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COMMISSION IMPLEMENTING DECISION

of 20.2.2018

granting an authorisation for a use of trichloroethylene under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Entek International 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) Trichloroethylene (TCE) is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1)(a) of that Regulation.

(2) On 2 September 2014, an application for authorisation was submitted by Entek International Limited in accordance with Article 62 of Regulation (EC) No 1907/2006 for the use of trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries.

(3) On 25 August 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[2] 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, the 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 the risk management measures and operational conditions are appropriate and effective in limiting the risk of the general population

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

[2] http://echa.europa.eu/documents/10162/17c8f218-7032-49e4-8de7-51206a306706

that could potentially be exposed via the environment. However, RAC also concluded, and it was further justified in the addendum to its opinion, 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 personal and static measurements of ambient concentrations of TCE in the working environment outside of the TCE containment of around 20 to 70 mg/m^3. RAC considered these ambient concentrations to be the result of fugitive emissions of TCE, likely to be caused by the "drag-out" of TCE vapours by the polyethylene separator sheet leaving the containment areas, as well as due to degassing of TCE from said sheet, prior to the winding operations. RAC noted that there appears to be only general ventilation in the production hall where this exposure takes place. Therefore, RAC considered this situation to be in 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.

(6) In its opinion, due to the deficiencies in the application of risk management measures to limit TCE emissions 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 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 of areview report 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 emissions of TCE from the sheets as they exit the containment area as well as to address those releases from the polyethylene separators themselves, indicating some measures that potentially could result in lower exposures, including appropriate use of local exhaust ventilation, of general mechanical ventilation, or a combination of both, among other.

(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 SEAC's 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[3], as well as the conditions set out in this Decision, are fully applied.

(9) In its opinion, the 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 RAC's assessment of the risk of the continued use of the substance, the applicant's research and development activities so far that have not lead to the identification of a technically and economically feasible alternative and the further need for research and development, the unlikelihood that a suitable alternative would be available earlier than in 12 years, the high costs and time

[3] http://ec.europa.eu/DocsRoom/documents/12344/attachments/1/translations/en/renditions/native

necessary to switch to an alternative, the long investment cycle, as well as 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 the risk management measures put in place for the protection of workers. Having evaluated the SEAC assessment, the Comission concurs with this recommendation.

(10) In view of the RAC and SEAC opinions, 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.

(11) 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.

(12) 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 that Regulation 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 of the European Parliament and of the Council[4] 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 EU Directives in the area of health and safety at work, in particular Council Directive 89/391/EEC[5], Council Directive 98/24[6], Directive 2004/37, Council Directive 92/85/EEC[7] and Council Directive 94/33/EC[8].

(13) 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[9] and Directive 2008/50/EC of the European Parliament and of the Council[10], as well as with emission limit values set to achieve compliance with the

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4 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, 29.06.1989, 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, 05.05.1998, 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, 20.08.1994, 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).

environmental quality standards established both in Directive 2008/105/EC of the European Parliament and of the Council[11] and by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[12]. 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.

(14) Since the United Kingdom notified on 29 March 2017 its intention to leave the Union, pursuant to Article 50 of the Treaty on European Union, the Treaties will cease to apply to the United Kingdom from the date of entry into force of the withdrawal agreement or, failing that, two years after the notification, unless the European Council, in agreement with the United Kingdom, decides to extend that period. As a consequence, and without prejudice to any provisions of the withdrawal agreement, this Decision only applies until the United Kingdom ceases to be a Member State.

(15) 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 conditions set out in Article 2 are fully applied. The authorised use is identified by the following authorisation number:

REACH/17/24/0	Use of trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in 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 fugitive emissions and, in particular, to limit emissons of trichloroethylene from the sheets as they exit the containment area as well as to address those releases from the polyethylene separators themselves;

[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).

(b) the authorisation holder shall implement regular occupational 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;

(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);

(c) 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 and as soon as possible, to further reduce workers' exposure to tricholoroetylene;

(d) the results of the measurements referred to in point (b), as well as the outcome and conclusions of the review and any actions taken in accordance with point (a) and (c), 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 Entek International Limited, NE12 5XG, Newcastle-Upon-Tyne, United Kingdom.

Done at Brussels, 20.2.2018

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION