RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

4-tert-butylbenzoic acid (PTBBA)
EC No 202-696-3
CAS No 98-73-7

Member State(s): Belgium

Dated: 19 September 2014

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

PTBBA was included in Annex VI of the CLP Regulation. The substance is classified as Repr.1B/H360F; STOT RE 1/H372; Acute Tox 4/H302. Note that no harmonized classification for the environment was established

The EU Risk Assessment Report (RAR) for PTBBA was published in July 2008 and Germany acted as Rapporteur (EU-RAR, 2008). The RAR concluded that further information and/or testing was required to address possible human health risks: a combination of an in vivo COMET assay and a bone marrow micronucleus test was recommended to adequately assess the genotoxic potential of PTBBA.

Some national occupational exposure limits are established :

Overview of the national Occupational Exposure Limits (OELs)

Country	**Occupational Exposure Limit (OEL)**	**Short-term Exposure Limit (STEL)**	**Source**
The Netherlands	2 mg/m^3	-	EU-RAR (2008)
Switzerland	2 mg/m^3	4 mg/m^3	EU-RAR (2008)
Germany	2 mg/m^3	4 mg/m^3	DFG (2012) BAuA (2006)
Portugal	10 mg/m^3	-	Info provided by the industry (KFT personal communication, 19-042013)

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 *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	x

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

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

3.1.3 Restriction

3.1.4 Other Union-wide regulatory risk management measures

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

An update of the full registration dossier was submitted in December 2013 by the registrant. The main change consists in the registration of the "use of pTBBA as chain stop agent" as intermediate.

Based on the information contained in the updated registration dossier, BE MSCA is recommending the following.

The authorization process is not considered as the best RMO anymore as the intermediate uses are out of the scope (title VII (Art. 2 (8))).

The inclusion in the CoRAP list was initially foreseen concerning the two issues identified (as mentioned above):
- Genotox/developmental effects
- Environmental exposure

However, since all the registered uses in the full registration are intermediate, this substance presents a low priority. This could be reconsidered if new data on exposure would become available.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY