EUROPEAN
COMMISSION

Brussels, 10.7.2019
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COMMISSION IMPLEMENTING DECISION

of 10.7.2019

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 (PMC ISOCHEM)

(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 22 February 2016, ISOCHEM ('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 solvent in one step of manufacturing of an active pharmaceutical ingredient used in an anti-protozoal drug.

(3) On 29 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 (the 'Agency')[2] on the application pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) On 27 February 2018, the Agency received notification that PMC ISOCHEM had succeeded in the rights and obligations of ISOCHEM. In its assessment, the Agency concluded that the notified change had no implications for the RAC and SEAC opinions. The Commission accepts that conclusion.

(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

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

[2] https://echa.europa.eu/documents/10162/542f1e32-4abd-8a90-51c4-fdf5b74b9eda

1907/2006 provided that the risk management measures and operational conditions described in the application and in further information submitted by the applicant are adhered to. However, as some measurements for inhalation exposure were performed using inappropriate methodology with a high limit of detection, the potential inhalation and dermal exposure caused by the outer surface of the dip pipe for transfer of diglyme significantly contributes to the overall exposure, and the justification provided for some of the input parameters where modelling was used is insufficient, RAC noted that the inhalation and dermal exposure needs to be further reduced by improving the level of risk management measures for the relevant tasks. RAC therefore 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], as well as the conditions set out in this Decision, 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 seven years. The Commission concurs with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments, and in particular, on one hand, RAC's conclusion that the risk to human health from the use of the substance is demonstrated to be adequately controlled, SEAC's conclusion on the socio-economic benefits of the continued use of the substance, the lack of a suitable alternative by the sunset date, the time necessary to search for a suitable alternative and for its implementation and regulatory approval, should one be found, and, on the other hand, the gaps in the analysis of alternatives and RAC's concerns related to the uncertainty of the exposure estimation.

(9) Therefore, it is appropriate that the review period be set at seven 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

[3] http://ec.europa.eu/docsroom/documents/24522

[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).

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.

(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 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 (EC No 203-924-4; CAS No 111-96-6) (diglyme), 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 conditions laid down in Article 2 of this Decision are fully applied:

Authorisation number	Authorised use
REACH/19/21/0	Use as a process solvent in one step of manufacturing of an active pharmaceutical ingredient used in an anti-protozoal drug

Article 2

The authorisation holder shall implement at the latest on 10 July 2021 the following risk management measures relating to the use referred to in Article 1:

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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 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) as regards the transfer of diglyme: a system which minimises the potential for dermal and inhalation exposure as well as pumps shall be installed to minimise emissions to air and exposure via dermal contact; sources of further diglyme emissions and dermal exposure shall be identified and addressed by sufficiently closed systems with tight connections;

(b) a closed sampling system shall be installed;

(c) housekeeping and cleaning procedures and practices shall be implemented in the areas where diglyme is not handled directly in order to effectively keep these areas free from contamination with diglyme.

Article 3

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 August 2024.

2. The authorisation shall cease to be valid on 22 August 2024 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 2023, unless a decision to withdraw the authorisation is adopted earlier in accordance with Article 61(2) and (3) of that Regulation.

Article 4

1. 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;

(ii) 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;

(vii) follow the hierarchy of control principles according to Directive 98/24/EC;

(b) the authorisation holder shall implement a regular measurement programme of surfaces in contact with diglyme. Those measurements shall:

(i) include at least wipe testing of contaminated surfaces;

(ii) take place annually;

(iii) ensure that effective housekeeping and cleaning procedures and practices are implemented, including in the areas where diglyme is not handled directly.

2. 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.

3. 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 actions taken in accordance with paragraph 2 and shall include them in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 5

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 6

This Decision is addressed to PMC ISOCHEM, 32 rue Lavoisier, 91710, Vert Le Petit, France.

Done at Brussels, 10.7.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION