The MAK Collection for Occupational Health and Safety

2-Methoxypropylacetate-1

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

A. Hartwig[1,*], MAK Commission[2,*]

[1] *Chair of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Institute of Applied Biosciences, Department of Food Chemistry and Toxicology, Karlsruhe Institute of Technology (KIT), Adenauerring 20a, Building 50.41, 76131 Karlsruhe, Germany*

[2] *Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Kennedyallee 40, 53175 Bonn, Germany*

* *email: A. Hartwig (andrea.hartwig@kit.edu), MAK Commission (arbeitsstoffkommission@dfg.de)*

Keywords: 2-methoxypropyl-1-acetate; MAK value; maximum workplace concentration; peak limitation; developmental toxicity; irritation

Citation Note: Hartwig A, MAK Commission. 2-Methoxypropylacetate-1. MAK Value Documentation, addendum – Translation of the German version from 2018. MAK Collect Occup Health Saf [Original edition. Weinheim: Wiley-VCH; 2019 Apr;4(2):451–461]. Corrected republication without content-related editing. Düsseldorf: German Medical Science; 2025. https://doi.org/10.34865/mb7065770e6519_w

Republished (online): 30 Apr 2025

Originally published by Wiley-VCH Verlag GmbH & Co. KGaA; https://doi.org/10.1002/3527600418.mb7065770e6519

Addendum completed: 22 Mar 2017

Published (online): 25 Apr 2019

The commission established rules and measures to avoid conflicts of interest.

2-Methoxypropylacetate-1[1)] / 2-Methoxypropyl acetate

MAK Value Documentation

A. Hartwig[1, *], MAK Commission[2, *]

DOI: 10.1002/3527600418.mb7065770e6519

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 workplace (MAK value) for 2-methoxypropylacetate-1 [70657-70-4]. Available publications and unpublished study reports are described in detail.
Critical effects of 2-methoxypropylacetate-1 are its irritancy and teratogenicity. A MAK value of 5 ml/m^3 had been set. This value is now reaffirmed based on the findings on the irritancy of the substance in a 28-day inhalation study with rats.
Since a local effect is critical, Peak Limitation Category I with excursion factor of 2 has been set. 2-Methoxypropylacetate-1 remains assigned to Pregnancy Risk Group B and it also remains designated with an "H" (for substances that can be absorbed through the skin in toxicologically relevant amounts).

Keywords

propylene glycol 2-methyl ether-1-acetate; 2-methoxypropyl-1-acetate; 2-methoxypropyl acetate; 1-propanol, 2-methoxy-, 1-acetate; mechanism of action; toxicokinetics; metabolism; (sub) acute toxicity; (sub)chronic toxicity; irritation; reproductive toxicity; fertility; developmental toxicity; peak limitation; prenatal toxicity; germ cell mutagenicity; absorption through the skin; sensitization; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

Author Information

[1] Chair of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Department of Food Chemistry and Toxicology, Institute of Applied Biosciences, Karlsruhe Institute of Technology (KIT), Adenauerring 20a, Building 50.41, 76131 Karlsruhe, Germany
[2] Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Kennedyallee 40, 53175 Bonn, Germany

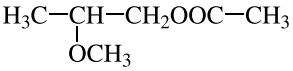
* Email: A. Hartwig (andrea.hartwig@kit.edu), MAK Commission (arbeitsstoffkommission@dfg.de)

1) MAK value applies for the sum of the concentrations of 2-methoxypropanol-1 and its acetate in the air.

2-Methoxypropylacetate-1 [1)]

[70657-70-4]

Supplement 2018

MAK value (2001)	**5 ml/m³ (ppm) ≙ 27 mg/m³**
Peak limitation (2017)	**Category I, excursion factor 2**
Absorption through the skin (2000)	**H**
Sensitization	**–**
Carcinogenicity	**–**
Prenatal toxicity (1988)	**Pregnancy Risk Group B**
Germ cell mutagenicity	**–**
BAT value	**–**
Synonyms	2-methoxypropyl-1-acetate 2-methoxypropyl acetate propylene glycol 2-methyl ether-1-acetate
Chemical name	1-propanol, 2-methoxy-, 1-acetate
Structural formula	
Molecular formula	$C_6H_{12}O_3$
Molar mass	132.16 g/mol
Boiling point at 1013 hPa	154.8 ± 13.0 °C (calculated; CAS 2016)
Density at 20 °C	0.959 ± 0.06 g/cm³ (calculated; CAS 2016)
Vapour pressure at 25 °C	4.17 hPa (CAS 2016)
log K_{OW} [2)]	0.481 (calculated; CAS 2016)
Solubility at 25 °C	58 g/l (calculated; CAS 2016)
1 ml/m³ (ppm) ≙ 5.484 mg/m³	**1 mg/m³ ≙ 0.182 ml/m³ (ppm)**

1) MAK value applies for the sum of the concentrations of 2-methoxypropanol-1 and its acetate in the air.

2) octanol/water partition coefficient.

For 2-methoxypropylacetate-1, documentation from 1988 (documentation "2-Methoxypropyl-1-acetate" 1990) and supplements from 2000 (supplement "2-Methoxypropylacetat-1" 2000, available in German only) and 2001 (supplement "2-Methoxypropylacetat-1" 2001, available in German only) are available.

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 and vapour with a blood:air partition coefficient < 5 (see List of MAK and BAT Values, Sections I b and I c). According to the formula of Buist et al. (2012), the blood:air partition coefficient of 2-methoxypropylacetate-1 is 2111. This supplement evaluates whether the MAK value and the pregnancy risk group for 2-methoxypropylacetate-1 need to be re-assessed as a result of the higher respiratory volume at the workplace.

1 Toxic Effects and Mode of Action

2-Methoxypropylacetate-1 is teratogenic in rats and rabbits. In a 28-day inhalation study with rats, irregular breathing occurred at concentrations of 560 ml/m^3 and above and at 2700 ml/m^3 also other clinical signs of irritation such as gasping, partial eyelid closure and, in some animals, a bloody discharge from the eyes and nose. There are no data available for the genotoxicity, carcinogenicity or sensitizing effects of the substance.

2 Mechanism of Action

The teratogenic effect is attributed to the acid produced during metabolism (ECETOC 2005). The mechanism is not known.

3 Toxicokinetics and Metabolism

3.1 Absorption, distribution, elimination

There are no data available.

3.2 Metabolism

The half-life for the hydrolysis (ester cleavage) of 2-methoxypropylacetate-1 to 2-methoxypropanol-1 in rat plasma in vitro at 37 °C is approximately 10 minutes (Hoffmann and Jäckh 1985).

The hydrolysis of 2-methoxypropylacetate-1 to 2-methoxypropanol-1 is followed by oxidation to 2-methoxypropionic acid, the main metabolite in the urine (Miller et al. 1986).

Likewise, for the isomer 1-methoxypropylacetate-2, a half-life for hydrolysis of approximately 10 minutes was obtained with rat plasma in vitro (BASF AG 1984 d) and the rapid hydrolysis of the ester to the glycol ether was demonstrated in vivo in F344 rats (Domoradzki et al. 2003).

4 Effects in Humans

No reports of effects in humans are available.

5 Animal Experiments and in vitro Studies

5.1 Acute toxicity

5.1.1 Inhalation

Groups consisting of 1 male and 1 female beagle dog or Himalayan rabbit were exposed by inhalation to an average 2-methoxypropylacetate-1 concentration of 375 ml/m^3 for 6 hours. There was considerable restlessness in the beagle dogs at the start of the exposure, and strong salivation was observed in the female after about 15 minutes; the male beagle exhibited pronounced chewing and licking movements. In both species, the blinking frequency was increased and did not return to normal until 2 hours later. After 3 hours, the salivation and the licking movements decreased in the beagle dogs and after 6 hours were present only to a slight extent. Merely 3 minutes after the end of exposure, there were no unusual findings in the animals. In the rabbits, sporadic chewing and licking movements were seen only after 2.5 and 4.5 hours, at all other times there were no unusual findings in the animals. The ophthalmological and gross-pathological examinations carried out after the exposure in both species did not reveal irregular findings (BASF AG 1984 a).

5.1.2 Oral administration

Single 2-methoxypropylacetate-1 doses of 2610, 3830 or 5000 mg/kg body weight were administered by gavage to groups of 5 male and 5 female Wistar rats. Dyspnoea, apathy, abnormal posture, staggering and poor general condition were found in both male and female animals of the high dose group. One female died during the 14-day recovery period; general congestive hyperaemia and suspected gastric ulceration were found. The oral LD_{50} of 2-methoxypropylacetate-1 was therefore > 5000 mg/kg body weight (BASF AG 1984 b).

5.1.3 Dermal application

There are no data available.

5.2 Subacute, subchronic and chronic toxicity

5.2.1 Inhalation

In a study already described in the 1988 documentation (documentation "2-Methoxypropyl-1-acetate" 1990), groups of 5 male and 5 female Wistar rats were exposed (whole-body exposure) to 2-methoxypropylacetate-1 concentrations of 0, 110, 560 or 2700 ml/m³ (0, 600, 2950, 14 740 mg/m³) for 6 hours a day, on 5 days per week for 28 days. The purity of the test substance was 97.96%. According to the authors, the highest concentration corresponded to 95% of the vapour saturation concentration at 20 °C. In the animals of the high concentration group, marked clinical signs occurred during the exposure such as irregular and laboured breathing patterns, partial eyelid closure, in some animals a bloody discharge from the eyes and nose, squatting posture, slight apathy, pale skin, salivation and unkempt fur. Slight irregular breathing and unkempt fur were found also in the animals of the middle group, but not in the animals of the low concentration group. The findings were reversible and disappeared within a short period after the end of the exposure. No deaths occurred. In the high concentration group, the body weights of the male animals were significantly reduced on day 24, and those of the females on day 17. The body weight gains in the males of this group were significantly reduced during the entire exposure period up to the day of killing; in the females of this group, this effect was reversible in the period between the final treatment and killing. The weights and size of the thymus of all male and 3 female rats in the high concentration group were markedly decreased. Histological examination revealed atrophy of the thymus. A moderate increase in adrenal weights without any histological correlation was found in the male rats. In the males of the high concentration group, the absolute liver weights were decreased. There were no effects on the blood or bone marrow cellularity or the testes. In the males of the high concentration group, the glucose level in the blood was reduced and the thromboplastin time increased. In the female rats, urea and protein levels were reduced, the activity of alkaline phosphatase was increased and the number of polymorphonuclear granulocytes was slightly increased. There were no such effects in either of the lower concentration groups. Histopathological examination of the nasal cavity (plane of section II) and the lungs of the animals in the control group and the high concentration group, or the nasal cavity (plane of section IV) in all animals did not reveal any abnormal findings in connection with the exposure (BASF AG 1984 c, 1987; Ma-Hock et al. 2005). The NOAEC (no observed adverse effect concentration) for systemic effects is therefore 560 ml/m³ and that for irritation 110 ml/m³.

5.2.2 Oral administration

In a study already described in the documentation of 1988 (documentation "2-Methoxy-1-propanol" 1990), 2-methoxypropanol-1 doses of 0 or 1800 mg/kg body weight were administered by gavage to groups of 5 male Wistar rats on 10 consecutive days. In addition, further groups were given equimolar doses of 2-ethoxyethanol of 1800 mg/kg body weight or 2-methoxypropylacetate-1 of 2600 mg/kg body weight. At the end of the study, apart from clinical observations, haematological parameters were recorded, organ weights of the testes, thymus, liver, kidneys and spleen were

determined and the testes and thymus were assessed histopathologically. While reduced body weights, testis weights and thymus weights were found and pronounced thymus involution and diminished testes were seen during pathological examination in the animals treated with 2-ethoxyethanol, the body and organ weights were normal, and the pathological examinations yielded no unusual findings in the animals treated with 2-methoxypropanol-1 or 2-methoxypropylacetate-1. The haemoglobin level, erythrocyte count, haematocrit, mean corpuscular volume, mean corpuscular haemoglobin concentration, and thrombocyte and leukocyte counts were significantly reduced in the animals treated with 2-ethoxyethanol. The haemoglobin level (–8%) and erythrocyte count (–5%) were slightly, but significantly reduced in the animals treated with 2-methoxypropanol-1, whereas no significant haematological changes occurred in the animals treated with 2-methoxypropylacetate-1 (BASF AG 1982; Ma-Hock et al. 2005). The NOAEL for 2-methoxypropylacetate-1 was therefore 2600 mg/kg body weight and day.

5.2.3 Dermal application

There are no data available.

5.3 Local effects on skin and mucous membranes

5.3.1 Skin

In a study carried out according to OECD Test Guideline 404, 0.5 ml undiluted 2-methoxypropylacetate-1 (purity > 97%) was applied to the intact dorsal skin (about 6 cm^2 in each case) of 3 New Zealand White rabbits and covered with a semi-occlusive bandage. The bandage was removed after 4 hours and the application site washed with water. During the recovery period no unusual findings were observed in any of the animals; the primary irritation index was 0 of a maximum of 8. 2-Methoxypropylacetate-1 was assessed as not irritating to the skin (BASF AG 1997 a).

In a dermal developmental toxicity study (see Section 5.5.2), the daily application of undiluted 2-methoxypropylacetate-1 doses of up to 2000 mg/kg body weight led to mild skin irritation in rabbits (Merkle et al. 1987).

5.3.2 Eyes

In a study carried out according to OECD Test Guideline 405, 0.1 ml undiluted 2-methoxypropylacetate-1 (purity > 97%) was instilled into the left eye of 3 New Zealand White rabbits. Moderate to marked swelling and slight to moderate reddening of the conjunctiva were found after one hour. In addition, there was a slight to moderate watery discharge and hyperaemia of the blood vessels of the sclera. All findings were reversible after 7 days. Both the cornea and iris were normal. The primary irritation index was 2.33 of a maximum of 13. 2-Methoxypropylacetate-1 was assessed as not irritating to the eyes (BASF AG 1997 b).

5.4 Allergenic effects

There are no data available.

5.5 Reproductive and developmental toxicity

5.5.1 Fertility

In groups of 5 male Wistar rats, the testis weights were unaffected after gavage doses of 2-methoxypropylacetate-1 of 2600 mg/kg body weight and day for 10 days (see Section 5.2.2) (BASF AG 1982; Ma-Hock et al. 2005).

5.5.2 Developmental toxicity

The studies of the developmental toxicity of the substance are given in detail in Table 1.

In a study of prenatal toxicity in rats, a 2-methoxypropylacetate-1 concentration of 2700 ml/m^3 led to an increased number of dumbbell-shaped notches in the thoracic vertebral cartilage of the foetuses. At concentrations of 550 ml/m^3 and above, toxic effects were observed in the dams, such as reduced body weights, sedation, unkempt fur and gasping. The NOAEC for developmental toxicity was 550 ml/m^3 and that for maternal toxicity 110 ml/m^3. The effects in the foetuses were similar to those observed under the same study conditions with 2-methoxypropanol-1 (BASF AG 1985 a; Merkle et al. 1987).

Rabbits were found to be more sensitive to the developmental toxicity of 2-methoxypropylacetate-1 than rats (Merkle et al. 1987). In the prenatal developmental toxicity study in rabbits carried out by the same research group, the body weights of the female foetuses at concentrations of 145 ml/m^3 and above were reduced by 3% without simultaneous maternal toxicity, a finding which was not considered relevant to the evaluation. At the concentration of 550 ml/m^3, all foetuses had malformations of the heart, the paws or the sternum. At this concentration the body weights were reduced in the dams. The NOAEC for teratogenicity and maternal toxicity was 145 ml/m^3 (BASF AG 1985 b; Merkle et al. 1987).

No developmental or maternal toxicity was observed in rabbits after semi-occlusive dermal application of up to 2000 mg 2-methoxypropylacetate-1 between days 6 and 18 of gestation (BASF AG 1985 c; Merkle et al. 1987).

5.6 Genotoxicity

There are no data available.

5.7 Carcinogenicity

There are no data available.

Table 1 Studies of the developmental toxicity of 2-methoxypropylacetate-1 in rats and rabbits

Species, strain, number per group	Exposure	Findings	References
Prenatal developmental toxicity			
rat, Wistar, 25 ♀	**GD 6–15**, 0, 110, 550, 2700 ml/m³, vapour, whole body, 6 hours/day, examination: GD 20, purity: > 95%	**110 ml/m³: NOAEC for maternal toxicity**; foetuses: eye open on one side only (1/176, not dose-dependent, not at 2700 ml/m³); **550 ml/m³: NOAEC for developmental toxicity**; dams: body weights ↓ (GD 15 and 20), sedation, unkempt fur, gasping; foetuses: eye open on one side only (2/172); **2700 ml/m³**: dams: body weights ↓ (GD 15 and 20), uterus weights ↓, sedation, unkempt fur, gasping, eye irritation; foetuses: number of live foetuses per litter ↓, % of dead implantations ↑, foetal weights ↓ (♂, ♀), dumbbell-shaped notches of thoracic vertebral cartilage ↑ (foetuses: 12/189, litters: 7/23, controls: 0/217, 0/24)	BASF AG 1985 a; Merkle et al. 1987
rabbits, Himalayan, 15 ♀	**GD 8–18**, 0, 36, 145, 550 ml/m³, vapour, whole body, 6 hours/day, examination: GD 29, purity: > 95%	**145 ml/m³: NOAEC for teratogenicity and maternal toxicity**; foetuses: foetal weights ↓ (♀, –3%, not relevant to the evaluation); **550 ml/m³**: dams: body weights ↓ (GD 15, 18 and 21); foetuses: foetal weights ↓ (♂, ♀), % of dead implantations ↑, all foetuses (100%) malformed (heart and skeleton), number of variations ↑, developmental delays ↑	BASF AG 1985 b; Merkle et al. 1987
rabbits, Himalayan, 15–16 ♀	**GD 6–18**, 0, 1000, 2000 mg/kg body weight, dermal, undiluted, semi-occlusive, examination: GD 29, purity: > 95%	**1000 mg/kg body weight**: dams: mortality 1/15, mild skin irritation; **2000 mg/kg body weight: NOAEL for developmental and maternal toxicity**; dams: mild skin irritation	BASF AG 1985 c; Merkle et al. 1987

GD: gestation day; NOAEC: no observed adverse effect concentration; NOAEL: no observed adverse effect level

6 Manifesto (MAK value/classification)

The critical effects of 2-methoxypropylacetate-1 are its irritant effects and teratogenicity.

MAK value. There are no new data available.

The previous MAK value of 5 ml/m³ was established in analogy to 2-methoxypropanol-1 and this in turn was based on the former threshold limit value for 2-ethoxyethanol, which in the meantime has been lowered to 2 ml/m³. The systemic toxicity is, however, somewhat lower than that of 2-ethoxyethanol, as no testicular toxicity is caused by 2-methoxypropanol-1 and its acetate at the same molar dose. In a 28-day study with 2-methoxypropylacetate-1 (with a small scope of histopathological examinations), the NOAEC for systemic effects was 560 ml/m³ and that for clinical signs of irritation 110 ml/m³. Assuming that also no histopathological effects in the nasal tissues and the respiratory tract occurred at 110 ml/m³, a value of 5 ml/m³ is obtained by extrapolation of the data from the animal study to humans (1:3), assuming an increase in the effects observed with short-term exposure for long-term exposure (1:6) and using the preferred value approach. The previous MAK value has therefore been retained.

Peak limitation. As irritation is a critical effect, 2-methoxypropylacetate-1 is assigned to Peak Limitation Category I. An excursion factor of 2 is justified, as the LOAEC (lowest observed effect concentration) is five times higher than the NOAEC used for the derivation of the MAK value.

Prenatal toxicity. The developmental toxicity is similar to that found under the same study conditions with 2-methoxypropanol-1 (Merkle et al. 1987). Due to the rapid cleavage of the acetate group of 2-methoxypropylacetate-1 (Hoffmann and Jäckh 1985), which results in 2-methoxypropanol-1, both substances can be used analogously when assessing the systemic effects.

Rabbits were found to be more sensitive to the teratogenic effects of 2-methoxypropylacetate-1 (Merkle et al. 1987) and 2-methoxypropanol-1 ether than rats (Hellwig et al. 1994). In rats, the NOAEC for developmental toxicity (dumbbell-shaped notches in the sternal cartilage) was 550 ml/m³ and that for maternal toxicity 110 ml/m³ (Merkle et al. 1987). In rabbits, at the highest concentration tested of 550 ml/m³, malformations of the heart, the paws or the sternum occurred. The NOAEC for developmental and maternal toxicity was 145 ml/m³ (Merkle et al. 1987).

Taking the increased respiratory volume of humans at the workplace into consideration compared with that of animals at rest (1:2), a 15-fold difference between the NOAEC for teratogenicity in rabbits of 145 ml/m³ and the MAK value of 5 ml/m³ is obtained. Due to the severity of the effects, like 2-methoxypropanol-1, 2-methoxypropylacetate-1 remains assigned to Pregnancy Risk Group B.

Germ cell mutagenicity and carcinogenicity. No studies are available for the evaluation of the genotoxicity and the carcinogenicity of 2-methoxypropylacetate-1. Therefore, the substance is not classified in one of the categories for germ cell mutagens or carcinogens.

Absorption through the skin. No experimental data are available for the dermal penetration of 2-methoxypropylacetate-1. Amounts of up to 2600 mg were obtained from model calculations for 2-methoxypropanol-1 (supplement "2-Methoxypropanol-1" 2019). Comparative studies of the dermal penetration of glycol ethers and glycol ether acetates show that the dermal penetration rate of glycol ether acetates lies between 10% and 100% of that of the corresponding glycol ethers (Larese Filon et al. 1999; Dugard et al. 1984). Assuming the penetration rate to be lower by a factor of 10, exposure of both hands and forearms for one hour (about 2000 cm^2) would result in the total absorption of 260 mg 2-methoxypropylacetate-1. Although the NOAEC for systemic effects from the 28-day study with rats was 560 ml/m^3, systemic effects were found in the developmental toxicity studies with rats and rabbits in the dams even at the concentration of 550 ml/m^3 (3016 mg/m^3), for which reason a NAEC (no adverse effect concentration) of half this concentration, that is 275 ml/m^3, is assumed. Taking into account a possible increase in the effects over time (1:6), the increased respiratory volumes at the workplace (1:2), the extrapolation of data from animal studies to humans (1:2) and assuming complete absorption and a respiratory volume of 10 m^3, the respiratory absorption of 628 mg 2-methoxypropylacetate-1 would be obtained for inhalation exposure at the level of the NAEC. Therefore, the contribution of dermal absorption, of more than 25% of the systemically tolerable amount, is so high that the systemic absorption of hazardous amounts to the health cannot be excluded. 2-Methoxypropylacetate-1 therefore remains designated with an "H" (for substances which can be absorbed through the skin in toxicologically relevant amounts).

Sensitization. As there are no data available, the substance is not designated with "Sa" (for substances which cause sensitization of the airways) or "Sh" (for substances which cause sensitization of the skin).

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completed March 22, 2017