Regulatory Technical Bulletin

January 2004

Standard: ISO 10993-Biological Evaluation of Medical Devices with human tissue contact time (30 days or less)
Test Product: Ingeo Hydroentanglement fiber - Hygiene Wipes

The suitability of Cargill Dow LLC product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Cargill Dow LLC product, used in its final product in order to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

To help understand the biological interaction of Ingeo Hydroentanglement fiber for Hygiene Wipes, Cargill Dow LLC has conducted testing according to international standards. Huntingdon Life Sciences conducted all testing in compliance with Good Laboratory Practices (GLP) standards and the data generated is considered to be valid. The following formulation was evaluated:

>99% Cargill Dow LLC Ingeo Fiber
0.35% Lurol PL-809 (Goulston Technologies, Inc.)
0.09% Lurol PL-811 (Goulston Technologies, Inc.)

The following are the result from the biological evaluation of the above formulation:

Study: Eye Irritation to the Rabbit (BS EN ISO 10993-10, (1996)
Results: Polar and Non-Polar extracts from the above formulation had ocular scores of 0.0, thus it does not require labeling with the risk phrase R36 in accordance with Commission Directive 2001/59/EEC

Study: Cytotoxicity using elution technique ISO 10993-5, (1999)
Results: The neat eluate from sample of above formulation was non-toxic to MRC-5 cells.

Study: Skin irritation potential BS EN ISO 10993-10 (1996)
Results: No dermal reaction was observed at the test site of any animal throughout the duration of the study. Above formulation was classed as a negligible irritant in accordance with the criteria of ISO 10993-10.

Study: Skin sensitization potential BS EN ISO 10993-10 (1996)
Results: These results indicate that the above formulation does not elicit a sensitisation response in the guinea pig, there being no reaction observed at challenge.

This data is based on our current level of knowledge and covers above formulation only. Since conditions of use are outside of Cargill Dow LLC control, Cargill Dow LLC makes no warranty, expressed or implied, and assumes no liability in connection with any use of this information.

Cargill Dow LLC products have not been designed for nor are they promoted for end uses that would be categorized by either the United States FDA or by the International Standards Organization (ISO) as implant devices. Cargill Dow LLC products are not intended for use in the following applications: (1) in any bodily implant applications, or (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices, or (3) as any critical component in any medical device that supports or sustains human life.

PO Box 5830, MS114 Minneapolis, MN 55440-5830
t 1 800 66 INGEO (US only) +1 989 633 1746 (Worldwide)
www.ingeofibers.com