EUROPEAN
COMMISSION

Brussels, 1.3.2019
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COMMISSION IMPLEMENTING DECISION

of 1.3.2019

granting an authorisation for certain uses of 1,2-dichloroethane under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OLON Spa)

(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 therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 17 May 2016, OLON Spa ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of EDC as a solvent in the manufacturing of the active pharmaceutical ingredient epirubicin ('use 1') and as a solvent in the manufacturing of the active pharmaceutical ingredient prednisolone steaglate ('use 2').

(3) On 7 November 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 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 for the two uses of EDC applied for are appropriate and effective in limiting the risks to workers and the general population

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

[2] https://echa.europa.eu/documents/10162/41e7cf03-470e-87eb-f608-23218beff611 https://echa.europa.eu/documents/10162/dff1b727-bf1b-a75f-1c30-ba6236c834ea

that could potentially be exposed via the environment. The Commission, having evaluated the RAC assessment, concurs with that conclusion.

(6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the two uses of EDC applied for outweigh the risk to human health and the environment arising from those uses and that there are no suitable alternative substances or technologies for the applicant before the sunset date. The Commission, having evaluated SEAC's assessment, concurs with these conclusions.

(7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses 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 for both uses applied for. The Commission takes into account the relevant elements from RAC's and SEAC's assessments for both uses, and in particular RAC's conclusion that the risk management measures and operational conditions are appropriate and effective in limiting the risk, the likelihood that substitution would not be possible within shorter timelines, the estimated costs and the time required for the implementation of a potentially suitable alternative, including the re-designing of the manufacturing process and the obtaining of the marketing approval of the final product, as well as the fact that the socio-economic benefits of continued use clearly outweigh the risk to human health and that the situation is unlikely to change in the near future. The Commission concurs with SEAC's recommendation.

(9) Therefore, it is appropriate that, as regards both uses of EDC applied for, the review period be 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 languages of the Member States where the uses take 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 States 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 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. Furthermore, this Decision is without

[3] http://ec.europa.eu/docsroom/documents/26783
http://ec.europa.eu/docsroom/documents/26784

[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).

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 uses 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 are fully applied:

Authorisation number	Authorised uses
REACH/19/1/0	Use as a solvent in the manufacturing of the active pharmaceutical ingredient epirubicin

[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/19/1/1	Use as a solvent in the manufacturing of the active pharmaceutical ingredient prednisolone steaglate

Article 2

1. As regards the authorised uses 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 authorisations referred to in Article 1 shall cease to be valid on 22 November 2029 in case a 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 authorisation holder shall submit, upon request, to the competent authority of the Member State where the authorised uses 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 4

This Decision is addressed to OLON Spa, Strada Rivoltana Km 6/7, 20090, Rodano, Milano, Italy.

Done at Brussels, 1.3.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION