EUROPEAN
COMMISSION

Brussels, 16.5.2018
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COMMISSION IMPLEMENTING DECISION

of 16.5.2018

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 (Bracco Imaging s.p.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 referred to in Article 56(1)(a) of that Regulation.

(2) On 9 February 2016, Bracco Imaging s.p.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 processing aid in the purification of 5-amino-2,4,6-triiodoisophthalic acid dichloride by precipitation.

(3) On 6 April 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[2] on the application pursuant to the second 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 therefore that diglyme is a threshold substance.

(5) In its opinion, RAC also 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 1907/2006. Therefore, it is appropriate to grant an authorisation for the use of diglyme applied for, provided that the risk management measures and

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

[2] https://echa.europa.eu/documents/10162/8cd0d422-fc4a-37c3-a910-a3519b59bf5f

operational conditions described in the application and, in particular, in the chemical safety report[3], are fully applied.

(6) 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 twelve years. The Commission takes into account the relevant elements from RAC's and SEAC's assessments, and in particular RAC's conclusion that the risk to human health arising from the use of the substance is demonstrated to be adequately controlled, SEAC's conclusion that, although the assessment of the benefits of the continued use of the substance is based on potential losses by the applicant, some of which might be distributional in nature from a societal point of view, the socio-economic benefits of continued use of the substance are high, the lack of suitable alternatives before the sunset date, and the timeline needed for the transition to the most plausible alternative process identified, as well as the time needed for the approvals of the medicinal product by the corresponding regulatory authorities. The Commission concurs with the SEAC recommendation.

(7) Therefore, as regards the use of diglyme applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 should be set at twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.

(8) In their opinions, RAC and SEAC considered that additional conditions and monitoring arrangements for the use as described in the application were not necessary.

(9) 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 include a monitoring arrangement requiring 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.

(10) 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 either 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[4]. In addition, this Decision is without prejudice to the application of the Union Directives in the area of health and safety at work, in particular Council Directive

[3] http://ec.europa.eu/DocsRoom/documents/22581

[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).

89/391/EEC[5], Council Directive 98/24, Council Directive 92/85/EEC[6] and Council Directive 94/33/EC[7].

(11) This Decision is without prejudice to any obligation to comply with emission limit values set in accordance with Directive 2010/75/EU of the European Parliament and of the Council[8] and Directive 2008/50/EC of the European Parliament and of the Council[9], as well as with emission limit values set to achieve compliance with the environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council[10] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision should not necessarily result in compliance with emission limit values or environmental quality standards under other Union legislation, which may include separate or more onerous requirements.

(12) 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 are fully applied:

Authorisation number	Authorised use
REACH/18/8/0	Use of diglyme as a processing aid in the purification of 5-amino-2,4,6-triiodoisophthalic acid (EC No. 417-220-1; CAS No. 37441-29-5) dichloride by precipitation

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 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).

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).

10 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).

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).

Article 2

1. 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 22 August 2029.

2. The authorisation REACH/18/8/0 shall cease to be valid on 22 August 2029 in case a review report referred to in Article 61(1) has not been submitted by 22 February 2028, unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of Regulation (EC) No 1907/2006.

Article 3

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 4

This Decision is addressed to Bracco Imaging s.p.a, Via Folli 50, 20134, Milan, Italy.

Done at Brussels, 16.5.2018

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION