

Methanol – Addendum: re-evaluation of the BAT value

Assessment Values in Biological Material – Translation of the German version from 2019

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Abstract

In 2018, the German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area has lowered the maximum concentration at the workplace (MAK value) for methanol [67-56-1] to 100 ml/m³. The biological tolerance value (BAT value) was correlated to the MAK value. Therefore, the BAT value has to be re-evaluated.

After 8-hour exposure of test persons to 100 ml methanol/m³ with physical activity, a concentration of 15 mg methanol/l urine was measured. This is in line with the results of a field study in which a methanol concentration of approximately 100 ml/m³ corresponded to around 20 mg methanol/l urine.

Therefore, the BAT value has now been set to 15 mg methanol/l urine. Sampling time is at the end of exposure or the end of the working shift, for long-term exposure at the end of the shift after several shifts.

BAT (2018)	15 mg methanol/l urine Sampling time: end of exposure or end of shift; for long-term exposures: at the end of the shift after several previous shifts
MAK value (2018)	100 ml/m³ \triangleq 133 mg/m³
Absorption through the skin (1969)	H
Carcinogenicity	–
Prenatal toxicity (1995)	Pregnancy Risk Group C

Re-evaluation

The previously valid biological tolerance value (BAT value) of 30 mg/l urine from the year 1983 was derived in correlation to the maximum concentration at the workplace (MAK value), since there were insufficient data available on the direct correlation between the methanol concentration in urine and effects. The lowering of the MAK value from 200 to 100 ml/m³ in 2018 (translated in Hartwig and MAK Commission 2021) makes a re-evaluation of the BAT value necessary.

Relationship between external and internal exposure

Urine

Methanol can be excreted both in the form of its metabolite formate and unchanged with the urine. The urine and blood concentrations of methanol are proportional, with the concentration determined in urine being 20% to 30% higher than that in blood (DECOS 2010; Ferry et al. 1980). On the other hand, it was observed in a study with test persons that after a 2-hour exposure to 100 ml methanol/m³ the concentration in urine and blood is approximately the same (Ernstgård et al. 2005).

Elimination half-lives

DECOS (2010) gives an elimination half-life for urinary excretion of about 1.4 hours, Batterman et al. (1998) of 1.55 hours and Ernstgård et al. (2005) in the range of 1.7–1.8 hours; in Šedivec et al. (1981) a half-life of about 3.5 hours can be read from the figure (the text gives 1.5–2 hours).

Studies in test persons and in exposed workers

Since the documentation from 1983, numerous studies have been published in which the methanol and formate concentrations in the urine of test persons or exposed workers were examined (see Table 2). Investigations are available after 0.5 to 8 hours of exposure time in the concentration range of 100 to 800 ml methanol/m³, in which the test persons were exposed either at rest or during physical activity.

Studies in test persons

In a study in which eight test persons were exposed for two hours to 100 or 200 ml methanol/m³ during physical activity, the determination of the methanol concentrations in blood and urine showed twice as high values at the higher exposure concentration compared with the low one (Ernstgård et al. 2005).

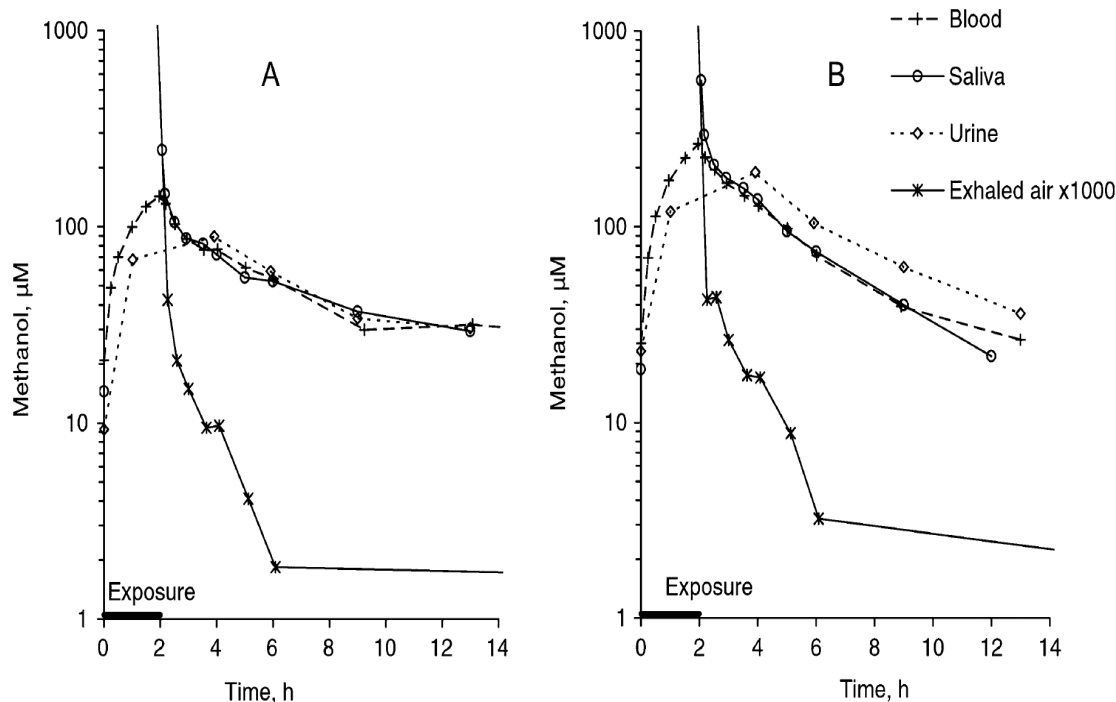


Fig. 1 Comparison of the methanol concentrations in the blood, saliva, urine and exhaled air of 8 test persons after two-hour exposure to 100 ml methanol/m³ (A) or 200 ml methanol/m³ (B) during light physical activity (50 W) (from Ernstgård et al. (2005), reprinted by permission of Oxford University Press on behalf of the Society of Toxicology <https://academic.oup.com/journals>)

Figure 1 from Ernstgård et al. (2005) shows a largely parallel course of methanol concentrations in blood and urine. Due to the extent of the endogenous formate production, exposure to up to 200 ml methanol/m³ air has no measurable effect on the formate concentration in urine and is therefore not suitable as a biomarker of methanol exposure.

In another study, 11 to 15 test persons were exposed for eight hours to 0, 100, 200 or 400 ml methanol/m³ either at rest or during physical activity and both formate and methanol concentrations in urine were determined. Urine samples at the end of exposure (Table 1) and during the 8-hour exposure showed a linear correlation between urinary methanol concentrations and exposure concentration. After exposure to the lowest concentration of 100 ml methanol/m³, the urine concentration was up to 8.6 mg methanol/l in 82% of the test persons without physical activity and up to 15.2 mg methanol/l in 75% of those with physical activity.

This study also shows that the concentration of formate in urine is unsuitable as a biological marker of methanol exposure (Franzblau et al. 1997).

Tab. 1 Urinary methanol concentrations after 8-hour exposure of test persons (according to Franzblau et al. 1997)

Exposure [ml/m ³]	Number of test persons	Methanol in urine ^{a)} [mg/l]
at rest		
0	15	1.5 ± 1.2
100	11	8.6 ± 5.7
200	15	17.9 ± 7.9
400	11	30.3 ± 7.2

Tab. 1 (continued)

Exposure [ml/m ³]	Number of test persons	Methanol in urine ^{a)} [mg/l]
physical activity (50 W)		
0	11	1.2 ± 0.7
100	12	15.2 ± 14.2
200	11	22.5 ± 15.1
400	11	46.0 ± 17.7

^{a)} mean value ± standard deviation

As described in the MAK documentation of 1999 (translated in Greim 2001), three volunteers were exposed for four consecutive days to average methanol concentrations of approx. 300 mg/ml (225 ml/m³) for eight hours each and the amount of methanol excreted with the urine was determined. The methanol concentrations in urine, which increased to a maximum of approx. 12 ± 1 mg/l urine in the course of the day, were back to normal the next morning, i.e. no methanol accumulation was detected in this study over the four days of the study. The urinary elimination half-life of methanol in humans after inhalation is about 3.5 hours (see Figure 2) (Greim 2001; Šedivec et al. 1981).

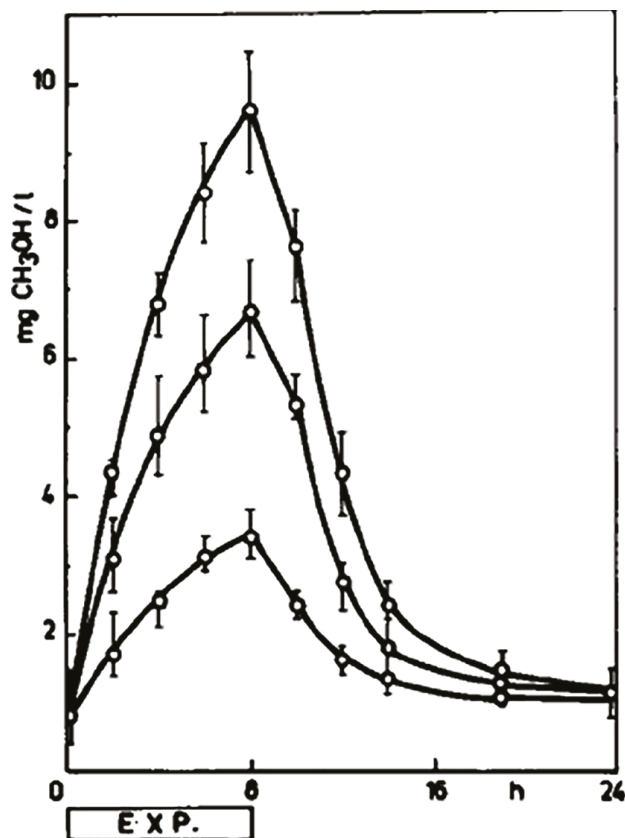


Fig. 2 Methanol excretion of four test persons during and after eight hours of exposure to 102, 205 or 300 mg methanol/m³; means with ranges (from Šedivec et al. (1981), reprinted by permission from Springer www.springer.com)

Workplace studies

The methanol concentration calculated on the basis of a regression function after an 8-hour working day exposure to 200 ml methanol/m³ is 42 mg methanol/l urine (95% confidence interval, 26–60 mg/l) (Kawai et al. 1991). The authors give the following regression equation: $c(\text{methanol in urine [mg/l]}) = 0.089 \times c(\text{methanol in the air [ml/m}^3\text{]}) + 23.56$.

Analysis of urine samples on the day after exposure showed increased methanol concentrations compared with controls, so that an accumulation of methanol over the working week should be considered.

For male workers exposed to methanol up to an 8-hour average of 2000 ml methanol/m³ and for female workers up to 4000 ml methanol/m³, a linear relationship was found between methanol exposure and the formate concentration in urine at the end of a shift. For the concentration of (1) formate or (2) methanol in urine (y), the following regression equations were given for men and women respectively:

$$(1) \quad y \text{ [mg/l]} = 0.089x \text{ [ml/m}^3\text{]} + 25.16 \text{ (} r = 0.798\text{)} \text{ or } y \text{ [mg/l]} = 0.049x \text{ [ml/m}^3\text{]} + 28.84 \text{ (} r = 0.888\text{)}$$

$$(2) \quad y \text{ [mg/l]} = 0.119x \text{ [ml/m}^3\text{]} + 2.75 \text{ (} r = 0.924\text{)} \text{ or } y \text{ [mg/l]} = 0.092x \text{ [ml/m}^3\text{]} + 14.70 \text{ (} r = 0.837\text{)}$$

where x is the 8-hour average value of methanol exposure in ml/m³. For non-exposed individuals, excretion of 1.89 ± 0.93 mg methanol/l urine and 26.2 ± 12.2 mg formate/l urine was reported (given as arithmetic mean). According to the authors' calculations, an 8-hour exposure to 200 ml methanol/m³ results in an additional excretion of 17 mg formate/l urine for men and 9.8 mg formate/l urine for women. At 100 ml methanol/m³, after eight hours, according to the calculations using the regression equations, 14.65 mg methanol/l urine for men and 23.9 mg methanol/l urine for women would result (Yasugi et al. 1992).

In another workplace study, a median excretion of 19.2 mg methanol/l urine was observed at an average exposure to 93 ml methanol/m³ (range 37–231 ml/m³) (Heinrich and Angerer 1982).

Tab. 2 Urinary concentrations of methanol and formate after inhalation exposure of test persons and workers to methanol

Methanol in air [ml/m ³]	Duration [h]	Methanol in urine [mg/l]		Formate in urine [mg/l]		References
		Control persons	Exposed persons	Control persons	Exposed persons	
Experimental studies at rest						
100	8	1.5 ± 1.2 (after 8 h) 1.1 ± 0.7 (0–8 h)	8.6 ± 5.7 (after 8 h) 5.2 ± 2.3 (0–8 h)	7.7 ± 9.3 (after 8 h) n. d.	12.9 ± 8.4 (after 8 h) n. d.	Franzblau et al. 1997
191	1.25	1.0 ± 0.4	2.2 ± 0.6	n. d.	n. d.	Cook et al. 1991
200	8	1.5 ± 1.2 (after 8 h) 1.1 ± 0.7 (0–8 h)	17.9 ± 7.9 (after 8 h) 11.0 ± 4.8 (0–8 h)	7.7 ± 9.3 (after 8 h) n. d.	13.2 ± 9.8 (after 8 h) n. d.	Franzblau et al. 1997
about 160	1 × 8 (n = 4)	mean: 0.73	6.5 (after 8 h)	n. d.	n. d.	Šedivec et al. 1981
225	1 × 8 (n = 4)	range: 0.3–2.6	9.5 (after 8 h)	n. d.	n. d.	
240	8 on 4 days (n = 3)	(17 ♂, 14 ♀)	12 ± 1 (after 8 h)	n. d.	n. d.	
200	4 (n = 25–26)	0–4 h: 0.2 ± 0.6 mg/4 h 4–8 h: 0.1 ± 0.1 mg/4 h	0–4 h: 0.9 ± 0.7 mg/4 h 4–8 h: 0.4 ± 0.2 mg/4 h	0–4 h: 1.7 ± 1.0 mg/4 h 4–8 h: 1.0 ± 1.1 mg/4 h 0–8 h: 2.7 ± 1.8 mg/4 h 0 h: 6.3 ± 3.6 4 h: 6.6 ± 4.3 8 h: 5.6 ± 3.7	0–4 h: 2.2 ± 1.7 mg/4 h 4–8 h: 1.0 ± 0.7 mg/4 h 0–8 h: 3.2 ± 2.1 mg/4 h 0 h: 6.7 ± 5.0 4 h: 7.1 ± 5.2 8 h: 6.1 ± 3.5	d'Alessandro et al. 1994; Chuwers et al. 1995; Osterloh et al. 1996
400	8	1.5 ± 1.2 (after 8 h) 1.1 ± 0.7 (0–8 h)	30.3 ± 7.2 (after 8 h) 19.3 ± 7.1 (0–8 h)	7.7 ± 9.3 (after 8 h) n. d.	19.8 ± 12.3 (after 8 h) n. d.	Franzblau et al. 1997
800	0.5 1 2 8	1.3 ± 0.8 range: 1.1–2 (according to time point)	3.2 ± 1.2 (5.8 ± 2.4 ^{ab}) 4 ± 1.4 (6.4 ± 2.8 ^{ab}) 11 ± 3.2 (13 ± 2.8 ^{ab}) 74 ± 33.5	n. d.	n. d.	Batterman et al. 1998

Tab. 2 (continued)

Methanol in air [ml/m ³]	Duration [h]	Methanol in urine [mg/l]		Formate in urine [mg/l]		References
		Control persons	Exposed persons	Control persons	Exposed persons	
Experimental studies 50 W physical activity						
100	2 (n = 8)	24-h urine: 1.15 (♂), 0.69 (♀) range: 0.42–2.76 GM: 20–30 µM = 0.64–0.96	GM: about 80 µM = 2.56 mg/l	♂: 131 mmol/24 h ♀: 224 mmol/24 h	♂: 298 mmol/24 h ♀: 104 mmol/24 h	Ernstgård et al. 2005
100	8	1.2 ± 0.7 (after 8 h) 0.9 ± 0.4 (0–8 h)	15.2 ± 14.2 (after 8 h) 8.7 ± 3.2 (0–8 h)	11.7 ± 10.5 (after 8 h) n. d.	10.0 ± 8.4 (after 8 h) n. d.	Franzblau et al. 1997
200	2 (n = 8)	24-h urine: 1.15 (♂), 0.69 (♀) range: 0.42–2.76 GM: 20–30 µM = 0.64–0.96	GM: about 200 µM = 6.4 mg/l	♂: 131 mmol/24 h ♀: 224 mmol/24 h	♂: 185 mmol/24 h ♀: 327 mmol/24 h	Ernstgård et al. 2005
200	8	1.2 ± 0.7 (after 8 h) 0.9 ± 0.4 (0–8 h)	22.5 ± 15.1 (after 8 h) 13.3 ± 6.4 (0–8 h)	11.7 ± 10.5 (after 8 h) n. d.	10.0 ± 7.6 (after 8 h) n. d.	Franzblau et al. 1997
400	8	1.2 ± 0.7 (after 8 h) 0.9 ± 0.4 (0–8 h)	46.0 ± 17.7 (after 8 h) 29.6 ± 8.6 (0–8 h)	11.7 ± 10.5 (after 8 h) n. d.	27.8 ± 21.2 (after 8 h) n. d.	Franzblau et al. 1997
Workplace studies						
93 (GM) (37–231)	8 (n = 20)	end of week shift, last 4 h: 1.1 ± 0.9 range: < 0.6–2.9 median: 1.1	21.8 ± 20.0 range: < 0.6–57.3 median: 19.2	12.7 ± 11.7 range: < 6.5–47.4 median: 8.4	29.9 ± 28.6 range: < 6.5–121 median: 20.7 no correlation with external exposure	Heinrich and Angerer 1982
Plant A: ♂: 262 ± 5.5 (GM) ♀: 223 ± 5.1 (GM) Total: 238 ± 5.2 (GM)	8	♂: 2.1 ± 0.97 (AM) ♀: 1.65 ± 0.81 (AM)	29.2 (calculated, at 200 ml/m ³) 22.3 (calculated, at 200 ml/m ³)	26.36 ± 12.98 25.96 ± 11.18	38.4 (calculated, at 200 ml/m ³) 34.0 (calculated, at 200 ml/m ³)	Yasugi et al. 1992
Plant B: ♂: 16 ± 3.4 (GM) ♀: 9 ± 1.9 (GM) Total: 14 ± 3.2 (GM); Maximum about 4000						
Maximum about 5500; calculation with regression equation for 200 16 ♂, 17 ♀	8	n = 91 1.9 ± 0.76 (AM) 1.73 (GM) (GSD: 1.62)	end of shift (8 h): 41.36 (calculated with regression equation)	n. d.	n. d.	Kawai et al. 1991

^{a)} modelled according to maximum blood concentration

AM: arithmetic mean; GM: geometric mean; GSD: geometric standard deviation; n. d.: not determined

Blood

Since the documentation of 1983, additional studies have been published in which the methanol and formate concentrations in the blood or serum of test persons or exposed workers were analysed (see Table 3). Only in one study the concentration of the lowered MAK value (100 ml methanol/m³) was used (Ernstgård et al. 2005). The detection limit of the method utilised is 0.3 µM (= 0.01 mg methanol/l blood). The authors consider the determination of methanol

concentrations in blood to be a suitable biomonitoring method. In contrast, the authors of the workplace study, which was used to derive the previously valid BAT value, point out that the parameter methanol in blood is to be regarded as specific, but not sufficiently sensitive. The determination of methanol in urine is regarded as a diagnostically more sensitive biomarker (Heinrich and Angerer 1982). The detection limit of the method used in this study is 0.6 mg methanol/l.

As can be seen from Table 3, the formate concentrations in serum are also not suitable for the derivation of a BAT value in blood.

Tab. 3 Concentrations of methanol and formate in blood or serum after inhalation exposure of test persons and workers

Exposure [ml/m ³]	Physical activity	Duration [h]	Methanol [mg/l blood]	Formate [mg/l serum]	References
100	50 W work	control	0.64 (venous) range: 0.3–2.4	n. d.	Ernstgård et al. 2005
		2 (n = 8)	3.72 (capillary blood)		
93 (37–23)	at work	control	< 0.6	n. d.	Heinrich and Angerer 1982
		8 (n = 20)	8.9 ± 14.7 median: 3.8 range: < 0.6–60.1		
191	at rest	control	0.55 ± 0.31	3.5	Cook et al. 1991
		1.25	1.88 ± 0.47	3.6	
200	50 W work	control	0.64 (venous) range: 0.3 – 2.4	n. d.	Ernstgård et al. 2005
		2 (n = 8)	7.91 (capillary blood) range: 7.3–8.3		
200	at rest	control	0.9 ± 0.6 (serum)	12.7 ± 6.4	d’Alessandro et al. 1994; Chuwes et al. 1995; Osterloh et al. 1996
		4 (n = 20 methanol, n = 26 formate)	6.5 ± 2.7 (serum)	14.3 ± 8.9	
200	at rest: 10 l/min	control	1.8 ± 1.2 (venous)	9.1 ± 1.3	Lee et al. 1992
		6	7 ± 1.2 (venous)	8.7 ± 2.4	
	exercise: 18.6 l/min	control	1.9 ± 0.9 (venous)	8.8 ± 1.8	
		6	8.1 ± 1.5 (venous)	9.5 ± 1.0	
400	at rest	control	2.65 ± 1.8	n. d.	Franzblau et al. 1995; Greim 2001
		8	13.4 ± 4.8		
800	at rest	control	1.8 ± 0.7 (venous)	n. d.	Batterman et al. 1998
		0.5	5.3 ± 1.4 (venous)		
		1	6.6 ± 1.2 (venous)		
		2	14 ± 1.5 (venous)		
		8	30.7 ± 6.9 (venous)		

n. d.: not determined

Background exposure

The background concentrations of methanol in the blood of the non-exposed test persons are on average between < 0.6 and 2.7 mg/l blood (see Table 3).

The background concentrations of methanol in the urine of non-exposed persons are on average between 0.7 and 2.1 mg/l (see Table 4).

Tab.4 Background concentrations of methanol in urine

Methanol in urine [mg/l]	References
0.7–2.3	ACGIH 2005
0.73 (0.32–2.61)	Šedivec et al. 1981
0.42–2.76	Ernstgård et al. 2005
1.15 (♂)	
0.69 (♀)	
1.0 ± 0.4	Cook et al. 1991
1.3 ± 0.8	Batterman et al. 1998
1.1 ± 0.9 (< 0.6–2.9)	Heinrich and Angerer 1982
1.9 ± 0.76 (AM)	Kawai et al. 1991
2.06 ± 0.74 (AM, ♂)	
1.33 ± 0.49 (AM, ♀)	
1.89 ± 0.93 (AM)	Yasugi et al. 1992
2.1 ± 0.97 (AM, ♂)	
1.65 ± 0.81 (AM, ♀)	

AM: arithmetic mean

Selection of Indicators

A study by Ernstgård et al. (2005) shows that the half-life in the blood is much shorter than that in urine and therefore there is no accumulation in the blood. The concentration in the blood drops very quickly immediately after the end of exposure. The concentration in the urine still increases after exposure. Due to the longer half-life in the urine, better detectability is ensured even if the level of exposure varies across the shift. The exposure over the entire shift can be better determined by analysing the concentration in the urine than by determining the concentration in the blood. Since the sampling is carried out some time after the shift, the matrix urine is more suitable than blood. Furthermore, the non-invasive sampling and thus easier availability are supporting the use of urine samples.

Re-evaluation of the BAT Value

There are not sufficient data on the direct relationship between the methanol concentration in urine and the effects that are suitable for setting a BAT value. Therefore, a derivation is made via the correlation to the MAK value of 100 ml/m³.

To derive a BAT value in urine, the experimental study by Franzblau et al. (1997) is used, since the exposure duration was eight hours at 100 ml methanol/m³ during physical activity and thus best reflects the situation at the workplace. The urinary concentration was given as 15 mg methanol/l under these conditions. Taking into account the half-life, this study does not contradict other studies with test persons (Ernstgård et al. 2005; Šedivec et al. 1981). It is also consistent with the workplace study by Heinrich and Angerer (1982), in which a median concentration of 19 mg methanol/l urine was found at external air concentrations of approx. 100 ml methanol/m³ (37–231 ml methanol/m³).

Therefore, based on the study by Franzblau et al. (1997) a

BAT value of 15 mg methanol/l urine

has been set. Sampling is at the end of exposure or end of shift; for long-term exposures at the end of the shift after several previous shifts.

When the BAT value of 15 mg methanol/l urine is not exceeded, no prenatal toxicity is to be expected.

Notes

Competing interests

The established rules and measures of the Commission to avoid conflicts of interest (https://www.dfg.de/en/dfg_profile/statutory_bodies/senate/health_hazards/conflicts_interest/index.html) ensure that the content and conclusions of the publication are strictly science-based.

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