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2-Diethylaminoethanol

MAK Value Documentation, addendum – Translation of the German version from 2022

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Keywords

2-diethylaminoethanol; irritation; upper respiratory tract; maximum workplace concentration; MAK value; momentary value; developmental toxicity

Abstract

The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) has re-evaluated the occupational exposure limit value (maximum concentration at the workplace, MAK value) and the pregnancy risk group of 2-diethylaminoethanol [100-37-8] considering also irritating and sensitizing effects. Relevant studies were identified from a literature search. The critical effect of 2-diethylaminoethanol is the local effect on the upper respiratory tract. There are no human data to derive a MAK value. In a 14-week inhalation study with rats already reported in the evaluation from 2007, the lowest concentration of 11 ml/m^3 is the NOAEC resulting in a MAK value of 2 ml/m^3. Since a local effect is critical, Peak Limitation Category I is retained. As data on humans are missing, an excursion factor of 1 and in analogy to other amines with a MAK value of 2 ml/m^3, a momentary value of 5 ml/m^3 is set. In a developmental toxicity study in rats reported in the evaluation from 2007, the highest concentration of 100 ml 2-diethylaminoethanol/m^3 corresponds to the NOAEC. There are no new data on developmental toxicity. Considering the increased respiratory volume at the workplace there is a 25-fold margin to the MAK value. Thus, Pregnancy Risk Group C has been retained for 2-diethylaminoethanol. There are no data showing a skin sensitizing potential in humans or animals. Data investigating respiratory sensitization are missing. According to skin absorption models, 2-diethylaminoethanol is not expected to be taken up via the skin in toxicologically relevant amounts and is thus no longer designated with “H”.

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MAK value (2021)	**2 ml/m³ (ppm) ≙ 9.7 mg/m³**
Peak limitation (2000)	**Category I, excursion factor 1**
Momentary value (2021)	**5 ml/m³ (ppm) ≙ 24 mg/m³**
Absorption through the skin	–
Sensitization	–
Carcinogenicity	–
Prenatal toxicity (2006)	**Pregnancy Risk Group C**
Germ cell mutagenicity	–
BAT value	–

CAS number	100-37-8
Molar mass	117.2 g/mol
Melting point	−68 °C (ECHA 2020)
Boiling point at 1013 hPa	162.36 °C (ECHA 2020)
Density at 20 °C	0.88 g/cm³ (ECHA 2020)
Vapour pressure at 22.4 °C	2 hPa (ECHA 2020)
log K_{OW} at 23 °C	0.21 (ECHA 2020)
Solubility at 20 °C	miscible with water (ECHA 2020)
pK_b value at 25 °C	10.1 (ECHA 2020)
1 ml/m³ (ppm) ≙ 4.863 mg/m³	**1 mg/m³ ≙ 0.206 ml/m³ (ppm)**

Documentation was published in 1997 (Greim 2000 b) followed by a supplement on peak limitation in 2000 (Greim 2000 a, available in German only) and a supplement on prenatal toxicity in 2007 (Greim 2007, available in German only).

The most sensitive end point is the local effect of 2-diethylaminoethanol on the upper respiratory tract.

In 2014, the Commission adopted a method (Brüning et al. 2014) for the derivation of MAK values for substances that induce local effects on the upper respiratory tract or eyes that is based on a comparative investigation of sensory irritation in humans and histopathological changes in rodents. It has been applied here to re-evaluate the MAK value.

Toxicokinetics

A blood:air partition coefficient of about 7500 was calculated using the formula of Buist et al. (2012).

Oral doses of 2-diethylaminoethanol are absorbed rapidly, distributed in the organism and excreted with the urine and faeces largely unmetabolized. The metabolites triethylamine oxide, diethylamine and ethylamine were found in the urine (Greim 2000 b).

In test persons given a single oral dose of 5.6 g of 2-diethylaminoethanol, the concentration in the plasma was highest after 3 hours and had decreased to nearly zero 8 hours after substance administration (Greim 2000 b).

2-Diethylaminoethanol is corrosive to the skin (Greim 2000 b). Using the model of Fiserova-Bergerova et al. (1990) and the IH SkinPerm model (Tibaldi et al. 2014), the amount of substance absorbed through the skin after application of a 0.5% aqueous solution under standard conditions was estimated to be 29 mg and 6.5 mg, respectively. According to the Regulation on Classification, Labelling and Packaging, at this concentration (0.5%), the substance does not need to be classified as an irritant.

Effects in Humans

There are no new data available.

As described in the documentation published in 1997, 2-diethylaminoethanol has an odour threshold of 0.011 ml/m^3 and leads to nausea and vomiting after a few seconds of accidental exposure to concentrations below 200 ml/m^3 (Cornish 1965; Greim 2000 b). Irritation of the eyes, nose and throat was observed at unspecified concentrations (Greim 2000 b).

The documentation from 1997 includes a case of accidental exposure at the workplace: As a result of a leakage in the distribution system of the steam heating system, 2500 employees from an office block were exposed to 2-diethylaminoethanol. The concentration of the substance in the air could not be determined in the investigation. Most of those affected suffered symptoms of irritation. In the 3 months following the exposure, asthma was diagnosed for the first time in 14 employees. For 7 of these a relationship with the workplace situation was regarded as certain, for the other 7 occupational exposure was at least suspected of being the cause. Irritation of the respiratory passages and subsequent persistent bronchial hyper-reactivity in the form of a "reactive airways dysfunction syndrome" were suggested as the pathomechanisms. Immunological tests were not carried out (Gadon et al. 1994; Greim 2000 b).

There are no other data for sensitizing effects on the skin or respiratory tract in humans.

Animal Experiments

There are no new data available. As the local effect on the respiratory tract is the most sensitive end point, this supplement reviews only those inhalation studies that are considered relevant for the evaluation and that reported the lowest effect concentrations.

Subacute, subchronic and chronic toxicity

F344 rats were exposed to 2-diethylaminoethanol for 6 hours a day on 5 days a week. In the first study, the animals were exposed 9 times to concentrations of 0, 10, 56 or 300 ml/m^3, and in the second study to concentrations of 0, 11, 25 or 76 ml/m^3 over a period of 14 weeks. According to the authors, the NOAECs (no observed adverse effect concentrations) of the studies were 10 and 11 ml/m^3, respectively. In the 14-week study, "transient breathing sounds after the end of exposure" were reported for all concentrations (Hinz et al. 1992). A copy of the original study report was obtained because it was not possible to classify the breathing sounds, their frequency per animal and per exposure group based solely on the description included in the publication. However, the data found there for the breathing sounds were contradictory. In the data for individual weeks of exposure, it was reported that the animals of the low and medium concentration groups developed rales and sneeze-like breathing sounds only with increasing length of exposure and that these effects subsided within an hour after the end of exposure. These effects developed earlier in the animals of the high concentration group, from the second week of exposure onwards, but generally subsided during the night. In the data for individual animals, however, the sneeze-like sounds that were reported in the text did not appear at all and the rales only on a few days: in the low concentration group, on day 29 in 1 of 25 male animals and on day 94 in 1 of 15 male animals, and in the medium concentration group only in 1 female animal after 57 days. No findings of any kinds of breathing sounds were documented for any of the other animals and days. These incidences contradict the description in the text. Inflammatory cell infiltration, focal hyperplasia and squamous metaplasia were observed in

the nasal mucosa at concentrations of 25 ml/m³ and above. At 75 ml/m³, the body weights were decreased by 7% and the systemic NOAEC was 25 ml/m³ (see Table 1; Exxon Biomedical Sciences Inc. 1990).

According to the approach described in the methods section of the study for the systematic compilation of clinical changes observed using the Irwin test, the findings under "respiration" in the category "unbiased behaviour" were evaluated as follows: breathing: normal, slow, laboured, gasping, apnoea, accelerated breathing. It is therefore to be assumed that any stable and adverse effects would have been recorded and that the isolated occurrence of rales in 2 animals during the study period is not to be regarded as a consistent effect of exposure to a 2-diethylaminoethanol concentration of 11 ml/m³. For this reason, the Commission has derived a NOAEC of 11 ml/m³ for local effects based on the findings of this study. Local histopathological findings were observed at concentrations of 25 ml/m³ and above.

The aerosol content was determined gravimetrically and by aerosol photometer. There were no differences in the mean values that were determined gravimetrically in the individual exposure groups and "converted to ppm". The relative values that were obtained by photometer in the 11, 25 and 75 ml/m³ groups were (control = 1.0) 1.4, 1.6 and 2.2, respectively (Exxon Biomedical Sciences Inc. 1990). As the 2 methods obtained different results for the aerosol content and the study did not provide specific data for the aerosol concentrations, these have not been included in the evaluation.

Tab. 1 Effects of 2-diethylaminoethanol after repeated inhalation exposure of rats

Strain, number per sex and group	Exposure	Findings	References
F344, 10 ♂, 10 ♀, + 5 ♂ per concentration for neuropathological examination	11 days, 0, 10, 56, 300 ml/m³, 6 hours/day, 5 days/week	ophthalmological and neurological (modified Irwin test) examinations prior to the beginning of exposure and at the end of exposure; **11 ml/m³**: **NOAEC**; **56 ml/m³**: findings in the nose: see Table 2; **300 ml/m³**: during and directly after exposure effects on the eyes, nose, respiratory tract, discharge from the nose and eyes, opacity, ulcus (eyes), laboured breathing, gasping, reduced activity and responsiveness, uncoordinated reflexes and uncoordinated movements, hypothermia, feed and water consumption ↓, body weights ↓, 9 ♂ and 5 ♀ died	Exxon Biomedical Sciences Inc. 1990; Hinz et al. 1992
F344, 10 ♂, 10 ♀, + 10 ♂, 10 ♀ per concentration for observation	14 weeks (+ 4 weeks observation), 0, 11, 25, 76 ml/m³, 6 hours/day, 5 days/week	neurological examinations (modified Irwin test) prior to the beginning of exposure and once a month, see text for evaluation of the described "breathing sounds"; **11 ml/m³**: **local NOAEC**; **25 ml/m³ and above**: findings in the nose: see Table 3, **systemic NOAEC**; **76 ml/m³**: cloudy cornea, body weight gains ↓, absolute and relative liver weights (♂) ↑ ($p < 0.05$), absolute and relative kidney weights (♂) ↑ ($p < 0.05$), findings in the nose: see Table 3	Exxon Biomedical Sciences Inc. 1990; Hinz et al. 1992

Tab. 2 Effects of 2-diethylaminoethanol on the nose of F344 rats after inhalation exposure for 11 days (9 exposures) (Exxon Biomedical Sciences Inc. 1990; Hinz et al. 1992)

Findings		Concentration			
		0 ml/m³	**10 ml/m³**	**56 ml/m³**	**300 ml/m³**
mononuclear cell infiltration	♂	0/10	1/10	6/10	–[a]
	♀	1/10	0/10	4/10	–[b]
squamous metaplasia	♂	0/10	0/10	1/10	–[a]
	♀	0/10	0/10	0/10	–[b]

[a] no data, mortality 9/10
[b] no data, mortality 5/10

Tab. 3 Effects of 2-diethylaminoethanol on the nose of F344 rats after inhalation exposure for 14 weeks (Exxon Biomedical Sciences Inc. 1990; Hinz et al. 1992)

Findings		Concentration			
		0 ml/m³	11 ml/m³	25 ml/m³	76 ml/m³
exudate in the lumen	♂	0/10	0/10	0/10	1/10
	♀	0/10	0/10	0/10	1/10
hyperplasia	♂	0/10	0/10	2/10	4/10
	♀	0/10	0/10	2/10	5/10
hyperplasia and squamous metaplasia	♂	0/10	0/10	3/10	5/10
	♀	0/10	0/10	2/10	4/10
goblet cell hypertrophy	♂	0/10	0/10	0/10	6/10
	♀	0/10	0/10	0/10	0/10
infiltration of various inflammatory cells	♂	0/10	0/10	4/10	5/10
	♀	3/10	4/10	3/10	10/10
infiltration of mononuclear cells	♂	0/10	0/10	0/10	0/10
	♀	1/10	0/10	0/10	0/10
focal necrosis of mucosa	♂	0/10	0/10	0/10	1/10
	♀	0/10	0/10	0/10	2/10
+4 weeks observation					
hyperplasia	♂	0/10	0/10	3/10	1/10
	♀	0/10	1/10	5/10	5/10
hyperplasia and squamous metaplasia	♂	0/10	0/10	1/10	4/10
	♀	0/10	0/10	2/10	2/10
goblet cell hypertrophy	♂	0/10	0/10	0/10	4/10
	♀	0/10	0/10	0/10	7/10
infiltration of various inflammatory cells	♂	2/10	2/10	5/10	6/10
	♀	6/10	8/10	7/10	7/10
focal necrosis of mucosa	♂	0/10	0/10	0/10	0/10
	♀	0/10	0/10	0/10	1/10

Local effects on skin and mucous membranes

2-Diethylaminoethanol was corrosive to the skin of rabbits in a study that applied the Draize method and in another that was carried out in compliance with OECD Test Guideline 404. The substance was likewise irritating to the eyes of rabbits (Greim 2000 b).

After occlusive application for 4 hours, a 5% solution still caused slight irritation to the rabbit skin and a 10% solution still induced necrotic effects in 1 of 4 or 6 animals (contradictory data were given in the discussion section of the study report) (ECHA 2020). No data were provided for skin penetration and the vehicle used. The substance is corrosive to the skin and miscible with water. According to the CLP Regulation, these types of substances are expected to cause skin irritation at concentrations of 1% and above. Therefore, irritation should no longer be observed at a concentration of 0.5%.

Allergenic effects

Sensitizing effects on the skin

A maximization test in groups of 10 male and 10 female Dunkin Hartley guinea pigs yielded negative results. Intradermal induction was carried out with 5% 2-diethylaminoethanol in propylene glycol and epicutaneous induction with a 25% preparation of the substance in ethanol. None of the 20 animals reacted to the challenge treatment with 5% 2-diethylaminoethanol in 70% ethanol or in 0.9% saline solution (no exact data) (Leung and Blaszcak 1998).

In a modified maximization test, groups of 10 Hartley guinea pigs were given 1% 2-diethylaminoethanol in olive oil for intradermal induction and a 5% preparation in olive oil for epicutaneous induction. The epicutaneous challenge treatment with 0.125%, 0.25%, 0.5% and 1% concentrations in saline solution did not produce a positive reaction in any of the animals (Nakamura et al. 1994).

In a Draize test carried out in 1958, 10 guinea pigs were given intradermal injections of 0.1% 2-diethylaminoethanol in distilled water on 10 consecutive days for induction. The challenge took place 2 weeks after the last injection for induction and the animals were examined 24 hours later. As there was no control group, the reactions after the challenge were compared with the reactions after the first induction injection. In all animals, the skin reactions observed after the challenge injection were weaker in comparison with those after the first induction injection. The authors of the study evaluated the test results as negative (Penwalt Corp 1984).

Sensitizing effects on the airways

There are no data available.

Structure–effect relationships

A number of publications that focused on mechanistic aspects (Enoch et al. 2012) or on the predictive structure–effect relationships of respiratory allergens with low molar mass (Jarvis et al. 2005) evaluated both 2-diethylaminoethanol and several other alkanolamines, or included them in a list of constituents of the training set used for this model. However, it is not clear why this approach was used, as an immunological effect of 2-diethylaminoethanol is not supported by corresponding clinical findings. The same is true for the other alkanolamines that were included in these publications.

Reproductive and developmental toxicity

As described in the supplement published in 2007, exposure of Sprague Dawley rats to 2-diethylaminoethanol from gestation days 6 to 15 did not induce developmental toxicity up to the highest concentration tested of 100 ml/m^3. The NOAEC for maternal toxicity was 33 ml/m^3 because feed consumption and body weight gains were reduced at concentrations of 66 ml/m^3 and above. The NOAEC for developmental toxicity was 100 ml/m^3 (Greim 2007).

Manifesto (MAK value/classification)

The most sensitive end point is the local effect of 2-diethylaminoethanol on the upper respiratory tract observed in humans and in animal studies.

MAK value. Data for humans that are suitable for deriving a MAK value are not available.

In a 14-week inhalation study with F344 rats, exposure to 2-diethylaminoethanol at the medium concentration of 25 ml/m^3 induced focal hyperplasia either alone (male and female animals together 4/20) or in combination with squamous metaplasia (5/20) in the respiratory epithelium of the nose as well as the infiltration of inflammatory cells in the nasal mucosa (7/20). In the discussion section of the study report, “slight breathing sounds” were reported to have been observed immediately following exposure in the animals exposed to 2-diethylaminoethanol concentrations of 11 and 25 ml/m^3; the sounds subsided within an hour after the end of exposure. However, these observations were made only in a total of 3 animals from different concentration groups on isolated days and were included in the tables of the study report (see Section “Subacute, subchronic and chronic toxicity”) that showed the findings in individual animals (Exxon Biomedical Sciences Inc. 1990). The Commission assumes that any stable and adverse effects would have been recorded and that the isolated occurrences of rales in 2 animals during the study period that were included in the findings for individual animals are not to be regarded as consistent effects of exposure to a 2-diethylaminoethanol concentration of 11 ml/m^3. Therefore, a 2-diethylaminoethanol concentration of 11 ml/m^3 was derived as the NOAEC

for local effects based on the findings of this study. Histopathological findings in the nasal epithelium were observed at 2-diethylaminoethanol concentrations of 25 ml/m³ and above, the systemic NOAEC for changes in body weights and organ weights.

The 2-diethylaminoethanol concentration of 11 ml/m³ is used as the basis for the extrapolation of animal data to humans (1:3) according to the method developed for irritant substances (Brüning et al. 2014) and results in a 2-diethylaminoethanol concentration of 3.67 ml/m³. By applying the preferred value approach, a MAK value for 2-diethylaminoethanol of 2 ml/m³ is derived. A time extrapolation is not needed because the NOAEC established after exposure for 11 days is the same as that determined after 14 weeks and no intensification of the effects was observed over time. This MAK value corresponds well with the values derived for other aliphatic amines that likewise have been assigned a MAK value of 2 ml/m³ for the induction of similar local effects. One such example is dimethylamine; a NOAEC of 10 ml/m³ was derived for this substance from the findings of a 12-month inhalation study in rats (Greim 1996).

Peak limitation. Due to its local effects, the substance remains classified in Peak Limitation Category I. There are no data available for humans; for this reason, an excursion factor of 1 has been established and a momentary value of 5 ml/m³ has been set in analogy to that derived for other aliphatic amines with a MAK value of 2 ml/m³.

Prenatal toxicity. 2-Diethylaminoethanol was previously classified in Pregnancy Risk Group C with a MAK value of 5 ml/m³. No new data are available. In a study of prenatal development toxicity in rats, the NOAEC for toxic effects on development was found to be the highest concentration tested of 100 ml/m³. After lowering the MAK value to 2 ml/m³ and taking into consideration the increased respiratory volume (1:2), this results in a margin of 25 between the MAK value and the NOAEC for toxic effects on development. 2-Diethylaminoethanol therefore remains classified in Pregnancy Risk Group C.

Absorption through the skin. The application of a 0.5% (a not irritating concentration) aqueous solution under standard conditions led to the absorption of 29 mg of 2-diethylaminoethanol through the skin. On the basis of the systemic NOAEC of 25 ml/m³ (120 mg/m³) that was derived from the findings of the subchronic study in rats and taking into consideration the extrapolation to chronic exposure (1:2), the increased respiratory volume at the workplace (1:2), the extrapolation of the data from animal studies to humans (1:2), the assumed 100% absorption by inhalation and the respiratory volume of 10 m³, this results in a systemically tolerable amount of 150 mg. Thus, absorption through the skin accounts for less than 25% of the systemically tolerable amount and the substance is no longer designated with an "H" (for substances which can be absorbed through the skin in toxicologically relevant amounts).

Sensitization. There are no clinical findings in humans relating to the skin sensitizing effects of 2-diethylaminoethanol and no positive findings from experimental studies in animals or from in vitro studies. There are no data available that can be used as evidence that the substance causes sensitizing effects on the respiratory tract. Therefore, 2-diethylaminoethanol is not designated with "Sh" or "Sa" (for substances which cause sensitization of the skin or airways).

Notes

Competing interests

The established rules and measures of the Commission to avoid conflicts of interest (www.dfg.de/mak/conflicts_interest) ensure that the content and conclusions of the publication are strictly science-based.

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