

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[®]

 $\begin{array}{c|cccc} \underline{Component} & \underline{Wt.\%} & \underline{Tolerance(Wt.\%)} \\ SiO_2 & 45.0 & \pm 2.0 \\ Na_2O & 24.5 & \pm 2.0 \\ CaO & 24.5 & \pm 2.0 \\ P_2O_5 & 6.0 & \pm 1.0 \\ \end{array}$

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.

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

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