EUROPEAN
COMMISSION

Brussels, 7.6.2019
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COMMISSION IMPLEMENTING DECISION

of 7.6.2019

granting an authorisation for a use of arsenic acid under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Circuit Foil Luxembourg SARL)

(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) Arsenic acid is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement laid down in Article 56(1)(a) of that Regulation.

(2) On 20 November 2015, Circuit Foil Luxembourg SARL ('the applicant') submitted, in accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation for the use of arsenic acid for the treatment of copper foil used in the manufacture of printed circuit board.

(3) On 31 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 Agency[2] on the application sent 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 arsenic acid in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and therefore arsenic acid is a substance for which it is not possible to determine a threshold. Pursuant to 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 in accordance with Article 60(4) of Regulation (EC) 1907/2006.

(5) RAC concluded that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and to members of the general population who could be potentially exposed via the environment.

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

[2] https://echa.europa.eu/documents/10162/a93efe3c-bf63-729b-bb93-1aff96d3e02a

(6) However, in order to improve the assessment of emissions and the exposure of workers, RAC recommended monitoring arrangements. The Commission, having evaluated RAC's assessment, concurs with that conclusion.

(7) In its opinion, SEAC concluded that the overall socio-economic benefits arising from the use of arsenic acid covered by the application outweigh the risk to human health arising from that use and that, while a technically feasible alternative is already available for technical approval by the applicant's customers, and actually already implemented by some of them, its implementation by the parts of the supply chain where substitution has not yet happened is not economically feasible. In addition, SEAC recommended that the applicant should comply with the schedule for substitution provided in the application and should therefore not use more than certain maximum quantities. The Commission, having evaluated SEAC's assessment, concurs with those conclusions.

(8) Based on the the opinions of RAC and SEAC, and in accordance with Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of arsenic acid covered by the application, 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, 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 Commission takes into account the relevant elements from the assessements of RAC and SEAC and, in particular, RAC’s assessment of the risk of the continued use of the substance, the fact that the socio-economic benefits of continued use outweigh the risk to human health associated to that use but also the uncertainties regarding the time needed for the implementation of the applicant's substitution plan towards an arsenic acid-free alternative in the entire supply chain, including the time required for the technical approval of the products by the applicant's customers that have not yet substituted. The Commission concurs with SEAC's recommendation.

(10) It is therefore appropriate to set a review period referred of seven years 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 is different from the official languages of the Member State where the use takes place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to require the holder of the authorisation 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 authorised use does not adversely affect human health or the environment having regard to the principle set out in 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

[3] http://ec.europa.eu/DocsRoom/documents/22402

of the Council[4], or to prevent and reduce exposure in accordance with Article 5 of that Directive. This Decision also does not affect the application of the Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC[5], 92/85/EEC[6], 94/33/EC[7], 98/24/EC[8] and Directive 2004/37/EC.

(13) This Decision does not affect any obligation to comply with emission limit values set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[9] or Directive 2010/75/EU of the European Parliament and of the Council[10], nor with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[11] or established in Directive 2008/105/EC of the European Parliament and of the Council[12]. Compliance with the provisions of this Decision does not necessarily imply compliance with other emission limit values or environmental quality standards under Union law, as those may include further or more onerous requirements.

(14) 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

1. An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of arsenic acid (EC No 231-901-9; CAS No 7778-39-4). The authorisation is granted 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:

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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 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 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).

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 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).

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).

12 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).

Authorisation number	Authorised use
REACH/19/17/0	Industrial use of arsenic acid for the treatment of copper foil used in the manufacture of printed circuit board

2. The authorisation referred to in paragraph 1 shall be subject to the condition that the amount of arsenic acid used by the authorisation holder in the authorised use does not exceed 1 tonne per year until 2020, 800 kg per year until 2022 and 700 kg per year until 2024.

Article 2

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 22 August 2024.

2. The authorisation shall cease to be valid on 22 August 2024 in case the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 has not been submitted by 22 March 2023, unless a decision to withdraw the authorisation is adopted earlier in accordance with Article 61(2) and (3) of that Regulation.

Article 3

The following monitoring arrangements shall apply:

(a) the authorisation holder shall conduct regular occupational exposure measurements relating to the use described in Article 1. Those measurements shall:

  (i) take place at least annually;

  (ii) be based on relevant standard methodologies or protocols and ensure a sufficiently low detection limit;

  (iii) comprise both personal and static (where appropriate) inhalation exposure sampling;

  (iv) be representative for the range of tasks with possible exposure to arsenic acid and of the total number of workers that are potentially exposed and include contextual information;

(b) the authorisation holder shall regularly measure the emissions of arsenic acid into the air relating to the use referred to in Article 1. Those measurements shall:

  (i) be undertaken according to standard sampling and analytical methods;

  (ii) ensure a sufficiently low detection limit, where appropriate;

(c) the authorisation holder shall use the information gathered in the measurements referred to in points (a) and (b) to regularly review the effectiveness of the risk management measures and operational conditions and to take action, as appropriate, in order to further reduce workers' exposure;

(d) the results of the measurements referred to in points (a) and (b) of this Article, as well as the outcome and conclusions of the review and any actions taken in accordance with point (c) of this Article shall be documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and,

upon request, shall be submitted to the competent authority of the Member State where the authorised use takes place.

Article 4

Upon request, the authorisation holders shall submit a succinct summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 5

This Decision is addressed to Circuit Foil Luxembourg SARL, Zone industrielle C. Salzbaach, 9559 Wiltz, Luxembourg.

Done at Brussels, 7.6.2019

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION