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COMMISSION IMPLEMENTING DECISION

of 15.12.2017

granting an authorisation for a use of ammonium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Veco B.V.)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(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/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Ammonium dichromate ('ADC') 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 11 February 2016, an application for authorisation was submitted by Veco B.V. ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of ammonium dichromate as photosensitive component in a polyvinyl alcohol photolithographic lacquer system for the manufacturing of mandrels which are used in nickel electroforming processes. In order to align the wording of the use with the terminology of Regulation (EC) No 1907/2006, that use should be referred to as 'ammonium dichromate as photosensitive component in a polyvinyl alcohol photolithographic lacquer system for the production of mandrels which are used in nickel electroforming processes'.

(3) On 15 November 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 Agency[2] 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 ADC in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 whilst it acknowledged that a threshold for the reprotoxic properties of this substance can be determined. The RAC concluded that ADC should be considered as a non-threshold substance with respect to risk characterisation, as there is likelihood for carcinogenic effects to occur even

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

[2] https://echa.europa.eu/documents/10162/1b08127f-588b-4a2e-a930-28758da10c12

following exposure to lower levels than threshold levels for reprotoxicity. 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, the RAC concluded that the risk management measures and operational conditions as described in the application are not appropriate and effective in limiting the risk. Due to uncertainties related to the data on worker exposure and on indirect exposure of man via the environment, the RAC recommended additional conditions and monitoring arrangements.

(6) In its opinion, the SEAC concluded that the overall socio-economic benefits arising from the use of ammonium dichromate applied for outweigh the risks to human health or 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. The Commission, having evaluated the SEAC assessment, concurs with this conclusion.

(7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of ammonium dichromate applied for, 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 conditions set out in this Decision, 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 seven years. The recommended review period takes into account RAC's assessment of the risk of the continued use of the substance, that the socio-economic benefits of continued use outweigh the risks by a substantial margin, the non-availability of suitable alternatives before the sunset date, the timelines required for further research and development to find a suitable alternative and to prove its industrial viability, and the absence of major uncertainties in the assessment.

(9) In view of the RAC and the SEAC opinion, the Commission considers appropriate that, as regards the use of ammonium dichromate applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at seven 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(s) of the Member State where the uses takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation 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 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

[3] http://ec.europa.eu/DocsRoom/documents/20583/attachments/1/translations/en/renditions/pdf

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].

(12) 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.

(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 ammonium dichromate (EC No 232-143-1 and CAS No 7789-09-5), 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 conditions set out in Article 2 of this Decision, are fully applied:

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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, 29.06.1989, 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 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, 20.08.1994, 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).

Authorisation number	Authorised use
REACH/17/28/0	Use as photosensitive component in a polyvinyl alcohol photolithographic lacquer system for the production of mandrels which are used in nickel electroforming processes

Article 2

The authorisation referred to in Article 1 shall be subject to the following conditions:

(a) the authorisation holder shall conduct regular occupational exposure measurements related to the use described in Article 1. These measurements shall:

  (i) take place at least annually. The first measurements shall be performed without delay and at the latest by 15 June 2018;

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

  (iii) ensure the use of method with detection and quantification limits allowing for a meaningful exposure evaluation for exposed workers;

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

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

(b) the authorisation holder shall continue to annually perform biomonitoring of workers with possible exposure to ADC by measuring chromium values in urine;

(c) the authorisation holder shall regularly, and at least annually, measure all emissions of chromium (VI) to wastewater related to the use referred to in Article 1. The measurements shall be undertaken according to standard sampling and analytical methods and ensure a sufficiently low detection limit;

(d) the authorisation holder shall use the information gathered in the measurements referred to in points (a) to (c) to review the effectiveness of the risk management measures and operational conditions and to implement measures for reducing exposure of workers. When, based on the review, action is considered appropriate, the authorisation holder shall take into account the hierarchy of control principles to select the appropriate risk management measures. In particular, consideration should be given to the feasibility of implementing full enclosure with air extraction around the area where tasks resulting in exposure are performed, namely the area for the preparation of the ADC-containing lacquers. When the full enclosure is not possible, reasons shall be documented;

(e) the results of the measurements and the contextual information referred to in points (a) to (c), as well as the outcome and conclusions of the review and any actions taken in accordance with 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, submitted to the competent authority of the Member State where the authorised use takes place.

Article 3

As regards the authorised use of ammonium dichromate, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 September 2024.

Article 4

The following monitoring arrangement shall apply:

– 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 Veco B.V., Karel van Gelreweg 22, 6961 LB Eerbeek, The Netherlands.

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