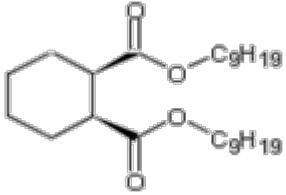


|  |   |                  |  |
|--|---|------------------|--|
| <b>FACTSHEET</b><br>Hexamoll® DINCH®                         |   |                  |  |
| <b>Chemical name</b>   | <b>Diisononylcyclohexane-1,2-dicarboxylate</b>  |                  |  |
| <b>Parameter</b>   | <b>Value / Descriptor</b>   | <b>Dimension</b> | <b>Comments</b>  |
| <b>HBM Guide value</b>                                       |   |                  |  |
| Guide value I (HBM-I:<br>Precautionary value)                | Sum of OH-MINCH and<br>cx-MINCH:<br>Adults: 4,5<br>Children: 3  | mg/L             | urine  |
| Year of issue  | 2014  |                  |  |
| Status   | published   |                  | Bundesgesundheitsblatt -<br>Gesundheitsforschung - Gesundheitsschutz<br>12 · 2014                    |
| <b>General Information</b>                                   |   |                  |  |
| CAS No.  | 4741 9-59-0   |                  |  |
| IUPAC name   | 1 ,2-Cyclohexane<br>dicarboxylic acid<br>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            |  |
| <b>Database</b>  |   |                  |  |
| TDI (EFSA 2006)  | 1   | mg/kg bw/d       | HBM-Commission decided to use the TDI<br>value   |
| RfD (Bhat et al. 2014)                                       | 0.7   | mg/kg bw/d       |  |
| Critical endpoint/ effect                                    | a) Nephrotoxicity:<br>Hematuria, degenerated<br>cells of the transitional<br>epithelium in the urine<br>b) Nephrotoxicity:<br>vacuolization of the tubular<br>epithelium (F1, m)<br>c) Bhat: thyroid<br>hypertrophy/hyperplasia in<br>adult F1 rats exposed in<br>utero (EPA/IARC criteria) |                  | a) NOAEL 107 mg/kg bw/d<br><br>b) NOAEL 100 mg/kg bw/d<br><br>c) BMDL <sub>10HED</sub> 21 mg/kg bw/d |
| <b>Kinetik terms</b>   |   |                  |  |
| Factor for metabolic conversion<br>(Fue)                     | Sum of OH-MINCH and<br>cx-MINCH:<br>0,1276  |                  |  |
| Proportion molar mass<br>metabolites to molar mass<br>DINCH® | 0,75  |                  | $[(\text{OH-MINCH} + \text{cx-MINCH}) : 2] / \text{DINCH} = [(314 + 328) : 2] / 424,7 = 0,75$        |
| Urine volume   | Children: 0,03<br>Adults: 0,02  | L/(kg bw · d)    |  |
| <b>Result</b>  |   |                  |  |
| Calculated HBM-values  | Children: $(1 \times 0,75 \times 0,1276) / 0,03 = 3,19$<br>→rounded: 3<br>Adults. $(1 \times 0,75 \times 0,1276) / 0,02 = 4,79$<br>→rounded: 4,5  | mg/L             | [TDI-value x (molecular weight<br>metabolites/molecular weight DINCH) x<br>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-l-value of 3 mg/L urine for children and 4.5 mg/L urine for adults could be derived from the TDI.