# FACTSHEET

**Hexamoll® DINCH®**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value / Descriptor</th>
<th>Dimension</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HBM Guide value</strong></td>
<td></td>
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<tr>
<td>Guide value I (HBM-I: Precautionary value)</td>
<td>Sum of OH-MINCH and cx-MINCH: Adults: 4,5 Children: 3</td>
<td>mg/L</td>
<td>urine</td>
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<td><strong>Year of issue</strong></td>
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<td>2014</td>
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<td><strong>Status</strong></td>
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<td></td>
<td>published</td>
<td>Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz 12 · 2014</td>
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## 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

## Database

- **TDI (EFSA 2006)**: 1 mg/kg bw/d
- **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)

## 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
- **Urine volume**: Children: 0,03 Adults: 0,02 L/(kg bw · d)

## Result

<table>
<thead>
<tr>
<th>Calculated HBM-values</th>
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<tbody>
<tr>
<td>Children: (1 × 0,75 × 0,03)/0,1276/0,03 = 3,19 →rounded: 3</td>
<td>mg/L</td>
<td>TDI-value x (molecular weight metabolites/molecular weight DINCH) x Fue/urine volume</td>
</tr>
<tr>
<td>Adults: (1 × 0,75 × 0,02)/0,1276/0,02 = 4,79 →rounded: 4,5</td>
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</tbody>
</table>

## Database

- **TDI (EFSA 2006)**: 1 mg/kg bw/d
- **RfD (Bhat et al. 2014)**: 0.7 mg/kg bw/d

## Critical endpoint/ effect

- a) NOAEL 107 mg/kg bw/d
- b) NOAEL 100 mg/kg bw/d
- c) BMDL-10%(ED): 21 mg/kg bw/d
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.