

REQUEST FOR ADDITIONAL INFORMATION

Legal name of applicant(s): Neoperl GmbH

Submitted by: Neoperl GmbH

Date: 25 August 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-2114565700-51-01/F

Submission Number: KB817823-47

	ECHA Request	Applicant Response
RAC Questions		
1	For static measurements, the quantitation limit of the method is given as 0.25µg Cr(VI)/sample. Can you clarify the volume of a sample? If it means 0.25µg Cr(VI)/m ³ , it is in discrepancy with the results reflected in the Table II-1 being much lower. Can you please explain the difference?	<p>The quantitation limit of 0.25µg Cr(VI)/sample is related to the analysis method used to analyse the amount of Cr(VI) of the filter sample obtained from the measuring devices used for the workplace measurements.</p> <p>The concentration values stated in Table II-1 are calculated based on the results obtained from the filter analysis [µg/sample] and divided by the sample volume [m³].</p> <p>For example: $0.25 \mu\text{g}/\text{sample} / 4 \text{ m}^3 = 0.0625 \mu\text{g}/\text{m}^3$</p> <p>This is the reason why the values in Table II-1 are lower than the quantitation limit of the analytical method.</p>
2	Please explain the difference between measurements listed in the Table II-1 "Static - Chrome bath" and "Static – Behind the chrome bath (behind plastic curtain)".	<p>The "Static - Chrome bath" measurements were conducted at the workplace of the plating line operators. Please see Figure 9 - 11 on page 43 in the CSR.</p> <p>The location where the "Static – Behind the chrome bath (behind plastic curtain)" (please refer to Figure 9 - 15 on page 53 in the CSR) measurements were done is not a workplace of the plating line operators. In this area "behind the chrome bath (behind plastic curtain)", maintenance work can sporadically be necessary.</p>
3	Please provide more details to describe working operations within WCS 2. Are the direct inspections of plating performed only during three shifts per week?	<p>In the automatic line, the racks with the parts move at a predefined pace through the different baths. The electroplating line and catwalk is not a permanent workplace for any regular activities. The WCS 2 scenario covers short walks by the plating line operator to visually inspect the electrolyte. For most of the time within this scenario, the electroplating line operator is not on the line but working at the control panel.</p> <p>The entire daily working time to operate the electroplating line is covered in three shifts. Within these shifts, the regular workplace inspections are conducted. Inspections by work safety group (occupational physician, safety officer, management) take place once a year. Further annual inspections take place within internal and external audits based on the management system ISO 9001, ISO 14001. 6S / 5S audits take place quarterly.</p>
4	Please specify the number of workers involved directly in plating operations during the year. According your given number of workers, only 4 persons are permanently involved directly in plating operations during the year, is it	- Yes, this is correct, only 4 persons are permanently involved directly in plating operations during the year.

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	so? Please specify the number of workers involved in WCS 3 and indicate how many of them are involved in WCS 3 only. Please specify how many workers are involved in WCS 9 only (not working as plating line operators).	<p>Maximum 30 employees are involved in WCS 3 and maximum 26 employees of them are involved in WCS 3 only.</p> <p>– Six workers (not working as plating line operators) are involved in WCS 9 "Rare maintenance - Overhaul of plating lines" only.</p> <p>A detailed overview of number of workers related to the WCS can be found in Table 9-6 of the CSR.</p>
5	Please specify ART modelling value for WCS 4, WCS 8 and WCS 9. Can you provide ART outputs and details of calculations?	Separate ART outputs for each of the scenarios (WCS 4, WCS 8, WCS 9) can be found as attachments to this request for additional information.
6	For the sake of completeness and cross checking, can you please provide exposure and risk estimations for WCS 7 (R&D).	This is not possible because Cr(VI) related working task falls under WCS 7. Therefore, no further calculations are provided.
7	Please specify that the values given in the Table 9-13: Exposure concentration for workers for CS6 actually are for CS9.	Indeed, this is a typo error. It can be confirmed that the data stated in Table 9-13 are related to CS9.
8	It seems to be not logical that the ART modelled exposure for WCS 9 is lower than for WCS 4, please check and explain.	This is related to the risk management measures, because local exhaust ventilation is available for WCS 9 but not for WCS 4. A 90 % reduction based on local exhaust ventilation is taken into account for the calculation of the WCS9.
9	Please explain which kind of measurement given in the Table II-1 relates to WCS 9?	<p>In Table II-1 only monitoring data are stated and no given measurements are related to the exposure calculations for WCS 9.</p> <p>Due to no sufficient monitoring data were available for WCS 9, the exposure was calculated using ART.</p>
10	Please explain in detail how you have obtained adjustment for frequency for all WCSs. If we assume 245 days/year for plating line operation and 2 shifts each day (16 hours), it gives 3920 hours or 235200 minutes. 18 minutes for WCS 4 would correspond to 0.01 % of all working time, and for other WCSs the used adjustments seem to be incorrect...	<p>The exposure is calculated per worker (8h/day, 245 days/year). Calculation with 16 hours for two shifts would demonstrate the exposure of two workers.</p> <p>Below is the calculation to adjust for frequency:</p> <p>WCS 4 - Annual hours worked per employee: 12 min/year 60 min 8 hours 245 days/year $60 \cdot 8 \cdot 245 = 117600 \text{ min/year}$</p>

		<p>$12/117600 = 0.01\%$</p> <p>WCS 8 - Annual hours worked per employee: 350 minutes</p> <p>$350/117600 = 0.30\%$</p> <p>Indeed, there is a typo error in the footnote of table 9-12 where an adjustment factor for frequency of 0.42% is stated. However, the calculation was done with the correct value of 0.30%</p> <p>WCS 9 - Annual hours worked per employee: 8 hours</p> <p>$480/117600 = 0.41\%$</p>
11	Please confirm the duration of activity and frequency for WCS 3 (8 h/shift, 2- 3 shifts – is it per week?)	This can be confirmed.
12	Please give details on personal measurements of plating line operators, RAC would like to understand the method used and its detection limit.	<p>The personal samples were taken at breathing level.</p> <p>The following sampling system was used: Personal-Air-Sampler GSA SG10-2 - volume flow rate [l/min] 10. The sampling takes place as E-dust ("inhalable dust") on quartz filters and the filter is eluted and the chromium content is determined by photometric analysis. The quantitation limit of the method is 0.25µg Cr(VI) / filter sample. The resulting amount of Cr(VI) [µg/sample] is divided by the sample volume [m³].</p>
13	Please specify concentration of Cr(VI) being in place for each WCS.	<p>WCS1 - Chromic acid with concentration of 500 g Cr(VI) trioxide / l.</p> <p>WCS2 - The concentration of the chromium electrolyte in the chrome bath is in the range of ■ - ■ [100 – 400] g/l.</p> <p>WCS3 - Finished parts and carriers (racks) are free of chromic acid contamination</p> <p>WCS4 - Chromic acid with concentration of 500 g Cr(VI) trioxide / l.</p> <p>WCS5 - waste water sampling of final wastewater: the residual concentrations of Cr(VI) in the effluent are mainly below the detection limit (0.005 mg/l).</p> <p>WCS6 - see WCS2</p> <p>WCS7 - see WCS2 and WCS1</p> <p>WCS8 - see WCS2</p>

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		WCS9 - see WCS2
14	Please confirm that biomonitoring of workers in urine and blood is performed once a year or specify the frequency.	This can be confirmed.

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:** 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.