Risk Management Option Analysis Conclusion Document

Substance Name: Talc
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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

This RMOA is focused on occupational exposure to talc not containing asbestos or asbestiform fibers via industrial or professional uses. Respirable talc may contain non-asbestos fibers (according WHO definition[2]) up to 30% total, which are highly biopersistent[3].

Under REACH, <1% of the total estimated yearly production of talc is registered. Most of the talc production is exempt from registration under REACH as talc is a mineral and in accordance with Article 2(7)(b) when not chemically modified. The part of talc production registered under REACH is as result of a chemical modification. In the production process, talc is treated with boiling hydrochloric acid (HCl) by some manufacturers, which is a chemical modification and for which a registration under REACH might then be required.

There is no indicative occupational exposure limit (OEL) for respirable talc in the EU (March 2021), but most European countries have established their own OEL. According to the ECHA online registration dossier, talc is generally classified as a 'nuisance dust' and should be kept within the limits set for each country, if appropriate[4].

The Dutch Expert Committee on Occupational Standards (DECOS 1991[5]) recommended an OEL of 0.25 mg/m^3, based on two epidemiological studies in rubber workers, and talc miners and millers, where minimal adverse effect level (MAEL) of 0.50 mg/m^3 and 1.8 mg/m^3 were found. Based on this information, an 8-h time-weighted average (TWA) level of 0.25 mg/m^3 was established for respirable cosmetic-grade talc. For industrial-grade talc (containing free silica and asbestos fibers) the regulations for asbestos and free silica was suggested.

According to MAK value documentation for talc (MAK 2012[6]): The previous MAK value of 2 mg/m^3 for talc has been withdrawn since more recent data from animal studies have indicated a retardation of clearance in this concentration range and changes in pulmonary function are still observed in humans. Exposure should be below the general threshold limit value for dust (respirable fraction) of 1.5 mg/m^3. Since talc always also contains very biopersistent fibers of the WHO definition, monitoring the concentration of talc in air should consider the concentration of talc (in mg/m^3) and the fiber fraction contained in the talc.

Recently, an OEL for poorly soluble low toxicity (PSLT) particles (including talc) of 1.25 mg/m^3 has been established in Germany (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin 2021[7]).

The use of talc is implemented in other EU legislation as well. Asbestos-free talc is used in the production of foods as an anticaking agent (E553b) and the purity of food-grade talc is stated in EU Commission Regulation No 231/2012[8]. Non-asbestos talc is included in Annex III of restricted substances and restricted for use in powdery products or cosmetic products intended to be used for children under 3 years of age[9]. In the Pesticide Residues Regulation, maximum residue levels for talc (E553b) applies as listed under Annex IV[10]. Furthermore, talc is listed as additive or polymer production aid intended to come into contact with food under the Plastic Materials and Articles

[2] WHO definition fibres: length to diameter ratio >3:1; length >5 µm; diameter <3 µm https://publications.iarc.fr/_publications/media/download/2609/7681930b8fcfab93a2365a4dca777526f96bf054.pdf
[3] Cralley, L. J., M. M. Key, D. H. Groth, W. S. Lainhart, and R. M. Ligo. 1968. 'Fibrous and mineral content of cosmetic talcum products', Am Ind Hyg Assoc J, 29: 350-4.
[4] https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/18727/7/1 (assessed 11 October 2021)
[5] https://www.ser.nl/api/Mfiles/DownloadFirstDocument?Id=2115a424-3173-4c66-a6ff-feca96317672
[6] https://onlinelibrary.wiley.com/doi/epdf/10.1002/3527600418.mb1480796nfae0022
[7] https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-900.html
[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0231&qid=1616060481036
[9] https://echa.europa.eu/nl/cosmetics-restricted-substances/-/legislationlist/details/EU-COSM_PROD-ANX_III_RESTRIC-100.035.328-VSK-010285
[10] https://echa.europa.eu/nl/cosmetics-restricted-substances/-/legislationlist/details/EU-COSM_PROD-ANX_III_RESTRIC-100.035.328-VSK-010285

Regulation[11].

2. CONCLUSION OF RMOA

The following risk management measures are concluded appropriate to address the concern for adverse effects of talc. It is proposed to:

- Draft a proposal for harmonized classification for talc as Carc. 2 (H351, inhalation) and STOT-RE 1 (H372, inhalation and lung).
- Draft a proposal for an indicative OEL, consider fiber concentration in respirable talc.

This combination of risk management options is expected to result in a decreasing incidence of lung diseases for workers in relevant fields of work.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	X
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	X
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Table: SVHC Roadmap 2020 criteria

	Yes	No
a) Article 57 criteria fulfilled?[1]	X	
b) Registrations in accordance with Article 10?[2]	X	
c) Registrations include uses within scope of authorisation?	X	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	X	

[1]Article 57 could be fulfilled due to health hazard (Carc. 2 and STOT-SE 1) according to CLP. There currently is no harmonized classification and labelling (CLH) for talc.
[2]Majority of production of talc is exempt from registration under REACH, as talc is a mineral.

Talc is used in a wide variety of different processes of manufacturing in different industries, as filling component (bleaching, whitening/filling agent, pharmaceuticals), carrier (coating, dye, paper industry), separator (rubber), processing aid (ceramics), non-reactive processing aid (agriculture), and anticaking agent (food). Cosmetic-grade talc is used in cosmetics, additive in personal care products and body powders.

Although talc is mostly considered as a harmless substance, concerns have been raised due to the severe irreversible lung dysfunction and non-malignant respiratory diseases (NMRDs) associated with occupational exposures. Case reports demonstrated similar

[11] https://echa.europa.eu/nl/plastic-material-food-contact/-/legislationlist/details/EU-PLST_FCM-ANX_I_AUTHORIS-100.035.328-VSK-24A24B

adverse lung effects after consumer exposure of talc, although to a much lesser extend as compared to occupational exposure. Talc may meet the Article 57 criteria for equivalent level of concern (57f) due to specific target organ toxicity upon repeated exposure. There is a concern for talc-induced lung tumour formation and NMRDs upon repeated exposure. During manufacture or use, the substance may pose risks, primarily via inhalation of dust and particulates.

3.1 Harmonised classification and labelling

No harmonized classification and labelling has been established for talc and therefore talc is not listed in Annex VI. The available data suggest the substance could be harmonized under CLP as Carc. 2 (H351, inhalation) and STOT-RE 1 (H372, inhalation and lung). Of the total 4635 C&L-notifiers (see 3.1.2), 96% (4429 notifiers) do not apply any self-classification of health hazards. This demonstrates the discrepancy of the available data on occupational exposure to talc and self-classification.

Harmonized classification will ensure that the hazards presented by the substance are clearly communicated to workers and consumers via a safety data sheet, according to Article 31 of REACH, and instigates the implementation of proper risk management measures at the workplace and public areas. Furthermore, harmonized classification has to be implemented on the portion of talc registered under REACH but also on the majority of talc production exempt from REACH registration. Therefore, it is concluded that CLH for Carc. 2 (H351, inhalation) and STOT-RE 1 (H372, inhalation and lung) is an appropriate and effective risk management option for talc.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Talc may be identified as an SVHC based on article 57(f) because of its association with lung tumor formation and NMRDs (e.g. pneumoconiosis). All SVHC criteria (with respect to the SVHC 2020 Roadmap) are met. However, the majority of talc production is exempt from registration under REACH. In addition, considering the large scale of use of talc, many authorisation requests are to be expected when authorisation is implemented for talc. This would make the use of talc unfeasible and unnecessarily more costly. Therefore, it can be concluded that SVHC identification seems not an effective risk management option in regulating the risks related to the use of talc.

3.3 Restriction under REACH

Talc is of concern mainly due to repeated exposure in workers (inhalation) and, to a lesser extent, in consumers (inhalation). A total ban on the manufacture and use of the substance would prevent all (potential) health risks. However, a total ban may be neither necessary nor proportionate. Restriction of specific uses can be considered, but seems not a suitable risk management option based on:

- Exposure levels for workers are already decreasing over the last years based on voluntary measures from industry.
- Numerous references values are already set (OELs and DNELs), and could be improved and harmonized as indicative OEL in the EEA.

3.4 Worker legislation (setting an OEL)

OELs vary greatly between countries and current OELs and DNELs for talc are often

above occupational exposure levels (0.5-15 mg/m^3) which are associated with lung dysfunction and impairment. Setting an indicative OEL guarantees safe occupational exposure limits for talc throughout the EEA and ensures a level playing field. Recently, an opinion of Advisory Committee on Safety and Health at Work (ACSH[12]) was adopted regarding prioritizing PSLTs, including talc, for development of an EU limit value under the Chemical Agent Directive 98/24/EC.

OELs in most countries do not consider fiber content in talc, while Danish and Finnish OELs do consider fiber content per cm^3. Respirable talc contains fibers corresponding to the WHO definition of fibers, up to 30%, and these fibers are highly biopersistent in the lungs. It thus would be advisable to include a limit for fiber concentration for respirable talc when setting an indicative OEL.

[12] https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/989e8222-d653-4879-83ee-9e9a237a1754/details

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

An indicate a preliminary timetable for the risk management measures discussed above are indicated in the table below.

Follow-up action	Date for intention	Actor
CLH proposal	July 2022	NL CA
Proposal for an indicative OEL		