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COMMISSION IMPLEMENTING DECISION

of 15.12.2017

granting an authorisation for a use of sodium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Gruppo Colle 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/EC[1], 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 27 October 2016, an application for authorisation was submitted by Gruppo Colle s.r.l. ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of sodium dichromate as mordant in wool dyeing.

(3) On 11 July 2017, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] 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 sodium dichromate in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore sodium dichromate 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 that Regulation.

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

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

[2] http://ec.europa.eu/docsroom/documents/24789

(6) In its opinion, due to the fact that the workers' exposure assessment was based on a single exposure measurement with limited contextual information, RAC recommended additional monitoring arrangements.

(7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of sodium dichromate 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 for the dyeing with dark colours. 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 sodium dichromate applied for limited to dyeing with dark colours, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report[3], as well as the monitoring arrangements set out in this Decision 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 seven years. The Commission takes into account the relevant elements from the RAC and the SEAC's assessments, and in particular the risk of the continued use of the substance, the fact that the risk management measures and operational conditions are appropriate and effective in limiting the risk to workers and the general population, the fact that the socio-economic benefits of continued use clearly outweigh the risk, the uncertainties in the analysis of alternatives submitted by the applicant, which are, however, recognised by SEAC to be inherent to the use applied for and do not undermine the conclusion on the suitability of alternatives, as well as the approximate timeline for finding and implementing an alternative, including the time for the necessary adaptation of the existing formulations. The Commission, having evaluated the SEAC recommendation, as well as the uncertainties as regards the time necessary to implement alternatives, considers appropriate to shorten the review period to four years.

(10) Given that the applicant submitted its application for authorisation after the latest application date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 and that the sunset date set out in Annex XIV to that Regulation has already passed at the time of the adoption of this Decision, it is appropriate to set the starting point for the review period as from the adoption of this Decision.

(11) Therefore, the Commission considers appropriate that, 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 is set at four years as from the adoption of this Decision.

(12) The applicant stated to have already discontinued the use of mordant dyes for lighter colours (light and medium colours), while substitution is difficult for dark colours. On these grounds, SEAC agreed with the applicant to restrict the scope of the use applied for to dyeing with dark colours (e.g. black, brown, navy blue) and included this aspect in the suggested conditions for authorisation. The Commission concurs with this condition.

(13) 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(s) of the Member State(s) where the use(s) take(s) place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate

[3] https://echa.europa.eu/documents/10162/cea8c78e-8f30-0690-dfc9-98ba970350ac

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(s) concerned.

(14) 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 2004/37/EC of the European Parliament and of the Council[4], 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/EEC[5], Council Directive 98/24[6], Directive 2004/37, Council Directive 92/85/EEC[7] and Council Directive 94/33/EC[8].

(15) 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 Council[9] and Directive 2008/50/EC of the European Parliament and of the Council[10], 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 Council[11] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[12]. 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.

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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 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).

7 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).

8 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).

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 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).

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 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).

(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 for the following use of sodium dichromate, (EC No 234-190-3 and CAS No. 10588-01-9 (anhydrous); CAS No. 7789-12-0 (dihydrate)), 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:

Authorisation number	Authorised use
REACH/17/27/0	Use of sodium dichromate as mordant in wool dyeing with dark colours

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 15 December 2021.

Article 3

The following monitoring arrangements shall apply:

(a) 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;

(b) the authorisation holder shall conduct regular occupational exposure measurements of sodium dichromate related to the use described in Article 1. Those measurements shall:

  (i) take place at least annually. The first measurements shall be performed at the latest by 15 June 2018*;*

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

  (iii) ensure a sufficiently low detection limit;

  (iv) comprise personal inhalation exposure sampling;

  (v) be representative of the range of tasks with possible exposure to chromium (VI) and of the total number of workers that are potentially exposed;

  (vi) include contextual information about the tasks with possible exposure to chromium (VI) on the sampling time related to shifts, the tasks performed and personal protection equipment (PPE) worn;

(c) the authorisation holder shall conduct regular measurements of emissions of chromium (VI) to waste water, according to standard sampling and analytical methods, ensuring a sufficiently low detection limit and including sufficient contextual information;

(d) the authorisation holder shall use the information gathered in the measurements referred to in points (b) and (c) to regularly review the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce exposure;

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

Article 4

This Decision is addressed to Gruppo Colle s.r.l., Via G. Di Vittorio 3/5, IT 59025 Usella Cantagallo, Prato, Italy.

Done at Brussels, 15.12.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION