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**COMMISSION IMPLEMENTING DECISION**

**of 29.1.2019**

**granting an authorisation for a use of 1,2-dichloroethane under Regulation (EC) No  
1907/2006 of the European Parliament and of the Council (Microbeads AS)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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**granting an authorisation for a use of 1,2-dichloroethane under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Microbeads AS)**

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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<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) 1,2-dichloroethane (EDC) 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 19 May 2017, Microbeads AS ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the industrial use of EDC as a swelling agent during the sulfonation reaction of crosslinked polystyrene beads in the manufacture of ion exchange resins for purification of radioactive waste.
- (3) On 31 January 2018, 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<sup>2</sup> 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 not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of EDC in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore EDC 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 apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of Regulation (EC) No 1907/2006.
- (5) In its opinion, 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

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<sup>1</sup> OJ L 396, 30.12.2006, p. 1.

<sup>2</sup> <https://echa.europa.eu/documents/10162/45587595-7fbd-bd47-0845-8bd68540a769>

environment. However, in order to minimise the atmospheric release of EDC and to eliminate its manual transfer, RAC recommended the implementation of the risk management measures as planned in the application.

- (6) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of EDC applied for outweigh the risk to human health or the environment arising from that use and that there are no suitable alternative substances or technologies for the applicant before the sunset date. The Commission, having evaluated the SEAC's 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 use of EDC applied for, provided that the risk management measures and operational conditions described in the application and in particular in the chemical safety report<sup>3</sup> 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. The recommended review period takes into account the relevant elements from RAC's and SEAC's assessments, the fact that the socio-economic benefits of continued use outweigh the risk associated with that use by several orders of magnitude, the time necessary for the transition to the identified most promising alternative, including the time needed for its development and testing, as well as the fact that SEAC did not identify any major uncertainty in the applicant's assessment of alternatives, and of the cost and benefits of continued use. The Commission concurs with SEAC's recommendation.
- (9) Therefore, the Commission considers appropriate that, as regards the use of EDC applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at 12 years as from the date of adoption of this Decision.
- (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 use 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 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 2004/37/EC of the European Parliament and of the Council<sup>4</sup>, 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

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<sup>3</sup> <https://ec.europa.eu/docsroom/documents/28641>

<sup>4</sup> 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).

work, in particular Council Directive 89/391/EEC<sup>5</sup>, Council Directive 98/24/EC<sup>6</sup>, Directive 2004/37/EC, Council Directive 92/85/EEC<sup>7</sup> and Council Directive 94/33/EC<sup>8</sup>.

- (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 Council<sup>9</sup> and Directive 2008/50/EC of the European Parliament and of the Council<sup>10</sup>, 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<sup>11</sup> and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council<sup>12</sup>. 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 use of 1,2-dichloroethane (EC No. 203-458-1, CAS No. 107-06-2) 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/19/12/0	Industrial use of 1,2-dichloroethane as a swelling agent during the sulfonation reaction of crosslinked polystyrene beads in the manufacture of ion exchange resins for purification of radioactive waste

<sup>5</sup> 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).

<sup>6</sup> 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).

<sup>7</sup> 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).

<sup>8</sup> 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).

<sup>9</sup> 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).

<sup>10</sup> 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).

<sup>11</sup> 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).

<sup>12</sup> 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 1,2-dichloroethane, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 29 January 2031 .
2. The present authorisation shall cease to be valid on 29 January 2031 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted 29 July 2029, unless a decision to withdraw the authorisation is adopted earlier pursuant to paragraphs 2 and 3 of Article 61 of that Regulation.

## *Article 3*

The following monitoring arrangements shall apply:

- (a) the authorisation holder shall install the active carbon filters in the central exhaust system of the production building related to the use described in Article 1 and as planned in the application in order to minimise the atmospheric release of 1,2-dichloroethane;
- (b) the authorisation holder shall install the equipment to pump 1,2-dichloroethane from steel drums related to the use described in Article 1 and planned in the application in order to eliminate the manual transfer of 1,2-dichloroethane;
- (c) the authorisation holder shall ensure the replacement of the gloves before their breakthrough time for 1,2-dichloroethane is exceeded;
- (d) the authorisation holder shall conduct regular occupational exposure measurements of 1,2-dichloroethane relating to the use described in Article 1. Those measurements shall:
  - (i) take place at least biannually;
  - (ii) be based on relevant standard methodologies or protocols with a sufficiently low detection limit;
  - (iii) comprise both personal and, if appropriate, static inhalation exposure measurements that are representative for the tasks with possible exposure to 1,2-dichloroethane and of the total number of workers potentially exposed. The planned maintenance-related and cleaning-related tasks shall be included;
  - (iv) include contextual information about the tasks with possible exposure to 1,2-dichloroethane;
- (e) the authorisation holder shall establish and implement (at least every two years) a programme to monitor the releases of 1,2-dichloroethane to the environment in order to evaluate the actual releases and the effectiveness of the introduced risk management measures. The measurements shall be based on relevant standard methodologies or protocols with a sufficiently low detection limit allowing meaningful analysis of releases;
- (f) the information gathered in the measurements referred to in points (d) and (e) shall be used to regularly review the appropriateness and effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce workers' exposure to 1,2-dichloroethane and its releases to the environment;
- (g) the results of the measurements referred to in points (d) and (e), as well as the outcome and conclusions of the review and any action taken in accordance with point

(f), 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 Microbeads AS, Vestvollvn 30A, N2019, Skedsmokorset, Norway.

Done at Brussels, 29.1.2019

*For the Commission*  
*Elżbieta BIENKOWSKA*  
*Member of the Commission*

