EUROPEAN
COMMISSION

Brussels, 12.6.2019
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COMMISSION IMPLEMENTING DECISION

of 12.6.2019

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 (N.V. Ajinomoto OmniChem S.A.)

(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 laid down in Article 56(1)(a) of that Regulation.

(2) On 21 November 2017, N.V. Ajinomoto OmniChem S.A. ('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 solvent for the synthesis of the anti-HIV active pharmaceutical ingredient dapivirine.

(3) On 10 September 2018, 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 third 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 that therefore diglyme is a threshold substance.

(5) RAC concluded that the risk to human health from the use of diglyme covered by the application 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 and in further information submitted by the applicant and reflected in the conditions of this Decision are adhered to. However, due to the lack of monitoring data related to the levels of exposures resulting from the

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

[2] https://echa.europa.eu/documents/10162/1bc86b55-4e24-3b24-34db-b4d2e532b99b

tasks performed, RAC recommended the implementation of additional conditions and monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with that conclusion.

(6) Therefore, an authorisation for the use of diglyme covered by the application should be granted, 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.

(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 seven years. The Commission concurs with SEAC's recommendation taking into account the relevant elements from RAC's and SEAC's assessments, and in particular the conclusion that the risk to human health from the use of the substance is demonstrated to be adequately controlled, the lack of technically and economically feasible alternatives despite the applicant's efforts to phase out the use of diglyme, the need for re-validation of the manufacturing process and regulatory re-approval should a suitable alternative become available, as well as the significant socio-economic implications in case of no authorisation.

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

(9) Therefore, it is appropriate to set the review period at seven years as from the date of adoption of this Decision.

(10) The language used for the 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 covered by the application takes place. Therefore, in order to facilitate the enforcement of compliance with 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 having regard to the principle set out in 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 and 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]. This Decision does not affect the application of 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 https://ec.europa.eu/docsroom/documents/31665

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).

(12) This Decision does not affect 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], or established 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 other emission limit values or environmental quality standards under Union law, as those 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 as well as the conditions set out in this Decision are fully applied:

Authorisation number	Authorised use
REACH/19/23/0	Use as a solvent for the synthesis of the anti-HIV active pharmaceutical ingredient dapivirine

Article 2

The authorisation shall be subject to the condition that, before the first production campaign using diglyme in the full scale commercial installation, the authorisation holder implements the following technical improvements in the risk management measures:

(a) the sampling and transfer system shall include the use of a grip tool for holding the pipette to avoid direct contact between pipette and operator as well as an improved stabilisation of the sampling bottle to minimise dermal exposures. Closed transfer and

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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 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).

sampling systems shall be introduced, and where that is not technically possible, the reasons therefore shall be documented;

(b) in relation to transfer activities, the local exhaust ventilation system described in the chemical safety report referred to in Article 1 shall be improved through implementation of a robust device which shall ensure improved aspiration around the opening of the drums;

(c) where the pilot installation is used, inhalation protection with independent air supply (assigned protection factor – APF - of minimum 20) shall be used when the centrifuge is emptied.

Article 3

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 12 June 2026.

The authorisation referred to in Article 1 shall cease to be valid on 12 June 2026 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 12 December 2024.

Article 4

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 annually;

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

(iii) ensure a sufficiently low detection limit;

(iv) comprise inhalation and if possible dermal exposure;

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

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

(b) the authorisation holder shall use the information gathered from the measurements referred to in point (a) to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions, in particular regarding the manipulations with potential exposure to diglyme, and to take action, as appropriate, to further reduce workers' exposure to diglyme;

(c) the results of the measurements referred to in point (a), as well as the outcome and conclusions of the review together with any actions taken in accordance with point (b), shall be documented and 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 5

Upon request, the authorisation holder shall submit a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report to

the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 6

This Decision is addressed to N.V. Ajinomoto OmniChem S.A., Cooppallaan 91, 9230, Wetteren, Oost Vlaanderen, Belgium.

Done at Brussels, 12.6.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION