



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Regulatory Management Option Analysis Conclusion Document

Substance Name: Beryllium (oxide)
EC Number: 231-150-7 (Beryllium)
215-133-1 (Beryllium oxide)
CAS Number: 7440-41-7 (Beryllium)
1304-56-9 (Beryllium oxide)
Authority: The Netherlands, RIVM
Date: December 2023

Cover Note

Bureau REACH started a Regulatory Management Option Analysis for Beryllium Oxide (BeO) in 2017. After signals from ILT to RIVM that there were concerns about the presence of beryllium (be) in electronical waste, to be processed at a recycling company. ILT requested a risk analysis by RIVM. The concern was expressed as follows:

“Beryllium is Carc. Cat 1B. According to ILT this is a large problem, but mostly for the processing of waste of electrical and electronical devices. A large amount of Beryllium has been measured in dust. Seems to be a worker hygienic issue. This could be mostly a recycling issue outside the scope of REACH”. Later it was specified that the focus was to be on Be oxide (BeO), including Be itself.

After careful considerations the NL-CA decided that no follow-up actions are needed and that the RMOA will be finalised without member state consultation in absence of a proposal for follow-up actions.

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Regulatory Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of Regulatory 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 2020¹.

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

Beryllium (oxide) is used in electrical and electronic devices. During the recycling process, potentially (too) high concentrations of beryllium can be found in the waste dust after shredding of waste materials. Taking the harmonized classification of beryllium (Carc 1B) into account, further risk management is taken into consideration.

REACH/ CLP

Beryllium was taken up in the Community Rolling Action Plan (CoRAP) upon the demand of the German Federal Institute for Occupational Safety and Health (BAUA) in 2013. The inclusion was motivated with regard to the concern that occupational respiratory exposure of workers to airborne beryllium dust might cause health risks, particularly beryllium sensitisation (BeS) and chronic beryllium disease (CBD) or berylliosis due to long term exposure. With view at its classification as Carcinogen 1B, according to Annex VI of the CLP regulation, beryllium fulfils the Article 57(a) criteria for identification as a substance of very high concern (SVHC) and authorisation was recommended as the best way to regulate this hazard. Setting and enforcing an EU-wide binding occupational exposure limit was also regarded as an important step to enhance worker protection throughout the EU, next to the authorisation.

Waste Framework Directive

Beryllium oxide is covered by the Waste Framework Directive, Annex III (2008/98/EC). Based on the harmonized classification, the following hazard property (HP) waste codes have been assigned:

- HP7 Carcinogenic: waste which induces cancer or increases its incidence
- HP6 Acute toxicity: waste which can cause acute toxic effects following oral or dermal administration, or inhalation exposure
- HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity: waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration
- HP4 Irritant – skin irritation and eye damage: waste which on application can cause skin irritation or damage to the eye
- HP13 Sensitising: waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs

No concentration limit has been set for the presence of beryllium oxide in waste.

Occupational Exposure Limits (OEL)

Germany advised in their 2016 RMOA that SCOEL and DG employment should derive an EU-wide OEL. In 2017, the SCOEL recommended a value of 0.02 µg/m³ for the setting of the (B)OEL. This value is significantly lower than the voluntary limit value of 0.2 µg/m³ that many companies have used. The Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work has been amended by Directive (EU) 2019/983, stipulating OEL for beryllium and its inorganic compounds as 0.2 µg/m³. A limit value of 0.6 µg/m³ applies during a transitional period of 7 years until July 11th 2026. As the latter value is significantly higher than the voluntary limit value that has been in place for several years, the implementation of the (B)OEL can be expected to go smoothly. Producers and down-stream users are exchanging best practices. Although the industries observed so far do not include waste-processing companies, which seem to fall outside the scope of REACH, the (B)OEL will also be valid for waste processing industry, protecting the workers there.

Critical Raw Materials Act

Beryllium is listed on the 2017 catalogue of Critical Raw Materials (CRM) for the EU (COM(2017) 490 final). Materials appearing on this list have been identified as critical for the EU due to a risk of supply shortage and their high importance for the economy. For

beryllium, the supply risk scores at 2.4 and the economic importance scores at 3.9. These scores indicate that beryllium has a medium criticality as compared to other raw materials.

WEEE & RoHS

The collection scheme of waste of electrical and electronic equipment (WEEE) is provided in the revised WEEE Directive 2012/19/EU, effective as of 14 February 2014. This Directive aims to increase the recycling of WEEE and/or the re-use.

The restriction of the use of hazardous substances in electrical and electronic equipment is described in RoHS Directive 2002/95/EC, entry into force February 2003. This legislation requires heavy metals to be substituted by safer alternatives. Revised version RoHS recast Directive 2011/65/EU became effective in January 2013. Beryllium is not covered by this Directive, but the inclusion of beryllium and BeO in Annex II of RoHS has been investigated.² At present, the inclusion is not recommended, but additional measures have been proposed to avoid inclusion in the future.

2. CONCLUSION OF RMOA

At this point in time, a regulatory management option under REACH is not considered to be relevant or proportional. The course of action is proposed to be the following:

- Obtaining sufficient information on the exposure to beryllium at the waste processing lines for mobile phones and microwave ovens. This would improve the evaluation if there is an actual concern, which is still unclear.
- The RoHS Annex II dossier on beryllium and its compounds states that given the relatively high technical importance of the substances and based on the result of the risk evaluation that beryllium and BeO in EEE pose medium risks during WEEE treatment and disposal, the inclusion of beryllium and BeO in ANNEX II of ROHS is currently not recommended. However, it should be discussed with the industry, where information can be found on the replacing of beryllium, especially in the components that are difficult to separate. If replacement should prove to be possible, a restriction on the use of beryllium in these parts could be re-evaluated.
- Discuss the possibility of restricting the shredding process (to closed systems). This would reduce exposure to not only beryllium, but also other harmful metals in dust. Shredding electrical and electronical waste is used to homogenize the materials, but minimizing or enclosure of this process would reduce exposure significantly.

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

The Oeko-Institut (2019) summarised in their ROHS Annex II Dossier for Beryllium and its compounds that it can be concluded that exposure to airborne beryllium might occur during the use phase of consumer EEE that contain high power electrical motors due to wear and tear of beryllium bearing sliding brushes. The resulting exposure levels are uncertain. Occupational exposure levels during the WEEE treatment are uncertain too. It is thought that the exposure at WEEE treatment plants remains below the OELs in force of 0.2 µg/m³. However, short term exposure peaks cannot be ruled out and depend on the processing technology and safeguard measures applied. Concern regarding occupational exposure addresses mechanical shredding and hot-metallurgic recycling processes as well as final disposal of residues from recycling and untreated WEEE.

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https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Beryllium_and_compounds_RoHS_Dossier_v2_final_20190925.pdf

Dutch authorities have performed several indicative measurements of beryllium in released dust and deposited dust on machines and floors of the waste treatment company of electronical waste. No beryllium above detection limit was found (0.05 µg per filter or 0.002 – 0.006 µg/m³ or 0.5 mg/kg waste fraction or dust). It was only found at 1 mg/kg in glass fraction from the stream separated electronical scrap. These measurements have only been performed at the line of tv screens, and not at the line of mobile phones or microwave ovens. Based on the use of beryllium in production lines, it can be expected that the exposure to beryllium is higher at these last two lines.

The use of beryllium in the manufacture of electrical and electronical devices is within the scope of REACH. The processing of the waste of these products is outside the scope.

To prevent the presence of beryllium in dust after waste processing, a restriction on the use of beryllium oxide could be an option. This risk management option was previously explored by Germany. The conclusion was that a restriction has a low chance of success, because beryllium is used in high-technology products. Alternatives will be difficult to find, and consumers do not come into contact with beryllium. In addition, production lines are mostly closed systems, protecting workers. The findings of RoHS support this conclusion.

Worker exposure at a waste processing line is addressed by the derived (B)OEL. Enforcement by national authorities is the best approach to ensure worker safety.

Currently, the available measurements at waste processing sites do not seem to exceed the limit value. However, there is a concern about exposure to beryllium at processing lines where different devices are processed. As EEE manufacturers have started to implement voluntary measures for phasing out beryllium from their products, risk management is already ongoing. Additional regulation can be considered, preferably at the process level.

4. References

European Commission, Directorate-General for Employment, Social Affairs and Inclusion, Papameletiou, D., Nemery de Bellevaux, B., Hartwig, A. et al., SCOEL/REC/175 beryllium and inorganic beryllium compounds – Recommendation from the Scientific Committee on Occupational Exposure Limits, Publications Office, 2017,

<https://data.europa.eu/doi/10.2767/72169>

Oeko-Institut for Applied Ecology (2019); ROHS Annex II Dossier for Beryllium and its compounds. Restriction proposal for substances in electrical and electronic equipment under RoHS:

https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Beryllium_and_compounds_RoHS_Dossier_v2_final_20190925.pdf

5. 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 |
|---|--------------------|-------|
| At this point in time, a regulatory management option under REACH is not considered to be relevant or proportional. | | |