EUROPEAN
COMMISSION

Brussels, 30.4.2024
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COMMISSION IMPLEMENTING DECISION

of 30.4.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to NeoPerl GmbH for a use of acids generated from chromium trioxide and their oligomers

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Acids generated from chromium trioxide and their oligomers are listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of those substances are subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 16 February 2021, Neoperl GmbH ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of acids generated from chromium trioxide and their oligomers. The use for which authorisation was sought is 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.

(3) The European Chemicals Agency sent the opinions[2] on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 31 March 2022 the Commission received the opinions.

(4) In its opinion, RAC concluded that it is not possible to determine a derived no-effect level for the carcinogenic properties of acids generated from chromium trioxide and their oligomers in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore acids generated from chromium trioxide and their oligomer are substances for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to those substances and an

[1] OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

[2] https://echa.europa.eu/documents/10162/23330cc0-2fc0-8982-5c6d-1c11300dd416

authorisation may therefore only be granted with respect to those substances under paragraph 4 of that Article.

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and to members of the general population who could potentially be exposed to hexavalent chromium (Cr(VI)) via the environment, posed by the use of acids generated from chromium trioxide and their oligomers described in the application.

(6) Nevertheless, in order to achieve further improvement of the risk management measures and operational conditions in place as to reduce exposure of workers to as low a level of Cr(VI) as technically and practically possible, in particular concerning certain operations involving possible direct contact with Cr(VI), RAC recommended certain conditions for authorisation. Moreover, RAC recommended monitoring arrangements due to minor shortcomings, aimed at complementing the overall dataset on exposure and emission. Having evaluated the RAC assessment, the Commission agrees with RAC's conclusion and recommendations.

(7) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health and the environment arising from the use of the substance. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the use outweigh the risk to human health or the environment arising from that use.

(8) For an alternative to be suitable it needs to be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required to submit a substitution plan.

(9) An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible. Certain potential alternatives may provide the functionality but at some loss of performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(10) In its opinion, SEAC concluded that there were no technically and economically feasible alternative substances or technologies available for the applicant, but that there were technically and economically feasible alternatives in the Union by the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that the identified alternatives are commercially available and seem to provide the overall functionality for the use for which authorisation is sought but that they require further testing and development to achieve the necessary performance, in particular in terms of corrosion resistance, colour fidelity, wear behaviour, and overall quality required by the applicant's customers. Therefore, the Commission agrees with SEAC's conclusion and considers that, although suitable alternatives are available in the Union, they are not yet technically feasible for the applicant.

(11) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion. Therefore, the Commission considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.

(12) The Commission recalls that the aim of the authorisation system is to ensure that substances of very high concern are progressively replaced by suitable alternative substances or technologies where these are available and technically and economically viable. The Commission also acknowledges that, as the substitution of chromium trioxide progresses, the applicant expects to reduce the overall quantities of that substance used throughout the review period, in accordance with the figures provided by the applicant to the Commission. Therefore, the Commission considers it appropriate to set out as a condition for authorisation that the quantity of chromium trioxide used in the use for which authorisation is sought should be reduced in line with the figures provided by the applicant to the Commission, in order to ensure that the substitution strategy is duly implemented and to facilitate the enforcement of that obligation.

(13) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of acids generated from chromium trioxide and their oligomers described in the application, provided that the risk management measures and operational conditions described in the chemical safety report, as well as the conditions set out in this Decision, are fully applied.

(14) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on a sufficient amount of material and reliable information. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require the authorisation holder to generate and include additional exposure and emission information in the review report.

(15) In its opinion, SEAC recommended that the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at ten years, until 16 February 2031. The Commission agrees with that recommendation, considering the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the socio-economic benefits of the use of the substance and the ongoing substitution efforts. More specifically, the Commission considers that the applicant's strategy to reduce the quantity of chromium trioxide used during the review period is a key factor for its agreement with SEAC's recommendation on the review period.

(16) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(17) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[3] to reduce the use of carcinogens, mutagens and reprotoxic substances at the place of work, in particular by replacing those substances, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(18) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of

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3 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

4 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

5 Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

6 Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

7 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

8 Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

9 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

10 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

11 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending

this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(19) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of acids generated from chromium trioxide and their oligomers: chromic acid (EC No: 231-801-5, CAS No: 7738-94-5), dichromic acid (EC No: 236-881-5, CAS No: 13530-68-2), oligomers of chromic acid and dichromic acid:

Authorisation number	Authorisation holder	Authorised use
REACH/24/4/0	Neoperl GmbH	In 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

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12], and to the condition set out in Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 and 3.

2. The authorisation holder shall reduce the total annual quantity of chromium trioxide used for the authorised use, compared to the total annual quantity of that substance used in 2020, by the following amounts and at the latest by the following dates:

   (a) 70% by 31 December 2029;

   (b) 90% by 31 December 2030.

   The authorisation holder shall, upon request, provide the relevant documentation, including the reduction progress to the competent authority of the Member State where the authorised use takes place.

3. The authorisation holder shall finalise by 30 April 2025, and afterwards when new information becomes available, a study to assess the feasibility of implementing additional measures as regards working contributing scenario 9, including improved cleaning practices, so as to minimise exposure to hexavalent chromium (Cr(VI)) to as low a level as technically and practically possible.

Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

[12] https://ec.europa.eu/docsroom/documents/49397

The authorisation holder shall act in accordance with the outcome of that study. The results of that study and the action taken shall be made available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 3

1. The review period shall expire on 16 February 2031.

2. The authorisation shall cease to be valid on 16 February 2031 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 16 August 2029.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 7 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to Cr(VI). The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in emission of Cr(VI);

   (b) be based on relevant standard methodologies or protocols;

   (c) comprise personal and static inhalation exposure sampling;

   (d) ensure a sufficiently low limit of quantification;

   (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, of the operational conditions and risk management measures for each of these tasks, and of the total number of workers that are potentially exposed;

   (f) be recorded so as to include contextual information about the tasks performed during sampling.

3. The authorisation holder shall continue to conduct an annual biomonitoring programme for a representative number of workers that are potentially exposed to Cr(VI).

4. The authorisation holder shall carry out a monitoring programme measuring the environmental emissions of Cr(VI) to the air and wastewater. The programme shall include measurements which shall:

   (a) as regards emissions to wastewater, take place four times per year; as regards emissions to air, at least annually, or more frequently if a significant increase of chromium trioxide consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in emissions of Cr(VI) following changes in the production process;

   (b) be based on relevant standard methodologies or protocols;

   (c) ensure a sufficiently low limit of quantification;

   (d) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

(e) be recorded so as to include contextual information associated with each of the measurements.

5. The authorisation holder shall use the information gathered by way of the measurements and related contextual information referred to in paragraphs 2, 3 and 4 to confirm and review, at least annually, the appropriateness and effectiveness of the operational conditions and risk management measures in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers and its assessment of the exposure of the general population via the environment. If needed, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible both workplace exposure to Cr(VI) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and Cr(VI) emissions to the environment.

6. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 2, 3 and 4, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraph 5, and shall make that information available, including pseudonymised or aggregated biomonitoring results, upon request, to the competent authority of the Member State where the authorised use takes place.

7. The authorisation holder shall document the steps taken to substitute acids generated from chromium trioxide and their oligomers in accordance with the substitution plan, including information on the efforts to convince the authorisation holder's customers to accept alternative Cr(VI)-free solutions and justification in case its customers do not accept alternative Cr(VI)-free solutions. Any deviations from the initial substitution plan and information on contingency measures taken shall also be documented. The authorisation holder shall make such documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 5

Where the authorisation holder submits a review report, it shall include the following:

(a) the information referred to in Article 2, as well as Article 4(6) and (7);

(b) the figures detailing the reduction of the quantity of chromium trioxide, in line with the commitments set out in the updated substitution plan.

Article 6

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use take place in an official language of that Member State.

Article 7

This Decision is addressed to:

Neoperl GmbH, Klosterrunsstr. 9-11, 79379, Müllheim, Germany.

Done at Brussels, 30.4.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION