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COMMISSION IMPLEMENTING DECISION

of 17.1.2019

granting an authorisation for certain uses of formaldehyde, oligomeric reaction products with aniline, under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Polynt Composites France)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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granting an authorisation for certain uses of formaldehyde, oligomeric reaction products with aniline, under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Polynt Composites France)

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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/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Formaldehyde (oligomeric reaction products with aniline) (technical MDA) 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 1 February 2016, Polynt Composites France ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for two uses of technical MDA in the formulation of an epoxy resin hardener containing technical MDA ('use 1') and in the industrial use of an epoxy resin hardener containing technical MDA aimed at immobilising spent ion exchange resins in a high containment matrix ('use 2').
- (3) On 27 March 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 Agency² 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 for both uses it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of technical MDA in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore technical MDA is a non-threshold substance. In accordance with Article 60(3)(a) of Regulation (EC) No 1907/2006, Article 60(2) of that Regulation does not

¹ OJ L 396, 30.12.2006, p. 1.

² <https://echa.europa.eu/documents/10162/716d97d6-9dcd-80fb-730a-8cb3f3db32a3>
<https://echa.europa.eu/documents/10162/54b6068f-f34e-182e-dae5-47fb5fb05987>

apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.

- (5) In its opinion on the two uses, RAC concluded that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population that could potentially be exposed via the environment. However, concerning use 1, due to the fact that some phases of the formulation processes can potentially release technical MDA into air, RAC recommended additional monitoring arrangements.
- (6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the two uses of technical MDA applied for outweigh the risk to human health or the environment arising from those two uses and that there are no suitable alternative substances or technologies for the applicant before the sunset date. The Commission, having evaluated the SEAC assessment, concurs with this conclusion.
- (7) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the two uses of technical MDA applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report³ 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 12 years for the two uses applied for. The Commission takes into account the relevant elements from RAC's and SEAC's assessments, and in particular RAC's assessment of the risk of the continued uses of the substance, the fact that the socio-economic benefits of the continued use outweigh the associated risk by several orders of magnitude, as well as the time necessary for the transition to the identified most promising alternative, including the time needed for testing and for the extensive process of obtaining regulatory approvals. The Commission concurs with the SEAC's recommendation.
- (9) In view of RAC and SEAC's opinions, the Commission considers appropriate that, as regards the two uses of technical MDA applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at twelve years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (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 language of the Member State where the uses take 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 the Member State concerned.
- (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 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 reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible in accordance with Article 4(1) of Directive

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<http://ec.europa.eu/DocsRoom/documents/22243>

2004/37/EC of the European Parliament and of the Council⁴, or to prevent and reduce exposure in accordance with Article 5 of that Directive. In addition, this Decision is without prejudice to the application of the Union law in the area of health and safety at work, in particular Council Directive 89/391/EEC⁵, Council Directive 98/24/EC⁶, Directive 2004/37/EC, Council Directive 92/85/EEC⁷ and Council Directive 94/33/EC⁸.

- (12) 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 Council⁹ and Directive 2008/50/EC of the European Parliament and of the Council¹⁰, 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 Council¹¹ and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹². 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.
- (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(4) of Regulation (EC) No 1907/2006 for the following uses of formaldehyde oligomeric react products with aniline (technical MDA) (EC No. 500-036-1; CAS No. 25214-70-4) provided that the risk management measures and operational conditions described in the chemical safety report

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 or mutagens 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).

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 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).

⁷ 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).

⁸ 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).

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 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 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).

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).

submitted pursuant to Article 62(4)(d) of that Regulation are fully applied:

Authorisation number	Authorised use
REACH/19/8/0	Formulation of an epoxy resin hardener containing technical MDA
REACH/19/8/1	Industrial use of an epoxy resin hardener containing technical MDA aimed at immobilising spent ion exchange resins in a high containment matrix

Article 2

1. As regards the authorised uses of technical MDA, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 August 2029.
2. The authorisations REACH/19/8/0 and REACH/19/8/1 shall cease to be valid on 21 August 2029 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 21 February 2028, unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of that Regulation.

Article 3

The following monitoring arrangements shall apply to the use with authorisation number REACH/19/8/0:

- (a) the authorisation holder shall conduct regular measurements of emissions to ambient air related to the authorised use. Those measurements shall:
 - (i) take place at least annually;
 - (ii) be based on relevant standard sampling and analytical methods with a sufficiently low detection limit;
 - (iii) include contextual information about the tasks possibly involving emissions of technical MDA;
- (b) the information gathered via the measurements referred to in point (a) shall be used to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions to prevent releases of technical MDA to the air and to take actions, as appropriate to further reduce its emissions to the air;
- (c) the results of the measurements referred to in point (a), as well as the outcome and conclusions of the review and any action taken in accordance with point (b), shall be documented, submitted upon request to the competent authority of the Member State where the authorised use takes place and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 4

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 5

This Decision is addressed to Polynt Composites France, Route d'Arras, 62320 Drocourt, France.

Done at Brussels, 17.1.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

