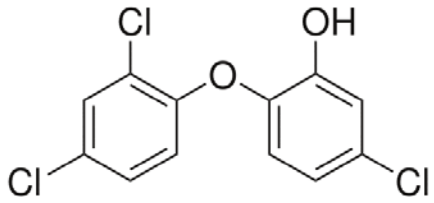
Derivation of **HBM value for** **TRICLOSAN** **based on** **BE – documentation**			
Substance	5-chloro-2-(2,4-dichlorophenoxy)phenol		
Parameter	**Value / Descriptor**	**Dimension**	**Comments**
HBM Guide value			
Guide value II (HBM-II, Health hazard value)	-	mg/l	not derived
Guide value I (HBM-I, Precautionary value)	children: 2 adults: 3	mg/l	(morning) urine, total triclosan (rounded value)
Year of issue	2015		
status	final		
General Information			
CAS No. substance	3380-34-5		
IUPAC name	5-chloro-2-(2,4-dichlorophenoxy)phenol		
Molar mass substance	289,53	g/mol	
HBM-parameter (metabolites)	total triclosan (urine)		
Molar mass HBM-parameter	289,53	g/mol	
Database			
Tolerable intake (TDI, RfD or comparable)	-		
Key study: Author(s) (Year)	DeSalva et al. (1989) [1]		
Species	rats		
Route/type of study	oral		
Study length (Exposure duration)	2 years		
Exposure pattern	via diet		
Critical endpoint/ effect	haematotoxicity; decrease in spleen weight		
POD_{HBM-I}	**12**	**mg/(kg bw x d)**	**NOAEL [2, 3]**
Assessment factors			**used by the HBM Commission**
Dose-response assessment factor	n.a.		
Severity of effect	-		
Adjusted exposure duration factor (time scaling)	n. a.		Oral study
Adjusted study length factor	n.a.		Chronic study
Route-to-route extrapolation factor	n. a.		
Adjusted absorption factor	n. a.		
Interspecies factor	4		allometric

	2,5		dynamic
Intraspecies factor	10		general population
Sensitive population factor	1		
Other adjustment factors e.g. quality of whole database	-		
Total assessment factor (TAF)	**100**		
Kinetik terms			
fue	0,54 [4]		fraction of dose excreted in urine, molar basis
Urine volume	0.02 0.03	L/(kg bw x d) L/(kg bw x d)	adults children
Result (Calculation)			
PoD_{HBM-I}/TAF (TDI analog)	0,12	mg/(kg bw x d)	12/100
Kinetic extrapolation and HBM value calculation	children: 0,12 x 0,54/ 0,03 = 2,2 adults: 0,12 x 0,54/ 0,02 = 3,2	mg/L	
Management			
The values apply to children or adults, respectively. If the HBM values are exceeded a check-up will be necessary at first.			

Rationale

The HBM Commission decided that HBM values may be derived amongst others from Biomonitoring Equivalents (BE values) [5]. This decision has been documented in two publications [6, 7].

Triclosan is a lipophilic, broad spectrum antimicrobial agent, which is used in many personal care products like toothpaste, shower gel etc. and in consumer products like textiles, toys etc..

This HBM value is based on the BE value for triclosan [8]. The NOAEL used for the calculation of BE and HBM-I values is 12 mg/kg bw /d, which has been derived by SCCP of the European Commission [2]. This value has been confirmed by SCCS in 2011 [3].

Monitoring studies, like the NHANES survey, indicate that at least in western countries the general population, without occupational exposure, is exposed to triclosan [9]. Within the NHANES survey 2009-2010, median and 95th percentile of the triclosan concentration in urine samples of the US population (n=2749) was 10.7 µg/l and 483 µg/l.

Tab. 1: NHANES 2009-2010 Triclosan concentrations in children and adults compared to HBM-I value. Margin of Safety is calculated as the ratio of the HBM-I value to the biomarker concentration.

Population	n	HBM-I	GM, mg/L	95th%ile. mg/L	MOS at GM	MOS at 95th %ile
Children, 6-11	415	2.16	0.0109	0.200	198	10.8
Adults, 20+	1914	3.24	0.0155	0.544	209	6.0

The time trend of Triclosan in the urine of the German general population was established by analyzing 660 urine samples of the German environmental specimen bank from the years 1995, 1997, 1999, 2001, 2003, 2005, 2006, 2007, 2008, 2009 und 2012. From each year 30 samples of males and 30 samples of females were analyzed. The samples came predominantly from 20 to 30 years old students of the university of Münster. Triclosan could be detected in all 660 samples measured. The median concentration for the analyzed years

ranged from 0,50 µg/L to 3,20 µg/L, the median concentration for the whole period was 1,37 µg/L. No differences between males and females could be determined. A time trend was not detectable for the survey period 1995-2012. Thus up to 2012 the analysis of urine samples of the German environmental specimen bank shows on the one hand lower values than for the American population but on the other hand does not reflect the voluntary waiver declaration of the producers.

Literature

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