EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING DECISION

of 3.2.2022

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Acton Technologies Limited for certain uses of bis(2-methoxyethyl)ether (diglyme)

(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 referred to in Article 56(1)(a) of that Regulation.

(2) On 19 June 2020, Acton Technologies Limited ('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 carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes) ('use 1') and as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes) ('use 2'). Use 2 takes place on two sites, with two different exposure scenarios respectively (hereinafter referred to as ES 1 and ES 2)[2] .

(3) On 5 May 2021, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)[3] of the European Chemicals Agency and sent to it pursuant to the second subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.

(4) In its opinions, 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

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

[2] The working contributing scenarios (WCS) for use 2 are set out in Table 1, p. 17 of the ECHA opinion.

[3] https://echa.europa.eu/documents/10162/212936c8-46c2-f96c-2446-67bf5c9e76fb
https://echa.europa.eu/documents/10162/13516f72-cc45-4076-a7c5-419fc6b7b31a

of Annex I to Regulation (EC) No 1907/2006 and that, therefore, diglyme is a threshold substance.

(5) RAC concluded in its opinions that the risk to human health from both uses 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 chemical safety report are adhered to. RAC noted that the current dataset allows to conclude that the applicant adequately controls the risk associated with the use of diglyme. However, for both uses, as regards workers' exposure, RAC recommended the implementation of additional biomonitoring measurements with the aim of verifying and supporting the results from air and dermal monitoring. Similarly, as regards exposure of the general population via the environment, RAC recommended the continuation of the monitoring of the emissions to the air compartment in order to enlarge the dataset and increase the robustness of the risk assessment. Furthermore, concerning use 2 as regards ES 1, RAC recommended as condition for authorisation the installation of a pump transfer system for the etchant pouring process covered in working contributing scenarios ('WCS') 2, to reduce accidental contact and to ensure that the exposure is further limited. The Commission, having evaluated RAC's assessment, concurs with these conclusions and recommendations.

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

(7) The assessment of suitability of alternatives is relevant, among others, for the determination of the review period in accordance with Article 60(9)(e) of Regulation (EC) No 1907/2006. A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible, the applicant for authorisation is required to submit a substitution plan. In order to be considered technically feasible, an alternative to the substance should be capable of providing the level of technical performance functionally necessary for the use applied for. Certain potential alternatives may provide some functionality but at some loss to performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying an additional effort which is reasonable taking into account the circumstances of the case.

(8) In its opinions, SEAC concluded that there are no available alternative substances or technologies for either use 1 or use 2. After evaluating SEAC's assessment, the Commission acknowledges that the identified alternative solvents provide some functionality needed for the use applied for but at a certain loss of performance. Taking into account the necessary characteristics needed in the etching process, in particular with regard to solubility, stability over a range of temperatures and viscosity, which enable surface modification of complex fluoropolymers, such loss of performance would result in insufficient quality in terms of the bonding strength of the treated surface. The identified alternative technology to the etching process does not require the use of any solvent, however it results in insufficient shelf life of the etched material or in insufficient quality in terms of the bonding strength of the treated

surface. The Commission therefore considers that the identified alternative solvents and etching technology should not be considered suitable in this case since the degree of the loss of performance does not allow achieving the qualification standards that the final products need to meet and does not allow the functionality needed for the use applied for. Consequently, the Commission agrees with SEAC's conclusion and considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternatives both in the Union and for the applicant.

(9) 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 for both uses. 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 is adequately controlled, the applicant's ongoing research and development activities, the time necessary for the development and implementation of a potential alternative, and the subsequent qualification by the downstream users of the resulting etchant mixtures, and SEAC's recognition that substitution would not be achievable within shorter timelines.

(10) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official languages of the Member States where the use 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 to the competent authority of that Member State 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 of the 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 to the substance is reduced to as low a level as is technically and practically possible 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 in accordance with 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[8], and Directive 2004/37/EC of the European Parliament and of the Council[9], as well as

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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).

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 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).

9 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 or mutagens at work (Sixth individual

any national binding occupational limit values which may be stricter than the applicable Union limit values.

(12) This Decision does not affect any obligation to comply with any other regulatory requirements including emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[10] or Directive 2010/75/EU of the European Parliament and of the Council[11] 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[12] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[13]. Compliance with the provisions of this Decision does not necessarily imply compliance with emission limit values or environmental quality standards under any other provisions of Union law, which 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 hereby granted in accordance with Article 60(2) of Regulation (EC) No 1907/2006 for the following uses of bis(2-methoxyethyl)ether (diglyme) (EC No 203-924-4; CAS No 111-96-6):

Authorisation number	Authorised use
REACH/22/2/0	As a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes)
REACH/22/2/1	As a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes)

Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (OJ L 158, 30.4.2004, p. 50).

[10] 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).

[11] 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).

[12] 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).

[13] 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).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[14], as well as to the condition set out in Article 2.

Article 2

The authorisation bearing number REACH/22/2/1 shall be subject to the following condition: as regards ES 1, the downstream user shall ensure that the pouring of the etchant for the tip etching, referred to in WCS 2, is performed with a pump transfer system.

Article 3

1. The review period shall expire on 3 February 2034.
2. The authorisation shall cease to be valid on 3 February 2034 if the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 3 August 2032.

Article 4

1. The monitoring arrangements referred to in paragraphs 2 to 8 shall apply.
2. The authorisation holder and the downstream users shall implement occupational exposure measurements. Those measurements shall:
    (a) be conducted annually;
    (b) be based on relevant standard methodologies or protocols;
    (c) ensure a sufficiently low detection limit;
    (d) comprise personal and stationary inhalation exposure measurements and dermal exposure;
    (e) be representative of the range of tasks with possible exposure to diglyme and of the total number of workers that are potentially exposed;
    (f) be recorded as to include contextual information about the tasks with possible exposure to diglyme.
3. The authorisation holder and the downstream users shall investigate and identify possible methods for conducting biomonitoring programmes.
4. If the methods referred to in paragraph 3 are available, the authorisation holder and the downstream users shall implement biomonitoring measurements. Those measurements shall:
    (a) be conducted annually
    (b) be based on relevant standard methodologies or protocols;
    (c) use a method with a limit of quantification allowing a meaningful exposure evaluation.
5. The authorisation holder and the downstream users shall implement measurements of emissions to the air from local exhaust ventilation. Those measurements shall:

[14] https://ec.europa.eu/docsroom/documents/45983
https://ec.europa.eu/docsroom/documents/45984

(a) be conducted annually;

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

(c) be representative of the operational conditions and risk management measures used at the sites where the authorised use takes place.

6. The authorisation holder and downstream users shall use the information gathered from the measurements referred to in paragraphs 2, 4 and 5 and related contextual information to regularly review the effectiveness of the risk management measures and operational conditions in place and to introduce measures, as appropriate, to further reduce workplace exposure to diglyme and emissions to the air to as low a level as technically and practically possible.

7. The authorisation holder and downstream users shall document and keep the information obtained from the monitoring programmes referred to in paragraph 2, 4 and 5, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 6, and shall submit that information, upon request, to the competent authority of the Member State where the authorised use takes place.

8. In the event that the authorisation holder submits a review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information documented in accordance with paragraph 7 of this Article.

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 take place in an official language of that Member State.

Article 6

This Decision is addressed to Acton Technologies Limited, Kilfinny, Adare, Co Limerick, Ireland.

Done at Brussels, 3.2.2022

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION