Recommendation from Scientific Expert Group

on Occupational Exposure Limits

for Ethylene glycol

8 hour TWA	:	$20 \text{ ppm} (52 \text{ mg/m}^3)$
STEL (15 mins)	:	$40 \text{ ppm} (104 \text{ mg/m}^3)$
Additional classification	:	"skin"

Substance:

Ethylene glyce	ol	(CH ₂ OH) ₂	
Synonyms EINECS N°	:	1,2-Ethanediol 203-473-3	; 1,2-dihydroxyethane; glycol
EEC N°	:	603-027-00-1	Classification : Xn; R22
CAS N°	:	107-21-1	
MWt	:	62.07	
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Conversion factor (20°C, 101 kPa) $: 2.58 \text{ mg/m}^2 = 1 \text{ ppm}$

Occurrence/use:

Ethylene glycol is a colourless, odourless viscous liquid with a sweetish taste. It has a MPt of -13°C, a BPt of 198°C and a vapour pressure of 0.008 kPa at 20°C. It has a vapour density of 2.2 times that of air.

Ethylene glycol is mainly used as an antifreeze in radiators of motor vehicles and as a solvent in other commercial products such as brake fluids, adhesives and printing inks. It is also an important raw material in the manufacture of polyester fibres. The production rate in the EEC is in excess of 1000 tonnes per annum.

<u>Health</u> Significance:

Ethylene glycol is rapidly absorbed and distributed after oral administration and inhalation. It is also absorbed percutaneously (Tyl, 1988; Frantz *et al.*, 1989, 1991).

Liquid ethylene glycol is strongly irritating to the human eye (Sykowsky, 1951). There have been two reports of contact sensitisation (Dawson, 1976; Hindson and Ratcliffe, 1975), but these are not considered to be sufficient to classify ethylene glycol as a sensitising agent.

The critical effect of ethylene glycol is irritation of the mucous membranes. Exposure of human volunteers to ethylene glycol aerosols for 20-22h/d for 30 days (average daily concentrations of 3-67 mg/m², average weekly concentrations of 17-49 mg/m²) resulted in no clinical symptoms, although there were occasional complaints of irritation in the throat (Wills *et al*, 1974). Concentrations at and above 140 mg/m² caused mucosal irritation to all individuals.

The acute toxicity of ethylene glycol to rats and mice is low. Well-conducted long-term inhalation studies are not available. An early study by Wiley *et al* (1936) reported no adverse effects in rats and mice exposed to a mean of 398 mg/m² ethylene glycol, 8h/d, 5d/w for 16 weeks, however the concentrations were not analytically controlled. Coon *et gl* (1970) observed severe eye irritation in the eyes of rats and rabbits exposed continuously to 12 mg/m² for 90 days (analytically controlled); whereas repeated exposures at 10 or 57 mg/m3 (8h/d, 5d/wk for 6 weeks) did not result in effects on the eyes or other organs. The main target organs after ingestion are the liver and kidneys (Coon *et al.*, 1970).

Ethylene glycol is not genotoxic to bacteria or mammalian cells in vitro (Henschler, 1991).

Clear dose-related developmental toxicity was observed in rats and mice after oral administration (NTIS, 1988) and inhalation (Tyl, 1985). No effect levels were 250 mg/kg (oral), 150 mg/m² (whole body exposure) and 1000 mg/m² (nose-only exposure).

Recommendation:

The study of Wills *et al* (1974), establishing a NOAEL of 67 mg/m³, for irritation of the mucosae in human volunteers, was considered to be the best available basis for proposing occupational exposure limits. Because this study involved exposure for 20-22 h/d, and large differences in response were seen with continuous exposure compared with exposure for 8 h/d in the studies of Coon *et al.* (1970), an uncertainty factor of 2 was considered adequate to allow for interindividual variation and for the absence of long term human data. Taking into account the preferred value approach, the recommended 8-hour TWA is 20 ppm (52 mg/m³). This is supported by the repeated exposure study of Coon *et al.* (1970). A STEL (15 mins) of 40 ppm (104 mg/m³) was proposed to limit peaks of exposure which could result in irritation. A "skin" notation was recommended as dermal absorption could contribute substantially to the total body burden.

At the levels recommended, no measurement difficulties are foreseen.

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