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COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 17.1.2019

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 (Bayer Pharma AG)

(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 10 May 2016, Bayer Pharma AG ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of EDC as an industrial solvent in the manufacture of the high-grade pure final intermediate of Iopromide, the active pharmaceutical ingredient for the X-ray contrast medium Ultravist®.

(3) On 4 August 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 that therefore 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 risk to workers and the general population that could potentially be exposed via the

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

[2] https://echa.europa.eu/documents/10162/da1d17cd-eaa0-d561-cdf4-4828c7f92aa3

environment. However, RAC considered the justification of the applicant regarding the difficulties in planning the exposure measurements of the maintenance tasks with high potential for exposure due to the infrequency of such tasks to be insufficient. Furthermore RAC also noted that highest exposures occur in tasks associated to the production and distillation units, particularly associated to the filling of big-bags, indicating these processes are not fully contained and that the engineering measures in place are not fully effective. RAC further concluded that the sources of exposure were not clearly identified and therefore recommended additional monitoring arrangements.

(6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the continued use of EDC 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 in terms of their technical and economic feasibility for the applicant before the sunset date. 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 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] 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 12 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 predicted increase of production and continued use of the substance, the fact that the socio-economic benefits of continued use significantly outweigh the risk to human health associated with that use, the low likelihood that this ratio would change in the near future, the long investment cycle of the applicant, as well as the time and the estimated net costs required for the implementation of a suitable alternative once one becomes available, including the re-design of the manufacturing process and the obtaining of the marketing authorisations of the final product in more than one hundred countries. The Commission concurs with SEAC's recommendation.

(9) In view of RAC and SEAC's 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 is set at 12 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(s) where the use(s) take(s) 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(s) 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

[3] http://ec.europa.eu/docsroom/documents/25161

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. 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 Directive 89/391/EEC[5], Council Directive 98/24/EC[6], Directive 2004/37/EC, 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 1,2-dichloroethane (EDC) (EC No. 203-458-1; CAS No. 107-06-2), provided that the risk management measures and operational conditions described

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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).

in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation are fully applied:

Authorisation number	Authorised use
REACH/19/10/0	Use of 1,2-dichloroethane as an industrial solvent in the manufacture of the high-grade pure final intermediate of Iopromide, the active pharmaceutical ingredient for the X-ray contrast medium Ultravist®

Article 2

1. 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.

2. The authorisation shall cease to be valid on 22 November 2029 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 22 May 2028, unless a decision to withdraw the authorisation is adopted earlier pursuant to paragraphs 2 and 3 of Article 61 of that Regulation.

Article 3

The following monitoring arrangements shall apply:

(a) the authorisation holder shall continue to implement regular occupational exposure measurements relating 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 use the method with the lowest detection limit, to allow meaningful assessment of exposures;

  (iii) comprise both personal and static (where appropriate) inhalation exposure sampling and be representative of the range of tasks and process steps with possible exposure to 1,2-dichloroethane, including transfer tasks in worker contributing scenarios 1 and 2 and planned maintenance, as well as of the total number of workers potentially exposed;

  (iv) include contextual information about the tasks with possible exposure to 1,2-dichloroethane;

(b) the authorisation holder shall measure emissions of 1,2-dichloroethane in ambient air around the site. Those measurements shall:

  (i) take place annually;

  (ii) be undertaken according to standard sampling and analytical methods;

  (iii) ensure a sufficiently low detection limit, where appropriate;

(c) the information gathered in the measurements referred to in points (a) and (b) shall be used to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce exposure of workers and the general population exposed indirectly via the environment and the releases of 1,2-dichloroethane to air. Measures to further reduce workers' exposure shall be undertaken, with particular focus on the

effectiveness of local exhaust ventilation, especially in relation to the tasks associated with the highest exposures described in worker contributing scenarios 1 and 2;

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

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 Bayer Pharma AG, Muellerstr. 178, 13353, Berlin, Germany.

Done at Brussels, 17.1.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION