EUROPEAN
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COMMISSION IMPLEMENTING DECISION

of 5.6.2024

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to PMC ISOCHEM for a use of bis(2-methoxyethyl)ether (diglyme) in the context of a review and repealing Implementing Decision C(2019) 5096

(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 uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 10 July 2019, by Commission Implementing Decision C(2019) 5096[2], an authorisation was granted to PMC ISOCHEM for the use of diglyme as a process solvent in one step of the manufacturing of an active pharmaceutical ingredient used in an anti-protozoal drug (authorisation number REACH/19/21/0). The review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 for that authorised use of diglyme expires on 22 August 2024.

(3) On 21 February 2022, PMC ISOCHEM submitted a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 for authorisation for the use of diglyme as a process solvent in one step of the manufacturing of an active pharmaceutical ingredient used in an anti-protozoal drug.

(4) The European Chemicals Agency sent the opinions[3] on the review report adopted by its Committee for Risk Assessment (RAC) and its Committee for Socio-economic Analysis (SEAC) to the Commission pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006. On 20 June 2023, the Commission received the opinions.

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1 OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj.

2 Commission Implementing Decision C(2019) 5096 of 10 July 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).

3 https://echa.europa.eu/documents/10162/6dbf5e64-df5c-03ba-4553-131ad7b8ffb3.

(5) In its opinion, RAC concluded that it is possible to determine a derived no-effect level 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 substance for which it is possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation.

(6) In its opinion, RAC concluded that the risk to human health from the use of diglyme described in the review report is adequately controlled as referred to in Article 60(2), first subparagraph, of Regulation (EC) No 1907/2006. However, in order to ensure continuation and improvement of current risk management measures and operational conditions, RAC recommended imposing monitoring arrangements with the aim of addressing some shortcomings in exposure estimates and of providing information on the trends in occupational exposure to diglyme. Having evaluated RAC's assessment, the Commission agrees with its conclusion and recommendations.

(7) Therefore, an authorisation for the use of diglyme as described in this Decision should be granted under Article 60(2) of Regulation (EC) No 1907/2006, provided that the risk management measures and the operational conditions described in the chemical safety report are fully applied.

(8) However, the Commission acknowledges the possibility that the authorisation holder may use diglyme in new commercial products to be developed in the future, as highlighted by SEAC. Therefore, for the sake of clarity, the Commission considers it appropriate to further specify the authorised use by aligning it with the information provided in the review report as assessed by SEAC. Thus, the use description should read 'as a process solvent in one step of the manufacturing of the active pharmaceutical ingredient ternidazole, used in an anti-protozoal drug'.

(9) The assessment of suitability of alternatives is relevant, among other things, for the determination of the review period in accordance with Article 60(9), point (e), of Regulation (EC) No 1907/2006. For an alternative to be suitable it needs to be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required, pursuant to Article 62(4), point (f), of Regulation (EC) No 1907/2006, to submit a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use for which authorisation is sought should be considered to be technically feasible.

(10) In its opinion, SEAC concluded that there were no suitable alternatives available for the authorisation holder and that there were no technically and economically feasible alternatives in the Union. The Commission, having evaluated SEAC's assessment and all relevant information available, acknowledges that the authorisation holder identified alternative solvents that would replace the substance, which were not considered technically feasible due to incompatibilities with reducing agents, with borane, with solvent recovery or which were unavailable. Moreover, the shortlisted alternative synthesis method was not considered technically feasible either, due to major technical limitations, including safety. Therefore, the Commission considers that it cannot be deemed that the identified alternatives allow the functionality needed for the use for which authorisation is sought. Thus, the Commission agrees with SEAC's conclusion that there are no suitable alternatives for the holder of the authorisation and in the Union.

(11) In its opinion, SEAC recommended that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set at 12 years. The Commission

agrees 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 is demonstrated to be adequately controlled, the lack of any technically feasible alternative despite the authorisation holder's research and development activities, as well as the time necessary to search for a suitable alternative and for its implementation and regulatory approval.

(12) The language used to describe the risk management measures and operational conditions in the review report may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(13) This Decision does not affect the obligation of the authorisation holder to ensure that the use of a substance 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, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1) and Article 5 of Directive 2004/37/EC of the European Parliament and of the Council[4] to reduce the use of carcinogens, mutagens or reprotoxic substances at the place of work, in particular by replacing those substances, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. 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[8] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(14) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC[9] or Directive

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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, mutagens or reprotoxic substances 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, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

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, ELI: http://data.europa.eu/eli/dir/1989/391/oj).

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, ELI: http://data.europa.eu/eli/dir/1992/85/oj).

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, ELI: http://data.europa.eu/eli/dir/1994/33/oj).

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, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

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, ELI: http://data.europa.eu/eli/dir/2008/50/oj).

2010/75/EU[10] of the European Parliament and of the Council, nor any obligation to comply 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[11] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(15) The authorisation should therefore be granted in the context of the review referred to in Article 61(1) of Regulation (EC) No 1907/2006. For reasons of clarity and legal certainty, Implementing Decision C(2019) 5096 should be replaced by this Decision.

(16) The measures provided for in this Decision are in accordance with the opinion of the committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(2) of Regulation (EC) No 1907/2006 to the following person for the following use of bis(2-methoxyethyl)ether (EC No. 203-924-4, CAS No. 111-96-6):

Authorisation number	Authorisation holder	Authorised use
REACH/24/19/0/R1	PMC ISOCHEM	As a process solvent in one step of the manufacturing of the active pharmaceutical ingredient ternidazole, used in an anti-protozoal drug

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[13].

Article 2

The review period shall expire on 31 December 2033.

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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, ELI: http://data.europa.eu/eli/dir/2010/75/oj).

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, ELI: http://data.europa.eu/eli/dir/2000/60/oj).

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, ELI: http://data.europa.eu/eli/dir/2008/105/oj).

13 https://echa.europa.eu/documents/10162/06459718-327b-e05e-2e14-f02860db8715.

The authorisation shall cease to be valid on 31 December 2033 if the review report has not been submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 31 June 2032.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 4 shall apply.

2. The authorisation holder shall carry out a monitoring programme on occupational exposure to diglyme. The programme shall include measurements which shall:

   (a) take place at least annually, or more frequently if a significant increase of diglyme consumption takes place on site, and shall be sufficiently frequent to capture any potential increase in exposure of workers to diglyme;

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

   (c) comprise personal and/or static inhalation exposure sampling;

   (d) ensure a sufficiently low limit of quantification;

   (e) be representative of all the tasks with possible exposure to diglyme, including maintenance tasks, of the operational conditions and risk management measures for each of these tasks, and of the total number of workers that are potentially exposed;

   (f) be recorded so as to include contextual information about the tasks performed during exposure sampling with possible exposure to Cr(VI).

3. The authorisation holder shall use the information gathered by way of the measurements referred to in paragraph 2 to review, at least annually, the appropriateness and effectiveness of the risk management measures and operational conditions in place. While doing so, the authorisation holder shall also review and, if needed, update its assessment of the combined exposure for the different groups of workers. If needed, the authorisation holder shall introduce measures to further reduce to a level as low as technically and practically possible workplace exposure to diglyme in accordance with the hierarchy of control principles set out in Article 5 of Directive 2004/37/EC.

4. The authorisation holder shall document and maintain the information from the monitoring programme referred to in paragraph 2, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the reviews and any measure taken in accordance with paragraph 3, and shall make that information available, upon request, to the competent authority of the Member State where the authorised use takes place.

Article 4

If a review report is submitted, it shall include the information referred to in Article 3(4).

Article 5

Upon request, the authorisation holder shall submit a brief 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

Implementing Decision C(2019) 5096 is repealed.

Article 7

This Decision is addressed to:

PMC ISOCHEM, 32 rue Lavoisier, 91710 Vert Le Petit, France.

Done at Brussels, 5.6.2024

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION