EUROPEAN
COMMISSION

Brussels, 15.12.2017
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COMMISSION IMPLEMENTING DECISION

of 15.12.2017

granting an authorisation for a use of 1,2-dichloroethane (EDC) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (GE Healthcare Bio-Sciences AB)

(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)(a) of that Regulation.

(2) On 8 February 2016, an application for authorisation was submitted by GE Healthcare Bio-Sciences AB ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the industrial use of EDC as an emulsifying solvent in the manufacture of porous particles for beaded chromatography and cell culture media.

(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 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 that EDC 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

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

[2] https://echa.europa.eu/documents/10162/398a4394-f80d-4b0d-a747-4a609bc41256

risk to workers, while they do not limit the risk to the general population that could potentially be exposed via the environment.

(6) In its opinion, due to the inadequacy of the risk management measures in place to prevent releases of EDC to the environment from various parts of the site, including the tank farm and process ventilation, RAC recommended additional conditions to control the emissions of EDC to the environment. RAC also recommended implementing occupational exposure measurements for the exposure scenarios described in the application. It is appropriate to use these measurements to review the effectiveness of the risk management measures and operational conditions.

(7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of EDC 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 for the applicant. 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 EDC 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, 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 assessment of the risk from the continued use of the substance, the lack of suitable alternatives by the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006 and the likelihood that substitution would not be possible within shorter timelines, the applicant's continuous research and development activities to find alternative solvents or processes and its project for a theoretical substitution, as well as the fact that the socio-economic benefits of continued use of the substance are in the order of tens of millions of euros.

(10) In view of RAC and SEAC opinions, the Commission considers appropriate that, as regards the use of EDC 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 of the Member State where the use of EDC 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.

(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 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/20585

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 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].

(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[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.

(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 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:

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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).

Authorisation number	Authorised use
REACH/17/33/0	Industrial use of 1,2-dichloroethane as an emulsifying solvent in the manufacture of porous particles for beaded chromatography and cell culture media

Article 2

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

(a) the authorisation holder shall review without delay the risk management measures and operational conditions and introduce measures, as appropriate to prevent release of 1,2-dichloroethane to the environment, in particular from process ventilation and the tank farm;

(b) the results of the review referred to in point (a) 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

As regards the authorised use of 1,2-dichloroethane, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 November 2029.

Article 4

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 1,2-dichloroethane related to the use described in Article 1. Those measurements shall:

  (i) take place at least annually;

  (ii) be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit;

  (iii) comprise both personal and static inhalation exposure sampling and be representative of the range of tasks undertaken in Working Contributing Scenarios 1 to 5 of the chemical safety report and of the total number of workers that are potentially exposed;

(c) the authorisation holder shall conduct regular measurements of emissions of 1,2-dichloroethane to the environment, 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 take action, as appropriate;

(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 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 5

This Decision is addressed to GE Healthcare Bio-Sciences AB, Björkgatan 30, BA 1-1, 75184 Uppsala, Sweden.

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