EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 28.3.2019

granting an authorisation for a use of 1,2-dichloroethane under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (EURENCO)

(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) 1,2-dichloroethane (EDC) 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) of that Regulation.

(2) On 22 February 2016, EURENCO ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the industrial use of EDC as a solvent for the synthesis of polyepichlorohydrin used as a precursor in the production of glycidyl azide polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.

(3) On 11 May 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 EDC in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore EDC is a non-threshold substance for the purposes of Article 60(3)(a) of that Regulation. In accordance with that Article, 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 not appropriate and effective in limiting the risk to workers and to the general population that could potentially be exposed via

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

[2] https://echa.europa.eu/documents/10162/3c348d2f-a4c5-3e48-2220-d292631a898f

the environment. Due to the uncertainties in the assessment of the risk for workers and the risk for humans via environment, RAC recommended additional conditions for the authorisation. The Commission, having evaluated RAC's assessment, concurs with its conclusion.

(6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of EDC applied for outweigh the risk to human health or the environment arising from that use, provided that the additional conditions and monitoring arrangements suggested by RAC are adhered to. SEAC further concluded that there are no suitable alternatives for the applicant before the sunset date. The Commission, having evaluated SEAC's assessment, concurs with those conclusions.

(7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use 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, SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at four years. The Commission takes into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's assessment of the risk of the continued use of the substance, that the socio-economic benefits of continued use clearly outweigh the risk for human health and the environment and the time needed for implementing a two-step substitution strategy consisting, first, of the development and the industrial implementation by 2021 of a less hazardous temporary alternative and, subsequently, of the implementation of a new synthesis process, which is still object of research and development and which will not involve the use of any hazardous substance. The Commission concurs with SEAC's recommendation.

(9) Therefore, it is appropriate that, as regards the use of EDC applied for, the review period be set at four 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 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.

(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 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 and 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

[3] http://ec.europa.eu/DocsRoom/documents/23164

European Parliament and of the Council[4], or to prevent and reduce exposure in accordance with Article 5 of that Directive. In addition, this Decision is without prejudice to the application of the Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7] and 98/24/EC[8] and Directive 2004/37/EC.

(12) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC[9] and 2010/75/EU[10] of the European Parliament and of the Council, as well as with emission limit values set to achieve compliance with the environmental quality standards established both by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] and in Directive 2008/105/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 1,2-dichloroethane (EC No 203-458-1; CAS No 107-06-2), 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 this Decision are fully applied:

Authorisation number	Authorised use

[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 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).

[7] 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).

[8] 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).

[9] 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).

[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 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).

[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).

REACH/19/7/0	Industrial use as a solvent for the synthesis of polyepichlorohydrin used as a precursor in the production of glycidyl azide polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives

Article 2

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

(a) the authorisation holder shall implement without undue delay the most appropriate risk management measures for waste water releases in order to reduce the environmental exposure to a level as low as is technically and practically possible;

(b) the authorisation holder shall conduct regular occupational exposure measurements of 1,2-dichloroethane relating to the use described in Article 1. Those measurements shall:

  (i) take place at least annually;

  (ii) be representative of the range of tasks undertaken where exposure to 1,2-dichloroethane is possible and of the total number of workers that are potentially exposed – especially those involved in the collection of samples and their analysis;

  (iii) be based on relevant standard methodologies or protocols and use analytical methods with the lowest detection limit;

  (iv) include contextual information about the tasks with possible exposure to 1,2-dichloroethane and of the total number of workers that are potentially exposed;

(c) the authorisation holder shall regularly measure emissions of 1,2-dichloroethane to waste water. Those measurements shall be based on relevant standard methodologies or protocols and use analytical methods with the lowest detection limit.

The authorisation holder shall use the information gathered via the measurements referred to in points (b) and (c) of the first paragraph to regularly review the effectiveness of the risk management measures and operational conditions, including the effectiveness and positioning of extraction ventilation, and to take action, as appropriate, to further reduce workers' exposure and environmental exposure to 1,2-dichloroethane.

The results of the measurements referred to in points (b) and (c) of the first paragraph, as well as the outcomes and conclusions of the review and any actions taken in accordance with the second paragraph, 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 use takes place.

Article 3

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 November 2021.

2. The authorisation shall cease to be valid on 22 November 2021 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 22 May 2020, unless a decision to withdraw the authorisation is adopted earlier pursuant to paragraphs 2 and 3 of Article 61 of that Regulation.

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 EURENCO, 1928, Avenue d'Avignon, 84700, SORGUES, France.

Done at Brussels, 28.3.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION