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1.4 Regulations and guidelines

Occupational exposure limits and guidelines for 2-butoxyethanol in workplace air are presented in Table 15.

Germany recommends a biological tolerance value for occupational exposure to 2-butoxyethanol of 100 mg/L butoxyacetic acid in urine, and recommends that butoxyacetic acid in urine collected for long-term exposures after several shifts be monitored as an indicator of exposure to 2-butoxyethanol (Deutsche Forschungsgemeinschaft, 2003).

The Health and Safety Executive (2002) in the United Kingdom recommends a biological monitoring guidance value for occupational exposure to 2-butoxyethanol of 240 mmol butoxyacetic acid/mol creatinine in urine [roughly equivalent to 200 mg/L butoxyacetic acid] measured after a shift.

In the European Union, 2-butoxyethanol is environmentally regulated as part of the Volatile Compounds Directive (European Union, 1999).

2. Studies of Cancer in Humans

In a case–control study at eight haematology departments in France, Hours et al. (1996) identified all locally resident patients aged 25-75 years who had acute myeloid leukaemia or myelodysplasia with an excess of blastoids that was newly diagnosed during January 1991-April 1993. The controls were patients from the same hospitals, matched for age $(\pm 3 \text{ years})$, department of residence and nationality (French or other), who had never been hospitalized for cancer or an occupational disease. All subjects were interviewed in hospital by a trained investigator and were asked about their occupational history, including details of tasks and products handled. An occupational hygieniest who was blinded to the case/ control status reviewed the information and classified the subject for exposure to each of four categories of glycol ethers, as well as to various potentially confounding substances. Analysis was by conditional logistic regression, and was based on 198 case-control pairs. After adjustment for level of education, exposure to the group of glycol ethers that included 2-butoxyethanol was associated with an odds ratio of 0.64 (95% confidence interval [CI]. 0.31-1.29), based on 20 exposed cases and 27 exposed controls. [The Working Group noted that the exposure category analysed included propyl and butyl glycol ethers. Furthermore, the high prevalence of exposure among controls (27/191) suggests that the index of exposure used was relatively non-specific.]

Country or region	Concentration (ppm) [mg/m ³]	Interpretation	Carcinogen classification
Australia	25	TWA	Sk ^a
Austria	20 [100]	TWA	
	40 [200]	STEL	
Belgium	20	TWA	Sk
	50	STEL	
Canada			
(Alberta)	20	TWA	Sk
	75	STEL	Sk
(British Columbia)	25	TWA	Sk
(Ontario)	20	TWA	Sk
(Quebec)	25	TWA	Sk
Brazil	39	TWA	
Czech Republic	[100]	TWA	Sk
	[200]	STEL	
Denmark	20	TWA	Sk
European Commission	20	TWA	Sk
	50	STEL	
Finland	20 [98]	TWA	Sk
	50 [250]	STEL	
France	2 [9.8]	TWA	Sk
	30 [147.6]	STEL	
Germany (MAK)	20 [98]	TWA	Sk
	80	Ceiling	
Hong Kong	25	TWA	Sk
Ireland	20	TWA	Sk
	50	STEL	
Italy	20 [97]	TWA	
Malaysia	20	TWA	Sk
Mexico	26	TWA	Sk
	75	STEL	
Netherlands	20	TWA	Sk
	40	STEL	
New Zealand	25	TWA	Sk
Norway	10	TWA	Sk
Poland	[98]	TWA	Sk
	[200]	STEL	
South Africa	25	TWA	Sk
Spain	20	TWA	Sk
	50	STEL	
Sweden	10	TWA	Sk
	20	STEL	
Switzerland	20 [100]	TWA	Sk
	80 [400]	STEL	

Table 15. Occupational exposure limits and guidelines for2-butoxyethanol

Country or region	Concentration (ppm) [mg/m ³]	Interpretation	Carcinogen classification
United Kingdom (OES)	25 50	TWA STEL	Sk Sk
USA			
ACGIH (TLV)	20	TWA	A3 ^b
NIOSH (REL)	5	TWA	Sk
OSHA (PEL)	50	TWA	Sk

Table 15 (contd)

From Arbejdstilsynet (2002); Health & Safety Executive (2002); Työsuojelusäädöksiä (2002); Deutsche Forschungsgemeinschaft (2003); Suva (2003); ACGIH Worldwide (2004); European Union (2004); INRS (2005)

MAC/MAK, maximum allowable concentration; OES, occupational exposure standard; PEL, permissible exposure limit; REL, recommended exposure limit; STEL, short-term exposure limit; TLV, threshold limit value; TWA, full-shift time-weighted average

^a Sk, skin notation

^bA3, confirmed animal carcinogen with unknown relevance to humans

3. Studies of Cancer in Experimental Animals

3.1 Inhalation

3.1.1 *Mouse*

Groups of 50 male and 50 female B6C3 F1 mice, 7-8 weeks of age, were exposed to 2-butoxyethanol (> 99% pure) vapour by whole-body exposure at concentrations of 0, 62.5, 125 or 250 ppm [0, 302, 604 or 1208 mg/m³] for 6 h per day on 5 days per week for 104 weeks. Complete necropsies were performed on all mice, at which time all organs and tissues were examined for macroscopic lesions and all major tissues were examined microscopically. Survival of male mice exposed to 125 or 250 ppm was significantly lower (by pair-wise comparison) than that of the control group (39/50 controls, 39/50 low-dose, 27/50 mid-dose (p = 0.021) and 26/50 high-dose (p = 0.015)). In females, survival was not affected (29/50 controls, 31/50 low-dose, 33/50 mid-dose and 36/50 high-dose). The body weights in control and treated animals were comparable except in high-dose female mice in which a 17% decrease in body weight was observed. In males, the incidences of haemangiosarcoma of the liver were: 0/50 (control), 1/50 (low-dose), 2/49 (mid-dose) and 4/49 (high-dose). The incidence in high-dose males (250 ppm) was significantly increased (p = 0.046, Poly-3 test) relative to controls and the trend test was positive (p = 0.014, m)Poly-3 test); this incidence exceeded the range in the historical control values (0-4%). Two of the four mice treated with 250 ppm that had liver haemangiosarcomas also had