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COMMISSION IMPLEMENTING DECISION

of 8.5.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Monroe Czechia s.r.o. for a use of dichromium tris(chromate)

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

Whereas:

- (1) Dichromium tris(chromate) 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 9 April 2021, Monroe Czechia s.r.o. ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of dichromium tris(chromate)². The use for which authorisation was sought is in a post-treatment step of the auto-deposition coating process of shock absorbers for automotive vehicles.
- (3) The European Chemicals Agency sent the opinions³ on the application for authorisation adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 7 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 dichromium tris(chromate) in accordance with Section 1.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore dichromium tris(chromate) 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 dichromium

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

² Different names and abbreviations are used to refer to the substance, including 'DCTC' in the chemical safety report, in the application for authorisation and in the opinions of RAC and SEAC.

³ <https://echa.europa.eu/documents/10162/6ad731c5-88ab-b936-2458-a7abc91b2d42>

tris(chromate) and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

- (5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application, as further detailed by the applicant at RAC's request, are not appropriate and effective in limiting the risk to human health posed by the use of dichromium tris(chromate) described in the application. RAC also considers that the risk management measures, on top of not sufficiently limiting the risk for workers and for humans via the environment, do not follow the hierarchy of control principles.
- (6) Therefore, RAC recommended imposing additional conditions for the authorisation that are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to, and that are in line with the hierarchy of control principles.
- (7) Moreover, in order to address certain shortcomings in occupational exposure estimates due to static measurements at only one point and to provide further reliable information on the effectiveness of the risk management measures and operational conditions implemented as a result of the additional conditions, as well as on the trends in exposure and emissions during the authorisation period, RAC recommended imposing monitoring programmes for both occupational exposure and environmental emissions of hexavalent chromium (Cr(VI)), the hazardous component of dichromium tris(chromate).
- (8) Having evaluated RAC's assessment, the Commission agrees with its conclusions and recommendations. Nevertheless, the Commission notes that the estimated highest excess cancer risk value for workers is higher than as regards other comparable applications for authorisation for the use of Cr(VI) substances. Although the Commission acknowledges that this value is a conservative estimate of the most likely excess risk values taken for the purpose of carrying out a risk-benefit analysis, it considers it appropriate to set out the measures concerning occupational exposure, recommended by RAC, as a condition for authorisation. Moreover, since the additional conditions recommended by RAC include an assessment through specific measurements of environmental emissions, the Commission considers that it is appropriate to set out the measures concerning environmental emission monitoring, recommended by RAC, as a condition for authorisation.
- (9) 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 dichromium tris(chromate). The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers that the applicant has demonstrated that the benefits of the continued use outweigh the risk to human health and the environment arising from that use.
- (10) 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.
- (11) 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 of performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case. Similarly, unless justified by particular circumstances, the Commission should not consider an alternative to be economically feasible where its use leads to a negative economic impact of a magnitude that would jeopardise the economic viability of the operations related to the use for which an authorisation is sought.

- (12) In its opinion, SEAC concluded that there were no technically and economically feasible alternative substances or technologies available for the applicant at the time of adoption of the opinion but there were technically and economically feasible alternatives available in the Union. The Commission, having evaluated SEAC's assessment and the relevant information available, notes that further testing and validation is still required to ensure that the shock absorbers coated with an alternative method meet all the qualification requirements in terms of corrosion and chemical resistance, sufficient adhesion and thermal resistance. Therefore, the applicant has demonstrated that it is not yet able to accommodate the loss of performance of the alternative method and would need more time to develop and implement an alternative. Moreover, the Commission also notes that spray coating could be implemented for a limited part of the production, but that this is not economically viable due to capacity constraints and high operating costs. The Commission therefore agrees with SEAC's conclusion that there are no suitable alternatives for the applicant and that there are suitable alternatives available in the Union.
- (13) In its opinion, SEAC concluded that the substitution plan submitted by the applicant is credible, and it is also consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion and considers, taking into account the availability of suitable alternatives in the Union for the use for which authorisation is sought and the substitution plan submitted by the applicant, that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies.
- (14) 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 dichromium tris(chromate) 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.
- (15) 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.

- (16) 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 until 21 September 2024. The Commission takes into account that recommendation, considering the relevant elements from RAC's and SEAC's assessments and, in particular, SEAC's conclusions on the risk to human health and on the socio-economic benefits of the continued use of the substance, as well as the timelines provided in the substitution plan.
- (17) However, as a review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 must be submitted at least 18 months before the expiry of the review period, the review period recommended by SEAC would make it impossible for the authorisation holder to submit a review report within that time limit. Therefore, in order to ensure that the authorisation holder has enough time for the preparation of a review report, the Commission considers that a longer review period should be set.
- (18) 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.
- (19) 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 Council⁴ 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/EEC⁵, 92/85/EEC⁶, 94/33/EC⁷, 98/24/EC⁸ and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

⁴ 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 and 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>).

⁵ 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>).

⁶ 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>).

⁷ 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>).

- (20) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC⁹ or Directive 2010/75/EU¹⁰ 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 Council¹¹ or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council¹². 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.
- (21) 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 dichromium tris(chromate) (EC No 246-356-2; CAS No 24613-89-6):

Authorisation number	Authorisation holder	Authorised use
REACH/24/9/0	Monroe Czechia s.r.o.	Post-treatment of the auto-deposition coating process of shock absorbers in automotive vehicles

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report¹³, and to the conditions set out in Article 2.

⁸ 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>).

⁹ 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>).

¹⁰ 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>).

¹¹ 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>).

¹² 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>).

¹³ <https://echa.europa.eu/documents/10162/58f7f364-523c-5b7e-ef8b-80becfa325a>

Article 2

1. The authorisation is subject to the conditions set out in paragraph 2 to 7.
2. By 8 November 2024, the authorisation holder shall introduce local exhaust ventilation, wet scrubbers or other engineering controls at relevant locations where hexavalent chromium (Cr(VI)) is emitted to reduce workplace exposure and emissions to the environment to as low a level as technically and practically feasible and in line with the hierarchy of control principles.
3. 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 for the first time by 8 August 2024, and thereafter at least annually or more frequently if a significant increase of dichromium tris(chromate) consumption takes place on site. The frequency of the measurements shall be sufficient to capture any potential increase in exposure of workers to Cr(VI);
 - (b) be based on relevant standard methodologies or protocols;
 - (c) ensure a sufficiently low limit of quantification;
 - (d) comprise personal and static inhalation exposure sampling;
 - (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 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 with possible exposure to Cr(VI).
4. The authorisation holder shall continue conducting a biomonitoring programme for a representative number of workers potentially exposed to Cr(VI).
5. 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 for the first time by 8 August 2024, and thereafter at least annually or more frequently if a significant increase of dichromium tris(chromate) consumption takes place on site. The frequency of the measurements shall be sufficient 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.
6. The authorisation holder shall use the information gathered by way of the measurements and related contextual information referred to in paragraphs 3, 4 and 5 to confirm and review, for the first time by 8 November 2024, and thereafter at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. 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 occupational exposure to Cr(VI) in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC and emissions of Cr(VI) into the environment.

7. The authorisation holder shall document and maintain the information from the monitoring programmes referred to in paragraphs 3, 4 and 5, 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 6, 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 3

1. The review period shall expire on 8 May 2026.
2. The authorisation shall cease to be valid on 8 May 2026 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 8 November 2024.

Article 4

The authorisation holder shall document the steps taken to substitute dichromium tris(chromate) 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 information referred to in Article 2(7) and Article 4.

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:

Monroe Czechia s.r.o., Rychnovská 383, 46342, Hodkovice nad Mohelkou, Czech Republic.

Done at Brussels, 8.5.2024

For the Commission

Thierry BRETON

Member of the Commission

