

# BIO-DETEK

INCORPORATED

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To Whom It May Concern:

With respect to the inquiry regarding MSDS for ZOLL Multi-Function Electrodes we present the following:

Excerpted From 29 CFR 1910. 1200 Hazard Communication

29 CFR 1910.1200(b)(5) This section does not require labeling of the following chemicals:

29 CFR 1910.1200(b)(5)(iii)

Any food, food additive, color additive, drug, cosmetic, or *medical* or veterinary *device* 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;

<http://www.fda.gov/opacom/laws/fdcaact/fdcaact1.htm> is the link to the cosmetic act and what they define a device as.

Also 29CFR1910.1200, Appendix B is the Hazard determination section where through evaluation one can determine the hazard a chemical poses and section 3 of this section points to Animal Data which, in my opinion, I believe our Cytotoxicity, Skin Irritation and Sensitization tests results for components apply to. (which is required under the FD&C Act for medical devices and why labeling is not required of medical devices and components)

1910.1200 Appendix E (advisory ) guidelines for employer compliance section 3, paragraph 3 third sentence states "The hazardous nature of the chemical and the potential for exposure are the factors which determine whether a chemical is covered. If it's not hazardous, it's not covered".

We hope this meets with your satisfaction and appreciate the inquiry.

Sincerely,



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