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COMMISSION IMPLEMENTING DECISION

of **XXX**

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

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

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

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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 therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 19 February 2016, Topocrom GmbH ('the applicant') submitted an application for authorisation in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of chromium trioxide in Topocrom functional chrome plating in closed reactor systems for the establishment of adjustable hemispherical surface structures.
- (3) On 16 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 second 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. In accordance with Article 60(3)(a) of Regulation (EC) No 1907/2006, 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/f6eb8fc1-0404-52d8-60cb-e63cd6a484aa>

risk to workers and to the general population that could potentially be exposed via the environment.

- (6) In its opinion, due to the fact that the assessment of risk to workers and to man via environment for some activities was based solely on modelling and that although corrective maintenance of general ventilation and local exhaust ventilation was well described, no information was provided on preventative maintenance, RAC recommended additional monitoring arrangements.
- (7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of chromium trioxide applied for outweigh the risks to human health and the environment arising from that use and that there are no suitable alternative substances or technologies. The Commission, having evaluated the SEAC assessment, concurs with this conclusion.
- (8) Therefore, 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.
- (9) 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 the RAC and SEAC assessments, and in particular the RAC's assessment of the risk of the continued use of the substance and its conclusions that the implemented risk management measures and operational conditions are appropriate and effective in limiting the risk, the fact that the socio-economic benefits of continued use, in the range of 5 million euros, clearly outweigh the risk to human health in the order of 0.3 million euros, the specific key functionalities of the use applied for and the low likelihood that a suitable alternative will be identified within a shorter timeframe. The Commission concurs with the SEAC recommendation.
- (10) Therefore, as regards the use of chromium trioxide applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at 12 years as from the sunset date set out in Annex XIV to that Regulation.
- (11) 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.
- (12) 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 either 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 or the obligation of the employer 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 in accordance with Article 4(1) of Directive

³ <http://ec.europa.eu/DocsRoom/documents/20664>

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. Furthermore, this Decision is without prejudice to the application of the Union Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC⁵, Council Directive 98/24⁶, Directive 2004/37 of the European Parliament and of the Council⁷, Council Directive 92/85/EEC⁸ and Council Directive 94/33/EC⁹.

- (13) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directive 2010/75/EU of the European Parliament and of the Council¹⁰ and Directive 2008/50/EC of the European Parliament and of the Council¹¹, as well as with emission limit values set to achieve compliance with the environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council¹² and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹³. 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.
- (14) 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-

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, 29.06.1989, p. 1).

⁶ 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, 05.05.1998, p. 11).

⁷ 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, 30.04.2004).

⁸ 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).

⁹ Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.08.1994, p. 12).

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 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).

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).

¹³ 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).

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 are fully applied:

Authorisation number	Authorised use
REACH/18/10/0	Topocrom functional chrome plating in closed reactor systems for the establishment of adjustable hemispherical surface structures

Article 2

1. As regards the authorised use of chromium trioxide, 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 REACH/18/10/0 shall cease to be valid on 21 September 2029 in case the 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

The following monitoring arrangements shall apply:

- (a) the authorisation holder shall continue to implement regular occupational exposure measurements relating to the use of chromium trioxide described in Article 1, including working contributing scenarios for which no measurements were provided. Those measurements shall:
 - (i) take place at least annually and be based on relevant standard methodologies or protocols;
 - (ii) ensure a sufficiently low detection limit;
 - (iii) comprise appropriate inhalation exposure sampling;
 - (iv) be representative of the range of tasks with possible exposure to chromium (VI) and of the total number of workers that are potentially exposed;
 - (v) include contextual information about the tasks with possible exposure to chromium trioxide;
- (b) the authorisation holder shall implement a preventative maintenance program for all the mechanical ventilation resources (general and local exhaust ventilation (LEV));
- (c) the authorisation holder shall regularly measure emissions of chromium (VI) to air related to the use referred to in Article 1. The measurements shall be undertaken according to relevant standard sampling and analytical methods;
- (d) the information gathered via the measurements required by points (a) and (c) shall be used to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce the exposure to workers and to the environment and in particular with regard to the

implementation of a preventative maintenance program for all the mechanical ventilation resources (general and LEV);

- (e) the results of the measurements described in points (a) and (c), as well as the outcome and conclusions of the review and any actions taken, as described in point (d), shall be documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, be submitted to the competent authority of the Member State where the authorised uses take place.

Article 4

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 5

This Decision is addressed to Topocrom GmbH, Hardtring 29, 79333 Stockach, Germany.

Done at Brussels,

For the Commission

Elżbieta BIEŃKOWSKA

Member of the Commission