EUROPEAN
COMMISSION

Brussels, 24.4.2019
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COMMISSION IMPLEMENTING DECISION

of 24.4.2019

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 (Life Technologies AS)

(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) Decision of the Joint Committee of the European Economic Area No 25/2008 of 14 March 2008 amending Annex II to the Agreement on the European Economic Area incorporated Regulation (EC) No 1907/2006 into the Agreement.

(2) 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.

(3) On 18 February 2016, Life Technologies AS ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of diglyme as a process chemical in the manufacture of Dynabeads®.

(4) On 21 June 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.

(5) 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 that, therefore, diglyme is a threshold substance.

(6) RAC 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, as the measurement data set

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

[2] https://echa.europa.eu/documents/10162/886a7d5a-9c98-b50e-639c-ec4cd76cdaeb

submitted as part of the application does not cover all tasks resulting in exposure to diglyme, and considering the expected increase of volume of diglyme used and possible subsequent increase of exposure to diglyme at the workplace in the next years, RAC recommended additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with that conclusion.

(7) Therefore, in accordance with Article 60(2) 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] 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 concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular RAC's conclusion that the risk to human health from the use of the substance are demonstrated to be adequately controlled, the significant socio-economic benefits of the continued use of the substance, the lack of any technically feasible alternative despite the applicant's research and development activities, and the time necessary for further research and development, validation and regulatory approval should an alternative become available in the future.

(9) Therefore, it is appropriate that 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 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 require 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.

(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 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/EC[4]. 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.

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3 http://ec.europa.eu/docsroom/documents/24152

4 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).

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).

(12) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directives 2008/50/EC[8] and 2010/75/EU[9] 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 by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] and in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under Union law, as these may include further 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(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/19/20/0	Use as a process chemical in the manufacture of Dynabeads®

Article 2

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 August 2029.

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

Article 3

1. The following monitoring arrangements shall apply:

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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 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 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 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).

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).

(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, as well as following any relevant change in the process which may influence the workers' exposure. The first measurement shall be performed as soon as possible, in order to validate the exposure scenarios;

(ii) be based on relevant standard methodologies or protocols;

(iii) ensure a sufficiently low detection limit;

(iv) be representative for the tasks with possible exposure to diglyme and of the total number of workers that are potentially exposed;

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

(b) the authorisation holder shall conduct measurements of releases to air and water from the use referred to in Article 1.

2. The authorisation holder shall, on the basis of the exposure measurements carried out in accordance with point (a) of paragraph 1, review the tasks with exposure potential and develop measures to reduce dermal exposure.

3. The authorisation holder shall use the information gathered from the measurements referred to in points (a) and (b) of paragraph 1 to regularly review the appropriateness and 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, while observing the hierarchy of control principles according to Directive 98/24/EC.

4. The authorisation holder shall document and submit upon request to the competent authority of the Member State where the authorised use take place the results of the measurements referred to in points (a) and (b) of paragraph 1, as well as the outcome and conclusions of the review and any action taken in accordance with paragraphs 2 and 3. The authorisation holder shall also include them 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 Life Technologies AS, Ullernchaussen 52, NO-0379, PO Box 114 Smestad, NO-0309, Oslo, Norway.

Done at Brussels, 24.4.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION