Committee for Risk Assessment

RAC

Opinion

proposing harmonised classification and labelling
at Community level
of **Trisodium hexafluoroaluminate (Cryolite), natural and synthetic**

ECHA/RAC/CLH-O-0000001052-90-02/F
ECHA/RAC/CLH-O-0000001051-92-03/F

Adopted

25 May 2010

Annankatu 18 | P.O. Box 400 | 00121 Helsinki | Finland
www.echa.eu | Tel.: + 358 9 68.61.80

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Opinion of the Committee for Risk Assessment on a dossier proposing harmonised Classification and Labelling at Community level

In accordance with Article 37 (4) of the Regulation (EC) No 1272/2008 ("the CLP Regulation"), the Committee for Risk Assessment (RAC) has adopted an opinion on the proposal for harmonised classification and labelling of

Substance Name:	**trisodium hexafluoroaluminate (cryolite), natural and synthetic**
EC Number:	**239-148-8, 237-410-6**
CAS Numbers:	**15096-52-3, 13775-53-6**

The proposals were submitted by ***Germany***
and received by RAC on ***11 September 2009***

PROCESS FOR ADOPTION OF THE OPINION

Germany has submitted CLH dossiers for natural and synthetic cryolite containing identical proposals together with the justification and background information documented in CLH reports. The CLH reports were made publicly available in accordance with the requirements of the CLP Regulation at http://echa.europa.eu/doc/consultations/cl/clh_axvrep_germany_CD000977-53.pdf on ***4 November 2009***. MSCAs and parties concerned were invited to submit comments and contributions by ***19 December 2009***.

ADOPTION OF THE OPINION OF RAC

Rapporteur, appointed by RAC: ***Bert-Ove Lund***
Co-rapporteur, appointed by RAC: ***Marja Pronk***

The opinion takes into account the comments of MSCAs and parties concerned provided in accordance with Article 37 (4) of the CLP Regulation.

The RAC opinion on the proposed harmonised classification and labelling has been reached on ***25 May 2010,*** in accordance with Article 37 (4) of the CLP Regulation; giving parties concerned the opportunity to comment. Comments received are compiled in Annex 2.

The RAC Opinion was adopted by ***consensus.***

OPINION OF RAC

The RAC adopted the opinion that ***trisodium hexafluoroaluminate (cryolite) (CAS 15096-52-3, 13775-53-6)*** should be classified and labelled as follows[1]:

Classification & Labelling in accordance with the Classification, Labelling and Packaging Regulation (Regulation (EC) 1272/2008):

Classification[2]: Acute Tox. 4 – H332 (already listed on Annex VI; entry revised by deletion of Acute Tox. 4 – H302)

STOT RE 1 – H372 (already listed on Annex VI)

Aquatic Chronic – H411 (already listed on Annex VI)

Specific concentration limits: none

M-factors: none

Notes: none

Labelling: GHS07, GHS08, GHS09 Dgr H332, H372, H411

Classification & labelling in accordance with Directive 67/548/EEC

Classification[3]: Xn; R20 (already listed on Annex VI; entry revised by deletion of R22)

T;R48/23/25 (already listed on Annex VI)

N;R51-53 (already listed on Annex VI)

Specific concentration limits: none

Notes: none

Labelling: T; N

R: 20-48/23/25-51/53

S: (1/2-)22-37-45-61

[1] Note that not all hazard classes have been evaluated

[2] This section should reflect all relevant entries for the C&L: classification, R-phrases, S-phrases, concentrations limits, nota.

SCIENTIFIC GROUNDS FOR THE OPINION

The Background Document, attached as Annex I, gives the detailed scientific grounds for the Opinion. The Opinion relates to the classification proposal by Germany that concerns deletion of the existing harmonised classification for acute oral toxicity and addition of classification for eye irritation and developmental toxicity to the existing classification. No changes to the existing harmonised classification for repeated dose toxicity and environmental effects are proposed. It should be noted that trisodium hexafluoroaluminate below is called cryolite.

Acute toxicity

The proposal concerns deleting the current Annex VI classification for acute oral toxicity (H302/R22). During the public consultation, two MSCAs were in support of this proposal whereas no information or comments opposing the proposal have been received.

RAC agrees that cryolite should not be classified for acute oral toxicity, as no mortality was observed in the three available acute toxicity studies in rats at doses up to or exceeding the criteria threshold. H302 and R22 should therefore be removed from the current classification entry in Annex VI. In contrast, the classification for acute inhalation toxicity is supported by data and should remain.

Eye irritation

The classification proposal contains a proposal to classify cryolite for eye irritation, based on some very limited indications for eye irritation from animal studies and from human occupational settings. During the public consultation, two MSCAs were not supporting this proposal whereas no information or comments supporting the proposal have been received.

RAC considers the available data on eye irritation not sufficiently robust for classification, as the data as well as the reporting is very limited. Thus, RAC does not support the proposal to classify for eye irritation.

Reproductive toxicity – developmental effects

The classification proposal contains a proposal to classify cryolite for developmental toxicity, based on postnatal growth retardation and pup organ changes in a 2-generation reproduction study with rats and the induction of bent ribs and bent limb bones in two developmental toxicity studies with mice. In the public consultation, one comment in support and one comment opposing this proposal have been received from MSCAs.

The database contains five developmental toxicity studies and one 2-generation study, and they are all very poorly reported. Regarding the five developmental toxicity studies, RAC is of the view that the maternal mortality in the two "positive" mouse studies is too high to allow any meaningful conclusions on developmental toxicity to be drawn from these studies (CLP Regulation, Annex I §3.7.2.4.4 "*Maternal mortality greater than 10 % is considered excessive and the data for that dose level shall not normally be considered for further evaluation.*"). Overall, there is then no support for classification from the developmental toxicity studies.

There is then also one 2-generation reproductive toxicity study where rats were fed cryolite via the diet, but it should be noted that the study is only available as a 17-lines summary. Aside from dental fluorosis, no other parental effects were reported. In the progeny, no malformations were observed, but the summary reports on pale livers and kidneys, enlarged hearts, and decreased pup weights at the top dose (1800 ppm, approximately 150 mg/kg

bw/day in the females). The liver and kidney are target organs for cryolite in other repeated dose toxicity studies, so the reported paleness at the time of weaning could be substance-related. However, it is impossible to evaluate how adverse these effects are considering that no further information is given in the available summary, and it is consequently difficult to use this information (on paleness) in relation to the classification criteria. The only quantitative data reported is a decreased pup weight at the highest dose (by 12-18% in F1, and by 11-26% in F2). The significant decreases are observed at days 7-21 in F1 and at days 4-21 in F2, but details on whether the effect was increasing, decreasing or stable over those days were not reported. The effect on the pup weight could potentially be viewed as a result of repeated dose toxicity (for which the substance is already classified), albeit in young animals, but as this effect is reported already on day 4 in F2, it could also be a sign of developmental toxicity. The CLP criteria say that "*altered growth*" in offspring is a reason to classify (CLP Regulation, Annex I §3.7.1.4), but note that "*small reductions in foetal/pup body weights*" need not to be considered (CLP Regulation, Annex I §3.7.2.4.3). The decreases observed in F1 (12-18%) obviously did not affect the animals possibility to reproduce, as no effects on the subsequent reproduction of F1-animals was reported. The decrease in F2 pup weight was bigger (11-26%), but as the F2-animals are not allowed to reach adulthood, the reversibility and degree of adversity can not be judged. The decreased pup weights, especially in F2 (11-26%), could be a reason for classification.

It is acknowledged that dental fluorosis (hypoplasia and hypomineralisation of dental enamel and dentine) has been observed in the 1930s in children of female cryolite workers. As this adverse effect only can arise in developing children, it could be discussed in relation to developmental toxicity. However, to our recollection other fluorides have not been classified in the EU as developmental toxicants based on dental fluorosis.

In summary, it is believed that the decreased pup weights in both generations of the 2-generation study in rats fed cryolite via the diet is the only sign of developmental toxicity in animal studies that can be assessed in relation to the classification criteria. In relation to Cat. 2 (CLP), it is a borderline case with regard to whether the 11-26% decrease in pup growth is sufficient for classification. Arguments against classification are that no reporting of maternal toxicity in such a short summary does not necessarily mean that aside from dental fluorosis there was indeed no other maternal toxicity, and that the decreased pup weight was not adverse enough to affect the reproduction in F1. Although being a borderline case, RAC does not support classification for reproductive toxicity, Cat 2 (CLP) (or Repro Cat. 3 (R63)), because the evidence for developmental toxicity is too limited and the quality of the reporting too poor to warrant classification.

ANNEXES:

Annex 1	Background Document (BD)[3]
Annex 2	Comments received on the CLH report, response to comments provided by the dossier submitter and rapporteurs' comments (excl. confidential information)

[3] The Background Document (BD) supporting the opinion contains scientific justifications for the CLH proposal. BD is based on the CLH report prepared by a dossier submitter.