EUROPEAN
COMMISSION

Brussels, 20.3.2020
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COMMISSION IMPLEMENTING DECISION

of 20.3.2020

granting an authorisation for a use of chromium trioxide under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Mahle Ventiltrieb GmbH and Mahle Polska Sp. z o.o.)

(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) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and its uses are therefore subject to the authorisation requirement laid down in Article 56(1)(a) of that Regulation.

(2) On 18 May 2018, Mahle Ventiltrieb GmbH and Mahle Polska Sp. z o.o. ('the applicants') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for the use of chromium trioxide in the functional chrome plating of engine valves for automotive applications. The applicants further specify in the application that the scope of the use is limited to valves used in engines of light gasoline and diesel vehicles and in heavy-duty diesel combustion engines.

(3) On 1 March 2019, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion 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 that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3)(a) of that Regulation. As a result, paragraph 2 of Article 60 of Regulation (EC) No 1907/2006 does not apply to that substance, and an

[1] OJ L 396, 30.12.2006, p. 1.

[2] https://echa.europa.eu/documents/10162/23917abc-ebfc-032b-27aa-b7d889459f17

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 are appropriate and effective in limiting the risk to workers and to members of the general population who could potentially be exposed via the environment posed by the use of chromium trioxide described in the application. The Commission, having evaluated RAC's assessment, agrees with that conclusion.

(6) However, in order to improve the assessment of emissions and the exposure of workers, RAC recommended monitoring arrangements. The Commission, having evaluated RAC's assessment, agrees with that recommendation.

(7) An authorisation may be granted under Article 60(4) of Regulation (EC) No 1907/2006 if there are no suitable alternative substances or technologies. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for. Some potential alternatives may provide this functionality but at some loss to performance or in a manner that involves technical compromises. The Commission considers that, given the economic and other incentives towards substitution that already arise from inclusion in the authorisation system, and in the light of the objective of progressive substitution, as a starting point, a potential alternative should not be considered technically viable where such losses to performance or technical compromises are not minor. Nevertheless, the Commission considers it must be possible to depart from this approach where justified by particular circumstances, including the specific function of the substance for the use applied for, the public interest at stake, or a low net difference between the socio-economic benefits and the risk to human health or the environment. The Commission also considers that no particular factors justify less strict technical feasibility requirements in this case. Where the Commission is able to conclude on lack of technically feasible alternatives to the substance, it is unnecessary to consider economic feasibility of substitution.

(8) In its opinion, SEAC concluded that the socio-economic benefits arising from the use of chromium trioxide covered by the application outweigh the risk to human health arising from that use and that there are no suitable alternative substances or technologies for the applicants. The Commission, having evaluated SEAC's assessment, agrees with that conclusion and considers that the applicants have demonstrated that no potential alternatives provide the level of technical performance functionally necessary for the use applied for and have discharged their burden of proof in demonstrating the absence of suitable alternatives.

(9) 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 covered by the application, provided that the risk management measures and operational conditions described in the chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006 are fully applied.

(10) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC, and based its conclusions on the existence of a sufficient weight of evidence allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary base in the future. Hence, it is appropriate to require the generation of additional exposure and emission information.

(11) 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 12 years. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's assessment of the level of risk linked to the use and the conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the long investment cycle associated with the use, the likelihood that substitution will not be possible within a shorter timeframe, the time necessary to fully implement possible alternatives, as well as the socio-economic benefits of continued use and the conclusion that they significantly outweigh the monetised risk to human health.

(12) The applicants submitted their application for authorisation after the sunset date in accordance with Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006. The applicable sunset date specified in Annex XIV to that Regulation has already been reached. It is therefore appropriate for the review period to be set at 12 years from the date of adoption of this Decision.

(13) The language used to describe the risk management measures and operational conditions included in the application for authorisation may be different from the official languages of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the authorisation holders to submit, upon request, a succinct summary of those risk management measures and operational conditions in an official language of that Member State.

(14) This Decision does not affect the obligation of the authorisation holders 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 either the obligation of the authorisation holders 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 Articles 4(1) and 5 of Directive 2004/37/EC of the European Parliament and of the Council[3] to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, and to prevent worker's 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], 98/24/EC[7] and Directive 2004/37/EC, as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

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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 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).

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).

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).

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).

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).

(15) This Decision does not affect any obligation to comply with emission limit values 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 this Decision does not necessarily imply compliance with any other 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 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 to the following persons for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorisation holder	Authorised use
REACH/20/9/0	Mahle Ventiltrieb GmbH	Use in functional chrome plating of valves used in engines of light gasoline and diesel vehicles and in heavy-duty diesel combustion engines
REACH/20/9/1	Mahle Polska Sp. z o.o.	

The authorisation is granted subject to full application of the risk management measures and operational conditions described in the chemical safety report[12].

Article 2

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 20 March 2032.

2. The authorisation shall cease to be valid on 20 March 2032 with respect to any holder of the authorisation who has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 20 September 2030.

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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).

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).

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).

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).

12 https://echa.europa.eu/documents/10162/36aafd27-9f09-4641-4b18-cfb66b97b791

Article 3

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

2. The authorisation holders shall implement the following monitoring programmes for chromium (VI):

   (a) occupational exposure measurements. Those measurements shall:

      (i) be conducted at least annually;

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

      (iii) comprise both static and personal inhalation exposure sampling;

      (iv) be representative of the range of tasks undertaken where exposure to chromium (VI) is possible, including tasks involving maintenance workers, and representative of the operational conditions and risk management measures typical for each of these tasks and of the number of workers potentially exposed;

      (v) be recorded as to include contextual information about the tasks with possible exposure to chromium (VI).

   (b) measurements of emissions to air from local exhaust ventilation. Those measurements shall:

      (i) be conducted at least every two years;

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

      (iii) be representative of the operational conditions and risk management measures used at the sites where the authorised use takes place.

3. The authorisation holders shall use the information gathered via the measurements referred to in paragraph 2 and related contextual information to confirm the effectiveness of the risk management measures and operational conditions as well as to review annually the effectiveness of the risk management measures and operational conditions in place and, if needed, to introduce measures to further reduce workplace exposure to chromium (VI) and emissions to the environment to as low a level as technically and practically feasible.

4. The authorisation holders shall ensure that the application of risk management measures at their sites is in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

5. The authorisation holders shall document and keep the information obtained from the monitoring programmes referred to in paragraph 2, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 3, and submit it, upon request, to the competent authority of the Member State where the authorised use takes place.

6. Following implementation of the risk management measures and operational conditions, the authorisation holders may reduce the frequency of measurements, once they can clearly demonstrate to the competent authority of the Member State where the use takes place that exposure of humans and releases into the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions function appropriately.

7. If an authorisation holder submits a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information documented in accordance with paragraph 5 of this Article in that report.

Article 4

Upon request, the authorisation holders shall submit a succinct 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 in an official language of that Member State.

Article 5

This Decision is addressed to:

1. Mahle Ventiltrieb GmbH, Industriestrasse 40, DE-61200 Wölfersheim, Germany;

2. Mahle Polska Sp. z o.o., ul. Mahle 6, 63-700 Krotoszyn, Poland.

Done at Brussels, 20.3.2020

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION