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COMMISSION IMPLEMENTING DECISION

of 28.2.2019

granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Federal - Mogul Friedberg GmbH)

(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) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and is therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 20 November 2015, Federal - Mogul Friedberg GmbH ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of chromium trioxide in functional chrome plating of piston rings for two-stroke and four-stroke large bore engines as applied in the industrial sectors construction and industry, power generation, railway and maritime.
- (3) On 22 December 2016, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency² on the application pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its opinion, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore chromium trioxide is a non-threshold substance for the purposes of Article 60(3)(a) of that Regulation. In accordance with that Article, Article 60(2) of that Regulation does not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of Regulation (EC) No 1907/2006.
- (5) In its opinion, RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/e76cd6cb-aba8-43ed-034f-3a67fa57d723>

risk to workers and the general population that could potentially be exposed via the environment. Due to the lack of representativeness of the data provided and lack of measurements in four of the nine worker contributing scenarios with potential exposure of workers as well as in the environmental contributing scenario, RAC recommended monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with its conclusion.

- (6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of chromium trioxide applied for outweigh the risk to human health or the environment arising from that use and that there are no suitable alternative substances or technologies for the applicant before the sunset date. Furthermore, SEAC recommended to describe in a more detailed way the use applied for in a possible review report. The Commission, having evaluated SEAC's assessment, concurs with that conclusion.
- (7) Based on RAC's and SEAC's opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of chromium trioxide applied for, provided that the risk management measures and operational conditions described in the application and, in particular, in the chemical safety report³, are fully applied.
- (8) In its opinion, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at 12 years. The Commission takes 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 appropriate and effective in limiting the risk, that the socio-economic benefits of continued use clearly outweigh the risk, the fact that the most promising alternatives are still in research and development phase, the unlikelihood that suitable alternatives could be identified within a shorter period, the applicant's long development and production cycle, the time for obtaining the necessary approvals from the original equipment manufacturers as well as the necessity for the applicant to ensure over long periods of time continuity of supply for the existing engines under contractual obligations. The Commission concurs with SEAC's recommendation.
- (9) Therefore, it is appropriate that, as regards the use of chromium trioxide applied for, the review period be set at 12 years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (10) The language used for the description of the risk management measures and operational conditions included 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 the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the authorisation holder to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of the Member State concerned.
- (11) This Decision does not affect the obligation of the authorisation holder to ensure that the use does not adversely affect human health or the environment pursuant to Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, it does not affect the obligation of the authorisation holder to ensure that the exposure to the substance is reduced to as low a level as is technically and practically possible pursuant to Article 60(10) of Regulation (EC) No 1907/2006 and the obligation of the employer to reduce the use of

³ <http://ec.europa.eu/DocsRoom/documents/20769>

a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible in accordance with Article 4(1) of Directive 2004/37/EC of the European Parliament and of the Council⁴, or to prevent and reduce exposure in accordance with Article 5 of that Directive. In addition, this Decision is without prejudice to the application of the Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC⁵, 92/85/EEC⁶, 94/33/EC⁷ and 98/24/EC⁸ and Directive 2004/37/EC.

- (12) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC⁹ and 2010/75/EU¹⁰ of the European Parliament and of the Council, as well as with emission limit values set to achieve compliance with the environmental quality standards established both by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹¹ and in Directive 2008/105/EC of the European Parliament and of the Council¹². Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.
- (13) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0), provided that the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation, as well as the monitoring arrangements set out in Article 3 of this Decision, are fully applied:

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 or mutagens 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).

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).

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).

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).

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).

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).

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).

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).

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).

Authorisation number	Authorised use
REACH/19/4/0	Use in functional chrome plating of piston rings for two-stroke and four-stroke large bore engines as applied in the industrial sectors construction and industry, power generation, railway and maritime

Article 2

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2029.
2. The authorisation shall cease to be valid on 21 September 2029 in case a review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 21 March 2028, unless a decision to withdraw the authorisation is adopted earlier pursuant to paragraphs 2 and 3 of Article 61 of that Regulation.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 4 shall apply.
2. The authorisation holder shall implement the following monitoring programmes for chromium (VI) related to the use described in Article 1:
 - (a) occupational exposure measurements.. Those measurements shall:
 - take place at least annually;
 - be based on relevant standard methodologies or protocols with a sufficiently low detection limit;
 - comprise both static and personal inhalation exposure sampling;
 - be representative of the range of tasks of workers and process steps with possible exposure to chromium trioxide and of the total number of workers that are potentially exposed;
 - include contextual information about the tasks with possible exposure to chromium trioxide;
 - (b) annual measurements of emissions to the air of chromium (VI) from all the sites. The measurements shall be performed according to relevant standard sampling and analytical methods.
3. The information gathered via the measurements required under paragraph 2 shall be used to regularly review the appropriateness and the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce the exposure to workers and emissions.
4. The results of the measurements described in paragraph 2, as well as the outcome and conclusions of the review and any actions taken, as described in paragraph 3, shall be documented and, upon request, submitted to the competent authority of the Member State where the authorised use takes place.

Article 4

In the event that a review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 is submitted, it shall include the following information:

- (a) the results of the measurements, the outcome and conclusions of the review and any actions taken pursuant to the second paragraph of Article 3;
- (b) a more specific description of the use as regards the types of engines, fuels and applications, or in terms of performance requirements ranges.

Article 5

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

Article 6

This Decision is addressed to Federal - Mogul Friedberg GmbH, Engelschalkstrasse 1, 86316 Friedberg, Germany.

Done at Brussels, 28.2.2019

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

