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COMMISSION IMPLEMENTING DECISION

of 7.6.2017

granting an authorisation for a use of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Caffaro Brescia S.r.l.)

(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) Sodium dichromate 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 9 November 2015, Caffaro Brescia S.r.l. ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorite.
- (3) On 19 September 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.
- (4) In its opinion, the RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore that sodium dichromate is a non-threshold substance. In accordance with Article 60(3)(a) of that Regulation, 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 that Regulation.
- (5) In its opinion, the RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population that could potentially be exposed via the environment.

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/a6451ea9-b19f-4c95-8bc9-edb01644bb9f>

- (6) In its opinion, the SEAC concluded that the overall socio-economic benefits arising from the use 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 in terms of their technical and economic feasibility for the applicant, their risk reduction capacity, their availability to the applicant, as well as their capacity to eliminate the exposure to chromium (VI).
- (7) Based on the RAC and SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is therefore appropriate to authorise the use of sodium dichromate 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, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years. The recommended review period takes into account RAC's conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risks, the negligible costs associated with the health impacts of continued use of the substance, the lack of suitable alternatives, the time necessary to implement a viable alternative if one becomes available in the future, the likelihood that substitution would not be possible within shorter timelines, the applicant's very long investment cycle, as well as the fact that the benefits of continued use outweigh the risks by a significant margin.
- (9) Therefore, as regards the use of sodium dichromate applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (10) In their opinions, the RAC and the SEAC considered that additional conditions and monitoring arrangements for the use as described in the application were not necessary but recommended additional occupational exposure measurements to be carried out for the purpose of a review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 to determine that the risk management measures and operational conditions are still appropriate and effective in limiting the risks.
- (11) The language used for description of the risk management measures and operational conditions included in the application for authorisation is different from the official language of the Member State where the use applied for 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 this Member States.
- (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 that Regulation 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 2004/37 of the

³ <http://ec.europa.eu/DocsRoom/documents/19107>

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 EU 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 sodium dichromate (EC No. 234-190-3, CAS No. 105888-01-9/7789-12-0) 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:

⁴ 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).

Authorisation number

Authorised use

REACH/17/19/0

Use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorite

Article 2

As regards the authorised use of sodium dichromate, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2029.

Article 3

The following monitoring arrangement shall apply:

- (a) on request of the competent authority of the Member State where the authorised use takes place, the authorisation holder shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions described in the chemicals safety report, in an official language of that Member State;
- (b) in case of a review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 concerning the use referred to in Article 1 of this Decision, the authorisation holder shall provide additional occupational exposure measurements, based on relevant standard reference methodologies and protocols, representative of the range of tasks undertaken, where exposure to Cr(VI) is possible and of the total number of workers potentially exposed on each site.

Article 4

This Decision is addressed to Caffaro Brescia S.r.l., via del Brennero 48, 56100 Pisa, Italy.

Done at Brussels, 7.6.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

