

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

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

Adopted on 30 November 2017

This agreement concerns

Substance name: Cadmium hydroxide

EC number: 244-168-5

CAS number: 21041-95-2

Molecular formula: Cd(OH)₂

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 (28 August 2017, submission number SPS-013556-17) on identification of *Cadmium hydroxide* as a substance of very high concern due to its carcinogenic and mutagenic properties and because of its specific target organ toxicity after repeated exposure properties (causing adverse effects on kidney and bone tissues).

The Annex XV dossier was circulated to Member States on 5 September 2017 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 20 November 2017 and agreed in the written procedure of the Member State Committee with closing date of 30 November 2017.

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

Cadmium hydroxide 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 1B².
- b) it meets the criteria of Article 57 (b) of REACH owing to its classification in the hazard class germ cell mutagenicity category 1B².
- c) 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 Regulation.

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 hydroxide is listed by Index number 048-013-00-0 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 it 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 hydroxide is listed by Index number 048-013-00-0 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 it meets the criteria for classification in the hazard class:

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

Equivalent level of concern:

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

Cadmium hydroxide is covered by Index number 048-013-00-0 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 as STOT RE1 (hazard statement H372: Causes damage to organs through prolonged or repeated exposure).

Cadmium hydroxide 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, due to:

- the adverse effects on kidney and bones, effects that depending on dose may be serious and even contribute to premature death,
- the continuous accumulation of cadmium in the body, which leads to continuous internal exposure and in practice irreversible effects once adverse effect levels are reached
- the occurrence of adverse effects in a significant part of the general population at present exposure levels, which are primarily of anthropogenic origin,
- uncertainties in deriving a safe exposure level, and
- high societal costs in terms of health care and shortening of life time and a decreased quality of life.

Conclusion: Cadmium hydroxide is identified as a substance of very high concern in accordance with Article 57(a), (b) and (f) of Regulation (EC) 1907/2006 (REACH) because it is a carcinogenic and mutagenic substance which also causes adverse effects on multiple organs after prolonged exposure, in particular *kidney* and *bone*, for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document (Member State Committee, 30 November 2017)