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**COMMISSION IMPLEMENTING DECISION**

**of 1.12.2017**

**granting an authorisation for a use of trichloroethylene under Regulation (EC) No  
1907/2006 of the European Parliament and of the Council (Microporous GmbH)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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**granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Microporous GmbH)**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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) Trichloroethylene (TCE) is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore is subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.
- (2) On 20 August 2014, an application for authorisation was submitted by Microporous GmbH ('the applicant') in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of trichloroethylene as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries ('use applied for'), pursuant to the subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (3) On 1 September 2015, 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 third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006. On 20 December 2016, the Commissions received an Addendum to these opinions.
- (4) In its opinion, RAC confirmed that it is not possible to determine a derived no-effect level (DNEL) for the carcinogenic properties of TCE in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore trichloroethylene 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 that Regulation.
- (5) In its opinion, RAC concluded that risk management measures and operational conditions are appropriate and effective in limiting the risk of the general population

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

<sup>2</sup> <https://echa.europa.eu/documents/10162/7b0b6b85-7090-4038-9ecd-3ca0820d131d>

that could potentially be exposed via the environment. However, as further justified in the addendum to its opinion, RAC concluded that the risk management measures and operational conditions as described in the application are not appropriate and effective in limiting the risk to workers. RAC reached this conclusion based on the results of static measurements of the ambient concentration of TCE (90<sup>th</sup> percentile of approximately 40 mg/m<sup>3</sup>) performed in close proximity to workstations, located outside of the TCE containment area of the plant (the workstations where mechanical processing of the separator sheet is carried-out). RAC considered these ambient concentrations to be the result of fugitive emissions of TCE, likely originating from adjacent solvent extraction and dryer units (the latter not fully encapsulated), as well as caused by evaporation of residual TCE remaining in the polyethylene separator sheets after drying, during mechanical processing operations. RAC considered this situation to be a breach of the principles of hierarchy of control measures defined in the occupational health and safety legislation and a continuous source of exposure to workers. In addition, RAC noted that except general mechanical ventilation no other collective risk management measures are used, and that workers exposed do not wear respiratory protective equipment.

- (6) In its opinion, due to the deficiencies in the application of risk management measures to limit TCE emissions, in particular in the working environment outside the TCE containment area, RAC recommended additional conditions and monitoring arrangements to further reduce the exposure of workers to TCE. These conditions included the requirement for the authorisation holder to continue implementing regular occupational exposure measurements, including personal inhalation exposure sampling and biomonitoring, relative to the use of TCE applied for. The outcomes and conclusions of these measurement should be documented and used to review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate. They should also be submitted in case a review report is submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006. Furthermore, RAC recommended that risk management efforts should be focused on limiting fugitive emissions of TCE from the containment area, indicating some measures that potentially could result in lower exposures, such as by potential relocation of tasks out of the production hall. Risk management efforts should as well address TCE releases from the polyethylene separators themselves. RAC also indicated that an appropriate use of local exhaust ventilation, of general ventilation, or a combination of both, are likely to reduce worker exposure in this area.
- (7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of TCE applied for outweigh the risks to human health or the environment arising from that use and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant before the sunset date. The Commission, having evaluated the SEAC assessment, concurs with this conclusion.
- (8) Therefore, in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of TCE 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>, as well as the conditions set out in this Decision, are fully applied.

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<sup>3</sup> <http://ec.europa.eu/DocsRoom/documents/14367/attachments/1/translations/en/renditions/native>

- (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 seven years. The recommended review period takes into account on one hand the applicant's inability to use the only technically feasible alternative identified, the high costs and long time necessary to switch to an alternative, the long investment cycle, the fact that the socio-economic benefits of continued use clearly outweigh the monetised risk to human health, and on the other hand RAC's concerns related to the appropriateness and effectiveness of risk management measures put in place for the protection of workers. Having evaluated the SEAC assessment, the Commission concurs with this recommendation.
- (10) On 26 September 2016, after the opinions of RAC and SEAC were submitted to the Commission, the applicant provided additional information regarding modifications made to the operational conditions and risk management measures in place in the installation, accompanied by supporting additional worker exposure data. The modifications included the redeployment, of workers performing mechanical processing operations, which were the main source of concern identified in the RAC opinion, to a segregated area. The Commission services, with the assistance of the ECHA secretariat, have assessed the additional information provided.
- (11) The Commission acknowledges that worker exposure to TCE in the relocated new mechanical processing area seems to have been significantly reduced. However, the summarised online monitoring data provided gives only limited contextual information that does not allow an assessment of the representativeness of the new exposure information with regard to the modified operational conditions and risk management measures. Furthermore, it is unclear whether the exposure in the main production hall has been reduced and whether workers are required to be there to undertake new tasks not described in the exposure scenario submitted as a part of the application. Consequently, the Commission considers that there is not sufficient basis to deviate from the recommendations made in the RAC and SEAC opinions and that information submitted on 26 September 2016, together with information obtained from continuing regular occupational exposure measurements should be used by the applicant to update the chemical safety report and in a potential review report for the use applied for.
- (12) In view of the RAC and SEAC opinions, and having taken due account of the additional information provided by the applicant, the Commission considers appropriate that, as regards the use of TCE applied for, the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 is set at seven years as from the sunset date set out in Annex XIV to Regulation (EC) No 1907/2006.
- (13) 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 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 the Member State concerned.
- (14) 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. Furthermore, 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 89/391/EEC<sup>5</sup>, Council Directive 98/24<sup>6</sup>, Directive 2004/37, Council Directive 92/85/EEC<sup>7</sup> and Council Directive 94/33/EC<sup>8</sup>.

- (15) 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.
- (16) 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 trichloroethylene (EC No. 201-167-4, CAS No. 79-01-6), 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, as well as the

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<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).

<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, 29.06.1989, 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, 05.05.1998, 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, 20.08.1994, 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).

conditions set out in Article 2 of this Decision are fully applied. The authorised use is identified by the following authorisation number:

Authorisation number	Authorised use
REACH/17/23/0	Use of trichloroethylene as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries

### *Article 2*

The authorisation referred to in Article 1 shall be subject to the following conditions:

- (a) the authorisation holder shall review the risk management measures applied in order to reduce emissions and, in particular, to limit fugitive emissions of TCE from the containment area and to address releases from the polyethylene separators themselves;
- (b) the authorisation holder shall implement regular occupational exposure measurements (with sampling done at least annually) relating to the use referred to in Article 1. Those measurements shall:
  - (i) be based on relevant standard methodologies or protocols;
  - (ii) comprise personal inhalation exposure sampling for trichloroethylene and biomonitoring (measuring TCA, a metabolite of TCE, in urine);
  - (iii) be representative of the range of tasks with possible exposure to trichloroethylene and of the total number of workers that are potentially exposed (including process, maintenance and laboratory workers);
  - (iv) the information gathered from the measurements referred to in point (b) including contextual information shall be used to review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, to further reduce workers' exposure to trichloroethylene. In particular, the authorisation holder shall assess whether the changes implemented in risk management measures and operational conditions after the submission of the application for authorisation have limited fugitive emissions from the containment area and from the separators themselves;
- (c) the results of the measurements referred to in point (b), as well as the outcome and conclusions of the review and any action taken in accordance with points (a) and (b), shall be documented, included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place.

### *Article 3*

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 April 2023.
2. The present authorisation shall cease to be valid on 21 April 2023 should the holder of the authorisation referred to in Article 1 not submit the review report foreseen in Article 61(1) by 21 October 2021, 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 4*

The following monitoring arrangements referred to in Article 60(9)(f) shall apply:

- 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 Microporous GmbH, Gewerbestraße 8, 9181 Feistritz im Rosental, Austria.

Done at Brussels, 1.12.2017

*For the Commission*  
*Elzbieta BIENKOWSKA*  
*Member of the Commission*

