

AGREEMENT OF THE MEMBER STATE COMMITTEE ON THE IDENTIFICATION OF CADMIUM SULPHATE AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) 1907/2006¹

Adopted on 27 November 2014

This agreement concerns

Substance name: Cadmium sulphate

EC number: EC No. 233-331-6

CAS number: 10124-36-4; 31119-53-6

Molecular formula: Cd.H₂O₄S

0=<u>s</u>-0 Cd²⁺

Structural formula:

¹ 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

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (26 August 2014, submission number DU000095-38) on identification of *Cadmium sulphate* as a substance of very high concern due to its carcinogenic, mutagenic and toxic for reproduction properties and because of its properties causing adverse effects on kidney and bone tissues (serious effects to human health that give rise to an equivalent level of concern to those of CMRs).

The Annex XV dossier was circulated to Member States on 1 September 2014 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 17 November 2014 and agreed in the written procedure of the Member State Committee with closing date of 27 November 2014.

Agreement of the Member State Committee in accordance with Article 59(8):

Cadmium sulphate is identified as a substance of very high concern because:

a) it meets the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category $1B^2$.

b) it meets the criteria of Article 57 (b) of REACH owing to its classification in the hazard class germ cell mutagenicity category $1B^2$.

c) it meets the criteria of Article 57 (c) of REACH owing to its classification in the hazard class reproductive toxicity category $1B^2$.

d) in accordance with Article 57 (f) of REACH it is a substance which causes adverse effects on kidney and bone tissues after prolonged exposure², for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH.

² Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

UNDERLYING ARGUMENTATION

FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Carcinogenicity:

Carcinogen 1B – Article 57(a)

Cadmium sulphate is listed as index number 048-009-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification in the hazard class:

• Carcinogenicity category 1B in accordance with Article 57(a) of REACH.

Mutagenicity:

Mutagen 1B – Article 57(b)

Cadmium sulphate is listed as index number 048-009-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class germ cell mutagenicity category 1B (hazard statement H340: "May cause genetic defects").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification in the hazard class:

 Germ cell mutagenicity category 1B in accordance with Article 57(b) of REACH.

Toxicity for reproduction:

Toxic for reproduction 1B - Article 57(c)

Cadmium sulphate is listed index number 048-009-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 1B (hazard statement H360FD: May damage fertility; May damage the unborn child).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification in the hazard class:

 Reproductive toxicity category 1B in accordance with Article 57(c) of REACH.

Equivalent level of concern:

Properties causing adverse effects on kidney and bone tissues – Article 57(f)

Cadmium sulphate has the ability to cause a large number of toxic effects as is evident from the harmonised classification. It is thus clear that cadmium sulphate may cause many different serious effects to human health, in addition to the ability to cause cancer, induce mutations and cause toxic effects on reproductive organs. Adverse effects on multiple organs after prolonged exposure to cadmium sulphate, in particular **kidney** and **bone**, motivated the classification as STOT RE Category 1, and it is in particular effects on kidney and bone that justify the equivalent level of concern to those substances listed in points (a) to (e) of Article 57 REACH.

Cadmium sulphate is considered to fulfil the criteria according to Article 57(f), i.e. there is scientific evidence of probable serious effects to human health which give rise to "equivalent level of concern" to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document *Cadmium sulphate* (Member State Committee, 27 November 2014)