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Tuesday, July 21, 2015

Re: Safety Data Sheet

Product Family:
Endodontic Titanium Posts

Dear Valued Customer:

In response to your request for a Safety Data Sheet (SDS) for Brasseler U.S.A. Dental, LLC, products, we offer the following information:

A Safety Data Sheet (SDS) has not been prepared for these product(s) because they meet the definition of "articles" as defined by the United States Department of Labor, Occupational Safety and Health Administration (OSHA), and is a "manufactured article" as defined by the Canadian Hazardous Products Act (R.S.C., 1985, c. H-3), and as such, the device is exempt from the requirement for an SDS.

US Federal OSHA (29 CFR 1910.1200(b)(6)(v)) defines an "article" as:

Article means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

The Canadian Federal Hazardous Products Act (R.S.C., 1985, c. H-3), Part II, Paragraph 12(i) and (j) exempt from the application of this part manufactured articles and devices listed in Schedule 1.

2 – Interpretation

"manufactured article"/« article manufacturé »

"manufactured article" means any article that is formed to a specific shape or design during manufacture, the intended use of which when in that form is dependent in whole or in part on its shape or design, and that, under normal conditions of use, will not release or otherwise cause a person to be exposed to a controlled product;

SCHEDULE 1 (Paragraph 12(j)) NON-APPLICATION OF PART II

(3) Any cosmetic, device, drug or food, as defined in section 2 of the Food and Drugs Act

For that reason, when the devices are used under reasonable conditions and in accordance with the directions for use, they should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.

Respectfully,

Brasseler USA
One Brasseler Boulevard
Savannah, GA 31419, USA

BY YOUR SIDE