



October 12, 2004

Re: Consil Orthopedic MSDS

To whom it may concern:

Per your recent request for a copy of an MSDS for our veterinary product Consil Orthopedic. 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). However, per these same regulations, medical or veterinary devices are specifically listed as not requiring an MSDS, the labeling for such devices being covered by regulations of the Food and Drug Administration, CFR Title 21.

That said, due to the occasional shipping and handling of the bulk material used in the production of our devices, we have on file a draft MSDS for the Bioglass[®] raw material. I have updated this document to reflect the Consil Orthopedic device name and have enclosed a copy for your reference.

Please contact me should you require any additional information on our device, Consil Orthopedic.

Respectfully,

David M. Gaisser
VP – Operations/RA/QA

NovaBone Products, LLC
13709 Progress Blvd, #33, Alachua, FL 32615
Tel: 386*462*7660 Fax: 386*418*1636
www.novabone.com



CONSIL ORTHOPEDIC PRODUCT SAFETY INFORMATION

SECTION 1. PRODUCT IDENTIFICATION

Product Name: Consil Orthopedic
Common Name: Bioglass[®] Synthetic Bone Graft Particulate
Company Name: NovaBone Products, LLC
13709 Progress Boulevard, #33
Alachua, FL 32615 USA
Phone: (386) 462-7660
Fax: (386) 418-1636

SECTION 2. COMPOSITION/CLASSIFICATION

Composition: 45s5 Bioglass[®]

<u>Component</u>	<u>Wt.%</u>	<u>Tolerance(Wt.%)</u>
SiO ₂	45.0	±2.0
Na ₂ O	24.5	±2.0
CaO	24.5	±2.0
P ₂ O ₅	6.0	±1.0

SECTION 3. DANGEROUS PROPERTIES

45s5 Bioglass[®] has no known dangerous properties

SECTION 4. EMERGENCY HELP AND FIRST AID PROCEDURES

Inhalation: Remove from exposure. Get medical attention if experiencing over exposure effects.
Ingestion: Induce vomiting in a conscious person, get medical attention.
Skin: Wash with plenty of soap and water.
Eyes: Flush with water for several minutes. Get medical attention. Take care not to rub eyes as glass particles may scratch surface of eye.

SECTION 5. FIRE AND EXPLOSION HAZARD

Non-combustible. Use extinguishing media appropriate to surrounding fire conditions.

SECTION 6. SPILLS OR ACCIDENTAL WASTE PROCEDURE

Spills should be cleaned up with a broom and dust pan or vacuum depending on size of spill. Take care not to inhale or ingest dust. Waste can be placed in a plastic trash bag to be disposed of according to applicable regulations.

SECTION 7. HANDLING AND STORAGE

No special precautions necessary. It is recommended that material be stored in unopened containers at ambient temperature (55-85°F) and humidity (rH<70%).



SECTION 8. RESTRICTION FOR EXPOSURE/PERSONAL PROTECTION

Protective safety glasses or goggles as well as gloves recommended

SECTION 9. PHYSICAL PROPERTY

Appearance/odor: Odorless white granules of glass or odorless white powder

Density: ≈ 2.73 grams/cc

Softening Point: ≈ 627 °C

Particle size: 90-710 μm

Solubility in water: unknown

Boiling point: N/A

Percent volatile: N/A

Vapor density: N/A

Evaporation rate: N/A

Vapor Pressure: N/A

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable

Incompatibility: Strong acids

Decomposition: N/A

Polymerization: Hazardous polymerization will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Route of entry: Inhalation - No
Skin - No
Ingestion - No

Health Hazards: None known
(acute and chronic)

SECTION 12. ECO-TOXICOLOGICAL INFORMATION/DECOMPOSITION

Stable to decomposition. Long term effects may include slight leaching of Na, Ca and P

SECTION 13 HANDLING OF WASTE

Waste can be placed in a plastic trash bag to be disposed of according to applicable regulations.

SECTION 14 INFORMATION ABOUT TRANSPORT

No special precautions required.

SECTION 15 EXISTING REGULATION

Classified as a medical device for human implantation. No known current risk classification as a veterinary device.

SECTION 16 OTHER INFORMATION

N/A