

Material Safety Data Sheet

Section 1 - Chemical Product and Company Identification

Product/Chemical Name: IODOFLEX* DRESSING

Chemical Formula: Mixture

CAS Number: Mixture

Other Designations: 0.9% Cadexomer Iodine Wound Dressing

General Use: Unit-dose paste with gauze backing for the treatment of chronic exuding wounds.

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

Date reviewed: August 13, 2009

Section 2 - Hazards Identification

☆☆☆☆☆ Emergency Overview ☆☆☆☆☆

HMIS	
H	1
F	1
R	0
PPE	X

Potential Health Effects

Primary Entry Routes: Eyes, Skin, Ingestion

Target Organs: Thyroid

Acute Effects

Eye: May be irritating to eyes.

Skin: May cause allergic skin reaction in individuals sensitive to iodine.

Ingestion: Swallowing may cause abdominal discomfort, headache, nausea, and vomiting.

Carcinogenicity: None of the components of this product are listed as a carcinogen by IARC, NTP or OSHA.

Medical Conditions Aggravated by Long-Term Exposure: Individuals with thyroid disorders may be at increased risk from exposure.

Chronic Effects: Chronic absorption of iodine may result in iodism with symptoms of hyper salivation, sneezing, conjunctivitis, laryngitis, headache, skin rash and gastric upset. May affect thyroid function.

Section 3 - Composition Information on Ingredients

Ingredient Name	CAS Number	%wt or % Vol
Iodine	7553-56-2	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Starch	9005-25-8	Proprietary

Section 4 - First Aid Measures

Eye Contact: Flush eyes (including under eyelids) with copious amounts of water for at least 15 minutes.

Skin Contact: No First Aid should be needed. If rash or other symptoms develop, discontinue use and consult a physician.

Ingestion: Contact a poison control center for instructions. Do not induce vomiting unless directed to do so by medical personnel.

After first aid, get appropriate in-plant, paramedic, or community medical support.

Special Precautions/Procedures: None.

Section 5 - Fire-Fighting

Flash Point: Not classified as flammable or combustible.

Flash Point Method: Not applicable

Burning Rate: Not applicable

Autoignition Temperature: Not determined

LEL (% vol in air): Not applicable

UEL(% vol in air): Not applicable

Flammability Classification: Not applicable

Extinguishing Media: Water spray, carbon dioxide, dry chemical or foam

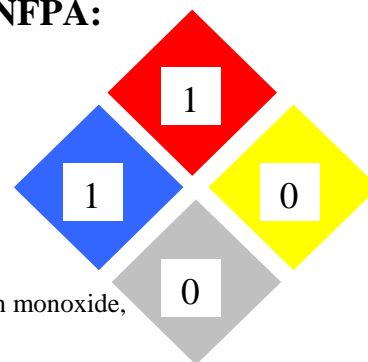
Unusual Fire or Explosion Hazards: None known.

Hazardous Combustion Products: Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, iodine.

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

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

NFPA:



Section 6 - Accidental Release Measures

Spill /Leak Procedures:

Small Spills: Pick up and place in a container for disposal.

Large Spills

Containment: Do not permit spilled material to enter sewers or waterways.

Cleanup: Wear appropriate protective clothing and equipment. Collect and place in a suitable container for disposal. Clean spill area with water and collect for proper disposal.

Section 7 - Handling and Storage

Handling Precautions: Wash thoroughly after handling. Avoid contact with eyes.

Storage Requirements: Store in a dry place below 77°F (25°C).

Section 8 - Exposure Controls / Personal Protection

Occupational Exposure Limits

Iodine	0.1 ppm Ceiling ACGIH TLV 0.1 ppm Ceiling OSHA PEL
Polyethylene Glycol	None Established
Starch	10 mg/m ³ TWA ACGIH TLV 5 mg/m ³ TWA OSHA PEL (respirable dust) 10 mg/m ³ TWA OSHA PEL (total dust)

The Following Controls are Recommended for the Use of this Product by Medical Professionals and Consumers:

Engineering Controls/Ventilation: No special ventilation is required for normal handling and use.

Respiratory Protection: None required for normal use.

Protective Clothing/Equipment: Impervious gloves recommended if skin contact is possible.

For Bulk Processing and Packaging the Following Controls are Recommended:

Engineering Controls/Ventilation: Use good general ventilation or local exhaust ventilation as required to maintain the concentration of contaminants below the exposure limits.

Respiratory Protection: If the occupational exposure limits are exceeded a NIOSH approved organic vapor/acid gas/particulate respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with OSHA 1910.134 and good industrial hygiene practice.

Protective Clothing/Equipment: Safety goggles, gloves and protective clothing are recommended.

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.

Section 9 - Physical and Chemical Properties

Physical State: Semi-solid

Appearance and Odor: Reddish-brown paste with a faint odor on a gauze backing.

Odor Threshold: Not determined

Vapor Pressure: 1.0 mm Hg @ 38°C (iodine)

Vapor Density (Air=1): 8.8 (iodine)

Formula Weight: Mixture

Density: Not determined

Specific Gravity (H₂O=1, at 25° C): 0.8

pH @ 20°C: 3-5

Water Solubility: Forms a gel

Other Solubilities: Not determined

Boiling Point: Not determined

Freezing/Melting Point: Not determined

Viscosity @ 25°C: Not determined

Refractive Index: Not determined

Surface Tension: Not determined

% Volatile: 0

Evaporation Rate (nBuAc = 1): <1

Section 10 - Stability and Reactivity

Stability: Stable

Polymerization: Hazardous polymerization will not occur.

Chemical Incompatibilities: Iodine reacts with powdered aluminum, active metals, acetylene, acetaldehyde and ammonium hydroxide.

Conditions to Avoid: Open flames, excessive heat (> 200°F).

Hazardous Decomposition Products: Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, iodine.

Section 11 - Toxicological Information

Toxicity Data:

Eye Effects: No specific data. Expected to be irritating.

Skin Effects: No specific data. Cadexomer iodine did not cause sensitization in animal studies. May cause allergic reaction in sensitive individuals.

Acute Inhalation Effects: No data available.

Acute Oral Effects: The LD50 in rats for cadexomer iodine is >6,800 mg/kg. The LD50 in rats for iodine is 14,000 mg/kg.

Chronic Effects: Toxicity studies with daily skin application for 6 months in rabbits showed no evidence of local or systemic toxic effects.

Carcinogenicity: No data available.

Mutagenicity: No data available.

Teratogenicity: Iodine crosses the placenta and has caused thyroid effects in the babies of women taking iodides.

Section 12 - Ecological Information

Ecotoxicity: Not determined

Environmental Fate: Not determined

Environmental Degradation: Not determined

Soil Absorption/Mobility: Not determined

Section 13 - Disposal Considerations

Disposal: Contact your supplier or a licensed contractor for detailed recommendations. Follow applicable federal, state, and local regulations.

Section 14 - Transport Information

DOT Transportation Data (49 CFR 172.101): Not Regulated

Section - 15 Regulatory Information

CERCLA: This product is not subject to CERCLA reporting requirements, however, many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute Health, Chronic Health

SARA 313: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None

CALIFORNIA: This product is not known to contain chemicals regulated under California Proposition 65.

Section 16 - Other Information

Additional Hazard Rating Systems: None Known