EUROPEAN
COMMISSION

Brussels, 27.6.2018
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COMMISSION IMPLEMENTING DECISION

of 27.6.2018

granting an authorisation for a use of Bis(2-methoxyethyl)ether (diglyme) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Merck KGaA)

(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) Bis(2-methoxyethyl)ether (diglyme) 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 23 May 2016, Merck KGaA ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the industrial use of diglyme as a solvent in the manufacturing process of cryptand intermediates for further conversion into cryptand 221 and cryptand 222.

(3) On 3 March 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 possible to determine a derived no-effect level (DNEL) for the reprotoxic properties of diglyme in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore that diglyme is a threshold substance.

(5) RAC also concluded that the risk to human health from the use of diglyme applied for is adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006, provided that the risk management measures and operational conditions described in the application are adhered to. However, even though RAC concluded that adequate control of risk is demonstrated, it recommended in its opinion additional occupational measurements for the review report in order to strengthen the level of

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

[2] https://echa.europa.eu/documents/10162/209f8c7a-b576-a15c-a70e-1669625fc790

certainty of the workers' exposure assessment since the exposure assessment is based on modelling with a small measured data set used to corroborate the results.

(6) Therefore, it is appropriate to grant an authorisation for the use of diglyme applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report are fully applied.

(7) 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 Commission takes into account the relevant elements from the RAC's and SEAC's assessments, and in particular RAC's conclusion that the risk to human health from the use of the substance is demonstrated to be adequately controlled, the significant socio-economic benefits of continued use of the substance, the lack of any suitable alternative despite the applicant's research and development activities, the time necessary to implement a suitable alternative if one becomes available in the future, as well as the likelihood that substitution would not be possible within shorter timelines. The Commission concurs with the SEAC's recommendation.

(8) In view of RAC's and SEAC's opinions, the Commission considers appropriate that, as regards the use of diglyme applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(9) In their opinions, RAC and SEAC considered that additional conditions for the use as described in the application were not necessary.

(10) However, given that the applicant submitted its application for authorisation after the latest application date referred to in Article 58(1)(c)(ii) of Regulation (EC) No 1907/2006 and the sunset date set out in Annex XIV to that Regulation has already passed at the time of the adoption of this Decision, it is appropriate to set the starting point for the review period as from the adoption of this Decision.

(11) The language used for description of the risk management measures and operational conditions included in the application for authorisation is different from the official language of the Member State where the use applied for 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 that Member State.

(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 eliminate or reduce to a minimum the risks to the health and safety of workers at work involving hazardous chemical agents pursuant to Article 5(2) of Council Directive 98/24[3]. In addition, this Decision is without prejudice to the application of the Union Directives in the area of health and safety at work, in particular Council Directive

[3] 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).

89/391/EEC[4], Council Directive 98/24, Council Directive 92/85/EEC[5] and Council Directive 94/33/EC[6].

(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[7] and Directive 2008/50/EC of the European Parliament and of the Council[8], 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[9] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10]. 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(2) of Regulation (EC) No 1907/2006 for the following use of Bis(2-methoxyethyl)ether (diglyme) (EC No 203-924-4; CAS No 111-96-6) 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 use
REACH/18/11/0	Industrial use of diglyme as solvent in the manufacturing process of cryptand intermediates for further conversion into cryptand 221 and cryptand 222

Article 2

1. As regards the authorised use of diglyme, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 27 June 2030.

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4 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).

5 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).

6 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).

7 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).

8 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).

9 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).

10 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).

2. The authorisation REACH/18/11/0 shall cease to be valid on 27 June 2030 provided that a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 27 December 2028, unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of Regulation.

Article 3

The following monitoring arrangements shall apply:

(a) the authorisation holder shall conduct regular occupational exposure measurements relating to the use referred to in Article 1. Those measurements shall:

  (i) take place at least annually;

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

  (iii) be representative of the range of tasks with possible exposure to diglyme and of the total number of workers potentially exposed;

  (iv) include contextual information about the tasks with possible exposure to diglyme;

(b) the information obtained from the measurements referred to in point (a) shall be documented and used to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce workers' exposure to diglyme and its emissions to the environment;

(c) the authorisation holder shall submit the information gathered in accordance with point (a), as well as documentation on the outcomes and conclusions of the review referred to in point (b), as part of the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 as well as, upon request, to the competent authority of the Member State where the use takes place.

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 Merck KGaA, Frankfurter Strasse 250, D-64293 Darmstadt, Germany.

Done at Brussels, 27.6.2018

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION