

ETHICON, INC.

a Johnson & Johnson company

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Sutures: Vicryl
Prolene

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Material Safety Data Sheets (MSDS) for Medical Device Products

This document is to address the Occupational Safety and Health Administration (OSHA) Hazard Communication Rule requiring manufacturers to warn of the hazards of chemicals which they supply to the workplace under circumstances where the employees may be exposed under normal conditions of use or in a foreseeable emergency.

All medical device products manufactured by Ethicon, Inc. undergo thorough biocompatibility (safety) testing in compliance with the blue book memorandum #G-95-1 entitled "Use of the International Standard ISO 10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", and are regulated for human use by the Food and Drug Administration (FDA).

For these products, hazard communication labels and MSDSs are not considered necessary since 1) medical devices or products regulated by the Food and Drug Administration are exempt from OSHA labeling requirements [29 CFR 1910.1200(b)(5)(iii)], 2) the chemicals in them do not pose a physical or a health hazard, and 3) the products are "articles" which, under normal conditions of use, do not result in worker exposure to a hazardous chemical.