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Hexamoll® DINCH

Petrochemicals
June 2017

Certificate for Use in Medical Devices

We hereby confirm Hexamoll® DINCH is suitable to produce medical devices that comply with **Regulation (EU) 2017/745**. In addition, the use of Hexamoll® DINCH is not subject to the phthalate labelling requirements of medical devices.

Hexamoll® DINCH based medical devices produced by customers passed the respective tests according to **DIN EN ISO 10993**, e.g. cytotoxicity (ISO 10993-5), haemolysis (ISO 10993-4), absence of pyrogens (ISO 10993-11), irritation and sensitisation (ISO 10993-10 and ISO 10993-10/A).

Furthermore, PVC compound based on Hexamoll® DINCH passed the systemic injection, intracutaneous and implant tests to fulfill the requirements of **United States Pharmacopeia (USP), Monograph 88, Class VI.**

No cytotoxicity occurred with Hexamoll® DINCH up to the highest concentration tested (1000 µg/ml) in the Balb 3T3 cellular in-vitro test system. Further, all regulatory mandated studies undertaken with Hexamoll® DINCH in the framework of chemicals legislations did not show any indication for cytotoxicity. In the meantime, lack of cytotoxicity is also confirmed by independent third party studies as published in peer-reviewed journals.

For the United States of America, **FDA Medical Device Master Files (Nos. 1484 and 16323)** can be referred to, e.g. in a 510(k) pre-marketing notification.

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Note:
These statements are based on our current knowledge and experience. In view of many factors that may affect processing and application of our product, this does not relieve processors from carrying out their own investigations and tests; neither does it imply any guarantee of certain properties, nor the suitability of the product for a specific purpose. It is the responsibility of the recipient of our products to ensure that any proprietary rights and existing legislation are observed. ® = registered trademark of BASF.