Hexamoll® DINCH® for medical applications

Rely on safe treatment

The non-phthalate plasticizer for maximum safety
Hexamoll® DINCH® offers the highest level of safety for medical devices

What are plasticizers?
Plasticizers are added to rigid PVC (Polyvinylchloride) to turn it from being hard and brittle to soft and flexible.

One size does not fit all!
Plasticizers are used in a wide area of applications, ranging from industrial applications like electrical underground cables to sensitive applications like medical devices. Based on the diverse and different needs of each application area, the requirements for plasticizers hence differ. Some products are made to withstand extreme temperatures, some make plastics very resistant to physical and environmental stress and others are specially designed for close human contact applications. BASF offers a range of plasticizers suitable for various applications and is convinced that its plasticizers are safe for its intended use.

Hexamoll® DINCH® is the safe plasticizer for intensive human contact
Sensitive applications, such as medical devices, have very special requirements. During medical treatment, patients come into close contact with medical devices. For patients who undergo intensive medical treatment, they could be exposed to medical devices for a prolonged period of time. Therefore it is crucial that safe raw materials are used in the manufacture of medical devices. BASF has developed the non-phthalate plasticizer Hexamoll® DINCH® (Cyclohexane-1,2-dicarboxylic acid diisononylster), which is specially formulated for sensitive applications.

Due to its excellent toxicological profile and low migration rate, Hexamoll® DINCH® offers a maximum level of safety. It can be used as a safe substitute for traditional phthalates in sensitive applications.

Meeting stringent requirements in sensitive applications? Hexamoll® DINCH® - the highest level of safety where it counts. At BASF, we don’t just make chemicals – we create chemistry.
**Sensitive application areas for disposable medical devices**

BASF recommends exclusively Hexamoll® DINCH® in sensitive applications:

<table>
<thead>
<tr>
<th>Application</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis</td>
<td>Blood contact devices are typically used in dialysis tubes, where patients are undergoing treatment several times per week for a prolonged time. Due to the prolonged exposure it is important to use the safest raw materials possible. Hexamoll® DINCH® is perfectly suited due to its low migration rate.</td>
</tr>
<tr>
<td>Intravenous therapy</td>
<td>During intravenous therapy, solutions come into contact with PVC bags and tubing before they enter the human body. Using Hexamoll® DINCH® ensures minimal migration of plasticizers from the storage container to the solution.</td>
</tr>
<tr>
<td>Blood bags</td>
<td>Safety is of high importance when using blood storage bags made with plasticizers for treatment of newborns, young children and patients who require frequent transfusions. Several studies have shown that blood storage containers with Hexamoll® DINCH® can preserve the function and viability of platelets and red blood cells. Hexamoll® DINCH® is a safe choice for applications with blood contact.</td>
</tr>
<tr>
<td>Masks</td>
<td>Breathing masks come in close contact with the skin as well as the saliva of the patients. Hexamoll® DINCH® has a low tendency to be extracted by saliva, as compared to conventional products.</td>
</tr>
<tr>
<td>Enteral feeding</td>
<td>Safe enteral feeding sets are very important for patients who depend on feeding. Furthermore, the plasticizer should not migrate into the feeding solution. Hexamoll® DINCH® is the best choice due to its low migration.</td>
</tr>
<tr>
<td>Catheters</td>
<td>Catheters are placed inside the human body. Hexamoll® DINCH® ensures that the risk of migration into the body is kept at an absolute minimum.</td>
</tr>
<tr>
<td>Gloves</td>
<td>Many medical professionals wear gloves on a daily basis. These have to be comfortable and stretchable whilst ensuring a low migration rate.</td>
</tr>
</tbody>
</table>
Excellent toxicological profile

Hexamoll® DINCH® is the alternative plasticizer for sensitive applications. BASF has invested over EUR 5 million in toxicological research thus far to meet the most recent OECD guidelines. Hexamoll® DINCH® is the best researched non-phthalate plasticizer. In addition, it is the most eco-efficient among the five most frequently used non-phthalate plasticizers in the market.

Hexamoll® DINCH® has an excellent toxicological profile with no relevant hazards for the following endpoints:

<table>
<thead>
<tr>
<th>Environmental hazards</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroxisome proliferation</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Reproductive hazard</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Testicular toxicity</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Impairment of fertility</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Developmental toxicity</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Teratogenicity</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Endocrine action</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Accumulation within the body</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

1 The statement that Hexamoll® DINCH® is the best researched non-phthalate plasticizer is based on an assessment of acute toxicity, skin irritation, eye irritation, sensitization, repeated dose toxicity, genotoxicity in vitro, genotoxicity in vivo, carcinogenicity, toxicity to reproduction (developmental toxicity, fertility), acute aquatic toxicity, biodegradation and bioconcentration, according to the applicable OECD guidelines effective as of November 2011.

2 www.oeea.de
Outstanding technical properties

- Low viscosity
- Low density
- No inherent smell
- Low volatility
- Good cold flexibility

Our commitment

- Global supply security from a dedicated plant in Germany
- Capacity increased from 25,000 tons/year to 100,000 tons/year in 2007
- Second production plant and further increase to 200,000 tons/year by 2013
- Dedicated infrastructure assures highest quality

Hexamoll® DINCH® complies with a wide range of regulatory requirements:

Food contact
- German BfR – Plastic recommendation for food contact
- Switzerland (list II, Annex 1 of “Verordnung des EDI über Bedarfsgegenstände” (SR817.023.021))
- Japan Hygienic PVC Association (JHPA)
- Chinese Standard GB 9685-2008
- Australia NICNAS
- Korea

Toys
- EN 71-3
- EN 71-5
- EN 71-9

Medical Devices
- CEN EN ISO 10993-17(2002): Safety evaluation
- Directive 2007/47/EC

Duties lie with product manufacturer for individual approvals and for compliance with the respective national legislation.
**Hexamoll® DINCH® is registered for REACH**

Hexamoll® DINCH® complies with stringent laws and standards. The use of Hexamoll® DINCH® to produce medical devices complies with EU Council Directive 93/42/EEC, DIN EN ISO 10993, United States Pharmacopeia (USP), Monograph 88, Class VI and FDA Medical Device Master File (No. 1484). The alternative plasticizer offers the highest level of safety and is REACH registered. There is an increasing trend in Asia-Pacific following regulations and movements in US and EU regarding the use of plasticizers in sensitive applications.

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**At a Glance: Hexamoll® DINCH® is especially qualified for sensitive applications**

1. Complete set of regulatory studies regarding physico-chemical, ecotoxicological and toxicological studies available

2. All studies have been conducted within the last years according to the most recent versions of the OECD/EU testing guidelines

3. External study reviews by authorities such as EU’s EFSA, SCENIHR and Australia’s NICNAS are published

4. Specific regulatory requirements can be met

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3. Duties lie with product manufacturer for individual approvals and for compliance with the respective national legislation.
4. REACH : REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006). It deals with the Registration, Evaluation, Authorization and Restriction of Chemical substances.
BASF is the world’s leading chemical company: The Chemical Company. Its portfolio ranges from chemicals, plastics, performance products and crop protection products to oil and gas. We combine economic success, social responsibility and environmental protection. Through science and innovation we enable our customers in almost all industries to meet the current and future needs of society. Our products and system solutions contribute to conserving resources, ensuring healthy food and nutrition and helping to improve the quality of life. We have summed up this contribution in our corporate purpose: We create chemistry for a sustainable future. BASF posted sales of about €73.5 billion in 2011 and had more than 111,000 employees as of the end of the year. BASF shares are traded on the stock exchanges in Frankfurt (BAS), London (BFA) and Zurich (AN). Further information on BASF is available on the Internet at www.basf.com.
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