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TOXICOLOGICAL EVALUATIONS

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TOXICOLOGICAL EVALUATION

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2-Methyl-3-butyn-2-ol

No. 205

CAS No. 115-19-5

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2-Methyl-3-butyn-2-ol

This Toxicological Evaluation replaces a previously published version in volume 6.

1 Summary and assessment

On single oral administration, 2-methyl-3-butyn-2-ol proves to be harmful (LD_{50} rat oral ca. 1420 and 1950 mg/kg body weight; LD_{50} mouse oral 500 and 1800 mg/kg body weight; depending on the source of information). The LC_{50} (4 hours) for rats is > 21300 mg/m³. In mice, the LC_{50} after 2-hour exposure is reported as 2000 mg/m³. In the inhalation hazard test in rats, mortality following 30 minutes, 1 hour and 4 hours of exposure was found to be 0 out of 12, 2 out of 12 and 6 out of 6 animals, respectively. On intraperitoneal and subcutaneous administration to mice LD_{50} values of approx. 1200 mg/kg body weight (intraperitoneal), and 1161 and 2340 mg/kg body weight (subcutaneous) have been found. The clinical signs of toxicity observed in rats after oral and inhalation administration and in mice after intraperitoneal injection include dyspnoea, apathy, narcosis as well as lying on the abdomen and the side.

On subacute oral administration to rats of 0 (controls), 50, 200 and 800/600 mg 2-methyl-3-butyn-2-ol/kg body weight for 28 days, sedation and narcosis, hypothermia, retarded body weight gain in connection with lower feed consumption and increased mortality were found to occur at the high dose level. Changes in the haematology and clinical chemistry parameters were seen at doses of 200 mg/kg body weight and above (increased neutrophil count, polychromasia) and particularly at the high dose level (decreased leukocyte count and haemoglobin concentration, anisocytosis, elevated alanine aminotransferase activity, elevated cholesterol level as well as bilirubin and total protein concentration). Macroscopic examination and histopathology did not reveal any changes. The *no observed effect level* is 50 mg/kg body weight.

In the rabbit, 2-methyl-3-butyn-2-ol is mildly irritating to the skin, while it is severely irritating to the eye.

In the modified split adjuvant skin test in the guinea pig, there are no indications that 2-methyl-3-butyn-2-ol might have a sensitising potential.

In the Salmonella/microsome assay, 2-methyl-3-butyn-2-ol has no mutagenic potential, either with or without metabolic activation. In the mouse micronucleus test, 2-methyl-3-butyn-2-ol shows no clastogenic effect following intraperitoneal administration.

In an embryotoxicity/teratogenicity study of 2-methyl-3-butyn-2-ol involving oral administration to rats of doses of 0 (controls), 45, 130 and 400 mg/kg body weight, maternal toxicity was seen in the highest dose group in the form of body weight loss associated with reduced feed consumption, as well as apathy, reeling and piloerection, which were reversible at the end of treatment. The foetuses of this dose group showed reduced foetal weights, skeletal variations and retardations, but no detectable teratogenic effects. The *no observed adverse effect level* for the mothers and the foetuses thus was found to be 130 mg/kg body weight.

2 Name of substance

2.1	Usual name	2-Methyl-3-butyn-2-ol
2.2	IUPAC name	2-Methyl-3-butyn-2-ol
2.3	CAS No.	115-19-5
2.4	EINECS No.	204-070-5

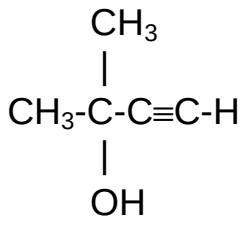
3 Synonyms, common and trade names

3-Butin-2-ol, 2-methyl-
1-Butyn-3-ol-, 3-methyl-
Dimethylacetylenecarbinol
Dimethylacetylenylcarbinol
Dimethylethynylcarbinol
Dimethylethynylmethanol
α,α-Dimethylpropargyl alcohol
1,1-Dimethylpropargyl alcohol
1,1-Dimethylpropargylalkohol

1,1-Dimethylpropynol
1,1-Dimethyl-2-propynol
Ethynyldimethylcarbinol
2-Hydroxy-2-methyl-3-butyne
Isopentinol
Methylbutinol
3-Methyl-butin-1-ol-3
2-Methylbutin-3-ol-2
2-Methyl-3-butin-2-ol
Methylbutynol
2-Methyl-2-hydroxy-3-butyne

4 Structural and molecular formulae

4.1 Structural formula



4.2 Molecular formula C_5H_8O

5 Physical and chemical properties

5.1	Molecular mass, g/mol	84.12	
5.2	Melting point, °C	2.6	(Budavari et al., 1989; Hort and Taylor, 1991)
		3 (solidification point)	(Lide and Frederikse, 1996; Falbe and Regitz, 1991)
5.3	Boiling point, °C	102–105	(BASF, 1996)
		103.6	(Hort and Taylor, 1991)
		104	(Lide and Frederikse, 1996)
		104–105	(Budavari et al., 1989; Falbe and Regitz, 1991)
5.4	Vapour pressure, hPa	20 (at 20 °C)	(BASF, 1996)

5.5	Density, g/cm³	0.8608 (at 20 °C) (BASF, 1996) 0.8618 (at 20 °C) (Lide and Frederikse, 1996) 0.8672 (at 20 °C) (Budavari et al., 1989; Falbe and Regitz, 1991; Hort and Taylor, 1991)
5.6	Solubility in water	Miscible (Budavari et al., 1989; Falbe and Regitz, 1991; Hort and Taylor, 1991)
5.7	Solubility in organic solvents	Miscible with acetone, benzene, cellosolve (ethylene glycol ethyl ether), tetrachloromethane, cyclohexanone, diethylene glycol, ethyl acetate, kerosene, methyl ethyl ketone, monoethanolamine, petroleum ether (Budavari et al., 1989) Miscible with acetone, benzene and tetrachloromethane (Falbe and Regitz, 1991)
5.8	Solubility in fat	In soy bean oil (Budavari et al., 1989) Partition coefficient n-octanol/water log P_{ow}: 0.32 (BASF, 1996)
5.9	pH value	Neutral (BASF, 1996)
5.10	Conversion factor	1 ml/m³ (ppm) ≙ 3.43 mg/m³ 1 mg/m³ ≙ 0.29 ml/m³ (ppm) (at 1013 hPa and 25 °C)

6 Uses

Used as an acetylene equivalent in palladium-catalysed coupling reactions with halogenides, and in the production of vitamins A and E, fragrances and pharmaceuticals (Falbe and Regitz, 1991).

7 Experimental results

7.1 Toxicokinetics and metabolism

No information available.

7.2 Acute and subacute toxicity

Acute toxicity

The acute toxicity data for 2-methyl-3-butyn-2-ol are summarised in Table 1. On the basis of these data, the chemical proved to be harmful upon oral administration to rats and mice, LD_{50} values being approx. 1420 (BASF, 1966) and 1950 mg/kg body weight (Brown et al., 1955) for the rat, and 500 (Balinina, 1987) and 1800 mg/kg body weight (Keil et al., 1954) for the mouse. Following inhalation of 2-methyl-3-butyn-2-ol at 21300 mg/m³ air for 4 hours there were no deaths, and hence the LC_{50} was > 21300 mg/m³ (BASF, 1988). The clinical signs of toxicity observed in rats after oral administration and inhalation included dyspnoea, apathy, narcosis as well as lying on the abdomen and the side. All autopsies were without abnormal findings (BASF, 1966, 1988). Upon intraperitoneal injection of 2-methyl-3-butyn-2-ol into mice, LD_{50} values were given as approx. 1200 mg/kg body weight (BASF, 1966) and approx. 2340 mg/kg body weight (Soehring et al., 1955), while for subcutaneous injection a value of 1161 mg/kg body weight was reported (Kitagawa et al., 1956).

Beginning of Table 1

Table 1. Acute toxicity of 2-methyl-3-butyn-2-ol

Species, strain, sex[1)]	Route of administration	Dose (mg/kg b. w. or mg/m³)	Effect	Observation period	Reference
Rat	oral	ca. 1.65 ml/kg b. w., ≙ ca. 420 mg/kg b. w.	LD_{50}; reeling, apathy, dyspnoea, lying on the abdomen and side; necropsy without findings	7 days	BASF, 1966
Rat	oral	1950	LD_{50}	n. d.	Brown et al., 1955
Mouse	oral	500	LD_{50}	n. d.	Balinina, 1987
Mouse	oral	1800	LD_{50}	n. d.	Keil et al., 1954
Rabbit	dermal	ca. 0.2 ml/kg b. w., ≙ ca. 172 mg/kg b. w.	no skin lesions or systemic findings	n. d.	BASF, 1966
Rat, Wistar, male, female	inhalation (4 hours)	21300	accelerated and intermittent breathing, narcosis-like state, lying on the abdomen and/or side, deteriorated general condition, apathy, reeling to unsteady gait, free of clinical signs from day 9 of the observation period; necropsy without findings	14 days	BASF, 1988

Table 1. Acute toxicity of 2-methyl-3-butyn-2-ol					
Species, strain, sex[1)]	Route of administration	Dose (mg/kg b. w. or mg/m³)	Effect	Observation period	Reference
Rat	inhalation	n. d.[2)]	mortality after 30 minutes, 1 hour and 4 hours of exposure was 0 out of 12, 2 out of 12 and 6 out of 6 animals, respectively; clinical signs of toxicity: mucous membrane irritation, narcosis; necropsy: hydrothorax in several cases	n. d.	BASF, 1966
Mouse	inhalation (2 hours)	2000	LC_{50}; breathing difficulties, impaired co-ordination, irritation of the upper respiratory tract, apathy, immobility	n. d.	Balinina, 1987
Mouse	intraperitoneal	ca. 1.4 ml/kg b. w., ≙ ca. 1200 mg/kg b. w.	LD_{50}; reeling, apathy, dyspnoea, lying on the abdomen and side; necropsy: occasional diarrhoea	7 days	BASF, 1966
Mouse	subcutaneous	1161	LD_{50}; somnolence, convulsions	n. d.	Kitagawa et al., 1956
Mouse	subcutaneous	ca. 2340	LD_{50}	24 hours	Soehring et al., 1955

1) where specified
2) atmosphere saturated with vapour at 20 °C
n. d. no data
b. w. body weight

End of Table 1

Subacute toxicity

Groups of 10 male and 10 female rats (BOR:WISW/SPF Cpb) received 2-methyl-3-butyn-2-ol (98.5% pure), dissolved in water, by gavage at dose levels of 0 (controls), 50, 200 and 800 mg/kg body weight/day for 4 weeks. Marked signs of toxicity were seen at the high dose, so that after 3 days, treatment of these animals was interrupted for one day and then resumed at a lower dose level of 600 mg/kg body weight/day. The high dose caused marked sedation and narcosis, hypothermia, delayed body weight gain with reduced feed consumption as well as increased mortality (5 females and 3 males). Haematology tests carried out on 5 males and 5 females from each group at the end of the study revealed a significant reduction in leukocyte count, a reduced haemoglobin concentration and an increased reticulocyte count in the high-dose female rats. The differential blood counts obtained for the males treated with 200 mg/kg body weight and the high-dose males

and females revealed a significant rise in the percentage of neutrophils with segmented nuclei and a corresponding decrease in lymphocytes (leftward shift). All the males and females in the study exhibited a dose-dependent increase in polychromasia from 200 mg/kg body weight, and additionally, both the females treated with doses of and above 200 mg/kg body weight and the males given 800/600 mg/kg body weight showed a dose-dependent increase in erythrocyte anisocytosis. Moreover, many ring-shaped erythrocytes were observed at the high dose level (no further details). The clinical chemistry results obtained for the high-dose animals of both sexes revealed significantly elevated levels of alanine aminotransferase activity and cholesterol in the plasma, the females additionally showing significantly increased plasma concentrations of bilirubin and total protein. Post-mortems on the animals which died prematurely (800/600 mg/kg body weight) revealed hyperaemia of the lungs, focal reddening of the gastric fundus mucosa and bloody small intestinal contents. Histopathologically, the mucosal reddening corresponded to hyperaemia, focal bleeding in the mucous membrane and, in some cases, focal erosive or ulcerative gastritis. The animals which were sacrificed at the end of the study exhibited neither macroscopic nor histopathological changes. Histopathological studies were made of the brain, heart, bone and bone marrow (femur, sternum), liver, lung, stomach, spleen, kidney and adrenal glands, and of any other organs that appeared abnormal on gross examination. The organ weights were within the control range. Under these study conditions, the *no observed effect level* was 50 mg/kg body weight/day (Bayer, 1984).

Following repeated administration of 2-methyl-3-butyn-2-ol to mice, guinea pigs and rabbits, hyperaemia and dermatitis were observed (no further details; Balinina, 1987).

7.3 Skin and mucous membrane effects

The acute skin irritancy of undiluted 2-methyl-3-butyn-2-ol was studied in a patch test on the clipped dorsal skin of white rabbits. Following exposure for 1 or 5 minutes, no changes were noted at 24 hours after application. A 15-minute exposure resulted in marginal reddening, whilst 20-hour exposure caused slight reddening. The findings cleared up completely after 8 days. A 20-hour application of the undiluted substance to the rabbit ear also caused slight reddening 24 hours after the end of exposure, the effect

being reversible after 8 days (BASF, 1966). Therefore, the chemical was slightly irritating to the skin.

In order to study the acute eye irritancy, 50 µl neat 2-methyl-3-butyn-2-ol was instilled into the conjunctival sac of the rabbit eye. One hour after instillation, the test substance had caused severe redness as well as severe oedema formation and marked clouding of the cornea. After 24 hours, severe redness, slight oedema, severe clouding of the cornea and bleeding in the conjunctivae were observed. Eight days following instillation, severe redness and slight clouding of the cornea were still present, as well as staphyloma. The sodium chloride control carried out on the other eye caused no changes (BASF, 1966). Thus, 2-methyl-3-butyn-2-ol was severely irritating to the eye.

According to another report as well, the chemical was severely irritating to the eye. Observations included swelling, purulent keratoconjunctivitis and clouding of the cornea (no further details; Balinina, 1987).

7.4 Sensitisation

Ten male guinea pigs (Hartley; weighing approx. 300 g) had 4 0.1 ml doses of 2-methyl-3-butyn-2-ol applied to the shorn dorsal skin within a period of 10 days. In addition to the third application, 0.2 ml Freund's adjuvant was administered intradermally next to the dermal application site (modified split adjuvant test). A challenge with 0.1 ml of the neat substance on the clipped flank after 14 days gave no indications of a sensitising effect (Rao et al., 1981).

7.5 Subchronic and chronic toxicity

No information available.

7.6 Genotoxicity

7.6.1 In vitro

2-Methyl-3-butyn-2-ol (99.7% pure) was tested for mutagenic potential in the Salmonella/microsome assay (standard-plate incorporation test) using

Salmonella typhimurium strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538. Concentrations of up to 12500 µg/plate were employed. The tests were carried out in the presence and absence of metabolic activation (S9 mix from Aroclor 1254-induced rat liver). No bacteriotoxicity was observed up to the highest concentration tested. There were no indications of mutagenic activity either with or without metabolic activation (BASF, 1980).

A further Salmonella/microsome assay, which in view of the chemical's high vapour pressure was carried out as a desiccator test, also showed 2-methyl-3-butyn-2-ol (approx. 98.3% pure) to be devoid of mutagenicity in the *Salmonella typhimurium* strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 with and without metabolic activation (S9 mix from Aroclor 1254-induced rat liver). The test was performed with a saturated atmosphere (nominal concentration 51721 ppm; Dow, 1980).

7.6.2 In vivo

In a micronucleus test (in accordance with OECD guideline No. 474), groups of 5 male and 5 female NMRI mice were given single intraperitoneal doses of 2-methyl-3-butyn-2-ol (99.7%), dissolved in water, at 0 (vehicle control), 300, 600 and 1200 mg/kg body weight. In a preliminary study, 1200 mg/kg body weight was determined as the maximum tolerated dose. Positive control groups were treated with cyclophosphamide or vincristine at dose levels of 20 and 0.15 mg/kg body weight, respectively. Administration of the test substance resulted in clear clinical signs of toxicity (reeling at 300 and 600 mg/kg body weight, abdominal position, shallow breathing and narcosis-like state at 1200 mg/kg body weight). In the high dose and vehicle control groups, the bone marrow was studied at 24 and 48 hours after dosing, while in the groups receiving the two lower doses and the positive controls it was examined 24 hours after dosing. Per animal, 1000 polychromatic erythrocytes were evaluated. The positive control groups were found to have markedly increased counts of micronucleated polychromatic erythrocytes, whereas the test substance caused no increase in micronucleated polychromatic erythrocytes at any time point of investigation. The ratio of polychromatic to normochromatic erythrocytes remained unchanged. Thus, 2-methyl-3-butyn-2-ol was devoid of clastogenicity under these experimental conditions (BASF, 1995).

7.7 Carcinogenicity

No information available.

7.8 Reproductive toxicity

In a preliminary study to an embryotoxicity/teratogenicity study, 9 or 10 pregnant rats/group received 2-methyl-3-butyn-2-ol (dissolved in distilled water) by oral gavage at dose levels of 0 (vehicle controls), 50, 150 and 300 mg/kg body weight on days 6 to 15 of gestation. During the study, clinical signs of toxicity, food consumption and body weights were recorded. On the day of the last administration, the animals were sacrificed, and haematology and clinical chemistry tests were carried out, as well as urinalyses. The liver and kidneys were weighed. In the highest dose group, the dams were noted to have reduced clotting time, alkaline phosphatase activity and increased total protein, globulin and cholesterol levels. Relative liver weight was statistically significantly increased in that dose group. Other study parameters were unchanged. The 150 mg/kg group was observed to have a reduced clotting time, while both lower dose groups exhibited increased total protein and globulin levels (no further details; BASF, 1997).

Based on the results of the dose-finding study described above, the subsequent embryotoxicity/teratogenicity study (conducted in accordance with OECD guideline No. 414) investigated groups of 25 pregnant rats receiving 2-methyl-3-butyn-2-ol, dissolved in distilled water, by oral gavage at dose levels of 0 (vehicle controls), 45, 130 and 400 mg/kg body weight on postcoital days 6 to 15. Necropsy was performed on the dams on postcoital day 20. The animals of the highest dose group exhibited transient body weight loss and reduced food consumption on initiation of treatment. Clinical signs of toxicity observed in all animals of that dose group included apathy, unsteady gait and/or piloerection, which were reversible after the end of treatment. In the foetuses of the high dose group, mean foetal body weight was significantly reduced (6% less than controls) and the rate of skeletal variations (rudimentary cervical and accessory 14th ribs) and retardations (delayed ossification of the skull bones, sternebrae and thoracic vertebral bodies) was increased, but there were no teratogenic effects. In the 130 and 45 mg/kg dose groups, substance-related effects were noted neither in the dams nor in the foetuses. Under these experimental conditions, signs of

maternal and foetal toxicity were seen only at the top dose level of 400 mg/kg body weight, and therefore the *no observed adverse effect level* for dams and foetuses was 130 mg/kg body weight (BASF, 1997).

7.9 Effects on the immune system

No information available.

7.10 Neurotoxicity

No information available.

7.11 Other effects

The concentration of 2-methyl-3-butyn-2-ol to cause 50-percent haemolysis in vitro was 0.67 mol/l (equivalent to 56.4 mg/ml) in human blood and 0.6 mol/l in canine blood (equivalent to 50.5 mg/ml; Soehring et al., 1955).

When a phrenic nerve-diaphragm preparation of the rat was electrically stimulated, concentrations of 1 to 2 x 10^{-3} M 2-methyl-3-butyn-2-ol had a paralysing effect, which was partly preceded by mild excitation and was noted with both indirect and direct stimulation (Soehring et al., 1955).

2-Methyl-3-butyn-2-ol showed no local anaesthetic effect when applied to the skin of guinea pigs (Soehring et al., 1955).

The HD_{50} (hypnotic dose) to induce a 5-minute lateral position in the mouse was 780 mg/kg body weight after subcutaneous administration, compared with approx. 100 mg/kg body weight for phenobarbital (Soehring et al., 1955).

Subcutaneous administration of 2-methyl-3-butyn-2-ol to mice at 1200 mg/kg body weight resulted in a mean sleeping time of 275 minutes after an average of 5.75 minutes. By comparison, a subcutaneous phenobarbital dose of 115 mg/kg body weight resulted in a sleeping time of 130 minutes with a delay of 38 minutes (Soehring et al., 1955).

Subcutaneous injection of 2-methyl-3-butyn-2-ol at 700 mg/kg body weight led to a 1.9-fold increase in the threshold for convulsions triggered by cardiazol (0.5% intravenous) in the mouse (Soehring et al., 1955).

2-Methyl-3-butyn-2-ol had an anticonvulsant effect in the rat. The oral ED_{50} (the dose abolishing the tonic-extensor phase in 50% of test animals) for electroshock-induced seizures was determined as 140 mg/kg body weight, whilst for phenobarbital it was 19 mg/kg body weight. The 2-methyl-3-butyn-2-ol dose to induce ataxia in 50% of rats treated with the chemical was 250 mg/kg body weight (Brown et al., 1955).

8 Experience in humans

No information available.

9 Classifications and threshold limit values

For the former USSR, a threshold limit value of 0.5 mg/m³ was reported for occupational exposure to 2-methyl-3-butyn-2-ol (Sidorov, 1991).

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