Hexamoll® DINCH®

The trusted non-phthalate plasticizer for medical devices

BASF
The Chemical Company
During medical treatment, patients come into close contact with medical devices. When manufacturing medical devices, it is therefore crucial that raw materials are used that adhere to strict toxicological and regulatory requirements.

BASF has developed the non-phthalate plasticizer Hexamoll® DINCH®, especially aimed for applications with close human contact. Hexamoll® DINCH® is perfectly suited for medical device applications, due to its excellent toxicological profile and a very low migration rate.

This plasticizer has been globally available since 2002 and is successfully used in applications with close human contact, such as toys, medical devices, food packaging, sports equipment, wall covering and flooring.

HEXAMOLL® DINCH® –
OUR COMMITMENT TO YOUR INDUSTRY

- The trusted non-phthalate plasticizer with excellent toxicological profile and a complete set of regulatory and toxicological studies
- The plasticizer with superior technical properties, such as improved cold flexibility and minimal migration rate
- Global supply security from two separately operating plants with a capacity of 200,000 metric tons per year
- High quality standards for product control, preloading inspection and traceability throughout BASF’s production and supply chain
- Global technical support from BASF experts in Asia, Europe and North America
Hexamoll® DINCH® films used to manufacture blood bags show excellent technical properties:

- Excellent HF (high frequency) weldability
- High retention of mechanical properties of the medical device after sterilization processes (e.g. water vapor, Ethylene Oxide, gamma-irradiation)
- Low melt viscosity in extrusion processes (e.g. calendering, tube extrusion)

Safety is of high importance when using blood storage bags made with plasticizers for treatment of newborns, young children and patients who require transfusions. Several studies, including studies on the intravenous route, have shown that blood storage containers with Hexamoll® DINCH® can preserve the function and viability of platelets and red blood cells.

HEXAMOLL® DINCH® WAS AWARDED THE SOLVIN AWARD SPECIAL PRIZE IN 2013 AS A SUBSTITUTE FOR DEHP IN BLOOD PRODUCT CONTAINERS.
In dialysis treatment, blood contact devices such as dialysis tubes are typically used for an extended period of time. Due to the prolonged exposure of patients to the medical device, it is important to use intensively tested raw materials. Hexamoll® DINCH® is well suited due to its low migration rate.

During intravenous therapy, pharmaceuticals come into contact with PVC bags and tubing before they enter the human body. Using Hexamoll® DINCH® helps minimize migration of plasticizers from the storage container to the pharmaceuticals.

Enteral feeding sets are very important for patients who depend on feeding. Its unique performance makes Hexamoll® DINCH® the perfect choice, because it reduces the migration of the plasticizer into the feeding solution.

Hexamoll® DINCH® is approved for specific applications by manufacturers and competent authorities and fulfills several legal requirements for use in sensitive applications:

- DIN EN ISO 10993
- United States Pharmacopeia (USP), Monograph 88, Class VI
- FDA Medical Device Master File (No. 1484)
- CFDA (China Food and Drug Administration)
- Japan MHLW (Ministry of Health, Labour and Welfare)

External study reviews during the notification process and by the EU’s EFSA and SCENIHR, the Health Advisory Board of the US NSF and also by other competent authorities, such as Australia’s NICNAS or the Chinese Food and Drug Administration to support the excellent toxicological profile.

Hexamoll® DINCH® offers a complete set of regulatory requirements, including physico-chemical, ecotoxicological and toxicological studies. They are conducted according to the most recent versions of the OECD/EU testing guidelines.

BASF initiated additional studies on the intravenous route to support the safe use of Hexamoll® DINCH® in medical devices.
About BASF
At BASF, we create chemistry – and have been doing so for 150 years. Our portfolio ranges from chemicals, plastics, performance products and crop protection products to oil and gas. As the world’s leading chemical company, we combine economic success with environmental protection and social responsibility. Through science and innovation, we enable our customers in nearly every industry to meet the current and future needs of society. Our products and solutions contribute to conserving resources, ensuring nutrition and improving quality of life. We have summed up this contribution in our corporate purpose: We create chemistry for a sustainable future. Further information on BASF is available on the Internet at www.basf.com
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