Risk Management Option Analysis Conclusion Document

Substance Name: Kieselguhr, soda ash flux-calcined

EC Number: 272-489-0

CAS Number: 68855-54-9

Authority: NL CA

Date: August 2017

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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

Table: Completed or ongoing processes[2]

RMOA	☐ Risk Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal (Sub-chronic toxicity (90 day): inhalation, 2011)[1]
		☒ CoRAP and Substance Evaluation[2]
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[3]
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	

[2] This table includes several processes ongoing or completed on Kieselguhr, soda ash flux-calcined or related substances that may be of relevance to being a constituent of the UVCB.

Other processes/ EU legislation	☒ Other (provide further details below)[3]

[1]Testing proposal: Deadline for submitting information was in 2011, but the dossier is not available on the echa website.

[2] Currently, silicon dioxide (and not Kieselguhr, soda ash flux calcined) is on the Co-RAP list; a substance evalution has been performed by the RIVM, The Netherlands. The registrants have been asked for additional inhalation studies, with a focus to provide more information on the toxicity of on nano-seized synthetic amorphous silica (SAS; nanosilica).

[3] In 2003, SCOEL has set an OEL of 0.05 mg/m^3 for crystalline silica dust (cristobalite, CAS 14464-46-1; Quartz, CAS 14808-60-7; Tridymite, CAS 15468-32-3; not Kieselguhr, soda ash flux-calcined). In June 2015, SCOEL has been asked by the European Commission to review SCOEL/SUM/094; This review resulted recently in a proposal by the COM for a BOEL of 0.1 mg/m^3 for each of these forms of silica (http://europa.eu/rapid/press-release_MEMO-16-1655_en.htm). To note, the currently proposed BOEL is higher that the NL-OEL of 0.075mg/m3 implemented for respirable crystalling silica (RCS). RCS can be a process generated substance.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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

3. NEED FOR FOLLOW-UP

Repeated inhalation of Kieselguhr, soda ash flux-calcined can cause silicosis, a form of occupational lung disease, which eventually can lead to lung cancer. There are several reports that show, both in experimental animals as well as in humans that were occupationally exposed to the substance, that it is detrimental to the lungs through inhalation. The available information on actual worker cases furthermore suggests that the established occupational exposure limited are insufficient to prevent effects. Consequently, the data available indicate there may be a risks for workers. Consumer risks are considered less likely as consumer uses are minimum. These may arise though from the use of Kieselguhr, soda ash flux calcined for cleaning swimming pools and the use of Kieselguhr, soda ash flux calcined is spray paints/coating for consumer use. Risks

for consumers are not expected from the uses described.

For four constituents of kieselguhr, soda ash flux-calcined, three of which are on the Dutch SZW-list of Cat.1 carcinogens, intentions for harmonized classification for carcinogenicity are expressed. Once one or more of these constituents will be classified as Carc.Cat.1 it is expected that most, if not all Kieselguhr, soda ash flux calcined compositions will also need to be self classified as carcinogen Cat. 1 (mixture ≥ 0.1% for a category 1A or 1B carcinogen, ≥ 1.0% for a category 2 carcinogen; CLP Annex I, table 3.6.2).

Table: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?		X
b) Registrations in accordance with Article 10?	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	

Identification and assessment of risk management options

Occupational safety and health directive

Recent (2015) monitoring data from DE-breweries suggest that worker exposure exceeds the occupational exposure limited defined in various EU Member States ranging between 0.1 mg/m^3 and 0.075 mg/m^3, the proposed EU limit value of 0.05 mg/m^3 and the TWA 0.1 mg/m^3 set by NIOSH. Furthermore, human health cases suggest that even the lowest value of 0.05 mg/m^3 is insufficient to reduce incidences to below the acceptable 1: 1.000. In 2016, the COM proposed a BOEL of 0.1 mg/m^3 for various forms of crystalline silica (http://europa.eu/rapid/press-release_MEMO-16-1655_en.htm). This is slightly higher than the OEL of 0.075mg/m3 implemented to date in NL for respirable crystalline silica (RCS). This proposal has been based on an impact assessment by IOM (May, 2011). The amendment of the Carcinogens and Mutagens Directive (2004/37/EC) to include work involving exposure to respirable crystalline silica dust generated by a work process and to set a Binding Occupational Exposure Limit Value (BOELV) of 0.1 mg/m^3 for respirable crystalline silica, was approved in trilogue discussion on 11 July 2017 and by the Council's Permanent Representatives Committee ("Coreper"). It has still to be formally adopted by the European Parliament.

Upon communication, the registrants indicated that the TWA setting of 0.1 mg/m^3 already adopted by them as an occupational limt value for safe work involved both health hazard, economical and technical feasibility aspects.

Once the various constituents of Kieselguhr, soda ash flux calcined will be classified as Carc. Cat.1, those fractions of Kieselguhr, soda ash flux calcined containing >0.1% of these constituents will fall under the Carcinogens and Mutagens Directive. The CMD will build a regulatory incentive to promote substitution of Carcinogenic forms of Kieselguhr, soda ash flux calcined as it specifies that less hazardous forms of Kieselguhr, soda ash flux calcined should be used for those applications where the technical specification will allow this type of substitution. Further, the requirements under the CMD will support further risk management measures forming a furher incentive to handle Kieselguhr, soda ash flux calcined in closed processes and prevent dust formation by all means. To what extend this will be taken up in practice and to what extend this will lead to a reduction in occupational health cases remains to be seen.

Though Kieselguhr, soda ash flux calcined is not yet (self) classified as carcinogen, its

possible toxic properties are well known. Further, as is indicated by the registrant, companies have already implemented measures to prevent dust formation. One may wonder therefore, if the classification of Kieselguhr, soda ash flux calcined as Carc. Cat. 1 will induce significant additional risk management measures at the workplace or lead to better enforcement of the measures already in place. Hence it is to be seen if harmonized classification will further improve workplace safety.

Risk management could also be addressed by ensuring any activites related to this substance is addressed in the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" http://www.nepsi.eu/.

Authorization

Once one or more of the constituents of Kieselguhr, soda ash flux calcined are classified as Carc. Cat.1, Kieselguhr, soda ash flux calcined can be considered as possible SVHC and proposed for Candidate Listing. It is anticipated that the high Tonnage of Kieselguhr, soda ash flux calcined and its wide dispersive use give the substance a relatively high priority for inclusion in Annex XIV. Once on Annex XIV, all uses of the substance will need to be authorised, providing a strong incentive for industry to either shift to less hazardous alternatives or prepare a detailed description of the conditions for safe use. This would better enable workers to work safely and may support enforcement agencies in their work, checking if the appropriate safety measures are in place at the corresponding workplaces. Authorisation would have the benefit of allowing industry to make case by case descriptions for safe use, which may be preferred over a "one fits all" proposal for restriction. Authorization will also address consumer uses, that are currently of less concern than workers, but who may similarly benefit from exposure reduction while handling Kieselguhr, soda ash flux calcined.

It is anticipated that Authorization will come with significant costs for industry, but also that it may lead to a significant reduction of the adverse health effects for workers (and potentially also consumers). Given the current situation of a well known occupational health concern with occupational health cases continuing to develop, Authorization could be an appropriate added measure to create an incentive for industry to further improve their work processes. However, as a result of the high tonnage and wide dispersive use, the high number of applications for authorisation anticipated also provide a serious downside of this risk management option as it will come with serious costs not only for industry applying for authorisation, but also for Member State Authorities, ECHA and the COM for processing these applications.

Restriction

Concern for workers focusses on the exposure to respirable fractions of Kieselguhr, soda ash flux calcined. The continuous development of occupational health cases and the data available on possible workplace exposures suggests a possible risk for workers. As the concern focusses only on those activities where exposure to fine and ultrafine particles is an issue, a targeted restriction could be considered: For consumers aimed at product design, making sure that consumers will not get exposed to aerosol generating products (like i.e. spray paints). For workers, this could involve a more binding prescription on measures to implement to prevent exposure to fine or ultrafine particles when working with Kieselguhr, soda ash flux calcined. However, with regard to consumers, there is no information known to the NL-CA that there is a current EU-wide risk from the uses at the market. Furthermore, once the several components of Kieselguhr, soda ash flux calcined will be classified as carcinogen, these will no longer be allowed for use in consumer products. For workers, restriction might be an option but may not be workable in practice because of possible strong site-to-site variations in the way Kieselguhr, soda

ash flux calcined is and can be handled. If considered a possibly interesting route, conditions for restriction should be further evaluated, for example in a dialogue with the different actors (i.e. registrants, DUs and worker representatives).

Conclusions on the most appropriate (combination of) risk management options

From the information presented, it is concluded that the first, most appropriate risk management options for Kieselguhr, soda ash flux calcined (e.g. Harmonised Classification of its different components and the development of an occupational exposure level) is already initiated by FR in their expressed intention to develop a CLH proposal. Also the second most appropriate risk management measure of developing a BOEL has been taken up by the COM and resulted in a proposal for a BOEL of 0.1 mg/m^3.

Once Kieselguhr, soda ash flux calcined is classified as Carc. Cat.1, SVHC identification becomes possible. As full substitution of this substance is possibly not possible now or in the future, one could question if SVHC listing and Authorization will be effective to reduce work place exposure. Furthermore, when Kieselguhr, soda ash flux calcined would be put on Annex XIV, a very high number of applications for authorisation are expected for a high variety of uses, which may not be so efficient in terms of use of resources for Industry, Member States, ECHA and the COM. Authorization is therefore considered not an appropriate risk management measure at this moment in time. Dialogue with the actors involved is suggested to explore the possibilities to further reduce workplace exposure within the context of the OSH regulation or through the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it”. Along these same lines, possibilities for a targeted restriction could be considered, for example, to strengthen any Social Dialogue Agreements and allow for the enforcement of good working practices.