EUROPEAN
COMMISSION

Brussels, 3.2.2022
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COMMISSION IMPLEMENTING DECISION

of 3.2.2022

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

(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 16 February 2016, 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') that takes place on the sites of five different downstream users, each of which applies an exposure scenario[2] ('ES').

(3) On 24 November 2017, the Commission received the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)[3] of the European Chemicals Agency on the application, sent pursuant to the third 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 of Annex I to Regulation (EC) No 1907/2006 and that, therefore, diglyme is a threshold substance.

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1 OJ L 396, 30.12.2006, p. 1.

2 The exposure scenarios are set out in Table 1, p. 10 of the ECHA opinion.

3 https://echa.europa.eu/documents/10162/c4b4d55e-99cb-e875-1da8-796b3a3fbe72. https://echa.europa.eu/documents/10162/483fd305-ad2b-6654-f63c-7ce335ba8203.

(5) RAC concluded that, while the risk to human health of the general population from both uses is adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006, the risk to workers from use 1 or and from use 2 as regards ES1, ES3 and ES4 is not adequately controlled in accordance with Article 60(2) of Regulation (EC) No 1907/2006, whereas the risk to human health from use 2 as regards ES2 and ES5 is adequately controlled in accordance with that provision, provided that the risk management measures described in the application are adhered to. It is therefore not appropriate to grant an authorisation based on Article 60(2) of Regulation (EC) 1907/2006 for use 1 and for the part of use 2 described in ES1, ES3 and ES4, but it is appropriate to grant an authorisation based on that provision for use 2 as regards ES2 and ES5, provided that the risk management measures and operational conditions described in the application and in the chemical safety report are fully applied.

(6) Regarding ES2 and ES5, due to uncertainties in dermal exposure and the lack of monitoring data related to the levels of workers' exposure resulting from the tasks performed and on the emissions into the environment, RAC recommended the implementation of additional measures, including monitoring programmes for occupational inhalation exposure and measurements of emissions to the air compartment. The Commission, having evaluated RAC's assessment, concurs with that conclusion and recommendation.

(7) Since adequate control was not demonstrated for use 1 and for use 2 as regards ES1, ES3 and ES4, RAC and SEAC assessed this part of the application on the basis of the provisions in Article 60(4) of Regulation (EC) No 1907/2006. For use 1 and for that part of use 2, due to lack of dose-response function for exposure to diglyme, it is not possible to characterise the risk when exposure is higher than the DNEL. A full quantitative assessment of the human health impact of the continued use not being possible, SEAC requested the applicant to conduct a break-even analysis. Having assessed that analysis, whilst taking account of any uncertainties in the assessment, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that, provided that the suggested conditions and monitoring arrangements are adhered to, the overall benefits of the use outweigh the risk to human health. However, SEAC pointed out that the break-even analysis was performed based on the actual exposed workforce at the time of the application (i.e. only male workers) and noted that, in case of a change in the workforce gender distribution, the results of a break-even analysis may not confirm that the benefits of continued use outweigh the risk. In this context, SEAC noted that the assessment was incomplete, as it only covered infertility but not developmental toxicity, which is one of the reprotoxic properties of diglyme due to which the substance is included in Annex XIV to Regulation (EC) No 1907/2006.

(8) Taking into account SEAC's conclusion that the applicant demonstrated that the socio-economic benefits of continued use outweigh the risk only for the actual workforce at the time of the application for which only male infertility is relevant, but not as regards a different gender distribution of the workforce, for which developmental toxicity is also relevant, and since the applicant submitted no evidence that would allow the Commission to conclude that changes in the gender distribution of the exposed workforce can be excluded, the Commission must conclude that the applicant has not discharged its burden of proof to demonstrate that the socio-economic benefits outweigh the risk, for use 1 and for use 2 as regards ES1, ES3 and ES4. On 3 and 15 January 2019, after the opinions of RAC and SEAC had been submitted to the Commission, the applicant provided an additional break-even analysis, which

considers the risk from developmental toxicity under different scenarios of the workforce gender distribution, and additional information regarding modifications made to the operational conditions and risk management measures for use 1 after the RAC and SEAC opinions had been submitted to the Commission, or planned to be introduced in the future. That additional information was not taken into account by the Commission in its assessment because the RAC and SEAC opinions on the application are complete and constitute sufficient basis to determine whether the conditions for authorisation are fulfilled and also because that information was submitted after the opinion-making phase. Where an applicant has failed to discharge its burden of proof before the committees, the fact of the Commission sending additional information submitted to it after the opinion-making phase back to RAC and SEAC for additional opinions, or of otherwise taking that information into account, would allow an applicant to interrupt or delay (even repeatedly) a decision making procedure with the result that an SVHC remains on the market for longer, or without the conditions and measures that may be established under an authorisation decision, in case it is granted, with possible consequent risks to public health and/or the environment. Given that it was for the applicant to submit all relevant information as part of its application, this would also constitute an abuse of process.

(9) Therefore, having regard to the conditions laid down Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to refuse the authorisation for use 1 and for use 2 as regards ES1, ES3 and ES4.

(10) 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.

(11) 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 and all relevant information available, 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.

(12) 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 four years from the sunset date for both uses. The Commission, taking into account the relevant elements from RAC's assessment, including where the applicant does not demonstrate adequate control of risks, as well as SEAC's assessment including that the applicant has demonstrated that the benefits of continued use outweigh the risks albeit with uncertainties, agrees with that recommendation.

(13) Considering that the sunset date for diglyme set out in Annex XIV to Regulation (EC) No 1907/2006 has already passed and that the review report referred to in Article 61(1) of that Regulation must be submitted at least 18 months before the expiry of the review period, the review period recommended by SEAC would not allow the authorisation holder sufficient time to submit a review report within the time-limit in the present case. For those uses, it is therefore appropriate to provide for a review period of four years from the date of adoption of this Decision.

(14) 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.

(15) 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],

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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).

and Directive 2004/37/EC of the European Parliament and of the Council[9], as well as any national binding occupational limit values which may be stricter than the applicable Union limit values.

(16) 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 nor any obligation to comply[11] 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.

(17) 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

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):

Authorisation number	Authorised use
REACH/22/1/0	Use as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes)

The authorisation is granted provided that the use is carried out by the downstream users implementing the ES2 and ES5, described in the chemical safety report

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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 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).

('downstream users'), and subject to the application of the risk management measures and operational conditions described in those exposure scenarios.

2. An authorisation is refused for the following uses of diglyme:

(a) use as carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity and as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity;

(b) use as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity as regards ES1, ES3 and ES4.

Article 2

1. The review period shall expire on 3 February 2026.

2. The authorisation shall cease to be valid on 3 February 2026 if the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 3 August 2024.

Article 3

1. The monitoring arrangements referred to in paragraphs 2 to 9 shall apply.

2. The downstream users shall implement the following monitoring programmes:

(a) occupational exposure measurements. Those measurements shall:

(i) be conducted annually;

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

(iii) ensure a sufficiently low detection limit;

(iv) comprise personal and stationary inhalation exposure measurements and if possible dermal exposure;

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

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

(b) measurements of emissions to the air from local exhaust ventilation. Those measurements shall:

(i) be conducted annually;

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

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

3. The downstream users shall use the information gathered from the measurements referred to in paragraph 2 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 to as low a level as technically and practically feasible, in particular for tasks which involve direct handling of diglyme.

4. The downstream users shall further investigate the use of automation or other means to further reduce potential of exposure with regard to tasks which involve direct handling of diglyme related to the etching process itself, and properly document it.

5. The downstream users shall periodically verify the availability of the methodology for a wipe testing of contaminated surfaces and document their investigation. If and as soon as the methodology is available, the wipe testing of contaminated surfaces shall be implemented at least twice a year to monitor the implementation of the general housekeeping and work practices. Once effective cleaning and work practices eliminating or minimising transfer of diglyme are in place and confirmed by two consecutive monitoring results, annual dermal exposure monitoring shall be organised according to point (a)(vi) of paragraph 2.

6. The downstream users shall undertake an assessment of the feasibility of the installation of a specific air treatment system dedicated to minimisation of diglyme emissions to the atmosphere and properly document it.

7. The downstream users shall document and keep the information obtained from the monitoring programmes referred to in paragraph 2, 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 3, and submit them, upon request, to the competent authority of the Member State where the authorised use takes place.

8. Following implementation of the risk management measures and operational conditions, the downstream users may reduce the frequency of measurements, once they can clearly demonstrate to the competent authority of the Member State where the use takes place that exposure of the general population and releases into the environment have been reduced to as low a level as technically and practically possible.

9. If 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 paragraphs 4 to 7 of this Article.

Article 4

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 5

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