The MAK Collection for Occupational Health and Safety

1-Ethoxy-2-propanol

MAK Value Documentation, addendum – Translation of the German version from 2018

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1-Ethoxy-2-propanol / 1-Ethoxypropan-2-ol

MAK Value Documentation

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Abstract

The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area has re-evaluated the maximum concentration at the work place (MAK value), the Pregnancy Risk Group and absorption through the skin of 1-ethoxy-2-propanol [1569-02-4].

1-Ethoxy-2-propanol is irritating to the eyes of rabbits and can damage the cornea. The critical systemic effects are pale foci in the lung and increased urine volume in rats after 13 weeks inhalation. The NAEC of these effects is estimated at 250 ml/m^3, which results in a decreased MAK value of 20 ml/m^3 (88 mg/m^3). This value also protects against possible irritation, as local effects are not observed up to 2000 ml/m^3 in the 13-week rat inhalation study.

Since the critical effect of 1-ethoxy-2-propanol is systemic, Peak Limitation Category II is retained. There is no specific toxicokinetic data available, so that the default excursion factor of 2 is confirmed.

New data on reproduction toxicity with 1-ethoxy-2-propanol are not available. 1-Ethoxy-2-propanol remains assigned to Pregnancy Risk Group C.

Skin contact is expected to contribute significantly to systemic toxicity and 1-ethoxy-2-propanol remains designated with "H".

Keywords

1-ethoxy-2-propanol; 1-ethoxypropan-2-ol; toxicokinetics; metabolism; (sub)acute toxicity; (sub)chronic toxicity; developmental toxicity; peak limitation; prenatal toxicity; absorption through the skin; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

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1-Ethoxy-2-propanol[1)]

[1569-02-4]

Supplement 2018

MAK value (2017)	**20 ml/m³ (ppm) ≙ 86 mg/m³**
Peak limitation (2006)	**Category II, excursion factor 2**
Absorption through the skin (2006)	**H**
Sensitization	**–**
Carcinogenicity	**–**
Prenatal toxicity (2006)	**Pregnancy Risk Group C**
Germ cell mutagenicity	**–**
BAT value	**not yet established**

Documentation for 1-ethoxy-2-propanol was published in 2007 (documentation "1-Ethoxy-2-propanol" 2007, available in German only). In addition, documentation for the BAT value is available (documentation "1-Ethoxy-2-propanol and 1-Ethoxy-2-propyl acetate" 2009); however, a BAT value has not been established.

In 2016, the Commission began using a revised approach for assessing substances with a MAK value based on systemic effects and derived from inhalation studies in animals or studies with volunteers at rest; this new approach takes into account that the respiratory volume at the workplace is higher than under experimental conditions. However, this does not apply to gases or vapour with a blood:air partition coefficient < 5 (see List of MAK and BAT Values). A blood:air partition coefficient of 2111 was calculated for 1-ethoxy-2-propanol using the formula of Buist et al. (2012). This supplement evaluates whether the MAK value and the pregnancy risk group of 1-ethoxy-2-propanol need to re-assessed as a result of the higher respiratory volume at the workplace.

1) MAK value applies for the sum of the concentrations of 1-ethoxy-2-propanol and 1-ethoxy-2-propyl acetate in the air.

Toxicokinetics and metabolism

Absorption, distribution, elimination

A new in-vitro study is available for the absorption of the substance through the skin.

The dermal penetration of undiluted 1-ethoxy-2-propanol and a 50% aqueous solution of the substance was determined in human full thickness skin using an in vitro diffusion system. A dose of 200 µl/cm² of the test substance was applied occlusively and the concentration of the test substance in the receptor solution of the diffusion cell was recorded for 8 hours. A dermal flux of 1398 ± 400 µg/cm² and hour was determined after application of undiluted 1-ethoxy-2-propanol, and the dermal flux after application of the 50% aqueous solution was 2133 ± 101 µg/cm² (Korinth et al. 2012).

Subacute, subchronic and chronic toxicity

Inhalation

In a study with 13-week inhalation exposure to 1-ethoxy-2-propanol vapour concentrations of 0, 100, 300 and 2000 ml/m³ for 6 hours per day, on 5 days per week, in whole animal exposure chambers (whole-body exposure), pale foci were observed in the lungs of female Wistar rats during gross-pathological examination at concentrations of 300 ml/m³ and above and an increase in urine volume was found in male and female animals. A NOAEC (no observed adverse effect concentration) of 100 ml/m³ was determined in the 13-week study. However, the effects recorded at 300 ml/m³ were not accompanied by histopathological findings in the lungs or kidneys (BP Chemicals Ltd 1986; documentation "1-Ethoxy-2-propanol" 2007, available in German only), so that the actual NOAEC is probably slightly lower than 300 ml/m³.

After 9-day exposure at the same concentration, no effects on the lungs or urine volume were observed (documentation "1-Ethoxy-2-propanol" 2007, available in German only), which means that an intensification of the effect is to be expected with an increase in the exposure period.

Oral administration

After rats were given oral doses of 1-ethoxy-2-propanol of 1790 mg/kg body weight and day for 10 days, slightly reduced body weight gains, changes in the blood count and an increase in the relative liver weights were reported (documentation "1-Ethoxy-2-propanol" 2007, available in German only).

Reproductive and developmental toxicity

Developmental toxicity

In a developmental toxicity study in rats with daily exposure to 1-ethoxy-2-propanol from gestation days 6 to 15 for 6 hours per day, muzzle licking and slightly re-

duced body weight gains were observed at concentrations of 450 ml/m³ and above. It was suggested that the muzzle licking was caused by irritation. At 2000 ml/m³, ruffled fur, reduced startle reflex, reduced feed consumption and reduced body weight gains were reported in addition. The NOAEC for maternal toxicity was 100 ml/m³, the NOAEC for toxic effects on development was 2000 ml/m³ (documentation "1-Ethoxy-2-propanol" 2007, available in German only).

In a developmental toxicity study in rabbits with daily exposure to 1-ethoxy-2-propanol from gestation days 6 to 18 for 6 hours per day, slightly reduced feed consumption and slightly reduced body weight gains were reported at the highest concentration tested of 1200 ml/m³, which was determined to be the NOAEC for maternal toxicity and developmental toxicity (documentation "1-Ethoxy-2-propanol" 2007, available in German only).

Manifesto (MAK value/classification)

1-Ethoxy-2-propanol causes irritation of the eyes in rabbits and can induce corneal damage. The critical systemic effects induced by the substance are pale foci in the lungs and an increased urine volume in rats, although these findings lack a histopathological correlate (documentation "1-Ethoxy-2-propanol" 2007, available in German only).

MAK value. The NOAEC of the 13-week study in rats is probably only slightly lower than 300 ml/m³. This is because, although pale foci in the lungs and an increase in urine volume were observed at this concentration, neither of the effects was accompanied by histopathological findings in the lungs and kidneys (see documentation "1-Ethoxy-2-propanol" 2007, available in German only).

The increase in urine volume was not yet reported after one week, and the effects on the lungs were not observed after exposure for 9 days at the same concentration. This leads to the conclusion that an intensification of the effect is to be expected with an increase in the exposure period.

Evidence suggests that irritation does not play a role in the concentration range of the NOAEC. In the 13-week study in rats, no clinical signs of local irritation were observed in the animals up to concentrations of 300 ml/m³ and no adverse effects on the nasal epithelium were detected up to the high concentration of 2000 ml/m³. In a developmental toxicity study in rats, muzzle licking was observed at concentrations of 450 ml/m³ and above. It was suggested that this effect was caused by irritation. There are no data available for irritation to the eyes in humans. In biomonitoring studies at the workplace, irritation was not observed after exposure to concentrations up to 3.47 ml/m³ (documentation "1-Ethoxy-2-propanol" 2007, available in German only).

Based on the assumed NAEC (no adverse effect concentration) of about 250 ml/m³ determined from the 13-week inhalation study, the extrapolation of the NAEC from the animal study to humans (1:2), and taking into consideration the intensification of the effect over time (1:2) and the increased respiratory volume of the person at the workplace compared with that of the test animal at rest (1:2), this results in a

concentration of 31 ml/m³. After applying the preferred value approach, the MAK value has been lowered to 20 ml/m³.

Peak limitation. As the MAK value for 1-ethoxy-2-propanol was derived from systemic effects, this substance remains classified in Peak Limitation Category II. No specific data for the half-life are available. For this reason, the default excursion factor of 2 has been retained.

Prenatal toxicity. Conclusive developmental toxicity studies are available in rats and rabbits that found no effects up to concentrations of 2000 and 1200 ml/m³, respectively. This seems plausible based on the fact that propylene glycol ethers and their acetates appear to induce developmental toxicity only if a primary hydroxyl group is available or is formed by the cleavage of acetate during metabolism (documentation "1-Ethoxy-2-propanol" 2007, available in German only). Taking into consideration the increased respiratory volume of the person at the workplace compared with that of the test animal at rest (1:2), adequate 50-fold and 30-fold margins between the NOAEC for developmental toxicity and the MAK value of 20 ml/m³ are found. For this reason, 1-ethoxy-2-propanol remains classified in Pregnancy Risk Group C.

Absorption through the skin. New experimental data confirm that 1-ethoxy-2-propanol readily penetrates the skin; this had previously been assumed based on model calculations (documentation "1-Ethoxy-2-propanol" 2007, available in German only). According to an in vitro study, undiluted 1-ethoxy-2-propanol penetrates the human skin with a flux value of 1398 µg/cm² and hour. After 1-hour exposure of both hands and forearms (approx. 2000 cm²), the total amount of 1-ethoxy-2-propanol absorbed would thus be 2800 mg. Assuming complete absorption and a respiratory volume of 10 m³, 880 mg of 1-ethoxy-2-propanol would be absorbed by inhalation after 8-hour inhalation exposure at the MAK value (88 mg/m³). Therefore, the amount of substance absorbed through the skin is higher than the systemically tolerable amount. As a result of dermal exposure, observance of the MAK value alone can no longer provide protection from the adverse effects on health that were decisive in determining the threshold value. For this reason, 1-ethoxy-2-propanol retains its "H" designation (for substances which can be absorbed through the skin in toxicologically relevant amounts).

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