

COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS

Substance name: Cadmium fluoride

CAS number: 7790-79-6

EC number: 232-222-0

The substance is proposed to be identified as meeting the following SVHC criteria set out in Article 57 of the REACH

Regulation: Carcinogenic (Article 57 (a)); Mutagenic (Article 57 (b)); Toxic for Reproduction (Article 57 (c)); Equivalent level of concern having probable serious effects to human health (Article 57 (f))

Disclaimer: Comments provided during public consultation are made available in this document as submitted by the commenting parties. It was in the commenting parties own responsibility to ensure that their comments do not contain confidential information. The Response to Comments table has been prepared by the competent authority of the Member State preparing the proposal for identification of a Substance of Very High Concern. RCOM has not been agreed by the Member State Committee nor has the document been modified as result of the MSC discussions. The table does not contain any confidential information.

PART I: Comments and responses to comments on the SVHC proposal and its justification

General comments on the SVHC proposal

Number	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
6	2014/10/16	International NGO Health and Environment Alliance Belgium	We support the nomination of cadmium fluoride to the candidate list as an equivalent concern substance. -	Thank you for the support.

Specific comments on the justification

Number	Date	Submitted by (name, Organisation/ MSCA)	Comment	Response
1	2014/10/15	Member State Germany	The German CA supports the identification of Cadmium fluoride as SVHC. The Cadmium compounds Cd, CdO and CdS are already on the candidate list. To some extent cadmium compounds may be used as alternatives to each other and it is therefore considered important to follow a grouping approach and treat all these compounds in a similar manner. However, Cadmium Fluoride is not registered at all. Therefore, the benefit of identification of the substance for the candidate list seems to be low.	Thank you for the support.
2	2014/10/15	Industry or trade association International Cadmium Association Belgium	<p>Summary of Comments:</p> <p>The Annex XV report on Cadmium fluoride highlights two areas of risks:</p> <ol style="list-style-type: none"> 1. risk of increased bone and kidney effect on the general population due to exposure to Cd and its compounds from the environment, 2. risk to a large number of EU workers occupationally exposed to cadmium compounds. <p>These risks are taken forward as a basis to request that cadmium fluoride be submitted to the REACH authorization process.</p> <p>However, no effort is made in this Annex XV to try to link "uses" of cadmium fluoride to the risks to the general population. It is to be noted that no manufacture and no uses were reported; hence, no registration file under EU REACH was submitted.</p> <p>Moreover, the Annex XV fails to recognize that the vast majority (over 98%) of workers is exposed to cadmium and its compounds present as impurity in commodities.</p> <p>In these comments, industry will show that:</p> <ol style="list-style-type: none"> 1. The contribution of the industry deliberately using cadmium fluoride to general population Cd-exposure is insignificant as compared to the contribution of the industry manipulating goods in which cadmium is an impurity. In other words, the manufacture and formulation of cadmium fluoride has no influence on general population cadmium exposure, 2. The use of articles containing Cd and Cd compounds is already under many restrictions, prohibitions and limitations within the EU. Industry will show that exposure from the remaining articles, including their end of life, is insignificant 3. The sectors of industry that are deliberately using cadmium and its compounds only employ a small fraction of the estimated number of occupationally exposed workers (1.6%). These sectors deliberately using Cd and its compounds have a solid record of risk management and risk reduction; since 2008 they voluntarily 	<p>Thank you for your comments and the information provided. Comments regarding use, exposure, alternatives and risks may, where relevant, be considered at later stages of the risk management process.</p> <p>The justification for SVHC identification is based on intrinsic properties of the substance, not on use, exposure and risk. The latter is only briefly mentioned in the section on "Societal concern" for 57(f).</p>

			<p>implemented the Swedish Occupational Risk Agency management tools and implemented a DNEL based on the OEL set by SCOEL in 2010 (SUMDOC 136 2010).</p> <p>In clarifying these points, it will become clear that authorization of CdF₂ uses will not lead to any influence on general population and worker exposure, and as such will be insignificant to “ensure that the risks posed by the substance of very high concern will be properly controlled” (REACH art 55). Indeed, it will be clear that any Risks are already properly controlled.</p> <p>Some claim that the candidate listing of cadmium fluoride is quasi automatic, as that substance has been classified CMR. According to the findings of the Board of Appeal, though, ECHA is expected to assess “all the information which must be taken into account in order to assess a complex situation”, and all the evidence, which “is capable of substantiating the conclusions drawn from it” (Decision of the Board of Appeal in case A-005-2011, paragraph 75, judgment of the European Court of Justice in case C-12/03 P Tetra Laval [2005] ECR I-987, paragraph 39).</p> <p>We trust ECHA will take into account “all the relevant factors and circumstances of the situation the act is intended to regulate” (Decision of the Board of Appeal in case A-005-2011, paragraph 77), as we feel that position is also part of ECHA’s duty of sound administration – a general principle of EU law according to which, before they take any decision, institutions and bodies of the European Union with decision-making power have a duty to prepare it carefully and in particular to verify all the elements of fact which may have an impact on it (Case T-73/95, Estabelecimentos Isidoro M. Oliveira SA v Commission of the European Communities, paragraph 32 [1997] ECR II-381).</p> <p>The analysis of the most appropriate risk management option for cadmium fluoride (submitted by Sweden, March 2014) concludes that “Even though there are no registrations for cadmium fluoride, the substance is considered relevant for the Candidate list from a grouping point of view. At present, there are six cadmium compounds with a harmonised classification as Carc. Cat 1B; three of those are already on the Candidate list and a fourth has recently been proposed. To some extent cadmium compounds may be used as alternatives to each other and it is therefore considered important to treat all these compounds in a similar manner in order to promote substitution to other less toxic substances.” The six referred CMR Cadmium compounds are: Cd, CdO, CdS, CdCl₂, CdSO₄ and CdF₂.</p> <p>- Cd is mainly used (industrial use) for industrial batteries, alloys and when permitted for plating. A metal is never substitutable in its uses by a metal compound</p>	
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			<ul style="list-style-type: none"> - CdO is mainly used (industrial use) for industrial batteries and for electrical contacts. This oxidic compound cannot be substituted in its uses by any other Cd CMR compound - CdS is, besides its intermediate uses, mainly used in electrophotovoltaic applications and there is no way to be substituted by any other Cd CMR compound - CdCl₂ is, besides its intermediate uses, reported to be used as activator in photovoltaic layers; alternatives are sought but no substitute are available today and certainly not the other Cd CMR compounds - CdSO₄ is only reported to be used as intermediate in pigment manufacturing and photovoltaic component manufacture - CdF₂ is not registered above 1T use and is probably limited to minor laboratory reagent uses <p>In summary, there is no rationale a) for suspecting any substitution and b) for claiming for grouping under an authorization procedure, for substances for which no uses are reported.</p> <p>Given the fact there are no registrations for CdF₂, no detailed comments will be provided on this Annex XV dossier. We refer however to the detailed comments made on CdSO₄ Annex XV dossier which are in general also applicable to the Annex XV dossier CdF₂</p>	
3	2014/10/16	Member State Finland	The Finnish CA agrees that Cadmium fluoride meets the criteria as SVHC according to Article 57 a, b, c and f. The Finnish CA considers that after inclusion of the substance in the candidate list (for eventual inclusion in the Annex XIV) it still needs to be further considered which risk management measures would be the most appropriate. The coverage of existing measures shall be taken into account (e.g. Annex XVII restriction no 23).	Thank you for your comment and support.
4	2014/10/16	National NGO CHEM Trust United Kingdom	CHEM Trust supports the inclusion of cadmium fluoride in the REACH candidate list. It is important to also address the properties of concern (i.e. damage to kidneys and bones) in addition to its CMR effects. In particular the accumulation potential in the kidney is of high relevance. Therefore we support the inclusion of cadmium on the candidate list on the basis of 57(f) as well as 57(a), (b) and (c).	Thank you for the support.

5	2014/10/16	Member State Norway	<p>The Norwegian REACH CA supports the proposal to identify cadmium fluoride as a SVHC in accordance with article 57 a), 57 b), and 57 c) since cadmium fluoride is harmonised classified as carcinogenic (Carc. IB, H350: May cause cancer), mutagenic (H340: May cause genetic defects) and reprotoxic (H360FD: May damage fertility. May damage the unborn child).</p> <p>In addition the Norwegian REACH CA supports the proposal to identify cadmium fluoride as a SVHC in accordance with article 57 f) for equivalent level of concern owing to the adverse effects on kidney and bone tissue after prolonged exposure (harmonised classified STOT RE1, H372: Causes damage to organs through prolonged or repeated exposure). Since the toxic effects of cadmium fluoride is caused by the cadmium ion, the same justifications for equivalent level of concern given for cadmium applies to cadmium fluoride. Cadmium is on the Candidate List identified as an SVHC in accordance with Article 57a) and 57f).</p>	Thank you for the support.
7	2014/10/16	International NGO ChemSec Sweden	<p>Comments on the proposed SVHC properties summarised on page 4-8 of the Annex XV SVHC report:</p> <p>We fully support the inclusion of this substance on the REACH candidate list based on the hazardous properties shown below:</p> <p>Carc. 1B Muta. 1B Repr. 1B STOT RE 1</p>	Thank you for the support.

PART II: Comments and responses to comments on uses, exposures, alternatives and risks

No specific comments on use, exposure, alternatives and risks