Ingeo™ Wipes Toxicology Study & Regulatory Information

STANDARD
ISO 10993-Biological Evaluation of Medical Devices with human tissue contact time (30 days or less)

TEST PRODUCT
Ingeo hydroentanglement fiber for hygiene wipes

BACKGROUND
The suitability of NatureWorks 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 NatureWorks 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.

STUDY
To help understand the biological interaction of Ingeo™ hydroentanglement fiber for hygiene wipes, NatureWorks 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% NatureWorks Ingeo™ Fiber
- 0.35% Lurol PL-809 (Goulston Technologies, Inc.)
- 0.09% Lurol PL-811 (Goulston Technologies, Inc.)

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

STUDY	RESULTS
Eye irritation BS EN ISO 10993-10, (1996)	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
Cytotoxicity using elution Technique ISO 10993-5 (1999)	The neat eluate from sample of above formulation was non-toxic to MRC-5 cells.
Skin irritation potential BS EN ISO 10993-10 (1996)	No dermal reaction was observed at the test site throughout the duration of the study. Above formulation was classed as a negligible irritant in accordance with the criteria of ISO 10993-10.
Skin sensitization potential BS EN ISO 10993-10 (1996)	These results indicate that the above formulation does not elicit a sensitization response, there being no reaction observed at challenge.

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