Possibility for

MSCA Logo]

# SUBSTANCE EVALUATION

# CONCLUSION DOCUMENT

## as required by REACH Article 48

## for

# Beryllium

## EC No 231-150-7

## CAS No 7440-41-7

**Evaluating MemberState(s): DE**

Dated: 19th March 2014

# Evaluating MemberState Competent Authority

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## Year of evaluation in CoRAP: 2013

MemberState concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

**Please find (search for) further information on registered substances here:**

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

# Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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# 1. CONCERN(S) SUBJECT TO EVALUATION

Beryllium was selected for substance evaluation in order to clarify:

- The number of exposed workers

- The magnitude/levels of occupational exposure

Both information is needed to evaluate whether there is a risk for workers and whether a regulation, based on the harmonised classification as Carc. 1B and the known toxicity (short-term and long-term) via inhalation, is required.

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

# 2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

| **Conclusions** | **Tick box** |
|---|---|
| Need for follow up regulatory action at EU level<br>*[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]* | |
| *Need for Harmonised classification and labelling* | |
| *Need for Identification as SVHC (authorisation)* | X |
| *Need for Restrictions* | |
| *Need for other Community-wide measures* | |
| No need for regulatory follow-up action | |

# 3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

## 3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

- Beryllium is legally classified as Carc. 1B and is known to provoke chronic beryllium disease (CBD) and beryllium sensitization (BeS). Therefore a clear intrinsic hazard of the substance exists. The long-term systemic DNEL for inhalation was evaluated by the German CA to be 60 ng/m$^3$.
- The exposure data available show exposure levels one to two orders of magnitude above the DNEL value for several uses.
- A clear risk for workers exists throughout the EU.
- A high number of (approx. 65000) workers potentially exposed to Beryllium and its compounds has been identified. The actual number of workers at risk (exposure exceeding the DNEL) could not be identified based on the available data.

### 3.1.1. Need for harmonised classification and labelling

The chronic lung disease known as chronic beryllium disease (CBD) is characterized by the initial development of beryllium sensitization (BeS) and progressive development of granulomas and mononuclear cell infiltrates primarily in lung tissue. Past exposure to beryllium and evidence of beryllium sensitization are important parts of the clinical diagnosis of CBD. Beryllium sensitization is an early event associated with the development of CBD. Therefore beryllium appears to fulfill the criteria for classification as "Resp. Sens. 1, H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled." according to Regulation (EC) No. 1272/2008 (CLP).

As the harmonised classification as respiratory sensitizer would not change risk management measures for a substance already classified as Carc. 1B, the evaluating MSCA is currently not planning to harmonise classification and labelling for this endpoint.

### 3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Beryllium is classified as Carc. 1B according to Annex VI of CLP and therefore fulfils the criteria for a SVHC-Identification according to Article 57(a). The identification might be enhanced to also include an identification based on Article 57(f), due to the classification as STOT RE1 (chronic beryllium disease).

***Link to authorisation***

Beryllium is a material used for several modern applications and substitution might be hard to impossible in most cases, due to the specific chemical and physical properties of Beryllium.

Beryllium is carcinogenic and induces chronic beryllium disease (reflects the classification as STOT RE). No DMEL for carcinogenicity is attributable. Due to the low DNEL for CBD, situations might exist where workers are regularly exposed to concentrations of Beryllium (and/or its compounds) exceeding the DNEL. For some basic steps in the supply chain (e.g. foundries) it might be technically hard or even impossible to reach exposure levels lower than the DNEL. Therefore risks for workers exposed to beryllium exist.

Uses with a lower level of exposure (but at the moment still above the DNEL) might be able to reach RCRs ≤ 1 if higher levels of risk reducing measures are included. The effectiveness of and need for additional protective measures will be evaluated during the authorisation process.
Additionally, while most uses of Beryllium seem to be essential for modern industry, some other uses might not be needed or the option of substitution might exist. During the authorisation process these uses will be identified.

It has to be taken into account that the score for authorisation of Beryllium is expected to be low based on its intrinsic properties, low tonnage and industrial use. Nevertheless, the high number of potentially exposed workers combined with the high exposure significantly exceeding the DNEL, as identified for several uses, clearly shows the need for an EU-wide regulation. Based on the arguments mentioned above authorisation is seen as the best way to regulate Beryllium.

### 3.1.3. Need for restrictions

Since substitution of Beryllium might be impossible in most cases (including the problematic cases), a general restriction does not seem to be the best option.

### 3.1.4. Proposal for other Community-wide regulatory risk management measures

Beryllium is currently discussed by SCOEL in the context of setting an occupational exposure limit. Setting (and enforcing) an EU-wide binding occupational exposure limit is regarded as an important step, parallel to the authorisation, to enhance worker protection throughout the EU.

## 4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Indication of a tentative plan is not a formal commitment for the evaluating Member State. A formal commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier shall be made via the Registry of Intentions.

| Follow-up action | Date for intention | Actor |
|---|---|---|
| Annex XV-dossier for SVHC-identification and following authorisation. (RMOA with a view to potential preparation of an Annex XV dossier for SVHC identification and following authorisation) | 2015-2016 | German CA |