Social Europe

Recommendation from the Scientific Expert Group on Occupational Exposure Limits for ε-Caprolactam

SEG/SUM/67

1995

European Commission

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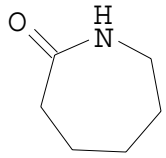
8 hour TWA	:	10 mg/m^3
STEL (15 mins)	:	40 mg/m^3
Additional classification	:	-

Substance:

ε-Caprolactam



Synonyms	:	hexahydro-2H-azepin-2-one; aminocaprolactam; 2-oxohexamethylenimine; cyclohexanone-isooxime
EINECS N°	:	203-313-2
EEC N°	:	613-069-00-2
Classification	:	Xn R: 20/22-36/37/38
CAS N°	:	105-60-2
MWt	:	113.16

Conversion factor (20°C, 101 kPa) : 4.7 mg/m^3 = 1 ppm

1. Occurrence/use

ε-Caprolactam is a white, hygroscopic, crystalline substance with an unpleasant odour. It has a MPt of 69°C, a BPt of 267 °C and a vapour pressure of 0.0001 kPa at 20°C. The saturated vapour concentration is 2.55 ppm (12 mg/m^3) and therefore crystallisation may occur at atmospheric concentrations relevant to the proposed limits.

ε-Caprolactam is one of the most widely used chemical intermediates, mainly in manufacture of Nylon 6 (polycaprolactam), for which uses include textiles, carpeting and cable insulation. ε-Caprolactam is also used in production of film, coatings and synthetic leather and as a curing agent for polyurethanes. The production rate in the EU is in excess of 100,000 tonnes per annum.

2. Health Significance

ε-Caprolactam is absorbed quite rapidly following ingestion or inhalation. The major route of elimination is via the urine.

The acute toxicity of ε-caprolactam in rats is moderate (LD50: 1155-1660 mg/kg; LC50 (2h): 450 mg/m^3).

When male rats were exposed to 125 mg/m^3 ε-caprolactam for 2.5 months (4h/d), disturbances in nervous system function, decreased respiratory rate, impaired spermatogenesis and decreased excretion of chloride were observed (Gabrielyan *et al*., 1975). No adverse effects were noted at 11 mg/m^3. In two older inhalation studies in guinea pigs, irritation of the respiratory tract occurred at concentrations of 118 - 261 mg/m^3 (7h/d, 7d) and minor inflammatory changes were found at a concentration 51 mg/m^3 (5-8h/d, 26-30d).

ε-Caprolactam gave negative results in a wide range of *in vitro* and *in vivo* genotoxicity tests (Greene *et al.,* 1979; Ashby *et al.,* 1985). No significant increase in tumour incidence or other treatment-related effects were noted when ε-caprolactam was given in the diet to mice (7500, 15000 ppm) and rats (23750, 7500 ppm) for 103 weeks (NTP, 1992)

Developmental effects have been observed only at maternally toxic doses in rat and rabbits after oral administration (Hazleton, 1980; Gad *et al*., 1984).

The critical effect of ε-caprolactam is irritation of the mucous membranes. Irritation of the skin and mucous membranes was reported in workers exposed to an average caprolactam concentration of 84 mg/m^3 for 9 months to 13 years (Kelman, 1986). There were no signs of systemic toxicity. Hohensee (1951) reported irritation of the mucous membranes in workers of a spinning-mill exposed to an average concentration of 61 mg/m^3 (duration not specified). Studies with human volunteers indicated that irritation of the upper airways occurred at and above 47 mg/m^3 (Ferguson and Wheeler, 1973). Concentrations up to 33 mg/m^3 were considered not to result in discomfort.

Recommendation

The study of Ferguson and Wheeler (1973), indicating a LOAEL of 47 mg/m^3 and NOAEL of 33 mg/m^3 for irritation of the upper airways in human volunteers, was considered to be the best available basis for proposing occupational exposure limits. This is supported by the occupational exposure studies of Hohensee (1951) and Kelman (1986). The recommended 8-hour TWA for total dust and vapour is 10 mg/m^3. A STEL (15 mins) of 40 mg/m^3 was proposed to limit peaks in exposure which could result in irritation.

No "skin" notation was considered to be necessary.

At the levels recommended, no measurement difficulties are foreseen, provided that the techniques selected are appropriate for mixtures of dust and vapour.

Key Bibliography

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