



Brussels, 1.9.2015
C(2015) 6007 final

COMMISSION IMPLEMENTING DECISION

of 1.9.2015

**granting an authorisation for uses of diarsenic trioxide under Regulation (EC) No
1907/2006 of the European Parliament and of the Council**

(Text with EEA relevance)

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

Whereas:

- (1) Diarsenic trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) An application for authorisation was submitted by Linxens France ('the applicant') on 21 November 2013 in accordance with Article 62 of Regulation (EC) No 1907/2006, for two uses of diarsenic trioxide, namely the formulation of diarsenic trioxide into a mixture and the industrial use of diarsenic trioxide as processing aid in gold electroplating.
- (3) On 22 October 2014 the European Chemicals Agency sent to the Commission the opinions of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)² pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) In its two opinions the RAC confirmed that it is not possible to determine a Derived No-Effect Level (DNEL) for the carcinogenicity (category 1A) properties of diarsenic trioxide and that it is a non-threshold substance. Therefore, it meets the criteria in Article 60(3)(a) of Regulation (EC) No 1907/2006 and authorisation cannot be granted for the use of that substance in accordance with Article 60(2) of that Regulation. RAC confirmed that, for both uses, the exposure assessment in the application is appropriate and that the risk management measures and operational conditions as described in the application, provided they are applied in practice, are effective in limiting the risk.

¹ OJ L 396, 30.12.2006, p. 1.

² <http://echa.europa.eu/documents/10162/018b9a4c-69af-49db-8611-5170ba9abd97>

- (5) In its two opinions, the SEAC confirmed the applicant's conclusions that the overall benefits arising from the formulation of diarsenic trioxide into a mixture and from the industrial use of diarsenic trioxide as processing aid in gold electroplating outweigh the risks to human health or the environment arising from those uses and that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant, both in accordance with the provisions in Article 60(4) of Regulation (EC) No 1907/2006.
- (6) It is therefore appropriate to authorise that use, provided that the risk management measures and operational conditions described in the application, in particular in the chemical safety report, are fully applied.
- (7) In its two opinions, 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 the lack of suitable alternatives at present in terms of their technical and economic feasibility, the very small level of risk associated with the continued uses of the substance by the applicant and the corresponding negligible benefits to society from not using the substance, as well as the significant and perpetual costs associated with the non-use of the substance, irrespective of the alternative chosen. The SEAC also considered the applicant's continuing efforts towards an alternative potentially being able to be implemented in a period of not less than three to five years.
- (8) It is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 at seven years.
- (9) In their opinions, the RAC and SEAC did not recommend any additional risk management measures and operational conditions, nor additional monitoring arrangements compared to those described in the application.
- (10) In order to facilitate the enforcement of the decision, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit, upon request, to the competent authority of the Member State where the uses take place, a succinct summary of the risk management measures and operational conditions of the relevant parts of the chemical safety report submitted as part of the application in an official language of that Member State.
- (11) 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 diarsenic trioxide (EC No. 215-481-4, CAS No. 1327-53-3), subject to full application of the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation³, corresponding to each respective use.

The authorised uses are identified by the following authorisation numbers:

³ <http://ec.europa.eu/DocsRoom/documents/7303/attachments/1/translations/en/renditions/native>
<http://ec.europa.eu/DocsRoom/documents/7304/attachments/1/translations/en/renditions/native>

[REACH/15/4/0]

Use: formulation of diarsenic trioxide into a mixture

[REACH/15/4/1]

Use: industrial use of diarsenic trioxide as processing aid in gold electroplating

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 May 2022.

Article 3

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

On request by the competent authority of the Member State where the authorisation holder is established, the latter shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions referred to in Article 1, in an official language of the Member State.

Article 4

This Decision is addressed to Linxens France, 37, rue des Closeaux, 78200 Mantes-La-Jolie, France.

Done at Brussels, 1.9.2015

For the Commission

Elżbieta BIEŃKOWSKA

Member of the Commission

