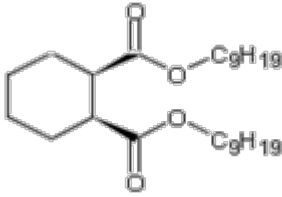


FACTSHEET Hexamoll® DINCH®			
Chemical name	Diisononylcyclohexane-1,2-dicarboxylate		
Parameter	Value / Descriptor	Dimension	Comments
HBM Guide value			
Guide value I (HBM-I: Precautionary value)	Sum of OH-MINCH and cx-MINCH: Adults: 4,5 Children: 3	mg/L	urine
Year of issue	2014		
Status	published		Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz 12 · 2014
General Information			
CAS No.	4741 9-59-0		
IUPAC name	1,2-Cyclohexane dicarboxylic acid di(isononyl)ester		
Molar mass	424,7	g/mol	
HBM-parameter	OH-MINCH, cx-MINCH		specific oxidized metabolites
Molar mass OH-MINCH, cx-MINCH	314, 328; mean 321	g/mol	
Database			
TDI (EFSA 2006)	1	mg/kg bw/d	HBM-Commission decided to use the TDI value
RfD (Bhat et al. 2014)	0.7	mg/kg bw/d	
Critical endpoint/ effect	a) Nephrotoxicity: Hematuria, degenerated cells of the transitional epithelium in the urine b) Nephrotoxicity: vacuolization of the tubular epithelium (F1, m) c) Bhat: thyroid hypertrophy/hyperplasia in adult F1 rats exposed in utero (EPA/IARC criteria)		a) NOAEL 107 mg/kg bw/d b) NOAEL 100 mg/kg bw/d c) BMDL _{10HED} 21 mg/kg bw/d
Kinetik terms			
Factor for metabolic conversion (Fue)	Sum of OH-MINCH and cx-MINCH: 0,1276		
Proportion molar mass metabolites to molar mass DINCH®	0,75		[(OH-MINCH + cx-MINCH) : 2]/ DINCH = [(314 + 328) : 2]/424,7 = 0,75
Urine volume	Children: 0,03 Adults: 0,02	L/(kg bw · d)	
Result			
Calculated HBM-values	Children: (1 × 0,75 × 0,1276)/0,03 = 3,19 →rounded: 3 Adults: (1 × 0,75 × 0,1276)/0,02 = 4,79 →rounded: 4,5	mg/L	[TDI-value x (molecular weight metabolites/molecular weight DINCH) x Fue]/urine volume

Management
If the HBM value is exceeded firstly a check-up will be necessary.

HED: human equivalent dose

Rationale:

Diisononyl cyclohexane-1,2-dicarboxylate (DINCH®) is mainly used as a plasticizer for the manufacturing of several products including toys and medicinal products. In addition it is authorised to be used in food contact materials. Since 2003 the substance has been detected in household dust samples.

A TDI-value of 1 mg/(kg bw · d) has been derived by the European Food Safety Authority (EFSA).

Based on the results of human metabolism studies, which were performed within the context of the BMUB/VCI-project, oxidised monoester (OH-MINCH, cx-MINCH) could be identified as robust and conclusive biomarkers for DINCH. Using these biomarkers a HBM-I-value of 3 mg/L urine for children and 4.5 mg/L urine for adults could be derived from the TDI.