Committee for Risk Assessment

RAC

Annex 2.2

Opinion
on gallium arsenide in relation to toxicity to reproduction
EC Number: 215-114-8
CAS Number: 1303-00-0

ECHA/RAC/A77-O-0000001412-86-11/A2.2

Adopted
23 July 2013
Note for the attention of Pilar Rodríguez Iglesias, Acting Chair of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment for an opinion on gallium arsenide in relation to toxicity for reproduction – revised mandate

The Committee for Risk Assessment (RAC) has been requested to draw up an opinion on data concerning toxicity to reproduction submitted during the public consultation on carcinogenicity according to the mandate from 30 November 2011 (Annex 1).

This note is to revise and extend the current mandate so that it also covers the request from the Commission to provide an opinion on the harmonised classification and labelling for reproductive toxicity of gallium arsenide taking into account the information submitted by Eurometaux in December 2011.

1. Background

On 25 May 2010 RAC adopted an opinion on a proposal for the harmonised classification and labelling of gallium arsenide. RAC concluded that a classification of carcinogenicity category 1A, reproductive toxicity category 1B and specific target organ toxicity – repeated exposure category 1 (Regulation (EC) 1272/2008) was appropriate.

On 1 December 2011 RAC adopted an opinion under a specific ECHA’s Executive Director request in accordance with Art. 77(3)(c) of REACH on gallium arsenide in relation to carcinogenicity. RAC recommended that gallium arsenide is classified as category 1B carcinogen with the hazard statement H350 (May cause cancer) according to the CLP Regulation. The opinion complements the opinion from 25 May 2010 in relation to the proposal for harmonised classification and labelling of gallium arsenide.

During the public consultation on carcinogenicity, a significant quantity of information was submitted by concerned parties, addressing not only carcinogenicity, but also toxicity to reproduction. Based on this information, the Commission requested ECHA to verify whether the information submitted with regard to toxicity to reproduction contains elements relevant for classification purposes that were not already examined by RAC when it adopted its opinion of 25 May 2010. On 30 November 2011, RAC was requested by ECHA’s Executive Director in accordance with Art. 77(3)(c) of REACH, to evaluate this submitted information on toxicity to reproduction in order to decide whether the previous opinion on the proposed classification for reproductive toxicity should be revised and draw up an opinion accordingly.

On 23 December 2011, Eurometaux submitted additional information highlighting that the data were not submitted during the public consultation in 2011 as it was limited to carcinogenicity. The Commission now requests ECHA to extend the current mandate from 30 November 2011 so that the new opinion of RAC can take into account the additional information submitted by Eurometaux in December 2011.

2. Terms of Reference

To allow the European Commission, on the basis of scientific advice, to decide, in accordance with Article 37(5) of the CLP Regulation, the appropriate harmonised classification and labelling for gallium arsenide.
classification and labelling of gallium arsenide, RAC is requested, pursuant to Article 77(3)(c) of REACH, to:

Further to the evaluation of the information on toxicity to reproduction submitted during public consultation on carcinogenicity to take into account also the information submitted by Eurometaux in December 2011 and draw up an opinion on the appropriate classification and labelling for reproductive toxicity accordingly.

3. Timescale for the RAC opinion

RAC is requested to assess the additional information and to adopt an opinion as soon as possible to assist the Commission to decide on the appropriate classification and labelling of gallium arsenide. It is also foreseen to hold a public consultation on the draft opinion prepared by RAC before its final adoption.

4. Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

Geert Dancet
Executive Director

Cc: Jukka Malm, Jack de Bruijn