REQUEST FOR ADDITONAL INFORMATION

Legal name of applicant(s):	Neoperl GmbH
Submitted by:	Neoperl GmbH
Date:	15 June 2021
Substance:	Acid generated from chromium trioxide and their oligomers, EC 231-801-5, 236-881-5
Use title:	The use of chromic acid in the functional electroplating of brass-made sanitary articles with the specific purpose of obtaining a final Cr(0) coating that provides a surface with high durability and chemical resistance.
Use number:	Use 1
Communication Number:	AFA-C-2114556836-35-01/F
Submission Number:	KB817823-47

	ECHA Request	Applicant Response
	Administrative questions	
1	The file seems to be copy protected, could you provide non-copy protected versions so as the facilitates the rapporteur's work in drafting the opinions?	Please find versions of the non-copy protected files in the confidential folder accompanying the responses. These files have been unprotected as requested.
	RAC Questions	
1	In the assessment of exposure of humans via the environment, you consider that 50% of the air emissions contribute to the wastewater Cr(VI) contamination. a) Please elaborate on the justification for assuming a 50% deposition from air to wastewater, and indicate the origin of this assumption. Please explain more specifically why 50% aerial deposition are used. As is noted in the CSR, atmospheric Cr(VI) containing particles can be transported by the wind, before they fall or are washed from air onto the land and water surface. However, there is no reasonable justification on the selection of 50% of the air emission. b) As worst case, please provide updated calculation spreadsheets for exposure (and hence the resulting excess risk) assuming 100% of the air emissions contributes to the wastewater contamination. c) Depending on the air emissions percentage, the values would be different.	**a)** "…Chromium (VI) compounds are not volatile and so are found in the atmosphere associated with aerosols or particulate matter. In the atmosphere, chromium (VI) can be reduced to chromium (III) if suitable reductants are present, however it is likely that in most situations, chromium (VI) will be relatively stable under the conditions present in the atmosphere. The chromium present on particulate matter and in aerosols can be transported to land surfaces via wet and dry deposition…" Source: European Union Risk Assessment Report; Volume 53 (CHROMIUM TRIOXIDE, SODIUM CHROMATE, SODIUM DICHROMATE, AMMONIUM DICHROMATE AND POTASSIUM DICHROMATE); 2005 "…The transport and partitioning of particulate matter in the atmosphere depends largely on particle size and density… The rates of wet and dry deposition are dependent upon several factors, including particle and aerosol size distribution… The mass mean aerodynamic diameter (MMAD) of chromium aerosols or particulates emitted from several industrial sources are ≤10 µm and it has been estimated that chromium containing particulates emitted from these industrial sources can remain airborne for 7–10 days and are subject to long-range transport…" Source: Toxicological Profile for Chromium; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service Agency for Toxic Substances and Disease Registry; September 2012 "…Particles with aerodynamic diameters of <20 µm can remain airborne for extended periods of time and can be transported considerable distances from emission sites…" Source: Chromium Katherine S. Squibb, Elizabeth T. Snow, in Handbook of Hazardous Materials, 1993 Estimates of atmospheric half-life for Cr(VI) reducing to Cr(III) range from 16h to 4.8 days. Source: Chromium (VI) Handbook; Independent Environmental Technical Evaluation Group (IETEG); Jaques Guertin et al.; 2005

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<td>Wastewater discharge plus 100 % of the air emission (0.1765kg/a + 0.2415 kg/a = 0.418 instead of 0.2973 Cr(VI) kg/a). Thus, further calculations of excess cancer risk should be updated accordingly.</td>
<td>
A 100 m radius was chosen for calculation of human via environment based on REACH guidance R.16. The concentration from the point of source will significantly decrease exponentially with every additional meter away from the point source due to the facts stated in the literature cited above. It is assumed that the main part will be transported over the distance of 100 m and will continue decrease over the distance. Therefore, based on a worst case decision 50% of the air emissions is used for calculation. However, there is no calculation justifying the selection of 50% of the air emission.

b) and c) Updated calculations assuming 100% of the air emissions contribute to the wastewater contamination; 0.418 instead of 0.2973 Cr(VI) kg/annum – please see below:

Human via the Environment - Fish
PEClocal/oral,predator = $2.03*10^{-4}$ µgCr(VI)/l * 1 l/kg * 2 = $4.07*10^{-4}$ µg/Cr(VI)/kg wet fish
Daily human intake via fish:
$4.07*10^{-4}$ µg/Cr(VI)/kg * 0.115 kg/d / 70 kg= $6.68*10^{-7}$ µg Cr(VI)/kg bw/day

Human via the Environment – Drinking water
Daily human intake via drinking water:
$2.03*10^{-4}$ µgCr(VI)/l * 2 l/d / 70 kg = $5.81*10^{-6}$ µg Cr(VI)/kg bw/day

Humans via Environment – PEC$_{local}$

<table>
<tr><th>Human via Environment – PECs</th><th>Local</th></tr>
<tr><td>Oral, contributions from drinking water</td><td>$5.81*10^{-6}$ µg Cr(VI)/kg bw /day</td></tr>
<tr><td>Oral, contributions from fish</td><td>$6.68*10^{-7}$ µg Cr(VI)/kg bw/day</td></tr>
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This yields an excess cancer risk from human via environment exposure due to Neoperl chrome plating activities of:

Excess risk for local population =
($5.81*10^{-6} + 6.86*10^{-7}$) µg/kg bw/day * $8*10^{-4}$ µg/kg bw/day = $5.18*10^{-9}$.

Hence, the potential intestinal cancer cases from oral uptake of the (local) general population is $9.48*10^{-5}$.

As can be seen in the table below, updated calculations with 100% from air emission for concentration / risk are in the same 10^{-x} range compared to the calculations using 50% from air emission:

<table>
<tr><th>Endpoint</th><th>100% water + 100 % air emission</th><th>100% water + 50 % air emission</th></tr>
<tr><td>PEClocal</td><td>$2.03*10^{-4}$ µg/l</td><td>$1.45*10^{-4}$ µg/l</td></tr>
<tr><td>PECoralpredator</td><td>$4.07*10^{-4}$ µg/kg</td><td>$2.89*10^{-4}$ µg/kg</td></tr>
<tr><td>Daily intake via fish</td><td>$6.68*10^{-7}$ µg/kg bw/day</td><td>$4.75*10^{-7}$ µg/kg bw/day</td></tr>
<tr><td>Daily intake via water</td><td>$5.81*10^{-6}$ µg/kg bw /day</td><td>$4.13*10^{-6}$ µg/kg bw /day</td></tr>
<tr><td>Excess risk local population</td><td>$5.18*10^{-9}$</td><td>$3.69*10^{-9}$</td></tr>
<tr><td>Excess cancer cases Müllheim</td><td>$9.48*10^{-5}$</td><td>$6.75*10^{-5}$</td></tr>
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Separate spreadsheet with updated calculations for HvE will also be provided.
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<td>Release via exhaust air. In Table I-1 (Annex I of CSR):

a) Please clarify why concentration of Cr(VI) in air emissions data from 2019 was not</td>
<td>a) Regular air measurements take place once a year. The measurement in 2019 was in February. The main reconstruction of the air system started in December 2018. However, to achieve the targeted cleaning performance, various optimisations were needed. Overall, all these optimisation measures were running until the end of 2019. Optimisation measures included a new fan motor, new silencer, changed demister panel (Demisterkissen) requirements, cleaning of the old pipelines,</td>
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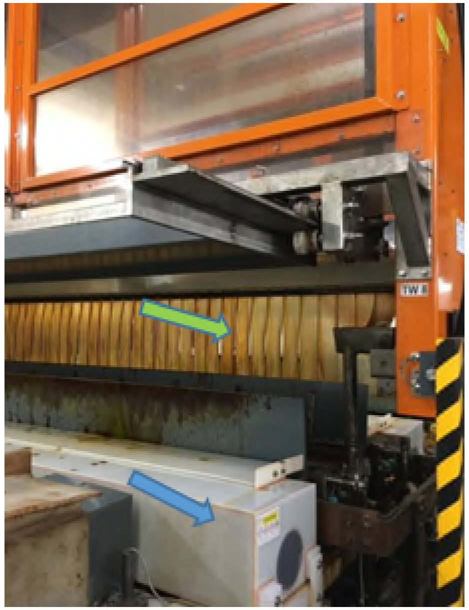
	taken into account, and only data from 2020 was used. As noted in CSR, the new exhaust ventilation system has been in place since 2019 and the applicant has conducted measurements on air emission on a regular basis from 2019. Therefore, data from this year should be taken into account. b) Please provide the limit of detection and the limit of quantification of the method.	measurement of the air volume and air speeds, adjustments to the cross-sections, and others. Thus, the values for air emission obtained in 2019, were not taken into account for the calculations, because they do not reflect the current situation on the applicants´ site. As can be seen in Table I-1 of Annex I of the CSR, the improvements are reflected in the reduction in air emissions from 2015 to 2019 and from 2019 to 2020. The decreased value from 2015 to 2019 can be attributed to the main reconstruction that took place in December 2018 and the decreased value in 2020 reflects the additional optimisation measures that were carried out in 2019. **b)** The limit of quantification of the method is 0.4 µg/m3. The limit of detection is not explicitly stated for this method, but is usually in the order of 1/3 of the limit of quantification.
3	Release via wastewater. In Table I-3 (Annex I of CSR): a) Please explain why concentration of Cr(VI) in wastewater emissions differ so much between years. For example, in 2016 and 2019, Cr(VI) in wastewater was equal or below the detection limit (0.005 mg/L). However in 2017 and 2018 a significant increase was observed (up to 0.025 mg/L). The annual amount of Cr(VI) used in 2015 to 2019 was however the same. Similarly, it seems illogical that the used amount is almost double in 2020 but the concentration of Cr(VI) in wastewater is significantly less than concentrations obtained in 2017 – 2018.	**a)** All values are below the legal threshold of 0.1 mg Cr(VI)/L according to the German Waste Water Ordinance ("Abwasserverordnung, AbwV"). The majority of the available monitoring data demonstrate concentrations of Cr(VI) below the respective detection limit (0.005 mg Cr(VI)/l), and the remaining results are below or equal 0.03 mg Cr(VI)/l. There is no known reason for the values above the detection limit but all values are significantly below the legal threshold. The increase of the Cr(VI) amount in 2020 was based on an substitution of the electrolyte in the chrome bath. This was due to an increased contamination of the chrome bath with “foreign” metal ions (e.g. copper, zinc), caused by fallen product parts from the rack into the chrome bath. The difference in the chrome bath had to be concentrated with new Cr(VI). The discharge into the wastewater was not increased because the amount of substituted material was disposed of via a licensed contractor company (Remondis GmbH).
4	High efficiency of respiratory protective equipment.	**a)** Protection factor is based on the used class 3 filter, which refers to an efficiency of 99.95% according to the EN standard. **b)** Self-Test: By sealing the aspiration port, creating a vacuum.

	a) Please clarify if this efficiency refers to a nominal or assigned protection factor. b) Please explain what measures you implement to achieve 99.95% efficiency of the respiratory protective equipment.	
5	Efficiency of the local exhaust ventilation. a) Please clarify the characteristics, positioning and efficiency of the local exhaust ventilation in the different WCS, when used.	**a)** Bath rim local exhaust: Chrome baths have local exhaust ventilation with 8.000 m3/h. During the electroplating process, the baths are closed to ensure the best possible suction via the local exhaust ventilation. All chrome baths have bath rim exhausts that are connected to the exhaust system. Blue arrows in Figure 1 indicate the position of the bath rim local exhaust ventilation on both sides of the chrome baths. *Figure 1*: Position of the bath rim local exhaust ventilation 

		Conveyor system local exhaust ventilation: Above the chrome plating baths, the conveyor system is encapsulated with local exhaust vented to the central air treatment unit (carriage suction). This prevents the release of chromic acid vapours when the racks are lifted out of the bath. Blue arrows in Figure 2 indicate the position of the bath rim local exhaust ventilation. Green arrow indicates plastic straps that direct the exhaust air from the chrome bath into the conveyor. White arrow indicates the exhaust duct into which the exhaust air from the conveyor is sucked. *Figure 2*: Conveyor system encapsulated with local exhaust  

6	You claim that the final articles do not contain Cr(VI) anymore. a) Please explain how you ensure 100% efficiency of the rinsing of final articles, as claimed.	**a)** Cascaded water rinsing to remove excess electrolyte in several subsequent steps to ensure 100% efficiency of rinsing of final articles. There is no drag-out of contaminated liquids with the product. Multiple-stage cascade rinsing implemented: 1 • Rinse unit 2 • Rinse unit 3 • Rinse unit 4 • Reduction Bath 5 • Rinse unit 6 • Ultrasonic unit 7 • Rinse unit (Bidest. water) 8 • Puls blow Dryer
7	Workplace measurements for waste and wastewater treatment scenario (WCS 5). a) Please explain how the provided measurements cover this task, if the work is located in a different area (basement). b) Please also clarify how the sampling under WCS 5 relates to the measurement of wastewater concentrations as presented in ECS1.	**a)** Plating operators are sharing the work and exposure to Cr(VI) in the WCSs. The task wastewater treatment (WCS5) is in part within the work shift of the plating line operator. For this task, the plating line operator moves to the basement. For the plating line operator, personal exposure measurements are conducted, thus, the measurements also include WCS wastewater treatment. Static measurements are also conducted to monitor the background concentration of Cr(VI) at the waste water treatment plant. The static measurements are below the personal measurements from the plating operators, thus the personal measurements are used for risk calculations. **b)** Sampling is carried within the German self-control regulation (*Verordnung des Umweltministeriums über die Eigenkontrolle von Abwasseranlagen (Eigenkontrollverordnung - EKVO*)) which is required according to §61 of the Water Resources Act. Each treated wastewater batch is tested, and the parameters to be checked including Cr(VI) are documented in the operating log. Wastewater can only be discharged if the values are in compliance with required limit values.

8	Sampling and maintenance tasks: based on the description of WCS 6 and 9, elaboration is needed on the tasks description and calculations. a) Please explain how sampling is done in WCS 6. b) Please explain in more details what each workers do in WCS 9 and what measures are implemented to reduce workers exposure. c) In WCS 9, please distinguish the calculations for each type of workers based on the task they do, eg workers who perform removal of sludge and chromic acid solution, cleaning, other activities. Please elaborate why you conclude that the excess risk in WCS 9 is much lower than for tasks for which measurements (static or personal) have been used instead of modelling. d) In WCS 9, please explain how the chromic acid solution is stored during the cleaning of the baths and then reused, and what measures are implemented to reduce workers exposure.	**a)** The worker has to wear adequate PPE including respiratory mask and the plant must remain in a safe condition (no plating activity during sampling). The bath is opened from the control panel and the sample is taken using a telescopic arm and then transferred in a closed flask to the laboratory. **b)** 1. Pump out chromic acid into IBCs -- *Internal worker* - Drum pump is used to pump chromic acid from the bath into IBCs. One worker is operating the drum pump and another is by the IBC standing nearby / in visual contact. Duration of activity: 1 to 3.5 hours 2. Removing sludge and the remaining chromic acid from the baths – *External company* - Climbing inside and removing it manually. For removing the sludge, a rubber blade is used. The residues in the bath are rinsed out to clean the bath. The sludge is stored in drums. Liquids are sucked into IBCs. 3. Removing and cleaning of bath rim ducts and drip trays – *External company* - Bath rim ducts and drip trays are placed on the ground of the cleaned bath and rinsed 4. Functional check for the local exhaust ventilation – *Internal worker* - Functional test via control panel 5. Refurbishing of fly bars and handling systems and inspection and replacing (if necessary) of anodes -- *Internal worker* - Tasks conducted in the cleaned bath 6. Refilling of chrome bath -- *Internal worker* - Duration of activity: 1 to 3.5 hour 7. Control of pump performance -- *Internal worker* - Functional test via control panel

		Duration of activity:
		External company
		Step 2 and 3: ***8 hours***
		Internal worker
		Step 1: *1 – 3.5 hours*
		Step 4: *0.25 hour*
		Step 5: *0.5 hour*
		Step 6: *1 – 3.5 hours*
		Step 7: *0.25 hour*
		Total: ***max. 8 hours***
		Measurements to reduce workers exposure: - Respiratory protection: Full-face mask (CL3 EPDM, Filter: M45x3 A2B2E2K2Hg P3 R D, with 99,95 % efficiency) - Dermal protection: Protective clothing (long sleeves) and chemical safety gloves (EN 388, EN 374-5) - The maintenance area including the entire disposal route is protected with PVC foil that is disposed of via the licenced external company. **c)** Calculation can be displayed in internal and external workers. Indeed the calculations need to be adjusted, because it is not 4 hours for each (internal and external worker) per session, it is 8 hours for each per session. Thus the adjustment factor for frequency changes from *“8 hours”* (= 4 hours x 2 times per year) to *“16 hours”* (= 8 hours x 2 times per year). Please see the corrected values in the table below:

Worker	Route of exposure and type of effects	Method of assessment	Exposure conc. (µg/m³)	Exposure value corrected for PPE* (µg/m³)	Exposure value corrected for PPE and frequency# (µg/m³)	Excess Lifetime Risk
internal worker	Inhalation Local Long-term	ART	12	0.006	4.90×10^{-5}	1.96×10^{-7}
external worker	Inhalation Local Long-term	ART	12	0.006	4.90×10^{-5}	1.96×10^{-7}

*Full face mask with 99.95% efficiency
#Adjustment for frequency: 16 hours per year represent 0.82% of the workday.

As can be seen in the table below, the exposure concentration calculated with ART are not lower than the monitoring data available. The ART-derived exposure concentrations are higher than the monitoring data because workers under WCS 4, 8 und 9 can be exposed to the highest level of exposure during these activities.
Excess risk in WCS 9 is much lower than for tasks for which measurements are available because of the adjustment factors (please refer to the third column in the table below):

WCS	Description	Method of assessment	Exposure conc. (µg/m3)	Excess risk	Adjustment factor
2 (risk includes scenario	Operation of automated plating line (including Delivery and storage of raw material, Waste and	Monitoring	0.05	2.00×10^{-4}	No

1, 5 and 6)	wastewater treatment and Sampling)				
3	Loading and unloading of racks	Monitoring	0.02	$8.00*10^{-5}$	No
4	Transfer of Cr(VI) – Decanting into dosing tanks and refilling baths	ART	15	$3.06*10^{-9}$	Full face mask Adjustment for frequency (12 minutes per year represent 0.01% of the workday)
7	Analysis of baths in laboratory	-	-	exempted	-
8	Regular Maintenance – Cleaning, repair and maintenance at the plating bath	ART	0.088	$5.24*10^{-10}$	Full face mask Adjustment for frequency (350 minutes per year represent 0.42% of the workday)
9	Rare maintenance – Overhaul of plating lines (internal and external workers)	ART	12	$1.96*10^{-7}$	Full face mask Adjustment for frequency (16 hours per year represent 0.82% of the workday)

The updated values for WCS9 have no significant influence on the combined potential lung cancer risk and the total excess cancer (please refer to answer of question 9 d) below).

d) The chromic acid is pumped into IBCs. The IBCs are closed and stored nearby the chrome bath during the cleaning process. The containers are new and approved for chromic acid. After filling, the IBCs are closed. The storage area / maintenance area is protected with PVC foil.

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<td>There are a number of inconsistencies in the reporting of the frequencies, durations, temperatures, number of workers. It is also unclear what tasks workers (especially plating operators) do.

a) Please clarify the durations and frequencies for WCS 2 in relation with the other scenarios involving plating operators.
b) Please clarify what tasks exactly were performed by workers when the personal measurements (Table II-1) were done, as these measurements are used to calculate excess risks for WCS 2 but also WCS 1, 5, 6.
c) Please clarify the number of workers under each WCS, and ensure consistency between the CSR and the SEA.
d) Please clarify the frequency of refilling the baths (WCS4) and explain how the frequency relates to the number of baths, volumes and concentration of substance in baths.
e) Please clarify the temperatures in WCS 2 and 6</td>
<td>a) Overview of duration of activity and frequencies for WCSs involving plating line operators:
<table>
<tr><th>WCS</th><th>Description</th><th>Duration of activity</th><th>Frequencies</th><th>Presented differently than in the CSR</th></tr>
<tr><td>1</td><td>Delivery and storage of raw material</td><td><0.5 hour</td><td>2 – 4 times / year</td><td>no</td></tr>
<tr><td>2</td><td>Operation of automated plating line</td><td>5 – 10 minutes / shift</td><td>daily (5 days / week)</td><td>5 – 10 minutes / shift (3 shifts / week)
Deleted: “3 shifts/ week”, to avoid misunderstandings. The Frequencies is stated per task. Added for more clarification: “daily (5 days / week)”</td></tr>
<tr><td>4</td><td>Transfer of Cr(VI) – Decanting into dosing tanks and refilling baths</td><td>1 -2 minutes</td><td>6-9 times / year</td><td>Frequency: 4-6 times / year
Changed to “6-9 times / year”, please see also answer 9 d) below.</td></tr>
<tr><td>5</td><td>Waste and wastewater treatment</td><td>0.5 hours</td><td>2 – 3 / day (5 days / week)</td><td>Added for more clarification: “daily (5 days / week)”</td></tr>
<tr><td>6</td><td>Sampling</td><td>0.5 hours</td><td>1 - 2 / month</td><td>no</td></tr>
<tr><td>8</td><td>Regular Maintenance – Cleaning, repair and maintenance at the plating bath</td><td>10 minutes</td><td>1 / week</td><td>no</td></tr>
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9	Rare maintenance – Overhaul of plating lines – internal worker	8 *hours*	2 *times/year*	no
9	Rare maintenance – Overhaul of plating lines – external worker	8 *hours*	2 *times/year*	no

b)

	June 2020	**October 2020**
Sampling location / Work activity	**Description of activity**	**Description of activity**
Personal – Plating operator	- Operating the plating line - Waste water treatment - Sampling - Storage room activities	- Operating the plating line - Waste water treatment - Sampling - Refilling chrome bath - Storage room activities - Maintenance work (Filter change (wastewater treatment plant), removal and readjustment of level controller (chrome bath))

c) Total number of employees in the WCS is 39. The SEA report has considered 39 workers to assess the Humans Health impacts.

		d) WCS4 - Frequency of use needs to be changed from *4-6 times / year* to *6-9 times / year.* Thus, the annual hours worked per employee need to be updated from *12 minutes / year* to *18 minutes / year*. Thus, the adjustment for frequency in calculation changed from *0.01 %* to *0.02%* of the workday. Changes result to the following updated calculations:

WCS	**Excess risk**	**Number of affected workers**	**Excess risk per WCS**
2 (risk includes scenario 1, 5 and 6)	2,00E-04	4	8,00E-04
4	4,59E-09	4	1,84E-08
8	5,24E-10	4	2,10E-09
9	9,80E-08	4	3,92E-07
Combined potential lung cancer risk			**8,01E-04**
Combined potential lung cancer risk - As stated in the CSR			**8,00E-04**

WCS	**Excess risk**	**Number of affected workers**	**Excess cancer cases**
2 (risk includes scenario 1, 5 and 6)	2,00E-04	4	8,00E-04
3	8,00E-05	26	2,08E-03
4	4,59E-09	4	1,84E-08
7	-	-	0,00E+00
8	5,24E-10	4	2,10E-09
9	9,80E-08	13	1,27E-06

		Total excess cancer cases **2,88E-03** The updated values for WCS4 marked in yellow and WCS9 (please refer to answer of question 8 c) above) marked in blue have no significant influence on the combined potential lung cancer risk and the total excess cancer cases (marked in green). **e)** WCS2: Worker contributing scenario 2 - Operation of automated plating line (PROC13) • Room temperature: 15 - 40°C • Process temperature: Above room temperature (44°C) WCS6: Worker contributing scenario 6 - Sampling (PROC8b) • Room temperature: 15 - 40°C °C • Process temperature: Above room temperature (44°C)
10	In the Analysis of Alternatives (AoA) Section 3.1 in page 12 it is written that “The applicant uses an aqueous solution of chromium trioxide (chromic acid H2CrO4) 50 % …” whereas in page 14 it is written “chrome plating …. concentration of 100-400 g/l CrO3 …”. a) Please indicate the correct % w/w concentration of CrO3 in the solution that is currently used for Cr6+electroplating as well as the % w/w concentration of all the other components in this solution (such as boric acid etc).	The applicant purchases an aqueous solution of chromium trioxide with a concentration of 50 % by weight. This purchased solution is used to (re-)fill the Cr(VI)-containing electroplating bath, which has a final concentration of [100 – 400] g/l CrO_3. The electroplating bath also contains 1 – 1,2 % H_2SO_4 and ca. 0,25 % of a wetting agent (Blank 1).
11	In AoA Section 6.1 it is written that the alternative Cr(III) electrolyte solution may contain Cr2(SO4)3 or CrCl3 as well as H3BO3 , buffering agents, ammonium salts.	a) The applicant had asked the providers of the electrolyte solution for information on the composition, but did not receive exact details regarding concertation and complete list of ingredients.

	a) Please indicate the exact % w/w concentration of all the components in the Cr(III) electroplating solution. b) Additionally, please present in a comparative table the time that the solutions for Cr(VI) and Cr(III) plating can be used continuously achieving the desired plating quality as well as any other important parameters. c) Would you consider it attainable to use a boric acid -free buffer for Cr(III) plating process, in order to reduce the overall dangerous properties of the mixtures used in plating procedure, according to CLP criteria?	b) The applicant expects that the use time for Cr(III)-based electrolytes is significantly lower compared to Cr(VI). As mentioned in the AoA, Cr(III) based electroplating often employs organic complexing and stabilizing agents. These will likely lead to a decomposition of the Cr(III) electrolyte solution and thus to a decreased use time. However, no detailed data can be provided, since Cr(III) has not been tested in a pilot industrial scale yet by the applicant. c) See AoA section 6.4: “Lately progress has been made on the developing agents to be used in the electroplating process instead of the boric acid. For example, the company Blank 2 developed boric acid-free liquid pH buffer, which shows good results when using it for the Nickel bath and is more environmentally friendly for the wastewater treatment. Another company Blank 2 also developed boric acid-free pH buffer and is getting first results of a year-long test trial.” The applicant will remain in communication with its potential suppliers for Cr(III)-based electrolytes to find boric acid-free solutions. Thus the applicant considers this attainable and intends to move to a boric-acid-free buffer as soon as is technically feasible and available on the market.
12	Please indicate what additional risk management measures could be implemented to eliminate releases to zero and minimise workers exposure even further. Please also provide an estimation of the costs it would entail.	The plant has been in operation since the 1990s and has been continuously improved to minimise workers exposure. Among others, process water is recycled and an improvement of the exhaust ventilation system took place in 2019 and 2020 with the aim of reducing air emission of Cr(VI) by half of the required limit value (0.15 g/h and 0.05 mg/m^3, respectively) set out in the German “ Technical Instructions on Air Quality”. Currently, additional risk management measures could be possible with a new construction of the plant. However, the applicant regularly checks whether it is possible to implement additional measures to further improve the existing plant according to the state of the art.
Questions on the Analysis of alternatives (AoA):		
1	Please clarify the substance that this application concerns because a) in AoA cover page it is written Chromic acid EC No:231-801-5 CAS No:7738-94-5 whereas in Section 3.1 it is written chromium trioxide CAS No:133-82-0 and EC No:215-	The substance subject to authorisation is listed as entry number 17 in Annex XIV of REACH. The term “Acid generated from chromium trioxide and their oligomers” is the umbrella term for: - Oligomers of chromic acid and dichromic acid (no EC and CAS number available) - Chromic acid (EC No:231-801-5; CAS No:7738-94-5) - Dichromic acid (EC No.: 236-881-5; CAS No.: 13530-68-2) The cover page of the AoA will be corrected to align with SEA, SP and CSR.

	607-8. Furthermore, in SEA, SP and CSR cover page it is written Acid generated from chromium trioxide and their oligomers EC No:231-801-5 and 236-881-5. b) The use in CTAC use 3 you refer to as covering your current use, covers chromic trioxide and not chromic acid. c) Then make appropriate corrections where it is needed	In section 3.1 of the AoA chromium trioxide is indeed listed. This will be corrected and aligned with the CSR. Regarding Use of CTAC: as stated and explained in ECHA Q&A ID 0805, an AfA for chromium trioxide covers the use of chromic acids and their oligomers generated from adding chromium trioxide to water. The applicant purchases the aqueous solution of chromium trioxide from its supplier, who is covered by the CTAC application.
2	In the AoA there is information from the applicant's tests and the CTAC and the Lanxess AfA. Also, in Section 3.3.3 page 22 it is written that Neoperl started to test potential alternatives since 2008. a) Please present an overview, in a table or a real time calendar chart from 2008 up to 2021, of all the alternatives assessed by Neoperl -especially those named "Category 1"- i.e. the alternatives that were tested by Neoperl as well as those for which knowledge has been shared from other sources such as AfAs, BAuA report etc. and outline for each alternative the reasons that was not selected.	The applicant has not listed any category 1 alternatives. Only two alternatives were tested by the applicant: PVD and Cr(III). PVD-coated parts were tested for their corrosion resistance in 2014. Cr(III)-based tests are provided in detail in the AoA in section 6.2 of the AoA and in Annex I. We have summarised all test results in one table (Table I), which is provided in a separate document ("CrIII Test results Neoperl since 2008.docx") and can be found as confidential attachment to the request for additional information. We have also included the new test results described below for question 8. Please see the answer to the question below regarding selection of alternatives.
3	Regarding the assessment of "Category 2" alternatives and the Table 'Assessment of alternatives Category 2 listed in the AfA of	For all substances listed as Category 2 in **section 5.2** of the AoA a literature research has been conducted. The result of the literature research is summarised in the column "Update since 2015 (literature research)". The columns "Technical limitations" and "Other concerns" were taken from the CTAC application.

	CTAC for the sanitary section application' (in AoA Section 5.1.1 page 36) please clarify if: a) all alternatives have been also assessed by Neoperl as possible alternatives, either by literature research or from BAuA reports etc. b) the comments under columns 'Technical limitations' and 'Other concerns' express the reasons for discarding them.	As explained in the AoA, the main reason for discarding the Category 2 alternatives is that the applicant does not produce final goods, but provides semi-finished parts (i.e. components of an article) made according to customer specifications to a wide range of customers. It would be therefore infeasible for the applicant to change the substrate for sanitary parts and avoid electroplating process as such, or to choose an alternative, which would result in parts incompatible with those of the applicant's customers. Therefore, in close cooperation with its customers, the applicant focused its substitution efforts on Cr(III); who have either been granted authorisation or have applied for authorisation for Cr(VI).
4	Regarding the requirements and the quality standards that Neoperl products must fulfill: a) are they obligatory according to EU legislation (and if yes. please specify which standard is applicable)) b) and/ or other European or international standards (and if yes please specify which standard is applicable) c) or are they Neoperl internal standards?	The applicant is obliged to fulfil quality requirements as stated in the contract between Neoperl and each individual customer. These requirements follow national and/or international standards, such as: - Kesternich test (DIN 50018 - Salt spray test (AASS; DIN EN ISO 9227; ISO 10289) - Temperature resistance (DIN EN ISO 2819) - Surface defects (ASME A112.18.1-2005/CSA B125.1-05) - Adhesion (ASME A112.18.1-2005/CSA B125.1-05; ASTM B571) - Plating thickness (DIN EN ISO 1456; DIN 53100)
5	In AoA Section 5.1.1, the Hexigone and the Cuptronic technologies are discussed. Could you please explain why you consider these technologies, when compared to Cr(III) plating, not suitable for the electroplating processes for the Neoperl products?	The Cuptronic technology aims to replace Cr(VI)-based etching of plastic substrates. The applicant uses brass parts and no etching is required. Publicly available information describe that the Hexigone technology is suitable for "automotive, architectural, aerospace and marine industries". Sanitary equipment is not mentioned. Based on the available information it can be assumed that adhesion of the Hexigone product is not sufficient to fulfil the requirements of the drinking water ordinance.
6	Would it be possible to provide information on whether your competitors are already using alternatives to Cr(VI) plating of parts for sanitary industry and if they are placing on the market parts produced by Cr(III) plating?	The applicant has few competitors in Europe. On a global level, Neoperl holds 70 % of the market. The applicant has no information whether competitors provide products manufactured using a Cr(VI)-free process. . The applicant would like to point out that they are working on Cr(VI)-free solution. However, they are providing semi-finished parts to their customers, who are still specifying products made from Cr(VI).

7	Since the initial sample testing by different customers has already started, would it be possible to provide the current feedback from your customers regarding the performance and the acceptability of the products produced with Cr(III) plating?	The applicant is in communication with selected customers to find suitable dates for the inspection of Cr(III)-plated parts. However, so far no suitable date was arranged yet. The applicant will continue this process.
8	In AoA Section 6.6 page 56 it is written: ‘Trivalent electroplating is not there yet, failing at most of the corrosion resistance tests…..even recently’ and in SP Section 3.2 page 18 it is written: ‘…the samples failed in terms of protection against corrosion……The focus behind is to avoid requiring a custom Cr(III)-electroplating process for different types of items, but rather to achieve a unified electroplating process for the entire product portfolio…’. Please present –if available- any new information or evidence that reduce the considerable uncertainty for the success of the corrosion resistance tests and the achievement of a unified electroplating process.	The applicant has received the test results of the external corrosion tests, which is provided in a separate document (“CrIII Test results Neoperl since 2008.docx”) and can be found as confidential attachment to the request for additional information (Tables II and III).
9	Please confirm that: a) In AoA Section 4 page 31 Table 8 should be read as Table 4-1 for Tonnage information b) In AoA Section 5 subsection 5.2 page 35 Table 9 should be read as Table 5-1 for Assessment of alternatives of category 2 c) In AoA Section 6.2 page 43 Table 6-5 should be read as Table 6-1	This is indeed an error in formatting. We will correct the references to sections and tables.

	d) In AoA Section 6.2 page 45 it is written section 3.3.4 but there is no such section; please indicate which section is meant e) In AoA Section 6.2 page 47 Section 3.3.1 should be read as Section 3.4.1 f) In AoA Section 6.3 page 50 Table 14 should be read as Table 6-4 and also in this table for Phase IV the duration should be corrected to 4 years as in the SP page 14 g) In AoA Section 6.4 page 54 Table 17 should be read as Table 6-6 h) In SP Section 3 page 13 Table 3-1 should be read as Table 2 i) In SP Section 3.2 page 17 Table 1 should be read as Table 2	
Questions on the Substitution plan:		
1	Since Phase II activities ‘Initial sample testing by customers’ and ‘Initial testing programs for corrosion resistance requirements’ end by the Blank 2 and Phase III activity ‘Start of customer approvals’ takes place Blank 2, please explain why there is lack of time and actions that could potentially reduce the approximately Blank 2 interval between Phase II and Phase III above-mentioned activities, although the customers’ approval is of critical importance. For example, would it be possible to produce the Cr(III) plated products at a contract manufacturing organization aiming to reach earlier to the customers’ approval for reasons of economy	Neoperl´s main challenge to implement the substitution of current Cr(VI)-base operations lie in the demand to meet the sanitary sector’s high standards and requirements demanded on the surfaces of sanitary products for decades, particularly those relating to corrosion and chemical resistance. In order to fulfil customers’ requirements using Cr(III)-based electroplating process, Neoperl is required to carry out customers approvals using the new in-house Cr(III)-based electroplating process, which can only to be set up after the new building construction is completed by Blank 2. Neoperl foresees that their customers will not be keen to undertake products approvals twice, i.e. one with an external Cr(III) electroplater (if any available) and once again with the Cr(III)-based process implemented at the Neoperl site. Quality is a very important matter and Neoperl and their customers operate in a highly competitive global market with non-EEA companies as well. As the investment into a new chrome plating facility based on Cr(III) within the EEA is a very significant expense for Neoperl (around Blank 2 of the annual group turnover), Neoperl would only proceed with the real costly steps of it (building new facility and purchase of equipment) when there is a certain evidence that the review period applied for would be granted and that the products would be accepted by their customers. From a financial point of view, Neoperl is simply not able to follow two different routes in parallel: i) investment into Cr(III)-based chrome plating

	of time and to ensure that they will continue to be your customers?	facility within the EEA and ii) as fallback option the preparation and execution of an investment into a Cr(VI)-based plant outside the EEA (the most likely non-use scenario).
2	Regarding the 4-year duration of Substitution Plan Phase IV: a) Would it be possible to increase production volumes and thus to produce earlier all the quantities of the Cr(VI) plated products projected in the contracts with your clients and stock them ready for delivery to your customers when needed, aiming to reduce the duration of this phase? b) Would it be possible along with the construction of the new plating facility to prepare a storage unit for the stocks of your products? c) Since there are similarities in Cr(VI) and Cr(III) plating processes, after fulfilling the production of projected Cr(VI) products, would it be possible to convert the existing Cr(VI) plating facility to Cr(III) plating facility, in order to increase the production of Cr(III) plated parts and thus to reduce the duration of this phase?	**a), b) and c)** On the one hand, Neoperl's electroplating plant is running at 100 percent capacity. This prevents to build-up an inventory. Given that, this would require to work towards building inventories, which does not suit the way the sanitary business operates for Neoperl. Neoperl supplies according to customer specifications, being reactive and adaptable to customer requirements. Neoperl´s customers' requirements are recognized to be volatile, which prevents Neoperl to estimate future demand with an acceptable degree of certainty. Although, Neoperl may be able to foresee future production volumes, it is not able to predict the different product portfolio items that will be demanded. Therefore, building inventories of Cr(VI)-electroplated items lacking information on the future demand will imply a very high risk to be assumed by Neoperl. To illustrate, building inventories would require (but not exclusively) to build a new warehouse, hire additional staff and increase raw material and production cost without having an stream on the turnover, which will heavily impact the cash flow and the financial position of the company. **Additional to c):** The Cr(III)-based operation requires more space than is available in a currently limited building area. Any conversion would require additional nickel baths, new chromium baths, drying equipment, ion exchanger systems, filter systems, changes in rack storage, additional formwork carriages, and new drive programs for the plant control system. Additional chemical treatment space would also be needed because the current treatment facility for Cr(VI) is not compatible with treating chemicals from a Cr(III)-based operation. Neoperl management has carefully considered these alternative options and has concluded that a new building to set Cr(III) facility is required. In parallel, customer needs are to be met at all times by the existing Cr(VI) plant.
3	Please explain what the implications would be of would be the implications in case an authorisation is granted with 7-year review period.	The authorisation of the existing Cr(VI)-based electroplating operations is strictly indispensable to ensure the economic affordability of the Cr(VI)-free conversion project. It is clear that the business cannot be supported by partial Cr(VI)-free items only. Accordingly, until the substitution plan has been completed in Blank 2, the applicant has no other alternative and must use its current Cr(VI)-

		based process at full capacity. A shorter than 10 years review would put the Cr(VI)-free implementation/substitution plan at risk. The Substitution Plan involves an investment in the region of € Blank 2 (€1 million - €50 million), a figure that is c.a. Blank 2 fold total annual net profit of the Neoperl GmbH and Blank 2 of the annual group turnover. The applicant is therefore applying for an authorisation for the period of time the business can reasonably expect to continue using chromic acid in the specific use. This time would allow the applicant to successfully implement a Cr(VI)-free electroplating process.
4	It is understood from the AoA and the SP that Neoperl cannot deliver to its customers Cr(III) plated parts without their approval. Do you have evidence available that supports this argument, for example a term describing this condition in the contracts with your customers, or any other relative documents such as letters or e-mails, to prove the applicant's engagement to this obligation?	Neoperl management is at the moment working to obtain clients\` declarations stating they request to be supplied with Cr(VI)- electroplated items. At the time of submitting the request for additional information, one declaration of the customer Blank 2 already arrived; other declarations have not arrived yet. Neoperl management commits to make these declarations available as soon as received. Neoperl will contact ECHA to discuss the best route to submit this additional information. Neoperl´s contracts with their clients do not explicitly refer to using Cr(VI)-electroplating, but rather the contracts order to fulfil quality requirements. As stated in the response to Question 4 of the AoA section above, these requirements follow national and/or international standards (please refer to Question 4 of the AoA section for details). Currently, Neoperl can only technically fulfil such quality requirements by employing their Cr(VI)-electroplating process. As describe in the Substitution plan the ultimate goal of Neoperl is to be able to fulfil to their clients with the same quality requirements using a Cr(III)-based process. Moreover, it should be mentioned that the majority of the Neoperl´s European customers hold their own authorisation for the use of chromium trioxide for sanitary applications (see AoA for further details). All applicants were either granted 12 years review period by the EU Commission or received recommendation for 12 years review period by ECHA. This means that the customers of Neoperl will continue to use chromium trioxide for their products until the end of the present decade and beyond. As Neoperl supplies items that are further assembly to Cr(VI)-electroplated components produced by the clients, there is a quality match restriction to be satisfied.

SEAC Questions		
Baseline and non-use scenario:		
1	Could you please clarify until which date Neoperl is covered by the CTAC Use3 authorization? And how the CTAC use-3 case is important for the baseline of your assessment (i.e. how does the CTAC use-3 application impact your non-use scenario?	The applicant understands that as from the date of the submission of responses to the requested additional information, the Commission has not yet published a decision on the review period for the Use 3 of the CTAC application. The applicant cannot know the period that the CTAC Use 3 will cover the use of the substance for their operations. The applicant has then decided to apply for their own individual application for authorization for a review period of 10-year, which will allow the completion of their transition towards Cr(III)-based operations and therefore moving away from the use of Cr(VI).
2	Could you please clarify further to what extent Neoperl at Mulleim is a Research & development, a production, logistics and distribution or an assembly site? What are (in details) the operations carried out at the Mullheim site?	Müllheim is mainly a production site. About 85 percent of the staff are directly or indirectly involved in production including other mandatory departments like Engineering, Logistics, Local Sales and Finance. Besides chrome electroplating plating, the main production activity is assembling of components. In addition, Müllheim is the location of some corporate functions like R&D, Product Management and IT.
3	Concerning the most likely non-use scenario, could you please better clarify if the plant in Mullheim will have to shut down completely or whether only the electroplating operations will have to close? Along the application this point is confusing since in some places the closure of the plant is evocated as NUS in other it seems that you are only talking about the CrVI-based operations. Could you please better clarify what are the reasons behind the need to maintain the building during ten years at Neoperl GmbH?	The most likely non-use scenario only considers that the Cr(VI) -based electroplating plant in Müllheim would be shut down and disassembled as it will became redundant. Subsequently the same electroplating process would be relocated outside of the EEA. A major consequence of relocating the entire production outside of the EU would imply the immediate redundancy of Blank 2 percent (1 to 25 percent) of Neoperl workers at Müllheim site, with the exception of head office, R&D, marketing and sales, all of which would continue operating. Although the assembly and electroplating plant in Müllheim would stop operating, the aforementioned commercial and management activities would remain. However, Neoperl's management has also considered that the risk of shutting down their electroplating operations and consequently attempting to relocate production to a non-EEA country may turn out to be insurmountable and therefore impacting to the extent that the business would have to be completely closed. Please note that analysis of impacts in the SEA has only considered the event of shutting down the Cr(VI) -based electroplating and assembly plant and not the closing of all operations at Müllheim. The reason for maintaining the building during 10 years is that the building may be used for other purposes than chrome plating if Neoperl have to shut down that part of operations, e.g. as rental warehouse for externals.

4	Could you please clarify if the tonnage range expected to be used all along the 10 years review period includes any foreseeable business growth?	The tonnages range applied for continued use has considered any foreseeable business growth. In other words, there is no anticipated increase in annual volume of use of Cr(VI) as applied for.
5	In page 13 of the SEA document, you indicate that for the OEM market there was a growth of Blank 2 per year during the last 10 years (2010-2019) while, in page 38, to estimate the economic impacts of the most likely NUS, you use for the future a growth rate of Blank 2 that you consider as being conservative. Could you please explain?	The text in page 38 is a typo and should read: “A conservative growth estimate was set at Blank 2 percent (1 to 10 percent) yearly to be in line with existing forecasts”. Please note that to estimate the economic impacts of the most likely NUS, a growth rate of Blank 2 (1 to 10 percent) percent was applied.
6	At page 43 of the SEA document it is stated that already in 2021, 15% of plating will be outsourced. Could you please provide the reasons for this?	To bridge the gap in production while new plants are established in Asia (most likely non-use scenario), Neoperl would be required to temporarily increase the outsourcing of Cr(VI)-electroplating of items to either EU or non-EU job shop platers. Neoperl currently outsources around Blank 2 percent (5 to 30 percent) of overall plating to job shop platers. In order to illustrate and estimate the loss of profit in the non-use scenario (relocation of operation to Asia), it was considered that during the first year of the relocation, the outsourcing will remain as current (i.e. Blank 2 percent). Later, during year 2 and 3 of the relocation, outsourcing should be required to increase 50 and 75 percent, respectively (as shown in Table 3-7 of the SEA report). The reason for stating year 2021 as the year of relocation start is to illustrate a relocation time frame only for the sake of the analysis. It should be note that the most likely non-use scenario (relocation of operation) would only be put in place if it becomes clear that authorisation will not be granted. .

<table>
<tr><th colspan="3">Human health impacts:</th></tr>
<tr><td>1</td><td>Concerning the monetisation of human health impacts

a) In the SEA, both values of 39 workers and 51 workers (4 in WCS2, 26 in WCS3, 4 in WCS5, 4 in WCS8 and 13 in WCS9) are indicated to be directly exposed please clarify which one is the exact figure?
b) Could you please elaborate what impacts are covered in your Human Health impact assessment? Do you cover: a. Only fatal cases b. Fatal and non-fatal cases?
c) If you covered only fatal cases, can you please update the assessment to include as well non-fatal cases?</td><td>a) Thirty nine workers were identified as potentially exposed to chromic acid at Neoperl plant (see CSR section 9.2), as described in SEA section 3.2.1 (page 35). The SEA report shows Table 3-2 “Summary of total combined occupational risk from the described scenario ES1 for the Use”, which was taken from the CSR report. This Table might have caused some confusion as if one sum up the total of workers listed in the Table gives 51 workers. However, some workers are assigned to more than one WCS.

Section 9.2 (page 29- 30) of the CSR offers a more comprehensive explanation on the approach taken for the occupational exposure. In total 39 employees are involved in the working scenarios covered. The emission source for nine employees is near field exposure, for 26 employees far field exposure and for four employees near and far field exposure. CSR Table 9-6 of the CSR gives an overview of the number of employees related to the workplace scenarios. Please see below.

CSR Table 9-6: Number of Workers Related to the Working Scenarios

<table>
<tr><th>Workplace Scenario</th><th>Use description</th><th>Number of workers involved</th><th>Number per Shift</th><th>Overlaps of employees</th></tr>
<tr><td>WCS1</td><td>Delivery and storage of raw material</td><td>4</td><td>2</td><td>-</td></tr>
<tr><td>WCS2</td><td>Operation of automated plating line</td><td>4</td><td>2</td><td>Same employees as listed under WCS1 “Number of workers involved”</td></tr>
<tr><td>WCS3</td><td>Loading and unloading of racks</td><td>25-30</td><td>4-6</td><td>4 employees, same as listed under WCS1 “Number of workers involved”</td></tr>
<tr><td>WCS4</td><td>Decanting into dosing tanks and refilling baths</td><td>4</td><td>2</td><td>Same employees as listed under WCS1 “Number of workers involved”</td></tr>
<tr><td>WCS5</td><td>Waste and wastewater treatment</td><td>4</td><td>1</td><td>Same employees as listed under WCS1 “Number of workers involved”</td></tr>
</table>
</td></tr>
</table>

WCS6	Sampling	4	1	Same employees as listed under WCS1 “Number of workers involved”
WCS7	Analysis of baths in laboratory	4	1	Same employees as listed under WCS1 “Number of workers involved”
WCS8	Regular Maintenance – Cleaning, repair and maintenance at the plating bath	4	2	Same employees as listed under WCS1 “Number of workers involved”
WCS9	Rare maintenance – Overhaul of plating lines	10	3 (per session)	4 employees, same as listed under WCS1 “Number of workers involved”
	Rare maintenance – Overhaul of plating lines (licenced external company)	3	3 (per session)	-
Total number of employees		**39**		

b) The humans health impact assessment considered only fatal cases.

c) RAC’s reference dose-response relationships for hexavalent chromium only refer to fatal cases of lung and intestinal cancer. However, for a more complete evaluation of the health impacts from continued use of chromium trioxide, the non-lethal cases might also be estimated.

The five-year survival rate for lung cancer is given as approximately 18.6%, while for colorectal cancer, the closest type to intestinal, it is approximately 64.5% [1]. IARC’s global cancer observatory gives similar numbers for lung cancer Europe, but a lower survival rate for colorectal cancer, as shown in Table 1 below

<table>
<tr>
<td></td>
<td></td>
<td>
Table 1: Cancer incidence and fatalities (projected 2018 data)
<table>
<tr><th></th><th>Mortality</th><th>Incidence</th><th>Mort/Inc.</th></tr>
<tr><td>Lung cancer</td><td>387,913</td><td>470,039</td><td>82.5%</td></tr>
<tr><td>Colorectal (intestinal) cancer</td><td>242,483</td><td>499,667</td><td>48.5%</td></tr>
<tr><td colspan="4">Source: IARC website - Cancer today [1].
Non-lethal cases are defined as those that the patient survives 5 years from the first diagnosis with cancer.</td></tr>
</table>
Applying the mortality rates from Table 1 to the excess mortality at the workplace gives an additional 6.10 x 10^{-4} non-lethal lung cancer cases. For HvE, there are an additional 1.01 x 10^{-4} non-lethal colorectal cancer cases and an additional 1.46 x 10^{-4} excess non-lethal lung cancer cases.

Please refer to the calculation spreadsheet attached as confidential file (Impact assessments_Neoperl.xlsx) for the updated humans health calculations, which includes non-fatal cases as well.

1. IARC website – Cancer today. Available online at https://gco.iarc.fr/today/online-analysis-table, accessed on 07 April 2021
</td>
</tr>
<tr>
<td>2</td>
<td>Concerning human health impacts via the environment, could you please provide more explanations on the exposed local and regional population? How many exposed people were considered in the impacts that you generically define as humans via the environment? Please provide separately the figures associated to these categories of people.</td>
<td>
The humans health impacts via the environment have been assessed according to the exposure and risks for the environment and humans via the environment described in the CSR section 9.2.1.3. Two routes of intake of Cr(VI) from the applicant`s activities by the general population have been considered: i) Oral Uptake by Drinking Water and Eating Fish and ii) Inhalation Uptake by Direct Exposure via Air Emissions (for further details refers to CSR Section 9.2.1.3 and RAC Question 1b and 1c above).

i) Oral Uptake by Drinking Water and Eating Fish

Based on a worst-case assumption drinking water sourced 100% from surface water [7] the concentration in (local) drinking water is 2.03*10^{-4} µg Cr(VI)/l. In Germany the background
</td>
</tr>
</table>

concentration of Cr(VI) in drinking water is between 0.06 and 0.51 µg/l (Stiftung Warentest, July 2019 [8]); UBA threshold < 0.3 µg/l [9].

The excess lifetime intestinal cancer risk for the general population for oral intake of Cr(VI) was determined by RAC [1] as:

Exposure to 1 µg/kg bw/day Cr (VI) relates to an excess risk of 8 x 10^{-4}

This yields an excess cancer risk from humans via environment exposure due to chrome plating activities of:

Excess risk for local population =
($4.07*10^{-4} + 6.68*10^{-7}$) µg/kg bw/day * $8*10^{-4}$ µg/kg bw/day = $5.18*10^{-9}$**.**

Müllheim has a population of 18,286 with a population density of 316 persons per km² [10].

Hence, the **potential intestinal cancer cases** from oral uptake of the (*local*) general population is **$9.48*10^{-5}$.**

ii) Inhalation Uptake by Direct Exposure via Air Emissions

The predicted exposure of the local population (PEC_{local}) from Cr(VI) in air is calculated from the release of a single point source (chromic acid scrubber stack) at the site. **Chromate concentration from other sources on the regional scale ($PEC_{regional}$) has been considered negligible**. Only the local exposure has been thus considered for the exposure via air emissions.

The applicant is situated in a business park. A 100 m radius was chosen based on REACH guidance R.16 Annex A.16 - 3.3.2 [7]. The concentration of Cr(VI) in air 100 m from the point source is in the 10^{-4} µg/m³ range. The concentration will significantly decrease exponentially with every additional meter away from the point source.

Application of the formula yields: The average concentration within 100 m distance of the source (using emission rate of 0.99 g/day):

Clocalair,ann = $1.85*10^{-4}$ µg Cr(VI)/m³

		The local concentration is below the ”target” air concentration of 1.7 ng Cr(VI) / m³, which was defined as acceptable level for neighbours living close to industrial and urban Cr(VI) emission sources. [11] The neighbourhood is characterized as follows: Industrial / business worker within 100 m radius: the applicant’s own site (622 employees), the building across the street to the east from the side, three buildings next to the applicants´ site to the south of the electroplating department and one building to the north of the site. Three buildings to the south are on the edge of the 100 m distance border, so for the “worst case” estimation, these are included in the calculation. This results in an estimation of 900 persons. **Local population**: It was estimated, that one of the buildings within the 100 m radius is used also as home for the business owner. This results in an estimation of 5 persons. **Total excess risk for neighbourhood:** Local population: $1.85*10^{-4}$ µg/m³ * 5 * $2.9*10^{-2}$ (lung cancer per µg/m³) **= $2.68*10^{-5}$ potential lung cancer cases** (based on 70 years of exposure; 24hr/day) Workers: $1.85*10^{-4}$ µg/m³ * 900 * $4*10^{-3}$ (lung cancer per µg/m³) **= $6.65*10^{-4}$ potential lung cancer cases** (based on 40 years of exposure; 8hr/day; 5 days/week) References from CSR report: [7] Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.16: Environmental exposure assessment; Version 3.0; ECHA; 2016 [8] Stiftung Warentest; https://www.test.de/Trinkwasser-im-Test-5049894-5049900/ (accessed March 2020) [9] Potentielle Schädlichkeit von Chrom im Trinkwasser. Einordnung der epidemiologischen Befunde zum Krebsrisiko nach Exposition von Populationen gegenüber Chrom(VI) im Trinkwasser und Vorschlag zur Ableitung einer Expositions-Risikobeziehung; Bericht zum Sondervorhaben des Umweltbundesamtes FKZ 363 01 399; Markus Roller; 2012

		[10] Landeskundliches Informationssystem Baden–Württemberg; https://www.leo-bw.de/detail-gis/-/Detail/details/ORT/labw_ortslexikon/8686/ort (accessed July 2020) [11] Bericht des Länderausschusses für Immissionsschutz (LAI) „Bewertung von Schadstoffen, für die keine Immissionswerte festgelegt sind - Orientierungswerte für die Sonderfallprüfung und für die Anlagenüberwachung sowie Zielwerte für die langfristige Luftreinhalteplanung unter besonderer Berücksichtigung der Beurteilung krebserzeugender Luftschadstoffe“; 61.0-06; 2004.
3	In Table 3-4 the human health impact assessment is derived using an excess risk of 7.20*10-5 for workers and 1.08*10-5 for human via environment. Where does these numbers come from? The excess risk seemed higher in previous tables (2.88*10-3 for workers and 7.56*10-4 for human via environment). Could you please provide detailed explanations?	The higher risk values are the total excess risk over 40 and 70 years, for occupational and HvE exposure, respectively. The lower values in Table 3-4 were adjusted for duration of exposure over the review period. However, while reviewing the calculations, it was realised that the excess risk in Table 3-4 was the annual excess risk. To calculate the excess cancer risk over the review period, one needs to multiply with the length of the requested review period, i.e. 10 years. The correct values are shown in the “HH Neoperl” tab in the accompanying calculations spreadsheet (Impact assessments_Neoperl.xlsx).
4	Could you please provide the spreadsheet with the calculation on human health impacts?	The spreadsheets (Impact assessments_Neoperl.xlsx) used for the calculations of humans health costs and the other SEA calculations are provided as confidential attachments to the request for additional information.
Socio-economic assessment:		
1	Please provide NON confidential ranges for all the socio-economic data that is reported to be confidential in the application. This will help	A new Public version of the SEA report has been produced, which shows the non-confidential ranges. This version is provided as attachment to this request for additional information.
2	For the cost items that are reported can you please clarify to which period they refer to and if they are annualised?	The cost items refer to a 10-year period (requested review period). Net present value (NPV) with a 4% discounted rate over 10 years was applied to annualised the cost items. The methodology employed in the report followed the European Chemicals Agency (ECHA) guidance for an SEA for an AfA.

3	Among the cost of relocation to China, it appears that “Electroplating equipment set up” is by far the largest cost item compared to e.g. the required investment of buildings and lands altogether. Moreover, does SEAC understands correctly that two different plots of land are going to be bought and two buildings are going to be built? Could you please provide further explanations on all these categories of costs?	The eventual relocation of operations to China would consider setting up a similar production facility as the one currently housed in Müllheim (Germany), where electroplating and assembly of items are carried in the same building/production facility for the sake of logistic and production efficiency. In China, Neoperl manufactures a full product range of hoses as well as assembling of aerators and other Neoperl products, however not covering the full product portfolio. This partial product portfolio produced in China currently requires the items to be electroplated at the Müllheim plant (Germany) and shipped to China for production completion. Besides, there is at present an injection moulding plant located in China. The facilities in China would require a significant upgrade to increase their capacity in order to take over the whole European production currently carries out in Müllheim (Germany). It is indeed anticipated that two different plots of land would be bought to build two buildings, one on each plot of land. The existing assembly line in China would be enlarge by building a facility of 1,500 m^2 on one of the new plots (500 m^2), while a brand new electroplating plant of about 3,000 m^2 (incl. basement) would be built on another plot of land (10,000 m2). For details, please see Table 3-6 of the SEA. The cost of the land purchase and two buildings construction is estimated in the range of € Blank 2 (€1 million to €10 million), while the cost of the Electroplating equipment set up and the automated assembly line is about € Blank 2.
4	SEAC considers that relocating production from Germany to China would, in all cases, involve relevant expenditures by economic actors within and outside the EEA. To assess whether the economic impacts included in your assessment would ultimately be incurred within the EU or not, SEAC would need to understand the breakdown of these costs, as well as the financial and organisational linkages between Neoperl GmbH, the Neoperl group based in Switzerland and the Chinese company operating the eventual new production lines under the most likely NUS. Could you please	Neoperl Holding based in Switzerland is the parent company of both Neoperl GmbH in Germany and Neoperl Far East in China. Therefore, Neoperl GmbH & Neoperl Far East (China) are 100 percent owned by Neoperl Holding.

	further elaborate on the final linkages between the Neoperl GmbH, the Neoperl group based in Switzerland and the aforementioned Chinese company?	
5	Could you please provide details of the calculations of the social costs?	Please find in the confidential folder the spreadsheet with the social costs calculation.
6	Could you please provide the spreadsheet with the calculation on socio-economic impacts?	Please find in the confidential folder the spreadsheet with socio-economic impacts calculations.

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

The confidentiality claims made in this report generally fall into two cases. Those cases and their justification are described below. Following that explanation is a summary table, which enumerates each instance of confidential information, which has been redacted in this report.

- **Blank 1**: Proprietary manufacturing information

  The details of how the applicant makes its products are confidential for the following reasons.

  - Demonstration of commercial interest. The details of product manufacture are closely held to prevent competitors from replicating procedures and procedures conditions. These details are only shared under strong non-disclosure agreements and are not made publicly available.
  - Demonstration of potential harm. If process information were to be revealed, competitors could try to copy the design and process, leading to loss of knowhow and market position. Even a portion of the full process information could be used to “reverse engineer” the process.
  - Limitation to validity of claim. This claim is valid indefinitely.

- **Blank 2:** Cost and time information

  - Demonstration of commercial interest. Information on the cost and time to substitute Cr(VI) could be used to calculate the applicant’s production cost and Cr(VI)-free products forecasted availability, which could be used by competitors to gain a market advantage or by suppliers to drive up the value of crucial materials. This also applies to historical investments incurred by the applicant as well as business performance figures, applicant´s market position, applicant client’s names and suppliers.
  - Demonstration of potential harm. Disclosure of the cost and time of substitution could harm the applicant’s business by giving insights to competitors and revealing potential vulnerabilities to suppliers.
  - Limitation to validity of claim. This claim is valid indefinitely.