The MAK Collection for Occupational Health and Safety

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Addendum to Toluene

Assessment Values in Biological Material – Translation of the German version from 2018

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Keywords: toluene; o-cresol; biological tolerance value; BAT value

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Addendum to Toluene

BAT value documentation

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Abstract

In 2017, the German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area derived a BAT value (biological tolerance value) for toluene [CAS NO. 108-88-3] in urine to characterize the internal exposure at the workplace. Available publications are described in detail.

The evaluation of the BAT value was based on the relationship between toluene uptake by inhalation at the level of the MAK value and the corresponding urinary excretion rate of unmetabolized toluene. An eight-hour exposure to the present MAK value of 190 mg toluene/m^3 correlated with a mean urinary toluene concentration of approximately 75 µg/L. Therefore, a BAT value of 75 µg toluene/L urine was evaluated. Sampling time is at the end of exposure or the end of the working shift.

Keywords

toluene; BAT value; biological guidance value; occupational exposure; toxicity

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Addendum to Toluene

BAT (2017)	**75 µg toluene/L urine**
	Sampling time: end of exposure or end of shift
BAT (2009)	**600 µg toluene/L blood** Sampling time: end of exposure or end of shift **1.5 mg o-cresol/L urine (after hydrolysis)** Sampling time: end of exposure or end of shift; in the case of long-term exposure: end of shift after several preceding shifts

MAK value (1993)	**50 mL/m³ ≙ 190 mg/m³**
Peak limitation (2002)	Category II, excursion factor 4
Absorption through the skin (1998)	H
Carcinogenicity	–

In 2009, the BAT values for toluene were re-evaluated and set as mean values in correlation with the MAK value for the toluene concentration in blood at the end of shift (600 µg/L blood) and the concentration of the metabolite o-cresol in urine (after hydrolysis) (1.5 mg/L urine) (see Angerer 2011).

In the meantime, a number of studies on urinary toluene as a biomarker of exposure to toluene have been published, which can be used to evaluate a BAT value. These are three experimental studies and 14 field studies of occupationally exposed individuals.

19 Re-evaluation

19.1 Metabolism and Kinetics

For detailed information on the metabolism and kinetics of toluene, please refer to the MAK Value Documentations (Greim 1993, 1998). In the following, only the elimination of unmetabolised toluene in urine will be discussed. In the study by Janasik et al. (2008), the renal excretion of toluene after four hours of exposure at rest in an exposure chamber (200 mg/m^3) was measured for 24 hours. The concentrations determined were in accordance with a two-compartment model with first-order kinetics and half-lives of 0.88 and 12.9 hours, respectively. On average, 0.0032% (0.0025–0.0049%) of the absorbed dose was excreted unchanged in urine within the first 24 hours. Ducos et al. (2008) observed that the renal excretion rate rapidly increased in six volunteers after six hours of exposure at rest in an exposure chamber at 47.1 mL/m^3, but reached steady state after three hours. In this study, 0.005% of the dose was excreted unchanged in urine.

19.2 Exposure and Effects

The correlation between airborne toluene levels and urinary toluene levels was investigated under laboratory and field conditions.

19.2.1 Experimental Studies

Table 1 summarizes the results of the experimental studies.

In the study by Ducos et al. (2008), six volunteers at rest were exposed to toluene concentrations of 10, 25 and 50 mL/m^3 in an exposure chamber. The toluene concentration in air was closely correlated with the toluene level in the urine samples at the end of exposure (r = 0.965). In the study by Janasik et al. (2008), six subjects were exposed to toluene at concentrations of 20, 60 and 100 mg/m^3 (5.3; 16; 27 mL/m^3) for eight hours. Urine samples were collected before exposure, every 2 hours during exposure and up to 24 hours from the onset of exposure. There was a very good correlation between toluene concentrations in the air and in urine samples collected during the last two hours of exposure (r = 0.998). In another study, five male subjects were exposed to toluene (Ferrari et al. 2008). After four-hour exposure at concentrations ranging between 5.1 and 42.7 mg/m^3 (1.3–11.2 mL/m^3), urinary concentrations were found to be 2.1–14.0 µg/L.

In the studies described, a concentration of 50 mL toluene/m^3 air thus corresponded to a urinary toluene concentration of 34 µg/L, 40 µg/L and 41 µg/L, respectively.

19.2.2 Occupational Health Studies

Table 2 summarizes the results of 14 occupational health field studies investigating the correlation between airborne toluene levels and urinary toluene levels. All studies showed a close correlation between toluene concentrations in the air and in workers' urine samples. In the studies, urinary concentrations between 20 and 133 µg/L corresponded to an external exposure at the level of the present MAK value of 50 mL/m^3.

19.3 Analytical Methods

In the studies described above, the analysis of toluene in urine was usually performed after extraction or enrichment by gas chromatography coupled to a mass spectrometer or a flame ionization detector. The limits of detection and quantitation of the methods described are in the range of 0.03–2 µg toluene/L urine. A GC-MS method for the determination of various aromatic compounds in urine is currently being prepared for publication by the Working Group "Analyses in Biological Materials" of the Commission.

External quality assurance for the determination of toluene in urine is achieved by participation in the interlaboratory comparison programme for occupational and environmental medical toxicological analyses (G-EQUAS) of the German Society for Occupational and Environmental Medicine (DGAUM).

Some authors have pointed out critical points regarding the sampling and storage of urine samples. Due to the risk of contamination, sampling must be performed in a room with a low atmospheric toluene concentration (Ducos et al. 2008). The sample must then be promptly transferred to the appropriate vials for analysis and stored at 4 °C or −20 °C to minimize analyte loss (Ducos et al. 2008; Fustinoni et al. 2000; Kawai et al. 1996).

19.4 Background Exposure

Table 3 shows studies investigating the background exposure of individuals not occupationally exposed to toluene. The number of subjects is small in each case. The toluene concentrations measured by Fustinoni et al. (2000) in urine samples from 18 inhabitants of Milan ranged between 0.13 and 0.29 µg/L. In another study by Fustinoni et al. (2007), toluene concentrations ranging between 0.09 and 0.59 µg/L urine (median: 0.14 µg/L; 95th percentile: 0.38 µg/L) were measured in a group of 75 individuals. A significant difference between smokers and non-smokers was not observed in this study. In studies by Ukai et al. (2007) (n = 12), Ducos et al. (2008) (n = 6) and Ferrari et al. (2008) (n = 5), the toluene concentrations measured in urine were each below the respective quantitation limit of the analytical method used (2 µg/L, 1 µg/L and 0.15 µg/L, respectively). In a study by Kawai et al. (1996), a group of office workers (n = 17) with no known toluene exposure was found to have considerably higher concentrations (geometric mean ± geometric standard deviation: 3.0 ± 1.6 µg/L) compared to the other studies.

19.5 Evaluation of a BAT Value for Toluene in Urine

On the basis of the results of the experimental studies described in the literature and of the occupational health field studies, a correlation can be established between the toluene concentration in air and in urine. Based on this correlation, the urinary toluene concentration can be determined that corresponds to an external exposure at the level of the MAK value of 50 mL/m^3. The relevant values range from 34 to 41 µg/L for the experimental studies and from 20 to 133 µg/L for the occupational health field studies.

The studies on toluene exposure conducted under experimental conditions do not seem to be suitable for evaluating a BAT value for the toluene concentration in urine. It can be assumed that, due to the lack of physical activity during the exposure chamber experiment, smaller quantities of the hazardous substance were inhaled than would be expected under occupational exposure conditions. Furthermore, the studies by Ducos et al. (2008) and Janasik et al. (2008) showed that the concentrations in the experimental studies tend to be lower and that no steady state conditions were achieved by sampling during exposure. Besides, additional percutaneous absorption must always be assumed at the workplace so that the expected workplace concentrations are higher.

The results of the occupational health field studies are generally in good agreement.

The studies by Takeuchi et al. (2002), Ghittori et al. (2004), Ukai et al. (2007) and Ducos et al. (2008) with values ranging from 69 to 85 µg toluene/L urine are of prime importance for the derivation of the BAT value as these studies boast a large number of measurements, the measured airborne concentrations include the current MAK value and take into account the use of personal protective equipment. The mean value of these studies is 76 µg toluene/L urine. The studies by Asakawa et al. (1999), Ferrari et al. (2008), Kawai et al. (1996, 2008, 2015) and Monster et al. (1993) with values ranging between 48 and 89 µg toluene/L urine also substantiate this value.

The studies by Fustinoni et al. (2000, 2007) yielded significantly lower values (20 and 24 µg/L, respectively). This was discussed by the authors in the publication and attributed to differences in the analytical method as well as sampling and sample storage.

In the studies by Ghittori et al. (1987) and Janasik et al. (2010) with values of 113 µg/L and 133 µg/L, respectively as well as 129 µg/L, dermal exposure cannot be ruled out due to a lack of information on the use of personal protective equipment.

On account of the aforementioned uncertainties, these studies are not included in the evaluation of the BAT value.

In the aforementioned studies, an eight-hour toluene exposure at the level of the currently applicable MAK value of 50 mL/m^3 corresponds to a urinary toluene concentration of

75 µg toluene/L urine.

This value is set as the BAT value.

Sampling takes place at the end of exposure or end of shift.

After toluene exposure, the BAT values of **600 µg toluene/L blood** and **1.5 mg o-cresol/L urine (after hydrolysis)** can additionally be used to assess the internal exposure (see Angerer 2011).

On the basis of the available data, at present no Biological Reference Value (BAR) can be derived for toluene in urine.

19.6 Interpretation

Contamination during sampling must be avoided. Therefore, sampling must take place in an atmosphere where the toluene concentration is as low as possible. The sample must then promptly be transferred to an appropriate headspace vial before dispatch. The vial must be tightly sealed. The sample may be stored at 4 °C until analysis or frozen when kept for more than two days.

The studies by Janasik et al. (2008), Kawai et al. (1996) and Fustinoni et al. (2000) found that relating the analytical result to the creatinine level of the sample does not yield any improvement, so that the BAT value is evaluated without relating to creatinine.

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Table 1 Experimental studies on toluene concentration in urine after exposure to toluene

Authors	Collective	Duration of exposure	Physical activity	Toluene concentration in air	Toluene concentration in urine (at the end of exposure) AM±SD (range)	Equation	r	Calculated urine concentration at 50 ml/m³ [µg/L]
Ducos et al. 2008	6 (male) subjects	6 hours	no	10, 25, 50 mL/m³	30.1 ± 6 µg/L[1)]	log y (µg/L) = 0.929 • log x (ml/m³) – 0.052 (n = 17)	0.965	34
Janasik et al. 2008	6 (male) subjects	8 hours	no	20, 60, 100 mg/m³ (5.3; 15.8; 26.3 mL/m³)	25.8 ± 15.8 µg/L[2)]	y (µg/L) = 0.41 + 0.207 • x (mg/m³) (n = 18)	0.998	40
Ferrari et al. 2008	5 (male) subjects	4 hours	n. s.	5.1–42.7 mg/m³ (1.3–11.2 mL/m³)	(2.1–14.0 µg/L)	log y (µg/L) = 0.88 • log x (mg/m³) – 0.39 (n = 5)	0.96	41

[1)] at 47.1 mL/m³; additional sampling every 2 hours during exposure
[2)] at 100 mg/m³; additional sampling after 6 hours of exposure
n. s. = not specified, AM = arithmetic mean, SD = standard deviation

Table 2 Field studies on toluene concentration in urine after occupational exposure to toluene

Authors	Collective/ workplace	Duration of exposure/ Sampling	Information on PPE	Toluene concentration		Equation	r	Calculated urine concentration at 50 mL/m³
				Air	Urine			
				GM ± GSD (range)	GM±GSD (range)			[µg/L]
Ghittori et al. 1987	n = 80 men	4 hours	n. s.	n. s.	n. s.	y (µg/L) = 0.60 • x (mg/m³) – 1.4	0.87	113
Monster et al. 1993	n = 9 23–51 years printing plant	8-h shift	no masks, no gloves (dermal exposure Ø estimated 5 min)	(27.3–609 mg/m³)	n. s.	y (µg/L) = 0.372 • x (mg/m³) + 17.9	0.92	89
Kawai et al. 1996	n = 115 men 2 plants: adhesive tape production and production of kitchenware	8-h shift	n. s.	3.9 ± 6.05 mL/m³ max: 98 mL/m³	n. s.	y (µg/L) = 1.523 • x (mL/m³) + 2.284	0.843	78
Asakawa et al. 1999	n = 27 men printing plant	n. s.	n. s.	10.6 mL/m³ (0.8–33,6 mL/m³)	AM 11.9 µg/L (<LOQ–44.5 µg/L)	y (µg/L) = 0.91 • x (mL/m³) + 2.34	0.820	48

Table 2 (continued)

Authors	Collective/ workplace	Duration of exposure/ Sampling	Information on PPE	Toluene concentration		Equation	r	Calculated urine concentration at 50 mL/m³
				Air	Urine			
				GM ± GSD (range)	GM±GSD (range)			[µg/L]
Fustinoni et al. 2000	n = 29 men 24–58 years printing plant	7 hours	PPE available, use not documented	80 mg/m³ (3–309 mg/m³)	Median 13 µg/L (5–47 µg/L)	y (µg/L) = 3.969 + 0.108 • x (mg/m³)	0.753	24
Takeuchi et al. 2002	n = 97 15 women, 82 men 19–65 years furniture manufacturing (11 without occupational exposure)	8-h shift	no gloves, no masks	4.2 ± 3.0 mL/m³ (0.4–54.3 mL/m³)	9.8 ± 2.3 µg/L (2.1–97.8 µg/L)	y (µg/L) = 6,06 + 1,26 • x (mL/m³)	0.740	69
Ghittori et al. 2004	n = 36 men 38.1 ± 12.6 years chemical industry	8-h shift	gloves, no masks	39.8 ± 2.2 mg/m³ (13.0–191.2 mg/m³)	28.51 ± 1.69 µg/L (8.75–114.4 µg/L)	y (µg/L) = 13.37 + 0.38 • x (mg/m³)	0.846	85
Fustinoni et al. 2007	n = 100 men 36 ± 8 years printing plant	7-h shift	n. s.	AM 56.7 ± 36.9 mg/m³ (6.0–162.0 mg/m³)	AM 8.7 ± 5.0 µg/L (1.8–23.9 µg/L)	log y (µg/L) = −0.262 + 0.685 • log x (mg/m³)	0.844	20

Table 2 (continued)

Authors	Collective/ workplace	Duration of exposure/ Sampling	Information on PPE	Toluene concentration: Air GM ± GSD (range)	Toluene concentration: Urine GM±GSD (range)	Equation	r	Calculated urine concentration at 50 mL/m³ [µg/L]
Ukai et al. 2007	n = 122 men 34.9 ± 11.4 years 6 plants: 4x printing plant, 1x production of inks, 1x adhesive tape production	8-h shift	gloves no masks	10.4 ± 4.3 mL/m³ (0.2–120.8 mL/m³)	12.9 ± 4.81 µg/L, (<LOD–204 µg/L)	y (µg/L) = 1.47 • x (mL/m³) – 0.6	0.83	73
Ducos et al. 2008	29 workers at printing plants examined over the course of one week (n = 94) 2 printing plants	at the end of shift	determination of dermal exposure	Median: 32 mL/m³ AM: 46.5 mL/m³ (3.6–148 mL/m³)	(5.9–230 µg/L)	Log y (µg/L) = 0.353 + 0.898 • log x (mL/m³)	0.921	76
Ferrari et al. 2008	n = 36 men 39.5 ± 14.3 years synthetic leather industry	4 hours (at the end of the first half-shift)	n. s.	7.29 ± 4.06 mg/m³ (0.22–57.20 mg/m³)	5.55 ± 2.70 µg/L (0.47–26.64 µg/L)	y (µg/L) = log x (mg/m³) • 0.68 + 0.14	0.93	49
Kawai et al. 2008	n = 473 men 18–58 years adhesive tape production	8-h shift	n. s.	1.6 ± 3.8 mL/m³ (<LOD–26.5 mL/m³)	4.4 ± 2.6 µg/L (<LOD–59.9 µg/L)	y (µg/L) = 2.3 + 1.34 • x (mL/m³)	0.67	69

Table 2 (continued)

Authors	Collective/ workplace	Duration of exposure/ Sampling	Information on PPE	Toluene concentration		Equation	r	Calculated urine concentration at 50 mL/m³
				Air GM ± GSD (range)	Urine GM±GSD (range)			[µg/L]
Janasik et al. 2010	Collective I: n = 19 paint factory	at the end of shift	n. s.	1.1 ± 2.2 mg/m³ (0.2–4.7 mg/m³)	2.0 ± 1.7 µg/L	y (µg/L) = 0.69 • x (mg/m³) + 1.44	0.72	133
	Collective II: n = 35 footwear factory		n. s.	105.4 ± 1.8 mg/m³ (31.9–349.4 mg/m³)	228.1 ± 1.7 µg/L	y (µg/L) = 0.71 • x (mg/m³) – 5.5	0.91	129
Kawai et al. 2015	Collective I: 211 men 40.7 ± 12.5 years furniture manufacturing	8-h shift	n. s	3.07 ± 3.58 mL/m³ max: 103.9 mL/m³	8.62 ± 2.27 µg/L max: 98.0 µg/L	y (µg/L) = 0,96 • x (ml/m³) + 8.21	0.753	57
	Collective II: 52 women 52.9 ± 7.9 years furniture manufacturing		n. s	4.20 ± 4.04 mL/m³ max: 163.2 mL/m³	14.04 ± 2.43 µg/L max: 225.7 µg/L	y (µg/L) = 1.26 • x (ml/m³) + 8.92	0.885	72

n. s. = not specified, AM = arithmetic mean, GM = geometric mean, GSD = geometric standard deviation, LOD = limit of detection of the analytical method, PPE = personal protective equipment

Table 3 Studies on background levels of toluene in the urine of individuals not occupationally exposed to toluene

Authors	Collective	Toluene concentration in urine
Kawai et al. 1996	n = 17 men office workers with no known occupational exposure to toluene recruited at plants participating in an occupational health field study	GM ± GSD: 3.0 ± 1.63 µg/L 95^{th} Upper Limit: 8.3 µg/L
Fustinoni et al. 2000	n = 18 (inhabitants of Milan)	Median 0.20 µg/L (0.13–0.29 µg/L)
Fustinoni et al. 2007	n = 75 random sample from the control group, n = 161; ♀ 82, ♂ 79; Age: 37 ± 10 years	AM ± SD: 0.166 ± 0.088 µg/L Median: 0.140 µg/L 95^{th} percentile: 0.379 µg/L Range: 0.094–0.593 µg/L
Ukai et al. 2007	n = 12 non-exposed men	<LOQ (2 µg/L)
Ferrari et al. 2008	n = 5 men before exposure chamber experiment	<LOQ (0.15 µg/L)
Ducos et al. 2008	n = 6 men before exposure chamber experiment	<LOQ (1 µg/L)

AM = arithmetic mean, GM = geometric mean, GSD = geometric standard deviation, LOQ = limit of quantitation of the analytical method

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