

Material Safety Data Sheet

Material Name: BIOSTEP AG

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer: Covalon Technologies, Ltd. 405 Britannia Rd. E., Ste. 106, Mississauga, ON L4Z 3E6 CANADA

Phone: 905 568-8400

Manufactured For: Smith & Nephew, 970 Lake Carillon Drive Suite 110, St. Petersburg, FL 33716 **Phone:** 1 800 876-1261

Date Reviewed: July 30, 2010

*** Section 2 - Hazards Identification ***

Primary Entry Routes: Skin contact.

Target Organs: N/A

Acute Effects: Temporary discoloration of affected areas or rashes and irritation in sensitized individuals.

Eye: Corneal irritation may occur as a result of mechanical abrasion. In the event of eye irritation, flush eyes with flowing water.

Skin: Skin irritation may result as an allergic reaction to the silver content of the dressing. Obtain medical attention in the event irritation develops or persists.

Ingestion: Ingestion of the dressing will act as a foreign body. Obtain medical attention.

Chronic Effects: Excessive or chronic exposure to silver by skin contact, ingestion or inhalation may cause Argyrosis – a local or generalized discoloration of the eyes, skin and mucous membranes, where grey or blue patches of pigmentation are formed.

*** Section 3 - Composition / Information on Ingredients ***

Ingredient	CAS #	% Weight
Denatured Collagen	9000-70-8	Proprietary
Sodium Alginate	9005-38-3	Proprietary
Sodium Carboxymethylcellulose Disodium	9004-32-4	Proprietary
Ethylenediaminetetraacetic Acid	6381-92-6	Proprietary
Silver Lactate	128-00-7	Proprietary
Sodium Chloride	7647-14-5	Proprietary
Sodium Hydroxide	1310-73-2	Proprietary
EDC	25952-52-8	Proprietary
NHS	6066-82-6	Proprietary

Occupational Exposure Limits: The American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value for the exposure of silver particles or aerosolized soluble silver compounds is 0.01 mg / m³ of air averaged over an eight hour shift.

Material Safety Data Sheet

Material Name: **BIOSTEP AG**

*** Section 4 - First Aid Measures ***

Eye: Corneal irritation may occur as a result of mechanical abrasion. In the event of eye irritation, flush eyes with flowing water.

Skin: Skin irritation may result as an allergic reaction to the silver content of the dressing. Obtain medical attention in the event irritation develops or persists.

Ingestion: Ingestion of the dressing will act as a foreign body. Obtain medical attention.

Chronic Effects: Excessive or chronic exposure to silver by skin contact, ingestion or inhalation may cause Argyrosis – a local or generalized discoloration of the eyes, skin and mucous membranes, where grey or blue patches of pigmentation are formed.

*** Section 5 - Fire Fighting Measures ***

Flash Point: Not available.

Flash Point Method: Not available.

Burning Rate: Not available.

Autoignition Temperature: Not available.

LEL (%vol. In air): Not available.

UEL (%vol. In air): Not available.

Flammability Classification: Dressing flammability has not been determined.

Extinguishing Media: Dressing is not reactive to water or other means of extinguishment. If involved in a fire, treat as a flammable solid.

Unusual Fire or Explosion Hazards: Not available, however, low explosion risk is expected.

Hazardous Combustion Products: Not available.

Fire-Fighting Instructions: Do not release runoff from fire control methods to sewers or waterways.

Fire-Fighting Equipment: Self Contained Breathing Apparatus should be worn.

*** Section 6 - Accidental Release Measures ***

Spill or Leak Procedure: Treat used dressing as medical waste. No special spill procedures required.

Regulatory Requirements: Follow applicable OSHA regulations (29 CFR 1910.120).

*** Section 7 - Handling and Storage ***

Handling Precautions: No special handling procedures required. If used, handle as per medical waste.

Storage Requirements: Store in a cool, dry environment. If pouches are opened, do not use. Keep away from moisture. Avoid extreme heat and strong oxidizing agents.

Regulatory Requirements: None.

*** Section 8 - Exposure Controls / Personal Protection ***

Engineering Controls: None required.

Handling Procedures and Equipment: No special handling procedures required. If used, handle as per medical waste.

Personal Protective Equipment: No special protection is required.

Comments: Never eat, drink, or smoke in work areas. Practice good personal hygiene after using this material, especially before eating, drinking, smoking, using the toilet, or applying cosmetics.

Material Safety Data Sheet

Material Name: BIOSTEP AG

*** Section 9 - Physical & Chemical Properties ***

Physical State: Solid sponge-like material.
Appearance: Grey / white.
Odor: Slight odor associated with the dressing.
Taste: Not available.
Volatility: Non-volatile.
Water Solubility: Silver component is sparingly soluble in water.
Vapor Pressure (mm Hg): Not applicable.
Critical Temperature: Not available.
Vapor Density (Air=1): Not applicable.
Boiling / Condensation Point: Not applicable.
Formula Weight: Not applicable.
Melting / Sublimation Point: Not applicable.
Water/oil dist. Coeff.: Not applicable.
Viscosity: Not applicable.
Specific Gravity: >1
pH (1% soln/water): Not available.
Evaporation Rate (nBuAc = 1): Not applicable.

*** Section 10 - Chemical Stability & Reactivity Information ***

Stability: Yes
Corrosivity: Non-corrosive.
Chemical Incompatibilities: The silver component is incompatible with these products: Acetylene, Acids, Amines, Ammonia, Hydrazine, Metal Sulfides, Peroxides, Strong oxidizers.
Conditions to Avoid: Avoid extreme heat and strong oxidizing agents.
Hazardous Decomposition Products: Not available.
Degradability: Proteolytic enzymes will degrade material.

*** Section 11 - Toxicological Information ***

Chronic effects on humans: Excessive or chronic exposure to silver by skin contact, ingestion or inhalation may cause Argyrosis – a local or generalized discoloration of the eyes, skin and mucous membranes, where grey or blue patches of pigmentation are formed.
Acute effects on humans: Temporary discoloration of affected areas or rashes and irritation in sensitized individuals.
Irritancy: Refer to acute effects on humans section in this MSDS.
Sensitization: Some individuals may be sensitized to silver metal or collagen.
Route of entry: Skin contact.
Mutagenicity: None known.
Teratogenicity: None known.
Carcinogenicity: None known.

*** Section 12 - Ecological Information ***

Ecotoxicity: Not determined.
Environmental Fate: If unused, silver may be recovered by recycling.
Environmental Degradation: Not available.
Soil Absorption/Mobility: Not determined.
Marine Pollutant: Not applicable.

Material Safety Data Sheet

Material Name: **BIOSTEP AG**

*** Section 13 - Disposal Considerations ***

Disposal: Material should be considered a medical waste after use. If unused, silver may be recovered by recycling. Dispose of according to applicable federal, state or local regulations. The state and local regulations may differ from federal regulatory requirements, and laws may change or be reinterpreted.

*** Section 14 - Transportation Information ***

DOT Transportation Data: (49 CFR 172.101): Not regulated.

Air Transport (ICAO/IATA): Not regulated.

Marine Transport (IMDG Code): Not regulated.

*** Section 15 - Regulatory Information ***

EPA Regulations: None known.

OSHA Regulations: None known. **State Regulations:** May vary from state to state.

TDG (Canada): Not regulated.

WHMIS: Not a WHMIS controlled product.

*** Section 16 - Other Information ***

Additional Hazard Rating Systems: None known.