SAFETY DATA SHEETS

This SDS packet was issued with item: 076676332

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

076676100 076676118 076676126 076676142 076676167 076676175 076676183 076676217 076676225 076676241 076676365 076676399 076676407 076676415 076676423 076676431 076676449 076676837 076676845 076676852 076676860

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

076676258

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Surgical Specialties Facility

15 December 2009

To Whom It May Concern:

The medical products manufactured by Surgical Specialties Corporation and Surgical Specialties Puerto Rico, Inc., both also doing business as (d/b/a) Angiotech are not considered chemicals or Hazardous materials. Therefore, they are excluded from the scope of OSHA's Hazard Communication (29 CFR Part 1910.1200) and do not require material safety data sheets (MSDS). The following excerpt from OSHA's Hazard Communication is noted:

1910.1200(b)(5)

This section does not require labeling of the following chemicals:

1910.1200(b)(iii)

Any food, food additive, color additive, drug, cosmetic, or <u>medical or veterinary device</u> or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

Furthermore, the materials used in the manufacture of Surgical Specialties products intended for human use have been determined to be safe in the quantity and form as they are presented in their final saleable form.

This applies to Sutures (with and without needles), Microsurgical Knives, Cannulas, Cystotomes, Fluid Distribution Sets, Bone Wax, Collagen Spacers as well as Punctal Plugs made from, Silicone, Collagen and PCL.

Kirsten Stowell Regulatory Affairs Specialist