Classification of 2-butoxyethanol (EGBE) (EC no. 203-905-0 - CAS no. 111-76-2)

By this the Glycol Ethers group, part of OSPA, wishes to inform EGBE Downstream Users of the consequences of the proposed new harmonised classification (CLH).

Regulatory Situation & Scientific Background

Germany introduced a proposal to change the harmonised classification for EGBE on several acute toxicity endpoints, as well as for STOT RE (specific target organ toxicity, repeated exposure), skin and eye irritation. This proposal was discussed by the Risk Assessment Committee (RAC) at ECHA and it did not agree with the classification proposal by Germany in all but one case. (see table 1)

EGBE is known to cause severe haemolysis in some animal species. Rats, mice and rabbits are particularly sensitive to this effect and the haemolysis is the main cause of toxic effects seen in these species. Guinea pigs and humans are resistant to the effect of haemolysis induced by EGBE exposure. For this reason, when there is data available on guinea pig to predict the toxicity in humans, it is more appropriate to use those data than data on rats, mice and rabbits.

The RAC agreed to this and relied on guinea pig data for the oral and dermal routes of exposure. However, for acute tox inhalation the RAC considered the available guinea pig data as not sufficiently reliable for the assessment of this specific endpoint, and therefore used the available rat studies instead, resulting in a category 3 for acute inhalation.

Table 1. Overview of classifications applicable for 2-butoxyethanol

Endpoint	Current Annex VI	REACH dossier	CLH proposal (Germany -March '17)	RAC conclusion (Sept '18) & predicted new ANNEX VI entry
Acute Tox oral	Cat 4*	Cat 4	Cat 4 ATE: 500 mg/kg	**Cat 4** **ATE: 1200 mg/kg**
Acute Tox inhalation	Cat 4*	Cat 4	Cat 3 ATE: 3 mg/L	**Cat 3** **ATE: 3 mg/L**
Acute Tox dermal	Cat 4*	Cat 4	Cat 3 ATE: 300 mg/kg	**No classification**
Skin	Skin Irrit 2	Skin Irrit 2	Skin Irrit 2	**Skin Irrit 2**
Eye	Eye Irrit 2	Eye Irrit 2	Eye Dam 1	**Eye Irrit 2**
STOT RE			Cat 2 (blood)	**No classification**

OSPA (Oxygenated Solvents Producers Association)
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.94.88 esig@cefic.be **www.esig.org**
A sector group of Cefic
European Chemical Industry Council - Cefic aisbl
EU Transparency Register n° 64879142323-90

Consequences for Downstream Users & steps undertaken by manufacturers

Labeling consequences of new classification

All mixtures with EGBE ≥ 10%: (eye + skin irritation) 	Cat 3: all mixtures with EGBE >30% : 
All mixtures with EGBE ≥15% : (eye + skin irritation + acute tox 4)	

For printing inks in particular, the European Printing Ink Association (EUPIA) includes in its Exclusion List substances with category 3 acute tox inhalation classification into category A, which means that the raw material is to be substituted within 6 months after reclassification. Only if, after technical investigation, it is found not to be possible to replace it in the short term, an exemption from substitution can be granted following the explicit approval of the EUPIA Technical Committee. Hence, a derogation is not possible if a substitute is available, which might be the case for EGBE. Downstream Users from the sector should bear in mind the financial aspect and technical feasibility required of any substitution, as for instance the replacement raw material might have a different price and in some cases a switch of substances might still necessitate changes to the technical processes. Additionally, there might be further impacts of such a substitution, as EGBE is made simultaneously along with a number of co-products. The disappearance of the EGBE market could also render the manufacture of DEGBE (and both acetates) uneconomic, and consequently disappearance of butyl markets could make the manufacture of other glycol ethers non-profitable (lack of plant loading).

EGBE manufacturers do not agree with the use of rat data to assess the acute inhalation hazard for humans. For occupational health and safety reasons, it was decided to address the data gap for the inhalation acute toxicity route by conducting a new guinea pig acute toxicity study for the inhalation route using a nearly saturated vapour concentration. Provided that the study results are negative, as for the other acute tox endpoints, a new annex CLH dossier will be submitted by a Member State authority to change the upcoming harmonized classification accordingly (meaning no classification or a lower category). **Therefore, EUPIA members and their customers are kindly requested to consider a derogation for EGBE, pending the delivery of the expected study results.**

Further consequences

The exposure scenarios will not change, as the toxicity has not changed but was interpreted differently. All DNELS will remain as current. Important to note: any acute tox classification does not entail further regulatory actions authorisation/restriction under REACH.

For more information please contact:
Cornelia Tietz, Sector Group Manager, Cefic,
+32 2.436.94.91 or cti@cefic.be.

About OSPA Glycol Ethers
OSPA GE is part of OSPA and a Cefic Sector Group from the Petrochemicals Europe cluster.