Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Beryllium
Chemical Group:	-
EC Number:	231-150-7
CAS Number:	7440-41-7
Submitted by:	Germany
Published:	20/03/2013

NOTE

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	Beryllium
EC number:	231-150-7
EC name:	Beryllium
CAS number (in the EC inventory):	7440-41-7
CAS number:	7440-41-7
CAS name:	Beryllium
IUPAC name:	Beryllium
Index number in Annex VI of the CLP Regulation	004-001-00-7
Molecular formula:	Be
Molecular weight or molecular weight range:	9.01 g/mol
Synonyms:	

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:

Be

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Classification according to part 3 of Annex VI, Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008:

Hazard Class and Category Code(s)	Hazard Statement Code(s)
Carc. 1B	H350i: May cause cancer by inhalation.
Acute Tox. 2	H330: Fatal if inhaled.
Acute Tox. 3	H301: Toxic if swallowed.
STOT RE 1	H372: Causes damage to organs through prolonged or repeated exposure.
Eye Irrit. 2	H319: Causes serious eye irritation.
STOT SE 3	H335: May cause respiratory irritation.
Skin Irrit. 2	H315: Causes skin irritation.
Skin Sens. 1	H317: May cause an allergic skin reaction.

Classification according to part 3 of Annex VI, Table 3.2 (List of harmonised classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008:

Classification

Carc. Cat. 2; R49: May cause cancer by inhalation.

T+; R26: Very toxic by inhalation.

T; R25-48/23: Toxic if swallowed.

T; R48/23: Toxic: danger of serious damage to health by prolonged exposure through inhalation.

Xi; R36/37/38: Irritating to eyes, respiratory system and skin.

R43: May cause sensitization by skin contact.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classification by the lead registrant includes 4 classifications of which 3 are already included under harmonised classification and one additional classification as

Carc. 2;H351: suspected of cancer.

Classification and labeling inventory additionally includes the following classifications:

Aquatic Acute 1:H400: very toxic to aquatic life.

Acute Tox. 3; H311: toxic in contact with skin.

Flam. Sol. 1; H228: Flammable solid.

Acute Tox. 2; H300: Fata if swallowed.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

☐ Article 44(1) (refined prioritisation criteria for substance evaluation)

☒ Article 45(5) (Member State priority)

3.2 Grounds for concern

☐ (Suspected) CMR	☐ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☐ Consumer use	☐ High RCR
☐ (Suspected) PBT	☐ Exposure of sensitive populations	☐ Aggregated tonnage
☐ Suspected endocrine disruptor	☒ Other (provide further details below)	

The German CA discovered a discrepancy between the registration dossiers (in which no professional use is identified) and the actual situation in Germany (at least three sites are known to work with beryllium alloys)

There is need to gather information about the actual number of exposed workers to beryllium possessing carcinogenic properties (Carc. 1B) in the EU and thereby perform a reassessment of the actual need to list beryllium in Annex XIV.

Since beryllium is classified as Carc. 1B it generally fulfills the criteria to be identified as a substance of very high concern. However, taking the relative low volume of 10-100 t/a on the one hand and the limited options for substitution in some of its specialized applications on the other hand into account the German CA questions whether listing beryllium in Annex XIV is proportionate. Beryllium is not manufactured in the EU and according to the registration dossiers there is no use identified that could lead to occupational exposure. Therefore, the German CA proposes to make beryllium a subject for the substance evaluation in order to clarify the status of occupational exposure originating from the use of beryllium in the EU.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☒ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	
☐ 100,000 – 1000,000 tpa	☐ > 1000,000 tpa	
☐ Confidential		
Please provide further details		

☐ Industrial use	☒ Professional use	☐ Consumer use	☐ Closed System
Please provide further details			

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☐ Compliance check	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC
☐ Annex XIV (Authorisation)	☒ Other (provide further details below)
☐ Annex XVII (Restriction)	
The registered substance is under SVHC scope (Carcinogenic (Article 57a) and currently under the status of RMO analysis.	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☒ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☒ Other (provide further details below)	
The German CA intends to assess whether or not beryllium can be handled safely at professional settings. For this purpose the German CA plans to communicate with industrial representatives or associations to identify sites in Europe where alloying beryllium takes place. The German CAs goal in these discussions is to clarify exposure concerns and to decide whether risks arising from these exposures towards beryllium need further regulatory measures.	

3.6 Potential follow-up and link to risk management

☐ Restriction	☐ Harmonised C&L	☐ Authorisation	☒ Other (provide further details)
As mentioned in paragraph 3.2 from the current point of view a potential follow-up measure of the substance evaluation of beryllium could be the re-evaluation of the most appropriate risk management options for beryllium. The substance evaluation is unbiased as to the results and therefore the most appropriate follow-up measure can not be predicted thus far.			