

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078432442

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

078658974



**Richard A. Davis**  
Director – RA/QA

17-Oct-13

Re: MSDS

Your request for a copy of an MSDS for our synthetic bone graft devices has been brought to my attention. The preparation and supply of an MSDS is a requirement for chemical materials as governed by the Occupational Safety and Health Administration regulations (CFR Title 29).

In the cited section as to the requirement for MSDS labeling, paragraph 1910.1200(b)(5)(iii) of the OSHA Hazard Communication Standard states:

**1910.1200(b)(5)**

This section does not require labeling of the following chemicals: ...

**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...

Medical and veterinary devices are specifically exempt by OSHA from requiring an MSDS, these devices being governed by the labeling regulations of the Federal Food, Drug, and Cosmetic Act found in CFR Title 21. An MSDS therefore is not required for our family of bone graft devices.

In summary, the medical devices manufactured by NovaBone Products are not considered to be hazardous materials nor do they contain any hazardous chemicals, based on evaluations made by NovaBone Products under the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Please contact me directly should you require additional information.

Respectfully,

A handwritten signature in blue ink that reads "Richard A. Davis".

Richard A. Davis  
Director – RA/QA