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COMMISSION IMPLEMENTING DECISION

of 29.7.2024

**granting an authorisation under Regulation (EC) No 1907/2006 of the European
Parliament and of the Council to Orelec for a use of chromium trioxide**

(Only the French 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/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006, and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.
- (2) On 15 December 2021, Orelec ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of chromium trioxide. The use for which authorisation was sought is hard chrome plating of injection moulds in order to provide hardness, wear resistance and good demoulding properties, critical for the manufacture of high-quality plastic parts.
- (3) The European Chemicals Agency sent the opinions² on the application adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), third subparagraph, of Regulation (EC) No 1907/2006. On 28 June 2023, 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 and mutagenic properties of chromium trioxide in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance 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 chromium trioxide and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

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

² <https://www.echa.europa.eu/documents/10162/9da756f1-44e1-d00e-0c51-66d8f3a68597>

- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application are not appropriate and effective in limiting the risk posed by the use of chromium trioxide described in the application to workers but are appropriate and effective in limiting the risk posed by that use to the general population, exposed via the environment. RAC expressed concerns with regard to the hierarchy of control principles, noting that workers' protection in worker contributing scenario 4 is fully dependent on the use of respiratory protective equipment. Therefore, RAC recommended imposing additional conditions for authorisation, including the implementation of increased local enclosure of the baths. Moreover, RAC recommended imposing additional monitoring arrangements with the aim to address minor shortcomings in exposure estimates and to corroborate the appropriateness and effectiveness of the risk management measures and operational conditions implemented as a result of the additional conditions. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.
- (6) In its opinion, SEAC concluded that the societal costs of not granting an authorisation are higher than the monetised risk to human health arising from the use of chromium trioxide. 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 arising from that use.
- (7) 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 by Article 62(4), point (f), of Regulation (EC) No 1907/2006 to submit a substitution plan.
- (8) An alternative that provides the functionality and level of technical performance necessary for the use for which an 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 of performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.
- (9) In its opinion, SEAC concluded that there were no technically feasible alternative substances or technologies available for the applicant and in the Union at the time of adoption of the opinion. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that further development and testing of the identified alternatives are necessary to fulfil the process requirements and achieve the required functionalities, especially hardness and possibly also corrosion resistance, for the most promising alternative, or for any other alternative, to become technically feasible, and considers that the applicant has demonstrated that it is not yet able to accommodate such loss of performance and would need more time to develop and implement an alternative. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicant and in the Union.
- (10) 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 chromium trioxide described in the application, provided that the risk management measures described in

the chemical safety report are applied and that the operational conditions described therein, as well as the conditions set out in this Decision, are fulfilled.

- (11) The Commission has based its assessment on all relevant scientific evidence available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, has concluded on the basis of 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 information about exposure and emissions in the review report.
- (12) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 7 years, until 15 December 2028. The Commission agrees with that recommendation, taking into account 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 not appropriate and effective to limit the risk, SEAC's conclusion on the socio-economic benefits of the continued use of the substance, as well as SEAC's conclusion on the time needed to implement an alternative.
- (13) 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.
- (14) This Decision does not affect the obligation of the authorisation holder to ensure that the 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 Council³ to reduce the use of carcinogens, mutagens or 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/EEC⁴, 92/85/EEC⁵, 94/33/EC⁶, 98/24/EC⁷ and Directive 2004/37/EC, or any

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>).

national binding occupational limit values which may be stricter than the applicable limit values under Union law.

- (15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC⁸ or Directive 2010/75/EU⁹ of the European Parliament and of the Council, 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 Council¹⁰ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹¹. Compliance with the provisions of 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.
- (16) 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 to the following person for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/24/35/0	Orelec	Hard chrome plating of injection moulds in order to provide hardness, wear resistance and good demoulding properties, critical for the manufacture of high-quality plastic parts

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 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>).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹², and to the conditions set out in Article 2.

Article 2

1. The authorisation is subject to the conditions set out in paragraphs 2 to 5.
2. Without delay, and at the latest by 29 January 2025, the authorisation holder shall implement increased local enclosure of the plating bath to ensure that exposure to hexavalent chromium (Cr(VI)), the toxic component of chromium trioxide, of workers who are not performing activities directly associated with the bath is reduced to as low a level as is technically and practically possible.
3. The authorisation holder shall conduct control measurements to validate the appropriateness and effectiveness of the additional risk management measures and operational conditions implemented in accordance with paragraph 2. If necessary, additional risk management measures or operational conditions shall be implemented to further reduce exposure to Cr(VI) to a level as low as is technically and practically feasible.
4. By 29 July 2025 and afterwards each time when new relevant information becomes available, the authorisation holder shall carry out a study to assess the feasibility of implementing one of the following measures:
 - (a) the segregation of the bath area from other areas in the workshop;
 - (b) the segregation of other activities from the bath while the bath is in use.The authorisation holder shall act in accordance with the outcome of that study.
5. The authorisation holder shall document and maintain the information from the outcome and conclusions of the study referred to in paragraph 4 and any measure taken in accordance with paragraphs 2 to 4, and shall make it 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 15 December 2028.
2. The authorisation shall cease to be valid on 15 December 2028 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 15 June 2027.

Article 4

1. The monitoring arrangements set out in paragraphs 2 to 6 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 exposure of workers to Cr(VI);

¹² <https://ec.europa.eu/docsroom/documents/55105>

- (b) be based on relevant standard methodologies or protocols;
 - (c) ensure a sufficiently low limit of quantification;
 - (d) comprise personal or static inhalation exposure sampling;
 - (e) be representative of all the tasks with possible exposure to Cr(VI), including maintenance tasks, the operational conditions and risk management measures for each of those 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 exposure sampling.
3. The authorisation holder shall continue to conduct an annual biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).
4. The authorisation holder shall carry out a monitoring programme measuring the environmental releases of Cr(VI) to the air and wastewater. 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 or if the production process is modified, 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) 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 set of measurements.
5. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraphs 2, 3 and 4 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions 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, based on the outcome of those reviews, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible occupational exposure to Cr(VI) and Cr(VI) emissions to the environment. Measures introduced to reduce occupational exposure shall follow the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.
6. The authorisation holder shall document and maintain the information gathered 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 review 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.

Article 5

If a review report is submitted, it shall include the information referred to in Article 2(5) and Article 4(6).

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 takes place. The brief summary shall be drafted in an official language of that Member State.

Article 7

This Decision is addressed to:

Orelec, 8, rue de la Roche Bleue, 49370 Bécon les Granits, France.

Done at Brussels, 29.7.2024

For the Commission
Thierry BRETON
Member of the Commission