9. EXPOSURE ASSESSMENT and related risk characterisation

9.0. Introduction

This exposure/risk assessment is generated in function of Borealis's authorisation application dossier for the following uses:

(1) The use of sodium dichromate as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system

Article 62.4(d) of REACH stipulates that the authorisation dossier shall contain a Chemical Safety Report (CSR) covering the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV, i.e Carcinogenic Cat.1b, Mutagenic Cat.1b and Reprotoxic Cat 1b.

Therefore, this CSR focuses on the carcinogenicity, mutagenicity and reprotoxicity endpoints (see Table 9).
In the Analysis of Alternatives (AoA) other endpoints are also considered for the comparison of potential alternatives.

Table 9: The hazard endpoints of the substance discussed in this CSR

#	Substance	Intrinsic property(ies)[1]	Latest application date[2]	Sunset date[3]
1	Sodium dichromate EC No: 234-190-3 CAS No: 10588-01-9	Carcinogenic (category 1B) Mutagenic (category 1B) Reprotoxic (category 1B)	21 March 2016	21 September 2017

[1] Referred to in Article 57 of Regulation (EC) No. 1907/2006
[2] Date referred to in Article 58(1) (c) (ii) of Regulation (EC) No. 1907/2006
[3] Date referred to in Article 58(1) (c) (i) of Regulation (EC) No. 1907/2006

On December 4, 2013 ECHA published the document „Application for Authorisation: Establishing a reference dose response relationship for carcinogenicity of hexavalent chromium"[vii], which constitutes the opinion of the Risk Assessment Committee (RAC) that hexavalent chromium is considered to be a non-threshold carcinogen. As a result, demonstrating adequate control is not possible and the SEA route is applicable.

The applicant, Borealis, therefore performed the risk assessment in the following way:

- With regard to the carcinogenicity effects, the Reference Dose Response Relationships as proposed by RAC were applied allowing the evaluation of the Excess Lifetime Risks (ELRs).

[vii] ECHA Website: http://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf

- The mutagenicity effects are considered as covered by the evaluation of the carcinogenicity effects.
- With regard to the reprotoxicity effects, RAC also generated an opinion regarding the reprotoxicity DNELs, which is at the moment of submission of the authorisation application not yet publicly available on the ECHA website, however the DNELs which will be published by RAC shortly, were received via the ECHA Secretariat and have been used throughout this AfA. The use of these DNELs allows the evaluation of adequate control. Minimization of emissions is also demonstrated in function of this endpoint.

The applicant demonstrates in this CSR that the risks related to the continued use of Cr (VI) have been minimized as far as technically and practically possible.

Evaluation of any potential hazards to the environment is not required within the framework of this authorisation application. Health hazards which may potentially relate to Cr(VI) exposure of the general population via the environment have been considered, however as there is no environmental exposure, exposure of the general population via the environment could be excluded (see Section 9.0.4.2.).

In the table below an overview of the use is defined. This will be further described in the coming sections.

Table 10: Use by workers in industrial settings; overview of the use of Borealis

IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
1	The use of sodium dichromate as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system	solution in water	**Process category (PROC):** PROC 1: Receipt and storage of raw materials PROC 8b: Filling/topping-up of cooling system PROC 1: Corrosion inhibition in a fully closed sytem PROC 8b: Sampling of water containing Cr(VI) and Cr(III) PROC 15: Lab analysis PROC 8a: Releasing equipment for maintenance, and maintenance of equipment **Environmental release category (ERC):** ERC 7: Industrial use of sodium dichromate in a closed system **Subsequent service life relevant for that use?:** No, not applicable as there is no contact/link between the substances used within cooling installation and product that is manufactured.

9.0.1. Overview of the use at Borealis, general description of the process

The ammonia/water absorption cooling system is a three phase process (Figure 3):

1. **Evaporation:** in this stage the low-boiling ammonia evaporates and in doing so it extracts heat from its surroundings – in this case, the heat from the monomer/solvent feed-stream to the polymerization reactor.

2. **Absorption**: the gaseous ammonia is absorbed in water. As a result, the partial pressure of the ammonia is reduced, allowing more ammonia to evaporate in the evaporation step.

3. **Regeneration:** the saturated water/ammonia liquid is pumped to a distillation tower operating at [redacted][4] where the ammonia is separated from the water by means of heat. In this case, burning of natural gas generates the heat. The ammonia is condensed with cooling water in a heat exchanger and circulated back to the evaporation unit. The liquid water is recovered at the bottom of the distillation unit and recycled to the absorption unit.

As can be understood from the description, the system is fully closed, operating either above or below atmospheric pressure. Any leakages in the system must be avoided to ensure the efficiency of the process. The process only uses a pump to transfer the water/ammonia mixture from the absorption to the regeneration step. No complex gas phase compressors are used which reduces the complexity and improves the reliability of the system.

It is important to note that the system contains both gaseous and liquid conditions, with high and low ammonia concentrations.

The water/ammonia absorption cooling system is constructed in carbon steel. Carbon steel will corrode in contact with a water/ammonia mixture especially at elevated temperatures. Typical corrosion rates of 0.6 mm/year are cited in the literature[viii.]

The following corrosion reaction can occur even in the absence of oxygen (anaerobic):

$$Fe + 2H_2O \rightarrow Fe(OH)_2 + H_2$$

This corrosion process affects the metal (carbon steel) transforming the iron (Fe) into iron oxide which does not contribute to the strength of the metal. As such the corrosion process reduces the wall thickness of the piping and equipment. The walls thickness of piping and equipment is in the first instance defined by the required strength. Reducing the thickness results in a situation where the piping or equipment can no longer resist the internal pressure or the mechanical forces which act on piping and equipment. Regular inspection of the equipment can reveal this process. When such damage is detected, in most cases the installation has to be stopped for repair leading to additional maintenance costs and loss of capacity. These inspection programs never cover the full installation but are spot checks. This means that still corrosion can occur unnoticed. As a result, in case of corrosion, small leaks or

[viii] Water: Handleiding voor het gebruik van water in de industrie, pag 159, 1971, Kluwer

even rupture of piping can occur which effectively will cause a loss of containment and release of ammonia.

A second effect of the corrosion process is the formation of hydrogen (H_2). Hydrogen is a gas which will not condensate in the heat exchanger of the absorption cooling process but will form gas pockets which effectively reduce the heat exchange surface of the heat exchangers and hence, it reduces the capacity of the absorption cooling. Hydrogen is also a very explosive gas. This means that if there is locally in the installation any corrosion with a loss of containment as a result, also hydrogen will be released.

In summary, corrosion needs to be avoided for at last 3 reasons:

1. Corrosion leads to the formation of explosive hydrogen gas, which reduces the capacity of the absorption cooling and can cause release of explosive mixtures
2. Corrosion may lead to loss of containment resulting in the emission of toxic ammonia
3. Corrosion causes damage to the installation which has to be repaired leading to additional maintenance costs and loss of capacity

To completely avoid corrosion, the system is run oxygen free and a corrosion inhibitor is added. The corrosion inhibitor interacts with the chemistry of the corrosion process and prevents the corrosion. The corrosion inhibitor used by Borealis is sodium dichromate. The main chemical reaction is:

$$Na_2Cr_2O_7 + Fe^{++} + H_2O \rightarrow Cr_2O_3 + Fe_2O_3 + 2NaOH$$

Sodium dichromate is generally recognised as the best available corrosion inhibitor for the water/ammonia medium. Because of the proven performance of sodium dichromate, the Borsig 1 installation was designed in the seventies without any corrosion allowance. This means that the thickness of the piping and vessel walls does not include any additional thickness on top of the thickness necessary to achieve the required mechanical strength of the equipment. This is only possible for systems where no corrosion is expected at all. Designing the installation without corrosion allowance minimises the use of material and optimizes heat transfer in heat exchangers (through the minimization of the wall thickness of the heat exchange surfaces).

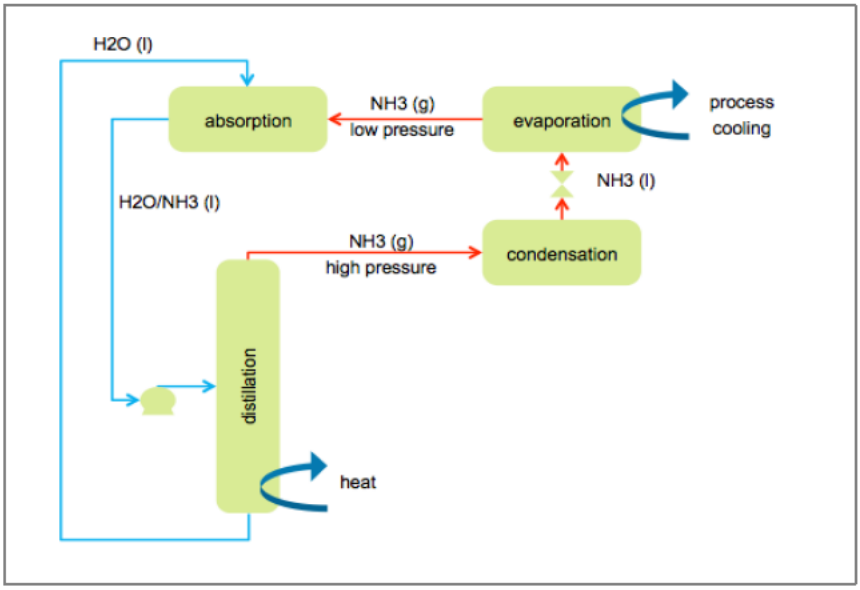

Figure 3 Absorption cooling process

9.0.2. Tonnage information & relevant applicable legislation

Tonnage information

The estimation of the yearly Cr(VI) consumption is calculated on basis of the historical volume of sodium dichromate purchased and the forecast for the coming years.

The required volume is determined based on the concentration of sodium dichromate that is determined during the bi-annual sampling/laboratory check of the water/ammonia/sodium dichromate mixture present within the absorption cooling system.

When a full replacement of the water/ammonia/sodium dichromate mixture is required in the two Borsig installations, 90 kg of sodium dichromate is required. For this reason, this amount is considered to be the maximum volume that could be required during one occasion. Typically only 60 kg/3 years is required (info based historical volumes).

For risk assessment purposes, the maximum value of 90 kg/year is taken into account. This assumes that on a yearly basis, the installation(s) are (combined) topped-up with 90 kg of sodium dichromate. This is reflected in WCS 9.1.3 (duration of exposure, operators involved). As the actual topping-up volume is less than 90 kg/year, this CSR presents a worst case estimate with regard to volume used and impact on human health. With regard to impact on the environment, as there is no release to the environment from this use, the fact that a worst case volume has been applied, has no impact on the environmental part of the evaluation.

Table 11: Tonnage sodium dichromate

Year	Purchased tonnage (kg)
2009	36*
2010	63
2011	-

Year	Purchased tonnage (kg)
2012	-
2013	-
2014	-
2015	45 + 18 = 63
2016-2024	60 (average/3 year)
Maximum* **	**90**

**In 2009 there was major shutdown with renewal of the water resulting in additional chromate usage.*

** [redacted]

**** Maximum in case of total replacement of the water mixture within the 2 Borsig installations.*

Relevant, applicable legislation

Occupational workplace exposure to Cr(VI) is regulated in most European countries. One such legislation requiring that employers reduce and replace the use of Cr(VI) substances is the Carcinogens and Mutagens Directive (2004/37/EC). As a result, National Occupational Exposure Limits (OELs) for inhalation have been set across Europe. These are specified according to the 8 hours *Time Weighted Average* (TWA) exposure. However, the currently specified OEL values range between 1 µg/m^3 and 50 µg/m^3, depending on the Member State, resulting in an enormous variation. In Table 12 an overview is given of the legislation(s) applicable to Borealis, which is located in the Netherlands.

In conclusion, as no EU binding threshold values have been established, the Dutch national value is considered key for Borealis. With regard to this CSR, the RAC/ECHA levels were used.

Table 12: Overview of currently applicable EU legislation for Borealis

Regulatory body / described limits	Cr (VI) limit	Member State/ Location	Related to:
Occupational health and safety			
Excess Lifetime Risks By RAC/ECHA (carcinogenicity/mutagenicity endpoint)	4:1.000 at 1 µg/m^3	Across EU	Inhalation exposure, workers
Excess Lifetime Risks of By RAC/ECHA (carcinogenicity/mutagenicity endpoint)	29:1.000 at 1 µg/m^3	Across EU	Inhalation exposure, general population
DNELs by RAC/ECHA (reprotox endpoint)	43 µg/m^3	Across EU	Inhalation exposure
DNELs by RAC/ECHA (reprotox endpoint)	43 µg/kg bw/day	Across EU	Dermal exposure
TGG8u / 8-hr TWA (Time weighted average – 8hr)	0.025 mg/m^3	The Netherlands (Geleen is located in the Netherlands)	Inhalation exposure, workers

Regulatory body / described limits	Cr (VI) limit	Member State/ Location	Related to:
Occupational health and safety			
TGG15min / STEL (Time weighted average – 8hr)	0.5 mg/m^3	The Netherlands (Geleen is located in the Netherlands)	Inhalation exposure, workers
OEL across the EU	1 - 50 µg/m^3	Different, based on Member State	Inhalation exposure, workers
Biomonitoring – urine levels ACGIH DFG Increased levels during a working day	At concentrations of 50 µg/m^3 10 µg chrome/L urine At concentrations of 25 µg/m^3 5 µg chrome/L urine	The Netherlands	Measure for total exposure (different routes)
Environmental			
Plant specific environmental license	No specific stipulations for emissions of Cr(VI) to water		Cr (VI) in water
Plant specific environmental license	No specific stipulations for emissions of Cr(VI) to air		Cr (VI) in air

9.0.3. Exposure routes assessed & general risk management measures

9.0.3.1. Environment

Scope and type of exposure and risk assessment

Sodium dichromate is classified as an Acute and Chronic Aquatic Toxicant Category 1 (respectively H400 and H410). These endpoints are not specified in Annex XIV of the REACH Regulation, and therefore not in the scope of this assessment (Table 13). In addition, technical controls and working procedures are in place to ensure that no emissions to the different environmental compartment take place (see section 9.1.1).

An overview of the scope of the exposure assessment and the type of risk characterisation required for the environment in function of this application are described in Table 13.

Table 13: Type of risk characterisation required for the environment in the scope of this assessment for ERC 7

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

Comments on assessment approach:

As mentioned above, in accordance with Regulation (EC) No 1907/2006, Article 62(4)(d), potential risks to the environment do not need to be considered. But more importantly, the applicant has technical controls and working procedures in place to ensure that there are no emissions to the environment. Further justification and details are provided in section 9.1.1.

9.0.3.2. Man via environment

Scope and type of exposure and risk assessment

Under normal circumstances, humans may potentially be exposed to Cr(VI) via the environment. However, in this case strict emission control measures (i.e. closed process system) to avoid emissions towards all compartments are in place (see section 9.1.1 for details). Consequently, the risk assessment of man being exposed via the environment is not relevant in this case.

The scope of exposure assessment and type of risk characterisation required for man via the environment are described in Tables 14 and 14.

Table 15: Type of risk characterisation required for man via the environment in the scope of this assessment under ERC 7 – CARCINOGENICITY ENDPOINT

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (ELRs, RAC opinion)
Inhalation: Local Long Term (based on respirable fraction)	Not required as no environmental exposure	Not applicable
Oral: Local Long Term (based on oral and non-respirable inhalative fraction)	Not required as no environmental exposure	Not applicable
Dermal: Local Long Term	Not required as dermal exposure is not relevant for a man via the environment assessment	Not required

Table 16: Type of risk characterisation required for man via the environment in the scope of this assessment under ERC 7 – REPROTOXICITY ENDPOINT

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (DNEL, RAC opinion)
Inhalation: Systemic Long Term (based on respirable fraction)	Not required as no environmental exposure	Not applicable
Oral: Systemic Long Term (based on oral and non-respirable inhalative fraction)	Not required as no environmental exposure	Not applicable

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (DNEL, RAC opinion)
Dermal: Systemic Long Term	Not required as dermal exposure is not relevant for a man via the environment assessment	Not required

9.0.3.3. Workers

Scope and type of exposure and risk assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in Table 16.

As stated in Section 3 Classification and Labelling, Cr(VI) is classified for several human health endpoints. For the purpose of the application for authorisation, the focus of the assessment relates to the endpoints specified in Annex XIV of the REACH Regulation, i.e. Carcinogenicity, Mutagenicity and Reprotoxicity.

The hazard information used to make the risk assessment is based on:

- the Dose Response Relationship provided by ECHA in the RAC opinion document[ix] for the carcinogenicity endpoint. Using these dose-response curves, the Excess Lifetime Risk is calculated for the relevant activities, and for the relevant routes of exposure (inhalation).
- The DNELs provided by the ECHA Secretariat for the reprotoxicity endpoint. Using these DNELs, the risk characterization ratios were determined for the relevant activities, and for the relevant routes of exposure (inhalation & dermal).

This allows comparison of exposure levels and Excess Lifetime Risks between the activities. The results of this comparison is presented in the section on combined exposure (Section 10).

The measures to minimize emissions are presented per contributing scenario in Exposure Scenario 1 (Section 9.1), where relevant.

The following structure can be identified throughout the document for each of the identified activities:

1) Assessment of minimization of emissions.
2) Determination of the exposure levels, by measurements.
3) Determination of the Excess Lifetime Risk related to the carcinogenicity endpoint for each activity.
4) Determination of the risk characterization ratios related to the reprotoxicity endpoint for the each activity.

[ix] Source ECHA:
http://echa.europa.eu/documents/10162/13579/rac_carcinogenicity_dose_response_crvi_en.pdf

Table 17: Type of risk characterisation required for workers – CARCINOGENICITY ENDPOINT

Route	Type of effect	Type of risk characterisation	Hazard conclusion (RAC opinion)
Inhalation	Local Long Term (based on respirable fraction)	Quantitative (dose-response curves)	Relevant dose response curve (lineair) based on excess lifetime lung cancer mortality risk: **Exposure to 1 µg/m^3 Cr (VI) relates to an Excess Lifetime Risk of 4 x 10^{-3}** (based on 40 years of exposure; 8hr/day; 5 days/week)
Oral	Local Long Term (based on non-respirable inhalative fraction)	Quantitative (dose-response curves)	Relevant dose response curve (lineair) based on excess lifetime small intestine mortality risk: **Exposure to 1 µg/kg bw/day Cr (VI) relates to an Excess Lifetime Risk of 2 x 10^{-4}** (based on 40 years of exposure; 8hr/day; 5days/week)
Dermal	Local Long Term	Not required	There are no data that indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.

Regarding the determination of Excess Lifetime Risks related to the carcinogenicity effect, only the inhalation route (inhalation of airborne Cr(VI)) will be considered for workers. There is no data to indicate that dermal exposure to Cr(VI) compounds is related to carcinogenicity effects in humans, consequently this route is not considered. The oral route is also considered irrelevant as based on general occupational hygiene principles, the operators are not allowed to eat or drink on the workfloor. In addition, as the substance is always manipulated as a solution, other potential sources of oral exposure (swallowing of non-respirable particles) can be excluded here as well.

In conclusion, only the inhalation route of exposure is considered in this AfA.

Table 18: Type of risk characterisation required for workers – REPROTOXICITY ENDPOINT

Route	Type of effect	Type of risk characterisation	Hazard conclusion (DNEL, RAC opinion)
Inhalation	Systemic Long Term (based on respirable fraction)	Quantitative (DNEL)	**43 µg/m^3 Cr (VI)**
Oral	Systemic Long Term (based on oral and non-respirable inhalative fraction)	Quantitative (DNEL)	Not considered applicable, considered covered by treating the total potential exposure volume as respirable fraction.
Dermal	Systemic Long Term	Quantitative (DNEL)	**43 mg/kg bw Cr (VI)**

With regard to the reproxic effects, the statements valid for carcinogenicity also apply here with one exception, namely the dermal route of exposure is to be considered as well. Therefore, for the reproxicity endpoint both the inhalation and the dermal route of exposure are considered within this AfA.

Elements A to E in the text below describe the potential routes of exposure to Cr (VI) for a worker at Borealis and how the exposure is controlled and minimized.

- A: types of exposure
- B: determination of exposure levels
- C: control of exposure
- D: procedures
- E: PPEs for occasional activities with potential for increased exposure

A. Types of exposure assessed and controlled at the Borealis site in Geleen:

Potential exposure of workers handling liquid solutions containing sodium dichromate during industrial use is restricted to the lowest possible level. Nevertheless, the following types of Cr(VI) related exposure *could* be relevant for workers at Borealis:

(1) Exposure by inhalation, respirable fraction
(2) Dermal exposure due to unintended contact with Cr (VI) liquids

For the carcinogenicity/mutagenicity endpoint, the inhalation route is considered the main route of exposure. The dermal route of exposure is not specifically addressed in relation to this endpoint as there is no evidence of carcinogenic effects via that route. For the reprotoxicity endpoint, both the inhalation route and the dermal route are considered to be of importance.

Exposure is controlled and minimized by means of:
(1) Design of the installation, i.e. collective measure to avoid emissions and/or exposure
(2) Procedures, i.e collective measure to reduce exposure in specific areas
(3) Personal Protective equipment, i.e. personal measures

In the following sections it is described in detail how the exposure levels for different routes of exposure are minimized.

B. Determining the exposure levels:

This section provides an overview on how exposure levels were determined, and which approaches have been used. Details on results can be found in the respective contributing scenarios (Section 9.1).

Levels of exposure by inhalation have been determined by

(1) Personal monitoring
(2) Static monitoring

Dependent on the type of activity either static or personal monitoring was performed. The static and/or personal monitoring information is always presented without accounting for the

PPEs used. However, for those activities PPEs are mandatory and thus always worn. It is also presented in the respective contributing scenario what the effect is on ELRs or RCRs.

Note on exposure measurements:
It should be noted that due to limitations of the portable equipment for personal monitoring, the detection limit for the personal measurements is significantly higher compared to the static measurement. More specifically the volume of air through the sampling device is higher for the static equipment. Hence, for this case static measurements could technically provide a more accurate representation of the actual exposure situation. However, for most of the actual activities covered within this AfA, the duration of the activity is so short that the added value of static measurement is minimal. For those activities preference was given to personal monitoring.

Further details on the monitoring campaign are provided in Annex A (English summary of the original Dutch reports). Dutch reports can be requested if required.

C. Control systems:

Apart from determining the exposure levels, ***control systems*** have been put in place:

(1) Process control systems
(2) Personal monitoring
(3) Biomonitoring in co-operation with external suppliers / Company Doctor / Authorities

Process control system: The production site in Geleen is equipped with a central, permanently staffed control room. This facility provides at all times an overview of the proper functioning of the installation and plays a key role in preventing any loss of containment.

Personal monitoring: Personal monitoring was done in preparation of this AfA. This was done both during sampling (Section 9.1.5) and during topping-up activity (Section 9.1.3).

Biomonitoring: However very unlikely, it cannot be excluded that workers could potentially be also exposed via other routes, biomonitoring, and thus measuring the concentration of chrome in the urine or blood is often preferred as this allows the evaluation of the internal chrome dose. Therefore, we identify biomonitoring as a control system.

Urine is the primary route of excretion for absorbed chromium. Measurements in blood and urine are considered most reliable for detecting elevated exposure to chromium (ATSDR, 2012). Chrome concentrations in plasma and urine are known to correspond to a recent exposure (1 – 2 days), while measurements of Cr(VI) in the blood, or more specific in the red blood cells (RBCs), is more indicative for repetitive exposures. This becomes evident from the half-live values and and is related to the non-permeability of Cr(VI) through the membrane of the RBCs. However, within the RBCs Cr(VI) is reduced to Cr(III) and the RBC's membrane is not permeable for Cr(III). Therefore, Cr(III) can remain in the RBC for life because it is essentially trapped within the cell (Aaseth et al, 1982). Measuring chromium in RBCs, and determining the ratio with levels in plasma/serum, may be a more specific indicator for Cr(VI) exposure. However, non-specific binding of Cr(III) to proteins on the outside of RBCs can be significant, particularly at higher concentrations (OEHHA, 2011).

The analysis in blood and urine is typically made for total chromium because it is difficult to differentiate between Cr(VI) and Cr(III) in the tests (ATSDR, 1998). But, it is possible to assess the level of Cr(VI) in blood.

The detection limit for the determination of chromium in urine was described to be 0.16 µg/L (ppb) (2014 Meeting of Scientific Guidance Panel (SGP) Biomonitoring California) when using ICP-MS. According to the same source, this detection limit is comparable with typical urinary chromium concentrations of approximately 0.2 µg/L found in the general population without occupational exposure (ATSDR, 2012; Paschal et al., 1998). In Germany a reference value of 0.6 µg/L (BAR or Biologische Arbeitsstoff-Referenzwert) was set related to the typical background concentration measured in urine in a non-exposed population. The "ArboUnie" who performed the biomonitoring for Borealis, indicated that when levels of chrome are expressed in comparison to the levels of creatinine, levels of 0.2-1.0 µg Chrome/g creatinine are representative for a population which is not professionally exposed to chrome. The upper-limit is described to be 3.0 µg Chrome/g creatinine for smokers.

When the chrome levels are expressed in function of the creatinine levels, ACGIH furthermore indicates that the creatinine levels should be within certain bounderies to ensure results are useable. The advised boundaries are creatinine levels > 0.3 g/L and < 3.0 g/L.

Limitations to the use of biomonitoring

Overall, the contribution of biomonitoring results (based on the current techniques) to the evaluation of minimisation of emissions is limited for the following reasons:

- No distinction is made between Cr(III) and Cr(VI)
- The background value for total Chrome in the general population is described to be approximately 0.6 µg/L (based on the information German Biologische Arbeitsstoff-Referenzwert)
- The correlations between the biomonitoring results and the concentrations in air reported in literature indicate that an operator should be exposed to high concentrations (far above the concentrations reported in this CSR) for elevated levels can be detected in urine:
    - Angerer et al. (1987)[x]: according to these authors plasma chromium levels of approximately 10 µg/l and urine chromium levels of 40 µg/l corresponded to an external exposure of 100 µg CrO_3/m^3 while erythrocyte chromium concentrations greater than 0.60 µg/l indicated exposures greater than 100 µg CrO_3/m^3.
    - Glyseth et al. (1977)[xi]: a urinary Chrome concentration of 40 µg Cr per liter of urine corresponded to an approximate workplace exposure of 50 µg Cr/m^3.
    - Gube et al. (2013)[xii]: after 6hr of exposure to 1 mg/m^3 Cr(VI) in air, the median level of chromium in urine was 0.88 µg/L. After exposure to 2.5 mg/m^3 Cr(VI), the median level of chromium in urine was 1.7 µg/L.

  There is a large discrepancy between these sources of information. However, taking into account the worst case that 50 µg Cr/m^3 corresponds to 40 µg Cr/L and based on

[x] Angerer J, Amin W, Heinrich-Ramm R, Szadkowski D, Lehnert G [1987]. Occupational chronic exposure to metals. Int Arch Occup Environ Health *59:503-512.*

[xi] Gylseth B, Gundersen N, Langård S [1977]. Evaluation of chromium exposure based on a simplified method for urinary chromium determination. Scand J Work Environ Health *3:28-31.*

[xii] Gube M, Brand P, Schettgen T, Bertram J, Gerards K, Reisgen U, Kraus T [2013] Experimental exposure of healthy subjects with emissions from a gas metal arc welding process--part II: biomonitoring of chromium and nickel. Int Arch Occup Environ Health; 86(1):31-7.

the assumption that a linear relationship is valid, workers that are exposed to 1 µg Cr/m^3 would have 0.8 µg Cr/L in the urine. This is already close to the background levels reported for the general population.

- There are confounding factors such as smoking, excessive alcohol consumption, dietary factors, and socioeconomic status (although we could assume that the percentage of smokers in the general population will be similar as in our group of operators).

Biomonitoring results for Borealis:

Biomonitoring results of Borealis workers after the activities of topping-up of the installation and taking of samples indicate that there is no relevant change of chrome levels as a consequence of performing an activity. The difference of + 0.1 µg total chrome/g creatinine noted for topping up the installation (Sept/Oct 2015) is within the ranges of the measurement error as biomonitoring performed during the other activities related to a decrease in chrome level (-) 0.2 µg total chrome/g creatinine for taking samples (Sept/Oct 2015) and (-) 1.3 µg total chrome/g creatinine for topping up the installation + sampling (Nov 2015).
Detailed results can be found in Appendix B.

D. Procedural measures to reduce exposure in specific areas:

There are different procedures in place to ensure that exposure is minimised and reduced in all cases:

- An integrated document management system is in place which contains the documentation of the different work processes at the site. This management system is generally available to all employees.
- Training programs are in place for new employees. Refreshment trainings are organized on regular basis. These programs both include more general trainings such as how to handle hazardous substances as task specific trainings on how to operate the installation.
- A task related risk assessment is done for all tasks. This risk assessment takes into account the hierarchy of risk management measures. The use and exposure to chemicals is evaluated and the available documentation and the implemented measures are assessed. This procedure is initiated upon changes of the installation, introduction of new products or in case of organizational changes which may affect the execution of the tasks.
- For each specific activity, the relevant PPE are determined via the PPE Matrix present within Borealis.
- For each activity that needs to take place, worker instructions are generated. These workinstructions are closely checked upon completion of the task.
- Several procedures are in place to avoid any loss of containment. Procedure 55 describes a leak detection and repair program. An internal communication database is used to document and communicate the results of this program. As a result of this strict program a high level of containment is obtained which is confirmed by the low consumption of sodium dichromate. Because large parts of the system works at subatmospheric pressure, loss in containment will result in entrance of oxygen in the system which will increase the consumption of sodium dichromate. Borealis has a

"NO leak policy" which includes prevention of leaks, fast intervention and cleanup in case of leaks in order to avoid any uncontrolled emission of sodium chromate.
- Alarm systems are in place, specifically detectors for NH_3 are installed which provide an early warning for any leakage.
- Procedures are in place to assure the proper execution of the procedures. Inspection and control rounds are organized by supervision to assure proper adherence to the Borealis safety principles.

E. Personal Protective Equipment for activities with potential increased exposure levels:

PPE specifications as described in this section correspond to PPEs that are currently used at Borealis. For avoidance of doubt, other PPE with the same or higher protection specifications – e.g. other supplier for the same PPE - could be used as well. The mentioned PPEs are prescribed procedurally for activities during which elevated exposure levels could occur. Based on the activities and the time during which they are carried out (see Section 9.1), the mentioned PPEs provide optimal protection.

1. Respiratory protection: mask

For activities during which an increased exposure level can potentially occur such respiratory PPEs are mandatory (prescribed in procedures).

The three activities identified in this CSR for which these measures are applicable are:
- Filling/topping-up of cooling system (PROC8b), See Section 9.1.3
- Sampling of water containing Cr(VI) and Cr(III) (PROC8b), See Section 9.1.5
- Preparation of equipment for maintenance (PROC8a), See Section 9.1.7 (note that these measures are not applicable for the maintenance activity itself as at that point, the equipment is chrome free)

During these activities a full-face ABEK-P filter mask with a combined K2/P3 filter (targets ammonia & dust; droplets & mist) is being worn (APF 20). Masks are replaced based on the potential exposure to ammonia. Due to the low smell threshold of ammonia (smell threshold is below the ammonia DNEL), the activities will be interrupted immediately based on smelling ammonia rather than the actual need for replacing the mask. Based on practical experience during the past years, the activities are always short enough not to require replacement of the mask during the activity.
Workers are regularly trained in the proper use of the personal protection measures. Filter masks are delivered in sealed bags to the plant and masks are always checked for appropriate expiry dates before use. Operators using breathing protection are not allowed to have facial hair.

2. Dermal protection: Gloves, protective clothing & safety goggles

For activities during which there is an increased potential for splashing to occur, dermal PPEs are mandatory (prescribed in procedures).

The three activities identified in this CSR for which these measures are applicable are:
- Filling/topping-up of cooling system (PROC8b), See Section 9.1.3
- Sampling of water containing Cr(VI) and Cr(III) (PROC8b), See Section 9.1.5

- Preparation of equipment for maintenance (PROC8a), See Section 9.1.7 (note that these measures are not applicable for the maintenance activity itself as at that point, the equipment is chrome free)

During these activities, suitable neoprene gloves, a double coated PVC splash suit (Trellchem) and PVC boots are worn. As can be seen on the picture below (Figure 4), the gloves are connected to the suit to avoid any leaks. Splash suits and other PPM are used only once after which they are cleaned, re-approved and re-packaged to avoid intermittent contamination. Breakthrough time for dissolved sodium dichromate for both the gloves and the splash suit is > 8 hours based on information from the supplier, whereas the duration of the sampling / preparation for maintenance activity is maximum 15 minutes, and the topping-up activity maximum 90 minutes.

Figure 4: Picture of operator wearing the relevant PPE

9.0.3.4. Consumers

There is no link between the cooling installation in which sodium dichromate is used and the product that is manufactured by Borealis. Consequently, downstream exposure and thus also consumer exposure is not applicable.

9.1. Exposure scenario 1: Use at industrial site – use as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system

In the table below an overview is provided of the different relevant contributing scenarios.

Table 19: Contributing scenarios of Uses

Environment contributing scenario(s):		**Section**
Industrial use of sodium dichromate in a closed system	ERC 7	9.1.1
Worker contributing scenario(s):		
Receipt and storage of raw materials	PROC 1	9.1.2
Filling/topping-up of cooling system	PROC 8b	9.1.3
Corrosion inhibition in a fully closed system	PROC 1	9.1.4
Sampling of water containing Cr(VI) and Cr(III)	PROC 8b	9.1.5
Lab analysis	PROC 15	9.1.6
Release equipment for maintenance, and maintenance of equipment	PROC 8a	9.1.7

Explanation on the approach taken for the ES

The contributing exposure scenario listed here above in Table 18, are the different process steps that are considered relevant for the use of the sodium dichromate in an ammonia based cooling installation.

However, due to the specific use conditions of this installation/process at the Borealis site, several contributing scenarios can be disregarded, as they are exempt from authorization. Detailed justification as to why certain scenarios are exempt is provided in the respective sections of the CSR listed in Table 18.

Table 20: Contributing worker scenarios considered exempt or not exempt

Worker contributing scenarios	**PROC**	**Exempt + Reason**
Receipt and storage of raw materials	PROC 1	Storage = no exposure (exempt)
Filling/topping-up of cooling system	PROC 8b	Exempt = NO
Corrosion inhibition in a fully closed system	PROC 1	Exempt = NO
Sampling of water containing Cr(VI) and Cr(III)	PROC 8b	Exempt = NO
Lab analysis	PROC 15	SR&D = exempt ECHA Q&A 585
Release equipment for maintenance, and maintenance of equipment	PROC 8a	Exempt = NO

Chromium (VI) in the finished article:

Not applicable, as there is no contact/link between the substances used within cooling installation and the polymer that is manufactured.

9.1.1. Environmental contributing scenario 1: Industrial use of sodium dichromate in a closed system

ERC 7 is the relevant environmental release category for Borealis's use, however there is plant specific information available to substantiate that the default factors are not applicable; see Table 21.

Based on this plant specific information it can be concluded that there **is no emission to the environment and thus exposure to air, water, soil and consequently man-via-the environment is negligible.**

There are procedures and worker instructions in place within Borealis that describe the precautions to avoid exposure to the environmental compartments for the activities of topping-up/filling, running of the system, sampling, lab analysis, maintenance, emptying prior to shutdown. The procedures and worker instructions are updated on regular basis. They justify the claim that there is no exposure to the environmental compartments.

In brief, the situation for the differenct fractions / potential releases is the following (details in section 9.1.1.1 & 9.1.1.2.3):

- Air: the installation is a closed system. There is no release to air from the closed installation, this was confirmed by exposure measurements. There are negligible releases during activities, which only take place on a couple of occasions per year.
- Waste water containing Cr(VI): stored on-site for re-use or treated as hazardous waste.
- Soil: the installation is a closed system. There is no release to soil, but if accidently some release would occur, there is a water tight floor and retention basin which is regularly checked, to ensure contamination of the soil is avoided at all times.

9.1.1.1. Minimization of emissions and resulting exposure

The aim of this section of the document is to present all implemented measures ensuring that the emissions are reduced to levels as low as practically and technically possible.

Table 21: Emission and exposure reduction measures

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Containment	• Raw materials are supplied in fully closed vessels (jerry cans). Storage location is outside in a dedicated area. Restricted access to storage area of sodium dichromate vessels. • The Borsig installations are fully closed systems. • The appropriate type of valves, gaskets and pumps (sealless pumps) are used to obtain full containment. • Sampling: dedicated sampling location equipped with low flow sampling valve. The sample valve is closed immediately after taking the sample. The sample is taken in a glass jar which is closed immediately after taking the sample. The sample is transferred to the lab in a closed jar. • Secondary containment is available throughout the site e.g. water tight floor, retention basins.

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Procedural and control technologies	• After use (i.e. after refilling) the containers (jerry cans or drums) are rinsed before disposal. Rinsing water is disposed as hazardous waste. • Worker instructions are in place detailing the specific tasks within this activity. These ensure that emissions and releases are minimized. • During the relevant activities, exposure concentrations (air) are monitored in function of this AfA. • The use of corrosion inhibitor has been minimized over the years by managing the root causes of corrosion such as oxygen in the system and by recovering the ammonia/water cooling fluid where possible. • Ammonia detectors with alarm to central control room are in place for early detection of any loss of containment.
Handling of the substance by trained personnel	• All personnel involved in any chrome related task receive general and task specific training. Training records are kept.
Cases of accident and where waste is generated	• Procedures are in place on how to act in case of emergency. • Firewater is retained. • In case of accidental release, PPE are used to avoid any potential exposure.
Management systems	• See section 9.0.3.3 §D

Table 22: Measures for environmental exposure reduction

Reduction of emission to?	Type of abatement?
Air	Following measures are forseen to prevent any emission to air: • Sodium dichromate, which is not volatile, is used within a fully closed system (PROC1). • Worker instructions are in place. • Emissions to air can only occur during an activity in which the system is partially open. This relates to the following: o 4 times per year a sampling operation that takes max. 15 minutes per occasion o Once every 3 years a topping-up/filling activity which takes approximately 30-90 min. In function of the risk assessment, a worst case frequency of once per year was taken into account. o See below in 9.1.1.2.3. for exposure details related to releases to air. Based on these limited activities taking place, emissions to air are clearly negligible and are not considered further.
Water	Following measures are forseen to prevent any emission to water: All measures are taken to avoid emission to water. • The system is fully closed. • Management systems are in place to prevent and minimize any leakage. • Procedures are in place to avoid any emission to waste water when emptying the installation. In case the complete installation is emptied prior to a shutdown of the production unit, all liquids from the ammonia/water cooling system are transferred to storage for reuse during startup of the unit. • In case of maintenance on smaller parts of the system (eg pumps) the system is emptied from liquid by transferring the liquid either to the rest of the system or to a dedicated drum. In the latter case the liquid is handled as waste. The waste is handled by a certified waste handler in the appropriate way. There will be no release whatsoever of waste water to the sewage treatment plant. So emissions to water and exposure via water can be excluded for this process.
Soil	Following measures are forseen to prevent any emission to soil: • The process installation is located on a water tight floor.

Reduction of emission to?	Type of abatement?
	• The check of the water tightness of the floor is part of the preventive maintenance system. • Rainwater on the watertight floor is captured in a sewer system and evacuated to waste water treatment. • Storage vessels are positioned in a retention basin.

9.1.1.2. Risk assessment and determination of Excess Lifetime Risks

9.1.1.2.1. Conditions of use

Table 23: Conditions of use related to environment

Amount used, frequency and duration of use
• Use at site: Not relevant as there is no exposure to the environment.
• Annual use at a site: max. 90 kg/year; reference to Table 11 is made for all details. However, the typical usage is 60 kg in 3 years time.
Conditions and measures related to sewage treatment plant
• On-site STP: There is an on-site STP (shared with other companies on the same location), however this not relevant as there is no release via wastewater.
• Discharge rate of STP: 2000 m^3/day (default) This is not relevant as there is no release via wastewater.
• Application of the STP sludge on agricultural soil: no
Conditions and measures related to treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: liquid waste will be treated by certified waste handler. Suggested waste treatment procedure: waste incineration of the waste water - added in the second incineration chamber after the rotary kiln, i.e. at the highest possible temperature – with solidification of the residues.
Other conditions affecting environmental exposure
• Receiving surface water flow rate: 18 000 m^3/day This is not relevant as there is no release via wastewater.

9.1.1.2.2. Releases

No releases to the local environment are foreseen as measures are in place to avoid this.

9.1.1.2.3. Exposure and risks for the environment and man via the environment

The installation of Borealis is situated in open air. Due to the nature of the installation, it is not expected that there is any relevant release of Cr(VI) to air. The measurements performed within the installation in function of WCS 9.1.4 (PROC1) and the control measurements performed in the office of one the employees confirms that there is no exposure of Cr(VI) to air when there are no activities ongoing. Therefore, the only emissions that could potentially occur are those related to the activities (topping-up WCS Section 9.1.3, sampling WCS Section 9.1.5 or maintenance WCS Section 9.1.7). Based on the measurements presented in

those scenarios for the last months (WCS 9.1.3: 0.000119 mg and < 0.0001 mg; WCS 9.1.5: < 0.0001 mg and 0.000196 mg), the sum of the releases related to these activities is considered representative for the last 6 months at least. Based on these numbers the total emissions to air are calculated to be maximum 0.000515 mg Cr(VI). If this were to be extrapolated to yearly release this would result in release of 0.001 mg/yr. This is negligible.

Table 24: Exposure measurements relevant for the risk assessment

Date Monitoring*	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
04-11-2015 (Borsig 1)	464 min	0.997	< 0.0001**	< 0.0001/0.997 **= < 0.0001003**	< 0.0001003 x 464/480 **= < 0.000097**
Selected value for risk assessment = worst case					< 0.000097

** static monitoring next to the Borsig 1 installation*
*** detection limit = 0.0001 mg Cr(VI)*

Table 25: Exposure measurements relevant for the risk assessment

Date Monitoring*	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
09-11-2015 (Office)	430 min	0.912	< 0.0001**	< 0.0001/0.912 **= < 0.00010965**	< 0.00010965 x 430/480 **= < 0.000098**
Selected value for risk assessment = worst case					< 0.000098

** static monitoring in the office of one of the employees (blanc)*
*** detection limit = 0.0001 mg Cr(VI)*

As there is no release of sodium dichromate to the local environment, exposure of man via the environment is excluded from the assessment. Indeed, the exposure of man via the environment related to the use of sodium dichromate at Borealis is non-existing, and thus there is no Excess Lifetime Risk for the general population related to the use of sodium dichromate at Borealis.

9.1.1.3. Conclusion on environmental exposure and risk assessment

Sodium dichromate is classified as an Acute and Chronic Aquatic Toxicant Category 1 (respectively H400 and H410). These endpoints are not specified in Annex XIV of the REACH Regulation. Therefore the direct effects and risks to the environment resulting from environmental release should not be evaluated in detail in function of this application for authorization.

In this specific case there is **no release of Cr(VI) to any of the environmental compartments** due to the use of sodium dichromate. It can thus be concluded that there is **no risk for the local/regional environment**. Consequently, it can also be concluded that there is **no additional risk to the general population in relation to the use of sodium dichromate at Borealis.**

9.1.2. Worker contributing scenario 1: Receipt and storage of raw materials (PROC1)

Borealis is a downstream user of sodium dichromate. Sodium dichromate is delivered by the supplier as a solution of 600 g/L sodium dichromate in water. Typically jerry cans of 15 L are supplied. Upon delivery, the closed barrels sodium dichromate are stored on the Borealis premises on a dedicated storage location in open air.

During this activity, the recipients (barrels) are not manipulated by Borealis operators, they remain in the storage location.

There is no potential for exposure identified in relation to this process step.
Aside from the fact that there is no potential for exposure during storage, we note also that storage is exempted from authorization.

9.1.2.1. Minimization of emissions and resulting exposure

The aim of this section of the document is to present all implemented measures ensuring that the emissions are reduced to levels as low as practically and technically possible.

Table 26: Emission and exposure reduction measures

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Containment	• Raw materials are supplied in fully closed vessels (jerry cans). • Storage location is outside. • Secondary containment is available e.g. water tight floor, retention basin. • Restricted access to storage area of sodium dichromate vessels.
Procedural and control technologies	• After use (refilling) the containers (jerry cans) are rinsed before disposal.
Handling of the substance by trained personnel	• All personnel performing this task receive training. • Personnel receive instructions in the correct use of PPE.
Cases of accident and where waste is generated	• Procedures are in place on how to act in case of emergency. • Firewater is retained. • In case of accidental release, PPE are used to avoid any potential exposure.
Management systems	• See section 9.0.3.3 §D

9.1.2.2. Risk assessment and determination of Excess Lifetime Risks

Since there is no potential for exposure related to storage, there is no Excess Lifetime Risk. Also, we note that storage is exempted from authorization.

9.1.2.2.1. Conditions of use

The conditions of use, described in the tables below, are the conditions taken into account to estimate exposure levels.

Table 27: Conditions of use related to receipt and storage of raw materials (PROC1)

	Method
Product (article) characteristics	
• Liquid Weight Fraction: 60% wt (in a water solution)	Not applicable
Amount used (or contained in articles), frequency and duration of use/exposure	
• Exposure duration (near field): no near field activities expected	Not applicable

	Method
Technical and organisational conditions and measures	
• Closed system as it regards closed vessels.	Not applicable
• Location: Outdoors	Not applicable
Conditions and measures related to personal protection, hygiene and health evaluation	
• Effective housekeeping practices in place?: Yes Demonstrable and effective housekeeping practices (daily cleaning, preventive maintenance of machinery, use of protective clothing et cetera) are present.	Not applicable
Other conditions affecting workers exposure	
• Process fully enclosed?: yes, closed vessels	Not applicable

9.1.2.2.2. Exposure and risks for workers

Exposure values for CSR

The 15 L vessels containing sodium dichromate are closed vessels, stored at a location where no activities take place.

Consequently, there is no potential for exposure during storage.

Carcinogenicity / Mutagenicity

The exposure concentrations and Excess Lifetime Risks related to the carcinogenicity and mutagenicity effects are reported in Table 27.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the dose-response curves presented by RAC were taken into account for the CSR for the carcinogenicity/mutagenicity endpoint. Using these dose-response curves, the Excess Lifetime Risks are calculated for each relevant activity.

Table 28. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion carcinogenicity)
Inhalation Local Long-term (based on respirable fraction)	**0 µg/m^3**	**ELR: 0** *RAC: Exposure to 1 µg/m^3 Cr (VI) relates to an Excess Lifetime Risk of 4 x 10^{-3}*
Oral Local Long-term (based on non-respirable fraction)	Not applicable	Considered covered under the inhalation route. *RAC: Exposure to 1 µg/kg bw/day Cr (VI) relates to an Excess Lifetime Risk of 2 x 10^{-4}*
Dermal	Not applicable	*There are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.*
Combined routes		**ELR: 0**

Reprotoxicity

The exposure concentrations and risk characterization ratios related to the reprotoxicity effects are reported in Table 28.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the DNELs for reprotoxicity provided by the ECHA Secretariat - following the RAC opinion which was not yet published at the moment of submission of this AfA - were taken into account for the CSR for the reprotoxicity endpoint. Using these DNELs, RCRs have been calculated for each relevant activity.

Table 29. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion reprotoxicity)
Inhalation Long-term systemic	**0 µg/m^3**	RCR: 0
Dermal Long-term systemic	**0 µg/kg bw/day**	RCR: 0
Combined		RCR: 0

Because there is no exposure during storage (RCR = 0), it is obvious that the risks related to the reprotoxicity endpoint are adequately controlled.

9.1.2.3. Conclusion on risk assessment for receipt and storage of raw materials (PROC1)

- The raw materials are delivered in closed barrels, jerry cans.
- Sodium dichromate is stored in a dedicated and restricted area which is located outside. No activities are performed nearby.
- There is no potential for exposure related to this activity.

There is no potential for exposure related to this activity, related ELRs and RCRs are 0. Hence, the emission and consequently the exposure related to Cr(VI) storage is minimized. No further measures are necessary.

9.1.3. Worker contributing scenario 2: Filling/topping-up of cooling system (PROC8b)

During this activity, the cooling installation is topped-up with sodium dichromate to achieve concentrations of 0.5 up to 0.7 % wt sodium dichromate. The exact amount of sodium dichromate that is required for this topping-up activity is determined during a bi-annual sampling activity that is further described in section 9.1.5.

The following steps are taken during the filling of the cooling system:

(1) The operator marks the area where this activity will take place, to indicate that this is a restricted area.
(2) The tubes that connect the vessels containing the sodium dichromate solution to the cooling installation are pre-filled with water to avoid air entering into the cooling system.
(3) The sodium dichromate solution is transferred from the recipient in which it is supplied (jerry can) to a bigger barrel (drum, 200 L) to allow transfer of the total required volume of sodium dichromate in one go.
(4) The original, empty jerry cans are rinsed with water to avoid remaining contamination of the jerry cans with sodium dichromate before disposal. The rinsing water is also supplied to the bigger barrel. The rinsing of the jerry cans is done 3 times. (After this rinsing step, the jerry can is considered to be clean and is disposed of as hazardous waste.)
(5) Hereafter, the cooling system is topped-up with the volume present in the bigger barrel using a vacuum pump system. The empty drum is now rinsed, and also the rinsing water is entered into the cooling installation.
(6) All equipment, vessels and PPE's used are rinsed. Rinsing water is collected and treated as hazardous waste (to be treated by external waste handler).

These process steps are explained by the pictures below:

Step 1: Preparation of area. Creation of restricted access zone.	

Step 2: An operator ensures the tubes that will be connected to the installation are pre-filled with water. In this stage, there is no potential for exposure to sodium dichromate, therefore "normal" clothing is worn.	
Step 3: Operator wearing full PPE gear ready to start the filling activity. - Full-face mask, K2/P3 filter - Splash suit - Gloves connected to suit - Boots Jerry cans with sodium dichromate (15 L) are situated on the ground.	

Step 3: Jerry cans (5), each containing 15 L of 600 g/L sodium dichromate.	
Step 3: Transfer of the sodium dichromate from the jerry cans to the 200 L drum.	

Step 4: Emptied jerry cans are rinsed with water (3x) and this rinsing liquid is also added to the drum.	
Step 5: The liquid is now sucked into the installation, the operator briefly checks whether this actually takes place. The liquid is sucked in as a vacuum is created and a suction pump (P1202) is used.	
Step 6: Rinsing of all equipment used. Rinsing water of the 200 L vessel is also transferred into the system.	

9.1.3.1. Minimization of emissions and resulting exposure

The aim of this section of the document is to present all implemented measures ensuring that the emissions are reduced to levels as low as technically possible.

Table 30: Emission and exposure reduction measures

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Containment	• The Borsig installations themselves are fully closed systems. The sodium dichromate is transfered in two steps from the transport jerry cans into the Borsig installation to avoid any loss of containment by spill and minimize near field exposure time. The transfer procedure allows a gentle and continuous transfer of liquid into the Borsig system. The subatmospheric pressure from the system itself is used as driving force to transfer the liquid. The frequency of topping up is minimized (max 1 per year) which minimizes the number of activities with potential exposure.
PPE	• The operator wears full PPE gear: PVC splash suit and boots, neoprene gloves and respiratory protection (full-face ABEK-P filter mask with a combined K2/P3 filter).
Procedural and control technologies	• Worker instructions are in place detailing the specific tasks within this activity. • After use (i.e. after refilling) the containers (jerry cans or drums) are rinsed before disposal. Rinsing water is disposed as hazardous waste. • Task risk assessment has been done for this activity. Minimization of exposure was obtained and confirmed by exposure measurements and biomonitoring.
Handling of the substance by trained personnel	• All personnel performing this task receive appropriate training. • Personnel receive instructions on the correct use of PPE.
Cases of accident and where waste is generated	• Procedures are in place on how to act in case of emergency. • Firewater is retained. • In case of accidental release, PPE are used to avoid any potential exposure.
Management systems	• See section 9.0.3.3 §D

9.1.3.2. Risk assessment and determination of Excess Lifetime Risks

A risk assessment was performed based on the measured data available. All relevant information related to the described minimization of Cr(VI) emissions and the exposure resulting from activities during this contributing scenario are described here.

9.1.3.2.1. Conditions of use

The conditions of use described in Table 30 are the conditions at which the activities take place and during which a static measurement was performed.

Table 31: Conditions of use related to filling/topping-up of cooling system (PROC8b)

	Method
Product (article) characteristics	
• Concentration of substance in mixture: > 25 % 60% wt (in a water solution)	Personal measurements
Amount used (or contained in articles), frequency and duration of use/exposure	
• Exposure duration: <= 1.5 hrs	Personal measurements
• Emission sources: Near field exposure is relevant	Personal measurements
Technical and organisational conditions and measures	
• Activity Class for liquids: Transfer of liquid products	Personal measurements
• Process temperature: Room temperature (15 - 25 °C)	Personal measurements

	Method
• Local exhaust ventilation (select efficiency): no	Personal measurements
• Place of use: Outdoor	Personal measurements
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: full-face mask with combination filter for ammonia and dust (efficiency for Cr(VI): 95 %) *Excess Lifetime Risks are presented both with and without taking into account the respiratory protective equipment.*	Personal measurements
• Dermal protection: neoprene gloves are worn with effective training (efficiency: 90 %) *Excess Lifetime Risks are presented both with and without taking into account the dermal protective equipment.*	Personal measurements
• Dermal protection: PVC splash suit and PVC boots are worn during this activity (only qualitatively taken into account)	Personal measurements
• Effective housekeeping practices in place?: Yes Demonstrable and effective housekeeping practices (daily cleaning, preventive maintenance of machinery, use of protective clothing et cetera) are present.	Personal measurements
Other conditions affecting workers exposure	
• Process fully enclosed?: no Process is not fully enclosed	Personal measurements

9.1.3.2.2. Exposure and risks for workers

Exposure values for CSR

Table 32: Exposure measurements relevant for the risk assessment

Date monitoring	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
08-10-2015 (Borsig 1)	86 min	0.173	0.000119	0.000689	0.000689 x 86/480 **= 0.000123**
04-11-2015 (Borsig 2)	32 min	0.0678	< 0.0001*	< 0.00148	< 0.00148 x 32/480 **= < 0.0000987**
Selected value for risk assessment = worst case					0.000123

** detection limit = 0.0001 mg Cr(VI)*

Note on duration & differences in noted exposure levels:
As can be seen from the table above the duration of this activity is different on the different occasions, resulting in different exposure levels. This is mainly due to the fact that less liquid is pumped in the system during the second occasion (5 x 15 L for Borsig 1 and 2 x 15 L for Borsig 2). For risk assessment purposes, the highest exposure levels were used.

In comparison to the static measurement, the MEASE 1.02.01 Exposure Assessment Tool was run. However as this tool cannot predict exposure levels < 0.001 mg/m^3 for inhalation, MEASE results for inhalation exposure were not retained. With regard to dermal exposure,

the MEASE tool was used.

The following assumptions within MEASE were made (for the dermal exposure estimate):

- PROC8b
- Aqueous solution > 25 % (efficiency of 90 %)
- Industrial use, 60 - 240 min
- OC: Non-dispersive use; Non-direct handling; Incidental contact level
- RMM: Properly designed/selected gloves (efficiency 90 %)

Carcinogenicity / Mutagenicity

The exposure concentrations and Excess Lifetime Risks related to the carcinogenicity and mutagenicity effects are reported in Table 32.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the dose-response curves presented by RAC were taken into account for the CSR for the carcinogenicity/mutagenicity endpoint. Using these dose-response curves, the Excess Lifetime Risks are calculated for each relevant activity.

Table 33. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation (RAC opinion carcinogenicity)**
Inhalation Local Long-term (based on respirable fraction)	**0.123 µg/m^3 (8hr daily average, without PPE)** **0.0062 µg/m^3 (8hr daily average, with PPE assuming 95% efficiency)** *Personal monitoring data*	**ELR (based on 8hr daily average, without PPE): 4.9 x 10^{-4}** **ELR (based on 8hr daily average, with PPE): 2.5 x 10^{-5}** *RAC: Exposure to 1 µg/m^3 Cr (VI) relates to an Excess Lifetime Risk of 4 x 10^{-3}*
Oral Local Long-term (based on non-respirable fraction)	Not applicable	Considered covered under the inhalation route. *RAC: Exposure to 1 µg/kg bw/day Cr (VI) relates to an Excess Lifetime Risk of 2 x 10^{-4}*
Dermal	Not applicable	*There are no data that indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.*
Combined routes		**ELR (based on 8hr daily average, without PPE): 4.9 x 10^{-4}** **ELR (based on 8hr daily average, with PPE): 2.5 x 10^{-5}**

It should be noted that this Excess Lifetime Risk mentioned in Table 32 represents the ELR of an operator on that day. The ELR referenced in that table does not yet take the frequency

into account.

In Table 33, the frequency is taken into account. This activity takes place once per 3 years. For risk assessment purposes, it is assumed that the activity takes place once per year (240 working days/year). In a next step (for the total ELRs; see section 10) it is taken into consideration that there are potentially 2 different operators performing this task.

Table 34. ELR in function frequency (without/with PPE)

Frequency of activity	ELR in function of frequency (without PPE)	ELR in function of frequency (with PPE)
Daily	4.9×10^{-4}	2.5×10^{-5}
1x / year (divided by 240)	2.1×10^{-6}	1.0×10^{-7}
ELR used to be used in SEA	**2.1×10^{-6}**	**1.0×10^{-7}**

Reprotoxicity

The exposure concentrations and risk characterization ratios related to the reprotoxicity effects are reported in Table 34.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the DNELs for reprotoxicity provided by the ECHA Secretariat - following the RAC opinion which was not yet published at the moment of submission of this Afa - were taken into account for the CSR for the reprotoxicity endpoint.

Using these DNELs, RCRs have been calculated for each relevant activity.

Table 35. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion reprotoxicity)
Inhalation Long-term systemic	**0.123 µg/m³ (8hr daily average, without PPE)** **0.0062 µg/m³ (8hr daily average, with PPE)** *Personal monitoring data*	RCR: 0.00286 (without PPE) RCR: 0.000143 (with PPE)
Dermal Long-term systemic	**0.2 µg/kg bw/day (70 kg bw, 8hr daily average, without PPE)** **0.02 µg/kg bw/day (70 kg bw, 8hr daily average, with PPE assuming 90 % efficiency)** *MEASE estimation*	RCR: 0.00465 (without PPE) RCR: 0.000465 (with PPE)
Combined		RCR: 0.00608 (without PPE) RCR: 0.000608 (with PPE)

Based on the RCR values reported for reprotoxicity, it can be concluded that the exposure and risks related to that endpoint are adequately controlled.

9.1.3.3. Conclusion on risk assessment for filling/topping-up of cooling system (PROC8b)

Within the boundaries of the described operational conditions and risk management measures:
For the ***reprotoxicity endpoint*** the resulting risk of this activity is **adequately controlled**, because **RCRs of 0.000608** are determined for **combined risks of both inhalation and dermal exposure** (with PPE, which are mandataroy during this activity).

For the ***carcinogenicity/mutagenicity endpoint*** the resulting risk of this activity is minimized, because the ELR is 2.5×10^{-5} if the activity were carried out on a daily basis. Taken into account a **worst case frequency of 1x/year** this results in an **Excess Lifetime Risk of 1.0×10^{-7} (remark: the typical frequency is 1x/3yrs).**
This is a factor 4,000 below the German traffic light model value for **"acceptable risk"** of 4 per 10,000

- The emissions and resulting exposure during this activity are considered minimized as far as practically and technically possible. This is done by minimizing the duration and frequency of the activity to typically once every 3 years per Borsig installation for 30 – 90 minutes (for risk assessment purposes a worst case of 1/year was assumed).
- The operator then follows strict worker instructions which clearly describe the work flow.
- The operator performing the activity wears full PPE gear: double coated PVC splash suit, connecting gloves in neoprene, PVC boots and a full-face ABEK-P (K2/P3) filter mask.

9.1.4. Worker contributing scenario 3: Corrosion inhibition in a fully closed system (PROC1)

During this activity, sodium dichromate and consequently Cr(VI), is used in a fully closed system (PROC1). In this system, the absorption and desorption of ammonia in water creates a cold surface much like in a regular household refrigerator. The created cold surface in used to chill the process stream in the polyethylene production process. The system is fully closed.

Figure 5: Aerial view of the installation[6]

**B1+2 stands for Borsig1 + Borsig2 which are the two absorption cooling systems present on the Borealis site.*

The absorption cooling system is of a large industrial size and it consists of several separate pieces of equipment such as heat exchangers, piping, pumps and absorption towers. An aerial view of the polyethylene production installation where the cooling installation is located is provided in Figure 5.

Sodium dichromate is consumed during the reaction and therefore the system needs to be topped-up every 3 to 4 years. We emphasize that during its use, the sodium dichromate is consumed. There is no loss related to this contributing scenario.

As the system in operation is fully closed, strictly controlled conditions apply, and exposure can be excluded. A monitoring campaign (static measurements) have been set-up to demonstrate that the system is indeed fully closed.

9.1.4.1. Minimization of emissions and resulting exposure

The aim of this section of the document is to present all implemented measures ensuring that the emissions are reduced to levels as low as practically and technically possible.

Table 36: Emission and exposure reduction measures

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Containment	• The Borsig installations themselves are fully closed systems. • The appropriate type of valves, gaskets and pumps (sealless pumps) are used to obtain full containment.
PPE	• No specific PPE are worn (no exposure), unless a manipulation of the installation is required. This is then covered under the respective contributing scenario.
Procedural and control technologies	• If activities within this area are to be performed, worker instructions are in place detailing the specific tasks within this activity.
Handling of the substance by trained personnel	• All personnel performing this task receive appropriate training. • Personnel receive instructions on the correct use of PPE.
Cases of accident and where waste is generated	• Procedures are in place on how to act in case of emergency. • Firewater is retained. • In case of accidental release, PPE are used to avoid any potential exposure.
Management systems	• See section 9.0.3.3 §D

The emissions and consequent exposures related to this task are considered to be minimized as far as technically and practically possible. No further measures are considered necessary.

9.1.4.2. Risk assessment and determination of Excess Lifetime Risks

A risk assessment was performed based on the measured data available. All relevant information related to the described minimization of Cr(VI) emissions and the exposure resulting from activities during this contributing scenario are described here.

9.1.4.2.1. Conditions of use

The conditions of use described in Table 36 are the conditions at which the activities take place and during which a static measurement was performed.

Table 37: Conditions of use for corrosion inhibition in a fully closed system

	Method
Product (article) characteristics	
• Concentration of sodium dichromate in mixture: 0.5 to 0.7 wt % (0.7wt% can be considered as a maximum)	Static measurements
Amount used (or contained in articles), frequency and duration of use/exposure	
• Exposure duration: max. 5 minutes, but actually not relevant as there is no exposure potential. *Far field – operators are present on the site, not necessarily within 1m of the source which is the closed installation. The walking paths on the plant are definitely more than 1m away from the installation itself.*	Static measurements
• Emission sources: Far field	Static measurements
Technical and organisational conditions and measures	
• Activity within a completely closed system (moving liquids within a closed	Static measurements

	Method
process)	
• Process temperature: [redacted][7] (absorption cooling system)	Static measurements
• Location: Outside	Static measurements
Conditions and measures related to personal protection, hygiene and health evaluation	
• Effective housekeeping practices in place?: Yes Demonstrable and effective housekeeping practices (daily cleaning, preventive maintenance of machinery, use of protective clothing et cetera) are present.	Static measurements
Other conditions affecting workers exposure	
• Process fully enclosed?: yes	Static measurements
• Segregation: No segregation	Static measurements
• Personal Enclosure: No personal enclosure	Static measurements

9.1.4.2.2. Exposure and risks for workers

Exposure values for CSR

Table 38: Exposure measurements relevant for the risk assessment

Date Monitoring*	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
04-11-2015 (Borsig 1)	464 min	0.997	< 0.0001**	< 0.0001/0.997 **= < 0.0001003**	< 0.0001003 x 464/480 **= < 0.000097**
Selected value for risk assessment = worst case					< 0.000097

** static monitoring next to the Borsig 1 installation*
*** detection limit = 0.0001 mg Cr(VI)*

Table 39: Exposure measurements relevant for the risk assessment

Date Monitoring*	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
09-11-2015 (Office)	430 min	0.912	< 0.0001**	< 0.0001/0.912 **= < 0.00010965**	< 0.00010965 x 430/480 **= < 0.000098**
Selected value for risk assessment = worst case					< 0.000098

** static monitoring in the office of one of the employees (blanc)*
*** detection limit = 0.0001 mg Cr(VI)*

The exposure measurements were performed in support of the fact that there is no exposure to sodium dichromate expected to originate from the installation when the installation is in "normal" operation and no other activities such as sampling take place.
This is confirmed by the exposure measurements (Table 37) which demonstrate that Cr(VI) cannot be detected (detection limit of 0.0001 mg Cr(VI); 0.000097 mg Cr(VI)/m^3). No distinction can be made between the measurements performed at that location (where a PROC1 is applicable) and in the office of one of the Borealis employees (control location) (Table 38). Hence, this activity is a non-exposure activity.

Carcinogenicity / Mutagenicity

The exposure concentrations and Excess Lifetime Risks related to the carcinogenicity and mutagenicity effects are reported in Table 39.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the dose-response curves presented by RAC were taken into account for the CSR for the carcinogenicity/mutagenicity endpoint. Using these dose-response curves, the Excess Lifetime Risks are calculated for each relevant activity.

Table 40. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion carcinogenicity)
Inhalation Local Long-term (based on respirable fraction)	0 µg/m^3	**ELR: 0** *RAC: Exposure to 1 µg/m^3 Cr (VI) relates to an Excess Lifetime Risk of 4 x 10^{-3}*
Oral Local Long-term (based on non-respirable fraction)	Not applicable	Considered covered under the inhalation route *RAC: Exposure to 1 µg/kg bw/day Cr (VI) relates to an Excess Lifetime Risk of 2 x 10^{-4}*
Dermal	Not applicable	*There are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.*
Combined routes		**ELR: 0**

Reprotoxicity

The exposure concentrations and risk characterization ratios related to the reprotoxicity effects are reported in Table 40.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the DNELs for reprotoxicity provided by the ECHA Secretariat - following the RAC opinion which was not yet published at the moment of submission of this AfA - were taken into account for the CSR for the reprotoxicity endpoint. Using these DNELs, RCRs have been calculated for each relevant activity.

Table 41. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion reprotoxicity)
Inhalation Long-term systemic	**0 µg/m^3**	RCR: 0
Dermal Long-term systemic	**0 µg/kg bw/day**	RCR: 0

Combined		RCR: 0

Because there is no exposure during normal operation (RCR = 0), it is obvious that the risks related to the reprotoxicity endpoint are adequately controlled.

9.1.4.3. Conclusion on risk assessment for corrosion inhibition in a fully closed system (PROC 1)

Within the boundaries of the described operational conditions and risk management measures:
- In general, the operator will **only sporadically be in the proximity of the installation**, and even then only for a limited time duration.
- Based on the **closed design** of the installation, it was suggested that there is **no potential for exposure related to this activity. This was confirmed in the measurement campaign**. The emission and consequently the exposure related to Cr(VI) during this activity are minimized and no further measures are necessary. The related **ELRs and RCRs are 0**.

- The emissions and resulting exposure during this activity are minimized as far as practically and technically possible. This activity takes place in a completely closed system, any exposure from the system is avoided (PROC1). This was confirmed by measurements. In addition, the duration and frequency time operators spend in the proximity of the installation is limited.
- Because this task does not relate to opening any part of the installation and because there is evidence that there is no exposure during normal operation, PPEs are not worn during this task.

9.1.5. Worker contributing scenario 4: Sampling of water containing Cr(VI) and Cr(III) (PROC 8b)

During this activity, a sample of water - containing Cr(VI) and Cr(III) - is taken to determine the sodium dichromate or the ammonia concentration. To ensure proper corrision inhibition, the required concentration of sodium dichromate in the water/ammonia sample is 0.5 to 0.7 %wt sodium dichromate. This concentration allows a minimal need for interventions of topping-up (section 9.1.3). As such Borealis minimizes the potential for exposure.

Based on the concentrations that are determined during this sampling campaign, the exact amount of sodium dichromate (or ammonia or water) that is required for the topping-up activity is determined (for more details on the topping-up activity, see section 9.1.3).

The sampling activity takes place 4 times per year, twice for the determination of the ammonia concentrations, twice for the determination of the sodium dichromate concentration. The duration of sampling is approximately 3 - 6 minutes/sample. On some occasions, it is required to take more than one sample (on different locations). At maximum, 3 samples are to be taken per sampling campaign. This means a typical exposure duration of 15 minutes. Whenever this task is performed, operators wear suitable PPEs (more details below; see also Figure 4).

The following steps are taken during the sampling activity:

(1) Preparation of the area. A restricted access zone is created.
(2) There are dedicated sampling points foreseen (see pictures in table below).
(3) The solution containing sodium dichromate is transferred from the installation to the sampling recipient, a glass bottle with a screw cap.
(4) The sampling recipient is closed as soon as the sample is taken. Hereafter, the sample is transferred to the lab for analysis (see section 9.1.6).
(5) During this activity the operator wears full PPE gear: PVC boots, double coated splash suit, neoprene gloves connected to the splash suit and full-face mask.

These process steps are explained by the pictures below:

Step 1: Preparation of area. Creation of restricted access zone. This is the same as for the contributing scenario of topping-up the installation.	

Step 2: Example of a dedicated sampling point.	
Step 3 & 4: Operator taking sample.	

Step 5: Operator wearing full PPE gear ready to start the filling activity. - Full-face mask, K2/P3 filter - Splash suit - Gloves connected to suit - Boots This is the same as for the contributing scenario of topping-up the installation, because the PPEs used are the same.	

9.1.5.1. Minimization of emissions and resulting exposure

The aim of this section of the document is to present all implemented measures ensuring that the emissions are reduced to levels as low as practically and technically possible.

Table 42: Emission and exposure reduction measures

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Containment	• The Borsig installations themselves are fully closed systems. • A low volume sampling valve is installed for well controlled sample taking. • The sample is taken in a glass jar which is closed immediately after taking the sample. The sample is transferred to the lab in a closed jar. • The sampling valve is closed again immediately after taking the sample. • Duration of sampling is maximum 15 minutes.
PPE	• The operator wears full PPE gear: PVC splash suit and boots, neoprene gloves and respiratory protection (full-face ABEK-P filter mask with a combined K2/P3 filter).
Procedural and control technologies	• Worker instructions are in place detailing the specific tasks within this activity. • Task risk assessment has been done for this activity. Minimization of exposure was obtained and confirmed by exposure measurements and biomonitoring.
Handling of the substance by trained personnel	• All personnel performing this task receive appropriate training. • Personnel receive instructions on the correct use of PPE.
Cases of accident and where waste is generated	• Procedures are in place on how to act in case of emergency. • Firewater is retained. • In case of accidental release, PPE are used to avoid any potential exposure.

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Management systems	• See section 9.0.3.3 §D

The emissions and consequent exposures related to the activities are considered to be minimized as far as technically and practically possible. No further measures are considered necessary.

9.1.5.2. Risk assessment and determination of Excess Lifetime Risks

A risk assessment was performed based on the measured data available. All relevant information related to the described minimization of Cr(VI) emissions and the exposure resulting from activities during this contributing scenario are described here.

9.1.5.2.1. Conditions of use

The conditions of use described in Table 42 are the conditions at which the activities take place and during which a static measurement was performed.

Table 43: Conditions of use related to sampling of water containing Cr(VI) and Cr(III)

	Method
Product (article) characteristics	
• Concentration of sodium dichromate in mixture: 0.5 to 0.7 wt % *This concentration refers to the maximum concentration expected in the Borsig installation.*	Personal measurements
Amount used (or contained in articles), frequency and duration of use/exposure	
• Exposure duration: approx. 15 mins / sampling occasion *The sampling activity takes place 4 times per year, twice for the determination of the ammonia concentrations, twice for the determination of the sodium dichromate concentration. When samples are taken, it takes approximately 3-6 minutes/sample. On some occasions, it is required to take more than one sample (on different locations). At maximum, 3 samples are to be taken per sampling campaign.*	Personal measurements
• Emission sources: Near field	Personal measurements
Technical and organisational conditions and measures	
• Activity Class for liquids: Transfer of liquids	Personal measurements
• Process temperature: [redacted][8] (absorption cooling system)	Personal measurements
• Local exhaust ventilation (select efficiency): no	Personal measurements
• Location: Outside	Personal measurements
Conditions and measures related to personal protection, hygiene and health evaluation	
• Effective housekeeping practices in place?: Yes (Demonstrable and effective housekeeping practices (daily cleaning, preventive maintenance of machinery, use of protective clothing et cetera) are present.)	Personal measurements
• Respiratory protection: full-face mask with combination filter for ammonia and dust (efficiency: 95 %) *Excess Lifetime Risks are presented both with and without taking into account the respiratory protective equipment.*	Personal measurements
• Dermal protection: neoprene gloves are worn with effective training (efficiency: 90%) *Excess Lifetime Risks are presented both with and without taking into account the*	Personal measurements

	Method
dermal protective equipment.	
Other conditions affecting workers exposure	
• Dermal protection: PVC splash suit and PVC boots are worn during this activity (only qualitatively taken into account)	Personal measurements
• Process fully enclosed?: no	Personal measurements
• Segregation: No segregation	Personal measurements
• Personal Enclosure: No personal enclosure	Personal measurements

9.1.5.2.2. Exposure and risks for workers

Exposure values for CSR – monitoring information

Table 44: Exposure measurements relevant for the risk assessment

Date monitoring	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
17-09-2015 (Borsig 1)	6 min	0.012	< 0.0001	< 0.00831	< 0.000104
04-11-2015 (Borsig 2)	11 min	0.0237	0.000196	0.00827	0.000190
Selected value for risk assessment = worst case					**0.000190**

The differences in exposure values reported in the above mentioned table (Table 43) are related to the duration of the sampling occasions. For the first sampling operation, which only took 6 minutes, the operator only took a sample at one sampling point. During the second sampling operation (11 minutes) the operator took a sample at 3 sampling points. When an operator takes samples for inspection of the concentration, this can be done at maximum 3 locations within the installation and this is what happened in the last sampling occasion. Therefore, the values with the highest exposure levels were used further in the risk assessment.

In comparison to the static measurement, the MEASE 1.02.01 Exposure Assessment Tool was run. However as this tool cannot predict exposure levels < 0.001 mg/m^3 for inhalation, MEASE results for inhalation exposure were not retained. With regard to dermal exposure, the MEASE tool was used.

The following assumptions within MEASE were made (in function of the dermal exposure estimate):

- PROC8b
- Aqueous solution < 1% (efficiency of 90 %)
- Industrial use, < 15 min
- OC: Non-dispersive use; Non-direct handling; Incidental contact level
- RMM: Properly designed/selected gloves (efficiency 90 %)

Carcinogenicity / Mutagenicity

The exposure concentrations and Excess Lifetime Risks related to the carcinogenicity and mutagenicity effects are reported in Table 44.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the dose-response curves presented by RAC were taken into account for the CSR for the carcinogenicity/mutagenicity endpoint. Using these dose-response curves, the Excess Lifetime Risks are calculated for each relevant activity.

Table 45. Exposure concentrations and risks for workers

Route of exposure and type of effects	**Exposure concentration**	**Risk characterisation (RAC opinion carcinogenicity)**
Inhalation Local Long-term (based on respirable fraction)	**0.190 µg/m^3 (8hr daily average, without PPE)** **0.0095 µg/m^3 (8hr daily average, with PPE assuming 95 % efficiency)** *Personal monitoring data*	**ELR (based on 8hr daily average, without PPE): 7.6 x 10^{-4}** **ELR (based on 8hr daily average, with PPE): 3.8 x 10^{-5}** *RAC: Exposure to 1 µg/m^3 Cr (VI) relates to an Excess Lifetime Risk of 4 x 10^{-3}*
Oral Local Long-term (based on non-respirable fraction)	Not applicable	Considered covered under the inhalation route *RAC: Exposure to 1 µg/kg bw/day Cr (VI) relates to an Excess Lifetime Risk of 2 x 10^{-4}*
Dermal	Not applicable	*There are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.*
Combined routes		**ELR (based on 8hr daily average, without PPE): 7.6 x 10^{-4}** **ELR (based on 8hr daily average, with PPE): 3.8 x 10^{-5}**

It should be noted that this Excess Lifetime Risk mentioned in Table 44 represents the ELR of an operator on that day. The ELR referenced in that table does not yet take the frequency into account.

In Table 45 the frequency is taken into account. On 4 occassions per year, samples are taken (2x for ammonia; 2x for sodium dichromate). However, this is done by different operators, so the frequency taken into account is 1x/year (based on 240 working days/year). In a next step (for the total ELRs; see Section 10) it is taken into consideration that there are 4 different operators performing this task.

Table 46. ELR in function frequency (without/with PPE)

Frequency of activity	ELR in function of frequency (without PPE)	ELR in function of frequency (with PPE)
Daily	7.6×10^{-4}	3.8×10^{-5}
1x / year (divided by 240)	3.2×10^{-6}	1.6×10^{-7}
ELR used to be used in SEA	**3.2×10^{-6}**	**1.6×10^{-7}**

Reprotoxicity

The exposure concentrations and risk characterization ratios related to the reprotoxicity effects are reported in Table 46.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the DNELs for reprotoxicity provided by the ECHA Secretariat - following the RAC opinion which was not yet published at the moment of submission of this Afa - were taken into account for the CSR for the reprotoxicity endpoint. Using these DNELs, RCRs have been calculated for each relevant activity.

Table 47. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion reprotoxicity)
Inhalation Long-term systemic	**0.190 µg/m³ (8hr daily average, without PPE)** **0.0095 µg/m³ (8hr daily average, with PPE assuming 95 % efficiency)** *Monitoring data*	RCR: 0.0044 (without PPE) RCR: 0.00022 (with PPE)
Dermal Long-term systemic	**0.0286 µg/kg bw/day (70 kg bw, 8hr daily average, without PPE)** **0.00286 µg/kg bw/day (70 kg bw, 8hr daily average, with PPE assuming 90 % efficiency)** *MEASE estimation*	RCR: 0.00066 (without PPE) RCR: 0.000066 (with PPE)
Combined		RCR: 0.0051 (without PPE) RCR: 0.00029 (with PPE)

Based on the RCR values reported for reprotoxicity, it is that the exposure and risks related to that endpoint are adequately controlled.

9.1.5.3. Conclusion on risk assessment for sampling of water containing Cr(VI) and Cr(III) (PROC 8b)

Within the boundaries of the described operational conditions and risk management measures:
For the ***reprotoxicity endpoint*** the resulting risk of this activity is **adequately controlled**, because **RCRs of 0.00029** are determined for **combined risks of both inhalation and dermal exposure** (with PPE, which are mandatory during this activity).

For the ***carcinogenicity/mutagenicity endpoint*** the resulting risk of this activity is considered minimized, because the ELR is 3.8×10^{-5} if the activity were carried out on a daily basis. Taken into account a **worst case frequency of 1x/year** this results in an **Excess Lifetime Risk of 1.6×10^{-7}** (remark: the typical frequency is 4x/year but this activity typically takes place by different operators).
This is a factor 2,500 below the German traffic light model value for **"acceptable risk"** of 4 per 10,000

- The emissions and resulting exposure during this activity are minimized as far as practically and technically possible. This is done by minimizing the duration and the frequency of the activity to typically 4 times per year (twice for sodium dichromate and twice for ammonia, for approx. 15 minutes). For risk assessment purposes, once per year per person was assumed as typically these are different operators that perform this task.
- The operator follows strict worker instructions which clearly describe the work flow.
- In addition, the operator performing the activity wears full PPE gear: splash suit, connecting gloves in neoprene, PVC boots and a full-face ABEK-P (K2/P3) filter mask.

9.1.6. Worker contributing scenario 5: Lab analysis (PROC 15)

The activity described with this contributing scenario is not subject to authorization according to ECHA's Q&A 585:

> *Does the exemption for the use of Annex XIV substances in scientific research and development under Article 56(3) of REACH also apply to analytical activities as monitoring and quality control?*
>
> *Yes, it does. Under Article 3(23) REACH, scientific research and development means any scientific experimentation, analysis or chemical research carried out under controlled conditions* ***in a volume less than one tonne per year****. Thus, scientific research and development can cover analysis, and* ***a substance may be exempted from authorisation under Article 56(3) REACH if used, on its own or in a mixture, in analytical activities such as monitoring and quality control.*** *For instance, routine quality control or release tests in laboratory scale using the substance as extraction solvent or analytical standard fall into the definition of 'scientific research and development' under Article 3(23) REACH and in the scope of the exemption foreseen in Article 56(3) REACH, as long as the quality control or release tests are carried out under controlled conditions and in a volume not exceeding one tonne per year and per legal entity.*

In conclusion, the lab analysis is exempt from authorisation.

Nevertheless, it should be noted that:

- Analysis of samples is limited to 4 samples/year.
- The sample contains max. 0.7 % sodium dichromate.
- Lab analysis are performed by an external lab (Intertek) where approved fume hoods are used standardly.

9.1.7. Worker contributing scenario 6: Releasing equipment for maintenance (PROC8a), and maintenance of equipment

The maintenance activity constists of following parts:
- making the equipment available for maintenance
- maintenance of the equipment
- taking the equipment back into service

In case the maintenance activity requires that the equipment is opened (loss of containment) or needs to be removed, this equipment will be rinsed and flushed free of product before opening or removing the equipment. Hence there is no exposure to sodium dichromate possible during the this type of maintenance itself. In case of other types of maintenance, there is no exposure because of the closed nature of the cooling system.

Making the equipment available for maintenance occurs following strict procedures. In case a smaller piece of equipment (e.g. a pump) is made available for maintenance, the equipment (e.g. a pump) is first isolated from the rest of the installation by closing the appropriate valves. Energy sources such as electricity, steam, cooling water etc are disconnected. Secondly, the liquid in the equipment is drained in a controlled way in a vessel. The concentration of sodium dichromate in this liquid is as in normal operation between 0.5 and 0.7 %. The equipment is flushed with water and the flushing water is also captured in the vessel. The rinsing liquid is send off-site as hazardous waste. Concentration of sodium dichromate in the flushing water is significantly below the concentration in process.

In case larger parts of the system are to be made available for maintenance, the cooling liquid in the equipment is captured and put aside in closed storage vessels for reuse. In this way, the use of sodium dichromate is minimized. The water used for flushing of the equipment is captured and send off-site as hazardous waste.

Hoses used for transfer of liquid are rinsed after use, rinsing water is captured and send of site as hazardous waste. This type of maintenance (maintenance of larger parts of the installation) is very infrequent and happens typically only every 6 years during a full maintenance shutdown of the installation.

Taking smaller parts of the installation back into service means opening the isolating valves. No additional water or sodium dichromate is added. In case larger parts of the system are taken into service, the liquid put aside is transferred back into the system prior to starting the system.

Hoses used for transfer of liquid are rinsed after use, rinsing water is captured and send of site as hazardous waste.

During the maintenance activity itself, there is no exposure to sodium dichromate.

9.1.7.1. Minimization of emissions and resulting exposure

The aim of this section of the document is to present all implemented measures ensuring that the emissions are reduced to levels as low as practically and technically possible.

Table 48: Emission and exposure reduction measures

Means to minimize emission	Description of the specific implemented measures, including efficiency where relevant
Containment	• The Borsig installations themselves are fully closed systems. • Equipment opened for maintenances is free of sodium dichromate. • The part of the installation to be opened for maintenance is first isolated from the rest of the installation by closing the appropriate valves. Secondly, the liquid in the system is drained in a controlled way in a vessel. The system is flushed with water and the flushing water is also captured in the vessel. The liquid is send off-site as hazardous waste. • When a certain part of the installation is taken back into service, this means the valves isolating that piece of equipment are opened. No additional water or sodium dichromate is added. In case larger parts of the system are taken into service, the liquid put aside is transferred back into the system prior to starting the system.
PPE	• The operator wears full PPE gear: PVC splash suit and boots, neoprene gloves and respiratory protection (full-face ABEK-P filter mask with a combined K2/P3 filter).
Procedural and control technologies	• General maintenance worker instructions are in place detailing the specific tasks within this activity. • Procedures are in place to assure that the equipment released for maintenance is free of sodium dichromate. • Procedures are in place to avoid any release to air, water or soil during flusing of the equipment to be released for maintenance. • All maintenance activities are managed by a work permit system specifying the activities and the boundary conditions of the maintenance work. • Task risk assessment has been done for each maintenance activity. • All maintenance work is communicated and approved by production supervision before commencement of work. • PPE are worn when equipment is flushed. • For each specific activity, the relevant PPE are determined via the PPE Matrix present within Borealis.
Handling of the substance by trained personnel	• All personnel performing this task receive appropriate training. • Personnel receive instructions on the correct use of PPE.
Cases of accident and where waste is generated	• Procedures are in place on how to act in case of emergency. • Firewater is retained. • In case of accidental release, PPE are used to avoid any potential exposure.
Management systems	• See section 9.0.3.3 §D

9.1.7.2. Risk assessment and determination of Excess Lifetime Risks

9.1.7.2.1. Conditions of use

The conditions of use described in Table 48 are the conditions at which the activities take place. Only the conditions of use related to making the equipment available for maintenance and for taking the equipment back in service are described. The conditions of use related to the actual maintenance are not described as these are not considered relevant as the equipment has to be free of contaminants before maintenance can take place.

Table 49: Conditions of use related to making the equipment available for maintenance and for taking the equipment back in service (PROC8a)

	Method
Product (article) characteristics	
• Concentration of sodium dichromate in mixture: 0.5 to 0.7 wt% *This concentration refers to the maximum concentration expected in the Borsig installation.*	Personal monitoring, sampling
Amount used (or contained in articles), frequency and duration of use/exposure	
• Exposure duration: < 15 mins / maintenance occasion (activity of making equipment available; taking back in service) *This is an irregular activity that takes place 2 times per year. Typically it is assumed that only 5 minutes are required for connecting and disconnecting hoses.*	Personal monitoring, sampling
Technical and organisational conditions and measures	
• Activity Class for liquids: Transfer of liquids	Personal monitoring, sampling
• Process temperature: room temperature *(during the sampling activity, higher temperatures were assumed assuring that this measurement represents a worst case estimation for this activity)*	Personal monitoring, sampling
• Local exhaust ventilation (select efficiency): no	Personal measurements, sampling
• Location: Outside	Personal monitoring, sampling
Conditions and measures related to personal protection, hygiene and health evaluation	
• Effective housekeeping practices in place?: Yes (Demonstrable and effective housekeeping practices (daily cleaning, preventive maintenance of machinery, use of protective clothing et cetera) are present.)	Personal monitoring, sampling
• Respiratory protection: full-face mask with combination filter for ammonia and dust (efficiency: 95 %) *Excess Lifetime Risks are presented both with and without taking into account the respiratory protective equipment.*	Personal measurements, sampling
• Dermal protection: neoprene gloves are worn with effective training (efficiency: 90%) *Excess Lifetime Risks are presented both with and without taking into account the dermal protective equipment.*	Personal monitoring, sampling
• Dermal protection: PVC splash suit and PVC boots are worn during this activity (only qualitatively taken into account)	Personal monitoring, sampling
Other conditions affecting workers exposure	
• Process fully enclosed?: no	Personal monitoring, sampling
• Segregation: No segregation.	Personal monitoring, sampling
• Personal Enclosure: No personal enclosure	Personal monitoring, sampling

9.1.7.2.2. Exposure and risks for workers

There is no exposure information available specifically to this activity, meaning transfer of chrome containing liquid (max. 0.7% sodium dichromate) from the system to a dedicated vessel.
However, as there is exposure information available for sampling (WCS 9.1.5), this

information was used as a worst case estimate for the first phase of this maintenance activity as well. It is considered worst case as within this activity the duration is similar, but the chrome containing solution is more contained compared to the sampling situation.

Exposure values for CSR – monitoring information

Table 50: Exposure measurements relevant for the risk assessment (exposure measurements for sampling)

Date monitoring	Duration	Volume (m^3)	Amount (mg Cr(VI))	Concentration (mg Cr(VI)/m^3)	Conc 8hr (mg Cr(VI)/m^3)
17-09-2015 (Borsig 1)	6 min	0.012	< 0.0001	< 0.00831	< 0.000104
04-11-2015 (Borsig 2)	11 min	0.0237	0.000196	0.00827	0.000190
Selected value for risk assessment = worst case					**0.000190**

With regard to dermal exposure, the MEASE tool was used.

The following assumptions within MEASE were made (with regard to the dermal exposure estimate):

- PROC8b
- Aqueous solution < 1% (efficiency of 90 %)
- Industrial use, < 15 min
- OC: Non-dispersive use; Non-direct handling; Incidental contact level
- RMM: Properly designed/selected gloves (efficiency 90 %)

Carcinogenicity / Mutagenicity

The exposure concentrations and Excess Lifetime Risks related to the carcinogenicity and mutagenicity effects are reported in Table 50.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the dose-response curves presented by RAC were taken into account for the CSR for the carcinogenicity/mutagenicity endpoint. Using these dose-response curves, the Excess Lifetime Risks are calculated for each relevant activity.

Table 51. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion carcinogenicity)
Inhalation Local Long-term (based on respirable fraction)	**0.190 µg/m^3 (8hr daily average, without PPE)** **0.0095 µg/m^3 (8hr daily average, with PPE assuming 95 % efficiency)** *Personal monitoring data*	**ELR (based on 8hr daily average, without PPE): 7.6 x 10^{-4}** **ELR (based on 8hr daily average, with PPE): 3.8 x 10^{-5}** *RAC: Exposure to 1 µg/m^3 Cr (VI) relates to an Excess Lifetime Risk of 4 x 10^{-3}*

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion carcinogenicity)
Oral Local Long-term (based on non-respirable fraction)	Not applicable	Considered covered under the inhalation route *RAC: Exposure to 1 µg/kg bw/day Cr (VI) relates to an Excess Lifetime Risk of 2 x 10^{-4}*
Dermal	Not applicable	*There are no data to indicate that dermal exposure to Cr(VI) compounds presents a cancer risk to humans.*
Combined routes		**ELR (based on 8hr daily average, without PPE): 7.6 x 10^{-4}** **ELR (based on 8hr daily average, with PPE): 3.8 x 10^{-5}**

It should be noted that this Excess Lifetime Risk mentioned in Table 50 represents the ELR of an operator on that day. The ELR referenced in that table does not yet take the frequency into account.

In Table 51 the frequency is taken into account. On 2 occassions per year, maintenance of certaint parts of equipment is needed. However, this is done by different operators, so the frequency taken into account is 1x/year (based on 240 working days/year). In a next step (for the total ELRs; see Section 10) it is taken into consideration that there are 2 different operators performing this task.

Table 52. ELR in function frequency (without/with PPE)

Frequency of activity	ELR in function of frequency (without PPE)	ELR in function of frequency (with PPE)
Daily	7.6 x 10^{-4}	3.8 x 10^{-5}
1x / year (divided by 240)	3.2 x 10^{-6}	1.6 x 10^{-7}
ELR used to be used in SEA	**3.2 x 10^{-6}**	**1.6 x 10^{-7}**

Reprotoxicity

The exposure concentrations and risk characterization ratios related to the reprotoxicity effects are reported in Table 52.

As this CSR is composed in agreement with the RAC opinion issued for sodium dichromate, the DNELs for reprotoxicity provided by the ECHA Secretariat - following the RAC opinion which was not yet published at the moment of submission of this AfA - were taken into account for the CSR for the reprotoxicity endpoint. Using these DNELs, RCRs have been calculated for each relevant activity.

Table 53. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation (RAC opinion reprotoxicity)
Inhalation Long-term systemic	**0.190 µg/m^3 (8hr daily average, without PPE)** **0.0095 µg/m^3 (8hr daily average, with PPE assuming 95 % efficiency)** *Monitoring data*	RCR: 0.0044 (without PPE) RCR: 0.00022 (with PPE)
Dermal Long-term systemic	**0.0286 µg/kg bw/day (70 kg bw, 8hr daily average, without PPE)** **0.00286 µg/kg bw/day (70 kg bw, 8hr daily average, with PPE assuming 90 % efficiency)** *MEASE estimation*	RCR: 0.00066 (without PPE) RCR: 0.000066 (without PPE)
Combined		RCR: 0.0051 (without PPE) RCR: 0.00029 (with PPE)

Based on the RCR values reported for reprotoxicity, it is concluded that the exposure and risks related to that endpoint are adequately controlled.

9.1.7.3. Conclusion on risk assessment for maintenance of the process line (PROC8a)

Within the boundaries of the described operational conditions and risk management measures:
For the ***reprotoxicity endpoint*** the resulting risk of this activity is **adequately controlled**, because **RCRs of 0.00029** are determined for **combined risks of both inhalation and dermal exposure** (with PPE, which are mandatory during this activity).

For the ***carcinogenicity/mutagenicity endpoint*** the resulting risk of this activity is considered minimized, because the ELR is 3.8 x 10^{-5} if the activity were carried out on a daily basis. Taken into account a **worst case frequency of 1x/year** this results in an **Excess Lifetime Risk of 1.6 x 10^{-7}** (remark: the typical frequency is 2x/year but this activity typically takes place by different operators).
This is a factor 2,500 below the German traffic light model value for **"acceptable risk"** of 4 per 10,000

- The emissions and resulting exposure during this activity are minimized as far as practically and technically possible. This is done by minimizing the duration and the

frequency of the activity to 2 times per year. For risk assessment purposes, once per year per person was assumed as typically these are different operators that perform this task.
- The operator follows strict worker instructions which clearly describe the work flow.
- In addition, the operator performing the activity wears full PPE gear: splash suit, connecting gloves in neoprene, PVC boots and a full-face ABEK-P (K2/P3) filter mask.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers – Use

In the previous sections (9.1.2- 9.1.7) the various activities performed by the different workers were described in contributing exposure scenarios. In this section, the combined exposure will be described. In the combined exposure, the exposure levels related to the different tasks an operator performs on a daily basis, are combined.

In these sections we calculated the combined exposure levels based on the static measurements/modelled exposure levels per activity taking into account the duration of the activities. As such, we obtain the total exposure for a worker during one shift.

It should be noted that workers can also perform activities not directly related to the production process involving Cr(VI). In other words, they perform tasks in other parts of the plant, which are non-Cr(VI) areas. These activities are non-exposure activities.

The number of workers relevant for the different functions is shown in Table 53.

Table 54: Different type of operators & relevant activities (assessment with PPE)

Operator	µg/m³ (8hr average)				
	Filling/topping-up of cooling system	**Corrosion inhibition in fully closed system**	**Sampling of water containing Cr(VI) and Cr(III)**	**Maintenance**	**Total inhalation exposure**
Production operator – topping-up	0.0062 (1x/year per operator; 1 occasion per year*)	0	Not applicable	Not applicable	0.0062 / 240 days = **0.000026**
Production operator – sampling	Not applicable	0	0.0095 (1x/year per operator; 4 occasions per year)	Not applicable	0.0095 / 240 days = **0.000040**
Production operator – maintenance	Not applicable	0	Not applicable	0.0095 (1x/year per operator; 4 occasions per year)	0.0095 / 240 days = **0.000040**

* A Frequency of 1x/year is a worst case assessment. The typical frequency is 1x/3 years. For risk assessment purposes the worst case of 1x/year was assumed.

Table 55: Different type of operators & Excess Lifetime Risks (with PPE) for carcinogenicity

Operators	Total Excess Lifetime Risk per person	# operators (total of 8)	Total Excess Lifetime Risk per group
production operator performing the refilling activity (with PPE)	= 0.000026 x 4/1000 *RAC: Exposure to 1 µg/m³ Cr (VI) relates to an Excess Lifetime Risk of 4 x 10⁻³* = 1.0×10^{-7} = 1.0/10,000,000	2	2.1×10^{-7}
production operator performing the sampling activity (with PPE)	= 0.000040 x 4/1000 *RAC: Exposure to 1 µg/m³ Cr (VI) relates to an Excess Lifetime Risk of 4 x 10⁻³* = 1.6×10^{-7} = 1.6/10,000,000	4	6.3×10^{-7}
production operator performing preparations for maintenance (with PPE)	= 0.000040 x 4/1000 *RAC: Exposure to 1 µg/m³ Cr (VI) relates to an Excess Lifetime Risk of 4 x 10⁻³* = 1.6×10^{-7} = 1.6/10,000,000	2	3.2×10^{-7}
production operator *when* performing *both* the refilling and sampling activity on one day (with PPE)*	= (0.000026 + 0.000040)x4/1000 *RAC: Exposure to 1 µg/m³ Cr (VI) relates to an Excess Lifetime Risk of 4 x 10⁻³* 2.6×10^{-7} 2.6/10,000,000 (sum of 1.0×10^{-7} + 1.6×10^{-7})	One of the operators listed already on the two lines above	

*In some rare occasions it could occur that the production operator performing sampling activities is the same the one performing topping-up activities on the same day. If this is the case then this operator will have the combined exposure of both activities (0.0062 µg/m³ + 0.0095 µg/m³ = 0.0157 µg/m³, taking into account the frequency of once per year (once per 240 days) this relates to re-calculated exposure levels of 0.000065 µg/m³). Meaning that this combination of activities relates to the highest Excess Lifetime Risks one person can have, namely the sum of both activities: 2.6×10^{-7}.

Table 56: Different type of operators & risk characterization ratios (with PPE) for reprotoxicity

Operators	RCRs (frequency not taken into account)
production operator performing the refilling activity (with PPE)	0.00061
production operator performing the sampling activity (with PPE)	0.00029
production operator performing preparations for maintenance (with PPE)	0.00029
production operator *when* performing *both* the refilling and sampling activity on one day (with PPE)	0.00090 (sum of 0.00061 + 0.00029)

*In some rare occasions it could occur that the production operator performing sampling activities is the same the one performing topping-up activities on the same day. If this is the case then this operator will have the combined exposure of both activities (0.0062 µg/m^3 + 0.0095 µg/m^3 = 0.0157 µg/m^3 for inhalation exposure and 0.02 µg/kg bw/day + 0.00286 µg/kg bw/day = 0.0227 µg/kg bw/day for dermal exposure). Meaning that this combination of activities relates to the combined RCRs one person can have, namely the sum of both activities, for both routes: 0.000896.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

The total annual releases of sodium dichromate to the environment from all the exposure scenarios covered are presented in the Table 56 below. This is the sum of the releases to the environment from all exposure scenarios addressed.

Table 57: Total releases to the environment per year from all life cycle stages:

Release route	Total releases per year
Water	0 kg/year
Air	0 kg/year
Soil	0 kg/year

10.2.1.2. Regional exposure

Environment

Sodium dichromate is classified as an Acute and Chronic Aquatic Toxicant Category 1 (respectively H400 and H410). These endpoints are not specified in Annex XIV of the REACH Regulation. Therefore the direct effects (both on a local and regional scale) and risks to the environment resulting from environmental release were not evaluated in detail in this CSR. In addition, there are worker instructions in place to ensure that there is no release of sodium dichromate to the environment. Exposure and risk to the environment from this use is non-existing.

Man via environment

As there is no environmental release, exposure of man via the environment is irrelevant for the use of sodium dichromate by Borealis.

10.2.2. Local exposure due to all wide dispersive uses

Not relevant for this CSR.

10.3. Conclusions

10.3.1. Scope of this CSR

Within this CSR, a risk assessment has been performed in function of Borealis's authorisation application dossier for the following uses:

(1) The use of sodium dichromate as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system

As Article 62.4(d) of REACH stipulates that the authorisation dossier shall contain a CSR covering the risks to human health and/or the environment related to the intrinsic properties specified in Annex XIV, i.e. Carcinogenic Cat.1b, Mutagenic Cat.1b and Reprotoxic Cat. 1b properties, this CSR focuses on those endpoints.

The applicant used this information to:

- Evaluate the daily (combined) worker exposure to determine Excess Lifetime Risks. An Excess Lifetime Risk means the additional risk to fatal cancer as a result of exposure to sodium dichromate (hence Chrome VI), in comparison to the risk to the fatal risk of the same type of cancer when not exposed to sodium dichromate.
- Evaluate the daily (combined) worker exposure and determine Excess Lifetime Risks based on the Reference Dose Response Relationship for carcinogenicity published by ECHA on December 4, 2013 (RAC/27/2013/06 rev.1).
- Evaluate the risk characterization ratios with regard to the reprotoxicity effects, using the DNELs communicated by the ECHA Secretariat. The use of these DNELs allows the evaluation of adequate control.
- Demonstrate minimization of risks for the uses applied for by demonstrating that the risks related to the continued use of sodium dichromate have been minimized as far as technically and practically possible.

10.3.2. Environmental exposure and risk assessment

Environment

This process is fully closed. There are worker instructions in place to ensure there is no emission to the environmental compartments. Hence, there is no risk related to the environment.

For reason of completeness, sodium dichromate is classified as an Acute and Chronic Aquatic Toxicant Category 1 (respectively H400 and H410). But, since these endpoints are not

specified in Annex XIV of the REACH Regulation, the direct effects (both on a local and regional scale) and risks to the environment resulting from environmental release do not have to be evaluated in detail in this CSR for an application for authorisation.

The overall tonnage taken into account for the exposure/risk assessment was <100 kg/year, typically 60 kg/3 years, and maximally 90 kg/yr.

Man via the environment

There are no emissions to the environment, hence exposure of man via the environment is not relevant.

10.3.3. Human health exposure and risk assessment

Minimization of exposure is demonstrated by technical means and by means of monitoring, namely the fact that the installation is a fully closed system. Furthermore, Borealis ensures that procedural systems are in place to safeguard the existing processes, and the frequency and duration of the activities are limited as much as possible. The number of activities are rare (sampling 4x/yr, topping-up 1x/3 yrs, maintenance 2x/yr) and the duration is short (sampling < 15 min and topping up ca. 1.5 hours and maintenance < 15 min). Furthermore, during the activities, personal protective equipment is also being worn to ensure further that exposure of workers is kept to the minimum. And lastly, efficient control mechanisms are in place to monitor the exposure.

Workers

- There are no regularly scheduled (daily, weekly, monthly) activities taking place with potential for exposure of workers to sodium dichromate. Any activities that are performed, take place only sporadically (one, two or four times per year) and typically by different operators. Exposure and risks were assessed per activity, as well as for the sum of the activities of a worker during his entire shift, i.e. combined exposure.

- The risk assessment for workers is based on exposure information related to personal monitoring information for the inhalation route of exposure and MEASE modelling for the dermal route of exposure. For the different type of operators, the overall exposure and Excess Lifetime Risks were determined for inhalation exposure in relation to carcinogenic effects. With regard to reprotoxic effects, adequate control of the risks was demonstrated both for the inhalation and dermal route of exposure.

- **With regard to carcinogenicity**: The overall exposure and Excess Lifetime Risks were determined for each worker type (for inhalation), taking into account that these activities only take place once/year per operator which is considered worst case. Typically different operators perform these tasks.

Table 58: Overview of ELR and additional cancer cases per operator type

Excess Lifetime Risk per operator type	ELRs 1/yr on 40 yr basis*	ELR 1/yr on 40 yr basis*	Frequency per yr per operator	Total frequency per year	# operators	Additional Cancer cases per operator type
production operator performing the refilling activity (with PPE)	1.0×10^{-7}	1.0/ 10,000,000	1/year**	1/year**	2	$2 \times 1.0 \times 10^{-7}$ = **2.1×10^{-7}**
production operator performing the sampling activity (with PPE)	1.6×10^{-7}	1.6/ 10,000,000	1/year	4/year	4	$4 \times 1.6 \times 10^{-7}$ = **6.3×10^{-7}**
production operator performing preparations for maintenance (with PPE)	1.6×10^{-7}	1.6/ 10,000,000	1/year	2/year	2	$2 \times 1.6 \times 10^{-7}$ = **3.2×10^{-7}**
production operator *when* performing *both* the refilling and sampling activity on one day (with PPE)	2.6×10^{-7} (sum of 1.0×10^{-7} + 1.6×10^{-7})	2.6/ 10,000,000				

* No re-calculation was done for the number of years; these values represent ELRs for 40 years.
** A Frequency of 1x/year is a worst case assessment. The typical frequency is 1x/3 years. For risk assessment purposes the worst case of 1x/year was assumed.

- **With regard to the reprotoxicity**: risk characterisation ratios were determined for the relevant activities. Both the inhalation and the dermal routes of exposure were taken into account.

Table 59: Overview of RCRs per operator type

RCR* per operator type	RCRs
production operator performing the refilling activity (with PPE)	0.00061
production operator performing the sampling activity (with PPE)	0.00029
production operator performing preparations for maintenance (with PPE)	0.00029
production operator *when* performing *both* the refilling and sampling activity on one day (with PPE)	0.00090 (sum of 0.00061 + 0.00029)

*RCR combined for the inhalation and dermal route of exposure

- Based on the RCRs presented, it can be concluded that the exposure is adequately controlled with regard to the reprotoxicity endpoint.

In conclusion

This application for authorisation meets the criteria as proposed by the EU Commission for the application for authorisation for low volume uses (volume < 100 kg per year):

- Volume < 100 kg/yr: the typical volume is 60 kg over 3 years, with a worst case maximum of 90 kg/yr;
- The volume limit covers all uses of the same substance by the same legal entity;
- The application for authorisation is made by the downstream user for his own use, not for a use down his supply chain;
- There is no consumer exposure.

However, we emphasize that **all elements with regard to CSR, AoA and SEA of a standard dossier have been handled in full in this application for authorisation**, because the Implementation Regulation for authorisation applications for uses in low quantities has not come into force at the time of submission. Moreover, this application for authorisation provides all elements required and a detailed justification for a very long review period.

Also, the CSR demonstrates that the risks related to continued use are extremely low and hence the related monetary impact to human health and environment in the socio-economic analysis is also extremely low.
We compared the outcome of the CSR with the "fit-for-purpose" criteria as presented during the EU COM/ECHA Workshop on Streamlining applications for authorisation November 17th 2015[xiii]:

- **There is no consumer exposure** (cfr. C*riterion n°1*: *No consumer exposure*)
- **The maximum Excess Lifetime Risk (carcinogenicity) for a worker is 2.6:10,000,000** which is a factor of 1,500 below the proposed *Criterion n° 2* (*Excess Lifetime Risk of all exposure groups < 4: 10,000*).
- Activities (all industrial use) only take place sporadically (one to 4 times per year)
- Maximum 8 operators are involved per year to perform the required activities.
- With regard to reprotoxicity, adequate control has been demonstrated. Indeed, the max. RCR is 0.00090, i.e. when the operator would perform both the sampling and refilling task in one day
- **There is negligible or no exposure to environment** and therefore **there is no exposure to man via the environment** (cfr. *Criterion 3*: *Excess Lifetime Risk to man via the environment < 4:100,000*).
- **The scale, also called the additional cancer cases**, **is 0.000001160** which is a factor of ca. 70,000 below the proposed *Criterion 4* (*Scale = additional cancer registrations = Σ(Excess Lifetime Risks x # people) < 0.08*[xiv]*).*

[xiii] http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/workshop-on-streamlining-applications-for-authorisation, presentation by Mrs. Elke Van Asbroeck

[xiv] The value of 0.08 corresponds to a human health cost (assuming fatal cancer) of 400,000€ over 40 years, or 10,000€ per year.

Meeting the “fit-for-purpose” criteria results in a very low risk to human health and the environment and hence to a very low impact in the socio-economic analysis. It demonstrates that **the emissions are indeed minimized**. In this particular case, the extremely low risk associated with the continued use of the substance results in an impact as close as ever possible to zero (€4 over 40 years, or €0.11 per year for fatal cancer cases). The risk assessment is presented in detail in the CSR, while the monetaray impact assessment is explained in detail in the socio-economic analysis.

We also note that the applicant had requested an exemption for this use on the basis that there is negligible exposure. The answer to the request is still pending. Hence, the applicant has decided to submit this “safety-net” application for authorisation, in which it is demonstrated, on the basis of measurement data, that the exposure to workers, environment and man via the environment is indeed negligible.

We conclude that this application for authorisation constitutes **an exceptional case**, **because the risk and hence the cost to human health and environment is as close as ever possible to zero**.