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COMMISSION IMPLEMENTING DECISION

of 22.5.2017

granting an authorisation for a use of ammonium dichromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Micrometal GmbH)

(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) Ammonium dichromate ('ADC') 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 December 2015, an application for authorisation was submitted by Micrometal GmbH ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of ammonium dichromate as a photosensitiser for production of micro components.

(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 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 ADC in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore ADC 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, 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.

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

[2] https://echa.europa.eu/documents/10162/35a4b34c-8a79-458c-b6f3-4fd8b7d50981

(6) In its opinion, due to the uncertainties related to the data on worker exposure and on indirect exposure of man via the environment, the RAC recommended additional conditions.

(7) In its opinion, the SEAC concluded that the overall socio-economic benefits arising from the use of ADC 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 feasibility.

(8) Based on the RAC and the SEAC opinions, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of ADC 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.

(9) 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 the low costs associated with the risks that arise from the continued use of the substance, the lack of suitable alternatives by the sunset date, the results of research and development undertaken by the applicant demonstrating that substitution would not be possible within shorter timelines, as well as the fact that the benefits of continued use outweigh the risks by a significant margin.

(10) Therefore, as regards the use of ADC 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.

(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(s) of the Member State(s) where the use of ADC 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 States 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 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 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 EU Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC[5], Council Directive 98/24[6],

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3 http://ec.europa.eu/DocsRoom/documents/19101

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).

Directive 2004/37 of the European Parliament and of the Council[7], Council Directive 92/85/EEC[8] and Council Directive 94/33/EC[9].

(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 Council[10] and Directive 2008/50/EC of the European Parliament and of the Council[11], 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[12] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[13]. 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 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:

Authorisation number	Authorised use
REACH/17/13/0	Use as photosensitiser for the production of micro components

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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).

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 22 November 2017;

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

  (iii) ensure a sufficiently low detection limit;

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

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

(b) the authorisation holder shall 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, where appropriate;

(c) the authorisation holder shall use the information gathered in the measurements referred to in points (a) and (b) to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate;

(d) the results of the measurements referred to in points (a) and (b), as well as the outcome and conclusions of the review and any actions taken in accordance with point (c), 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 2029.

Article 4

The following monitoring arrangements shall apply:

– the authorisation holder shall submit, upon request, to that 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 Micrometal GmbH, Renkenrusstrasse 24, 79639 Müllheim, Germany.

Done at Brussels, 22.5.2017

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION