR per µg Cr(VI)/m^3 given by the report RAC/27/2013/06 Rev.1 and a conversion factor of 0.52 for CrO_3).

For this WCS, 16 workers are exposed, 2 at a time. That corresponds to 24 days per year dispatched to 16 workers, for a task lasting not more than 2 hours. The ELR is given for 8h/day, 5 days a week. A time factor correction should also be applied. Considering an average of 365 workings day in a year, the factor correction will be:

121.6<u>6</u> [(365 working days/year*16workers)/(24 operating days/year*2workers per operation)].

The corrected ELR per operator is then 9.8E-8.

Supporting information based on measured data:

As presented in Annex I of the CSR, a monitoring program has been launched in August 2020. For the WCS3, maintenance operations have been simulated during two consecutive days, with one operator performing the maintenance task, and one worker being present as a helper to control and facilitate the work. In addition to personal sampling (one on the mechanic and one on the helper), static samplers were deployed, one close to the workplace and one in the walkway, close to the workplace.

Amongst the 8 measured data, 3 are lower the LOQ, 3 are at the LOQ, and 2 are twice the LOQ. The two significant data were measured during the same event, by the personal sampler worn by the mechanic and by the static sampler close to the workplace.

8h-TWA values measured close to the workplace (personal and static sampling, n=4, including 2 values at the LOQ) are coherent, with a mean concentration of 0.024 µg CrO_3/m^3 and a maximum concentration at 0.038 µgCrO_3/m^3. For the helper, the measured concentrations are lower than the LOQ in 3 cases out of 4. For this forth measure, the measured value is at the LOQ. The measured values are more than twice lower (mean 8h-TWA of 0.01 µgCrO_3/m^3, max. at 0.014 µgCrO_3/m^3).

These values show the variability of the exposure from lower the LOQ to twice the LOQ, and the fact that even if two operators are involved in the maintenance task, only the mechanic is significantly exposed to CrO_3.

Even if these supporting values are higher than the modelled data, they rely on measurements 2 times lower than the normal task duration (1h vs 2 hours). This has a direct impact on the total sampled volume and the LOQ. In conclusion, the modelled value is relevant for the risk assessment.

Remark 1: the worker exposure concentration of 0.0058 µg/m³ does not take into account the correction of RPE. We could divide this concentration by the APF factor of the RPE (APF = at least 20 regarding the supplier specification).

Remark 2: as it is explained by the RAC this ELR might be an overestimate. In fact, extrapolating outside the range of observation inevitably introduces uncertainties. 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.

Remark 3: the calculated ELR assumes that both operators are equivalently exposed, which seems to be an overestimation, based on the monitoring data showing that only one operator (mechanic) out of the two is exposed to the substance.

9.1.5. Worker contributing scenario 4: Passivation (PROC 13) – *Out of scope of the authorisation*

9.1.5.1. Conditions of use

This contributing scenario refers to the use of the diluted Cr(VI) solution at less than [redacted]% CrO_3 w/w.

The concentrated solution (WCS 2) is automatically diluted and transferred into storage tanks (Picture 4). Then this diluted solution feeds the passivation baths and recycled back. The quality of the passivation baths is continuously monitored with online measurement of conductivity, pH and colorimetry. Weary solutions are sent to the waste water treatment installation. As limpid passivation solution is a quality criteria, no sludge, due to dust deposition or precipitation, is anticipated in the passivation bath.
The passivation bath is an open system, with a very slowly rotating drum (less than one revolution per minute) where the copper foil path through and is poured into the Cr(VI) diluted solution. The open surface of the passivation bath is around 0.51 m², fitted with an air extraction. Once under full capacity, around 80 copper foil production lines, with the corresponding passivation baths will be dispatched in the workshops.
This process does not require the intervention of operators. Only monitoring activities are necessary. A team of 45 to 50 people per shift will operate in the passivation workshop, with not more than 40 people at a time.

[redacted]

Picture 14: Passivation bath, schematic view. (1) Schematic representation of the process. (2) Zoom-in of the passivation bath. *Note that the Cr(VI) is converted into Cr(III) during the passivation process, then the passivated cooper foil contains only Cr(III). Operators are physically separated from the passivation baths (walls/windows).*

The conditions of this task are described in the below table.

	Method
Product (article) characteristics	
• Considered liquid after extensive rinsing with clean water (low viscosity)	ART 1.5
• The vapour pressure of Cr(VI) is very low, arbitrary set at 0.0001 Pa	
• Concentration of substance in mixture: [redacted] g CrO_3/L.	ART 1.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: 8 hours/day	ART 1.5
• Continuous process	For information
Technical and organisational conditions and measures	
• Activity emission potential: relatively undisturbed surfaces (no aerosol formation)	ART 1.5
• Containment: Open surface considering > 3m² (around 6 passivation baths working together).	ART 1.5
• Localised controls: receiving hoods (80% reduction)	
• General ventilation: Enhanced general ventilation (5-10 air changes per hour)	ART 1.5
• Occupational Health and Safety Management System: only four people are authorised for doing this work, they are regularly made aware about the extremely hazardous of chromium trioxide.	ART 1.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No Employees do not have to intervene on the passivation bath, except for a quick visual check.	For information
• The employee has to put protective rubber gloves, rubber boots and a disposable all-in-one suit.	For information.
Other conditions affecting workers exposure	
• Place of use: Indoor	ART 1.5
• Process temperature (for solid): Ambient	ART 1.5
• Room volume: >3000 m^3	ART 1.5

9.1.5.2. Exposure and risks for workers

The exposure concentrations and risk characterization are reported in the following table.

Table 15. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration (90th percentile)	Risk characterisation
Inhalation, local, long-term	**6.3E-5 µg/m³ (ART 1.5)**	ELR = 1.3E-07

Conclusion on risk characterisation

Based on the a 40 year working life (8h/day, 5 days/week) the ELR for lung cancer mortality is equal to 1.3E-7 (regarding the ELR per µg Cr(VI)/m^3 given by the report RAC/27/2013/06 Rev.1 and a conversion factor of 0.52 for CrO_3).

For this WCS, 45-50 workers are exposed, 40 at a time. That corresponds to 260 days per year, for a task lasting a full shift (8 hours). The ELR is given for 8h/day. A time factor correction should also be applied. Considering an average of 240 workings day in a year, the factor correction will be:

1.25 [(8hour/day*260days/year*50workers)/(8hours/day*260days/year*40workers/intervention)].

The corrected ELR per operator is then 1.0E-7.

Supporting information based on measured data:

As presented in Annex I of the CSR, a monitoring program has been launched in August 2020. For the WCS4, samplings were made during 3 consecutive days, during not less than 293 minutes, with 8 data points for personal samplings (6 different operators), and 6 data points for static samplers. Operators did their daily job of control and monitoring the copper foil production, and static samplers were located either close to the passivation bath (n=3) or in the pathway close to the copper foil production lines.

For the static samplers, every measure is below the LOQ (n=6), so we can consider there is no difference between the sampling locations (passivation bath, background). For the personal samplers, 6 data points are below the LOQ and the remaining two are equivalent to the LOQ. The mean concentration is 0.007 µgCrO_3/m^3, with a maximum concentration of 0.013 µgCrO_3/m^3.

According to the applied sampling/analytical method, the LOQ is around 15 times higher than the modelled exposure value, respectively 0.010 µg/m^3 and 6.3E-5 µg/m³. Therefore, even if the actual values didn't show the adequation between the measurement and the modelling, the demonstrate the low exposure levels, 20 times lower than the lowest 8h-TWA as defined by the SCOEL (2017) [5] (0.1 µgCr(VI)/m^3, equivalent to 0.19 µgCrO_3/m^3). The LOQ could be lowered increasing the sampling duration.

Remark 1: as it is explained by the RAC this ELR might be an overestimate. In fact, extrapolating outside the range of observation inevitably introduces uncertainties. 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.

Remark 2: the measured values showed that the exposure level, whatever the measurement conditions, are lower than the LOQ or at the LOQ. The predicted values being so low that it's not technically possible to reach such an analytical level, for the time being. However, the measured values support the theoretical assumption of a very low level of exposure during this task, if any.

9.2 Conclusions

[5] Recommendation from the Scientific Committee on Occupational Exposure Limits, SCOEL/REC/386 Chromium VI compounds, adopted on 22/05/2017.

The exposure levels as determined in the exposure assessment show a risk level of low concern if the conditions of tasks are used. This is supported by the available monitoring values. As explained in Annexes I and II, the Applicant is implementing a monitoring program of worker exposure. Sampling/analytical conditions are well defined, as well as the operating conditions (sampling location, information of the worker, frequency…). The scoping study, allowing to have the first measured data, showed that the maximum concentration are below the lowest 8h-TWA as defined by the SCOEL for Cr(VI).

As a conclusion, the modelled data are considered relevant for the exposure calculation, supported by the measured values, and the monitoring program will allow to strengthen the confidence in the actual and future level of exposure.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

The table below represents the workers and the scenario (PROC) in which they are involved.

Table 16. Description of groups of workers for the combined exposure (inhalation)

	Workers 1 to 79			Number of workers per WCS
	W1-12 Group A	W13-28 Group B	W29-79 Group D	
WCS 1	X			**12**
WCS 2	X			**12**
WCS 3		X		**16**
WCS 4 – *Out of scope*			X	**45-50**
Number of workers per group of workers	**12**	**16**	**45-50**	

.

In conclusion, even if workers of Group A are involved in both WCS 1 and WCS 2, no combined exposure is expected as the exposure related to WCS 1 is judged to be null.

10.1.2. Consumer

Not relevant because there is no consumer use.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

Not relevant as the impact of Cr(VI) as such is therefore likely to be limited to the area around the source (*c.f.* section 3.1.1 of the EU-RAR(2005), and section 9.1.1.3 of the present document for more details).

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.

ANNEX 1 – Worker monitoring program – scoping study

A monitoring program was launched as soon as possible after the start of the plant (March 2020). This program was challenged by the following considerations:

- The plant started the production only 6 months earlier,
- The production level was limited compared to the full-scale operations as Authorised. The authorisation conditions allow the preparation of 1 tank of concentrated CrO_3 solution every week. Due to limited production capacities, at the date of the monitoring program one tank of concentrated solution was sufficient to feed the passivation bath during 4 to 5 months, compared to 1 week,
- As much as relevant monitoring data needed to be obtained in order to support the Review report and the modelling data.

So the aim of this program was to:

- Evaluate the technical and the logistical feasibility of monitoring worker exposures in real working conditions,
- To produce reliable exposure data, comparing results from personal samplers and static samplers,
- To provide recommendations for future and recurrent monitoring campaigns (see Annex 2).

The monitoring program was subcontracted to FoBiG with the sampling/analytical support of Eurofins.

1- <u>Sampling procedure for workplace measurements and analysis.</u>

The procedure applies for both personal and static sampling. The test method essentially matches to EN 13284-1 (02/2018) for sampling and ISO 16740:2005(E) for the analyses.

Equipment:

• Sampling pumps with an adjustable flow rate, capable of maintaining the selected flow rate to within ± 5 % of the nominal value throughout the sampling period (e.g. Gilian 12 produced by Sensidyne LP3 or SG10-2 produced by GSA Messgerätebau GmbH4).

• Samplers designed to collect the inhalable fraction of airborne particles. To specify ISO 16740 in this case, GSP (‘Gesamtstaubprobenahmesystem’5) samplers according to the German guideline IFA 7284 with cassettes for filters with a diameter of 37 mm are used for personaland static samplings. The GSP samplers are designed for a flow rate of 10 L/min. (0.6 m3/h).

• Filters inserted in cassettes. Deviating from ISO 16740, glass fibre filters without a binder are used (e.g. Whatman glass microfibre filters GF/A, 37 mm, Cat. No. 1820-0376). Several laboratory tests show that these filters have the lowest blank values for hexavalent chromium.

• Tubes (e.g. centrifuge tubes, type Brand™ No. 1148237) filled with 20 mL elution solution (see ISO 16740, chapter 7.12.3). Deviating to ISO 16740 the filters are transferred with forceps to the tubes with extraction solution immediately after sampling to increase the shelf life of the samples. This procedure is described in the German guideline DGUV-I 213-505.

• Flowmeter, portable, with an accuracy that is sufficient to enable the volumetric flow rate to be measured to within ± 5 % (e.g. mass flow meter TSI series 40008).

• Ancillary equipment: Thermometer, barometer, backpacks for personal sampling and tripods for static samplings.

Sampling

• The sampling period has to be long enough to reach the required LoQ. To reach a LoQ of 0.01 µg/m³ a sampling period of four hours is recommended. A sampling period of four hours conforms to the operating time of the pumps and there is no risk of overloading the filters.

• The pumps are calibrated before the samplings to the intended flow rate (for the GSP samplers this is 10 L/min. or 0.6 m3/h).

• Short-term measurements are possible but with a higher LOQ of only 0.05 µg/m³ (for a sampling duration of 45 minutes at the flow rate of 10 L/min).

• The performance of the pumps must be monitored frequently, at least once every 2 h.

• Information which is relevant for the evaluation of the results must be provided by the client (e.g. job description of the worker sampled, deviations from typical work routines, concurrent construction works that may result in release of Cr-VI (e.g. welding) or any conditions that are considered not representative of the workplaces monitored). In particular, tasks during which respiratory protection is worn (even if only for part of the job) must be indicated to the sampling staff before actual sampling.

• Relevant observations during sampling must be documented by the sampling staff (e.g. malfunction of sampling equipment, unforeseen events etc.).
• More general provisions (e.g. on the adequate temperature range of 5-40 °C) are described in the ISO standard 16740.

Analysis
General requirements
- All used reagents and filters must be pre-checked in the usual laboratory routine.
- To prepare the elution solution, 30 g of sodium carbonate and 66 mL of sodium hydroxide solution (30 % Suprapur) are dissolved in 1 L of ultrapure water.
- To prepare the impregnation solution, 10 g of sodium hydrogen carbonate are dissolved in 1 L of ultrapure water. (0.12 mol/L)
- To prepare the reagent solution, add 7 mL of concentrated sulfuric acid to a 250 mL volumetric flask half-filled with ultrapure water. 125 mg of 1,5-diphenylcarbazide are dissolved in 25 mL of methanol. The solution is placed in the 250 mL flask and made up to the mark.
- To prepare the eluent, 264 g ammonium sulfate and 65 mL ammonia solution 29% are dissolved in a 1 L volumetric flask with ultrapure water. This concentrated solution is kept in a polyethylene bottle and has a shelf life of 1 year. 100 mL of this concentrate are dissolved in 1 L of ultrapure water and used as an eluent.
- The ion chromatograph is set up in accordance with manufacturer's instructions. The visible detector is adjusted to measure absorbance at 540 nm. A linear calibration function is created from at least six points.
- More general provisions (e.g. on stability of reagents and equipment) are described in the EN standard 16740.

Picture 15. Table of analytical performance characteristics of Cr(VI) parameters

Characteristic	Description	Values
Ion chromatograph	Aquion by Thermo Fisher Scientific	--
Column	Guard column: AG 7.2 mm ID Separation column: AS 7.2 mm ID	7.2 mm inside di- ameter
Mobile phase	0.2 mol/L (NH4) 2SO4, 0.1 mol/L Ammonium hydroxide	0.2 mL/min
Reagent solution	see 5.1	0.07 mL/min
Reaction loop	--	125 µL
Detection	VWD UV/VIS by Thermo Fisher Scientific	540 nm
Accuracy	Deviation from the mean value of daily re- covery measurements	+/- 0.633%
Evaluation	Software „Chromeleon"	--
Detection limit according to DIN 32645	Determined by calibration before the measurement	0.007 µg/sample
Limit of quantification according to DIN 32645		0.02 µg/sample
Linearity and working range	Calibration in the linear range	0.001 – 1 µg/mL
Measurement uncertainty according to VDI 4219 (08/2009)	Calculated with a statistical certainty of 95%	8 %
Average of Blank	Determination with field blank filters	0.12 µg/sample

2- Monitoring program.

The monitoring campaign took place between 3-6 August 2020. Operators of WCS 2 were equipped of 2 personal samplers as only one operator at a time performs the given task. The objective was to obtain as much data as possible. On the other hand, only one sampler per operator was used for WCS 3 and WCS4 to account for the individual variability.

WCS2 - Dissolution
It was impossible to prepare a full-strength solution involving the dissolution of 16 barrels of CrO_3 per event. Rather, only four barrels were emptied on each of the two monitoring days.
The worker engaged in WCS 2 was monitored using two parallel personal sampling devices:
- One device sampled only for the duration of actual dissolution in the dissolution room.
- One device sampled during the actual dissolution and was kept running until the empty barrels were disposed of in the disposal area described above.

This approach was chosen (a) to increase the number of personal samples available and (b) to identify any possible higher exposures during the transfer of the empty barrels to the disposal site. Two different workers were monitored on the two monitoring days.

In addition to the personal samples, two stationary monitoring devices were set up in the dissolution room (Figure 2):

- One device was located close to barrel reverser door.
- One device was located close to the control panel.

The location of the sampling devices was chosen based on proximity to possible sources of Cr(VI) contamination and safety considerations, i.e. allowing the worker to move freely in the dissolution room and perform the tasks without being disturbed by the sampling equipment. Again, two stationary samples were primarily chosen to increase the number of samples, but the setup also allowed analyses of a possible impact of the sampling location in the dissolution room.

Due to technical issues, the samples generated on the second day were not made available.

WCS3 - Maintenance

With respect to WCS 3 (maintenance (repair)), it was envisaged that only simulations of maintenance activities could be monitored. However, it turned out that a true maintenance task could be monitored on day 1. A pump located one level below the dissolution room and pumping concentrated chromium trioxide solution (about 100 g CrO_3/L) failed. Monitoring covered removal of the defunct pump and associated cleaning activities.

A simulated task of a similar nature was monitored on day 2. This activity lasted for about an hour and involved two workers: one mechanic performing the actual maintenance task and most of the cleaning activities and a second worker helping, e.g. by getting required equipment from areas further away and assisting in cleaning. This second worker was for most of the monitoring period more than 2-3 m away from the actual maintenance site3. Both workers were monitored by personal sampling. The mechanic performing the maintenance task was the same on both days, while the helper was a different person on both days.

In addition, two stationary samples were obtained, one being close to the maintenance site and the other one being closer to the main location of the helper (i.e. about 2-3 m away from the actual maintenance site).

WCS4 - Passivation of copper foil

Within the passivation hall, two lines (lines A and B, each consisting of four passivation units, units 1 to 4) were operational at the time of monitoring, while the remaining two lines C and D were under construction. However, some work was still ongoing on some of the eight operational passivation units so that six to seven passivation units (depending on the monitoring day) on the two lines were running during monitoring.

A total of 8 personal samples were taken (2 on days 1-2 and 4 on day 3). Operators were instructed not to smoke during the monitoring period. For most of the time, WCS 4 operators are further away from the passivation bath. Two stationary samples were taken on monitoring days 1 to 3 (six in total) on lines A and B. On both lines, passivation unit number 1 was monitored by stationary sampling (i.e. monitoring points A-01 and B-01; three samples per line). The location was chosen based on the flow of air in the passivation hall. The sampling head is directed towards the machine.

The number of samples per WCS are summarised in **Picture 16**.

Picture 16. Summary of samples in the August 2020 campaign

WCS	Sampling	No. of samples
2	PERS WCS 2	2
	PERS WCS 2 EXT*	2
	STAT WCS 2	4
	Sub-Total	*8*
3	PERS WCS 3	4
	STAT WCS 3	4
	Sub-Total	*8*
4	PERS WCS 4	8
	STAT WCS 4	6
	Sub-Total	*14*
Total		**30**

3- **Results**

Monitoring results are compiled in the file Volta_CrO3_Occupational_measurements_Nov2020.xlsx here below:

Volta_CrO3_Occupa
tional_measurement

ANNEX 2 – Recommendations for future monitoring campaigns

The results of the monitoring campaign demonstrate the general feasibility and usefulness of the monitoring programme established. This programme may therefore be taken as a basis for future monitoring campaigns.
An annual monitoring program is the required frequency. During the first years of the plant, it is recommended to generated a substantial dataset.

General recommendations:
The tasks monitored should be properly documented, including e.g. the number of barrels emptied in WCS 2, any deviations from normal conditions (including e.g. unusual worker behaviour) and the type of personal protective equipment worn. Furthermore, workers sampled twice during the same campaign should be clearly identified (as was done in WCS 4 in the August 2020 campaign; see Table 6). In this context, unique identifiers for individual workers are useful that allow comparisons of Cr(VI) concentrations for individual workers over the years. Such identifiers may already exist within the company but have not been used during the August 2020 campaign. With more measurements, it will be extremely useful if monitoring results can be related to individual workers.

WCS2 – Dissolution

Sample no.	Sample	Sampling duration	Comment
1	Personal – in dissolution room only	Entire task	Stop sampling when worker leaves dissolution room (prior to transfer to waste disposal container)
2	Personal – in dissolution room and transfer	Entire task	Including transfer to waste disposal container.
3	Stationary – barrel reverser door.	As sample no. 1	Sampling head directed towards lid heater
4	Stationary – control panel	As sample no. 1	Sampling head directed towards middle of the room

WCS3 - Maintenance

<table>
<tr><th>Sample no.</th><th>Sample</th><th>Sampling duration</th><th>Comment</th></tr>
<tr><td>5</td><td>Personal – mechanic</td><td rowspan="4">Entire task</td><td></td></tr>
<tr><td>6</td><td>Personal – second worker</td><td></td></tr>
<tr><td>7</td><td>Stationary – maintenance workplace</td><td rowspan="2">Sampling head directed towards maintenance workplace</td></tr>
<tr><td>8</td><td>Stationary – location of second worker</td></tr>
</table>

Sampling should cover different locations and equipment within the plant.

WCS4 – Passivation of copper foil – not concerned by the present application.

<table>
<tr><th>Sample no.</th><th>Sample</th><th>Sampling duration</th><th>Comment</th></tr>
<tr><td>9</td><td>Personal</td><td rowspan="6">6 hours</td><td rowspan="4">Workers to be instructed not to smoke during monitoring</td></tr>
<tr><td>10</td><td>Personal</td></tr>
<tr><td>11</td><td>Personal</td></tr>
<tr><td>12</td><td>Personal</td></tr>
<tr><td>13</td><td>Stationary – Line A, unit 1 (A-01)</td><td rowspan="2">Sampling head directed towards passivation unit</td></tr>
<tr><td>14</td><td>Stationary – Line B, unit 1 (B-01)</td></tr>
</table>

ANNEX 3 – Limits of Biomonitoring Cr(VI) exposure

On broad, as stated in the SCOEL Recom 386 (2017)[6] for Cr(VI) compounds, the available analytical technics do not allow to make the distinction between exposure to hexavalent or trivalent compounds. Thus, in case of co-exposure, which is the case for the present use, it is not possible to identify/quantify an past exposure to Cr(VI).

"*[…] Cr VI will be reduced in the human body, to trivalent chromium in urine; thus when there is co-exposure to chromium III compounds it will be difficult to know what proportion came from the hexavalent and trivalent compounds. In such cases, speciation of the inhaled exposure is important in order to interpret biomonitoring data*." Page 10.

More precisely, there are two principal methods for biomonitoring of chromium in potentially exposed workers:
- • Method 1: Measurement of hexavalent chromium Cr(VI) in the erythrocytes of exposed subjects
- • Method 2: Measurement of total chromium in urine.

Only methods 1 is specific to Cr(VI), while method 2 measures total chromium. It would therefore be more meaningful to use method 1 in an assessment of Cr(VI) exposure at the workplace. However, the major disadvantage of this method is related to the fact that it requires sampling of blood, which is an invasive technique and therefore always associated with some risk to the worker. **Picture *17*** summarises the relationship between concentrations obtained by biomonitoring and calculated concentrations in air (both for CrO_3 and Cr(VI)). The risk at the Cr(VI) in air based on the relationship derived by RAC is also shown.

Picture 17. Relationship between biomonitoring-based chromium concentrations and calculated concentrations in air* as well as associated risk estimates**

Concentration in erythrocytes (µg Cr/L whole blood)	**Concentration in urine (µg Cr/L)**	**Concentration in air (µg CrO3/m^3)**	**Concentration in air (µg Cr(VI)/m^3)**	**ELR at Cr(VI) concentration**
9	12	30	16	0.062
17	20	50	26	0.10
25	30	80	42	0.17
35	40	100	52	0.21

* Based on the German documentation of biomonitoring-based values for hexavalent chromium (Bolt and Lewalter, 1994);
** based on RAC exposure-risk relationship for hexavalent chromium (ECHA, 2013; 2015).

These data illustrate that the relationship between biomonitoring-based values and chromium concentrations in air exist only for comparatively high concentrations that are associated with very high risks according to the exposure-risk relationship established by RAC (ECHA, 2013; 2015), which is not the case for the considered uses.

It must also be noted that a lower total chromium concentration of about 0.6 µg/L urine is typically considered to reflect background exposure without any occupational chromium exposure. This value represents the 95th percentile of total chromium in urine in the general population in both Germany and France (ANSES, 2017; Leng et al., 2009). Thus, any concentration measured in the urine of workers e.g. in the range of 0.1-0.5 µg/L urine may well reflect background exposure to chromium. The low Cr(VI) exposure modelled for the workplace (in WCS 2) corresponds to maximum chromium concentrations in urine of about 0.024 µg/L (at 0.0312 µg Cr(VI)/m^3 air; see Picture 17). It is evident that such an exposure level cannot be adequately measured given the background chromium exposure from other sources (diet, drinking water, smoking).

In conclusion, it is not considered relevant to implement a generalised biomonitoring program as a tool to monitor the level of exposure of operators to Cr(VI) compounds.

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