

December 12th, 2019.

Ref.: Safety Data Sheet

Product: Rest of Mouth

Angelus Code(s): 404.

Intended Use: Keep the mouth opened during the dental treatment.

Dear Customer:

A Safety Data Sheet (SDS) has not been prepared for these products because they meet the definition of “articles” as defined by the United States Department of Labor, Occupational Safety and Health Administration (OSHA). Additionally, the devices meet the definition of a “manufactured article” as described by the Canadian Hazardous Products Act (R.S.C., 1985, c. H-3), as well as, the definition of “articles” as specified by the European Regulation (EC) No 1907/2006 Of The European Parliament And Of The Council Of 18 December 2006 Concerning The Registration, Evaluation, Authorization And Restriction Of Chemicals (Reach). In view of these facts, the devices are 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”

“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

C1 - REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

In view of these, when the devices are used under reasonable conditions and in accordance with their intended use and instructions 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 instructions for use may affect the performance of the product and may present potential health and safety hazards.

Sincerely,



Cristiane Vila
Senior Researcher
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