

29 August 2019

**Comments from Endura S.p.A. on:**

**CLH report: Proposal for Harmonised Classification and Labelling**

**Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2**

**Substance Name: 2-(2-butoxyethoxy)ethyl 6-propylpiperonyl ether; piperonyl butoxide (ISO)**

CLH proposal by RAC	Comment from Endura S.p.A.
STOT SE 3; H335 – May cause respiratory irritation	Endura S.p.A. agrees that the acute inhalation study may justify H335.
Aquatic Acute 1; H400 – Very toxic to aquatic life; Acute M-factor: 1	Endura S.p.A. agrees that the available information justifies H400 and Acute M-factor = 1.
Aquatic Chronic 1; H410 - Very toxic to aquatic life with long lasting effect; Chronic M-factor: 1	Endura S.p.A. agrees that the available information justifies H410 and Chronic M-factor = 1.
EUH066 – Repeated exposure may cause skin dryness or cracking	Endura S.p.A. agrees that the sub-acute dermal study may justify EUH066 even though the relevant findings were observed after repeated exposure for 6 h/day under semi-occlusive coverage. These conditions are not relevant for dermal exposure scenarios in real life.

Furthermore, Endura S.p.,A. strongly supports to not classify PBO as Cat 2 for carcinogenicity. The CLH report recognises the MoA studies and concludes that liver adenomas in male mice observed after chronic PBO administration are not relevant for humans. The MoA involves CAR/PXR activation by PBO that occurs in murine, but not in human hepatocytes. Therefore, PBO should not be classified as Carc 2.