1. Identification

1.1. Product identifier
Product Identity: IODOFLEX™ Dressing
Alternate Names: 0.9% Cadexomer Iodine Wound Dressing

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use: Unit-dose paste with gauze backing for the treatment of chronic exuding wounds
Application Method: See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet
Company Name: Smith & Nephew
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716
Emergency Customer Service: Smith & Nephew 1-800-876-1261

2. Hazard(s) identification

2.1. Classification of the substance or mixture
STOT SE 3;H335 May cause respiratory irritation.

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

Warning

H335 May cause respiratory irritation.

[Prevention]:
P261 Avoid breathing dust / fume / gas / mist / vapors / spray.
P271 Use only outdoors or in a well-ventilated area.

[Response]:
P304+312 IF INHALED: Call a POISON CENTER or doctor / physician if you feel unwell.
P340 Remove victim to fresh air and keep at rest in a position comfortable for breathing.

[Storage]:
3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

<table>
<thead>
<tr>
<th>Ingredient/Chemical Designations</th>
<th>Weight %</th>
<th>GHS Classification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregelatinized Starch</td>
<td>50 - 75</td>
<td>Not Classified</td>
<td>[1][2]</td>
</tr>
<tr>
<td>CAS Number: 0009005-25-8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>50 - 75</td>
<td>STOT SE 3;H335</td>
<td>[1]</td>
</tr>
<tr>
<td>CAS Number: 0025322-68-3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iodine</td>
<td>1.0 - 10</td>
<td>Acute Tox. 4;H332</td>
<td>[1][2]</td>
</tr>
<tr>
<td>CAS Number: 0007553-56-2</td>
<td></td>
<td>Acute Tox. 4;H312</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1;H400</td>
<td></td>
</tr>
</tbody>
</table>

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

**General**
In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.

**Inhalation**
Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

**Eyes**
Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

**Skin**
No first aid should be needed. If rash or other symptoms develop, discontinue use and consult a physician.

**Ingestion**
Call a physician or poison control center for instructions. Do not induce vomiting unless directed to do so by medical personnel.

4.2. Most important symptoms and effects, both acute and delayed

**Overview**
**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.

**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. See section 2 for further details.

**Inhalation**

May cause respiratory irritation.

### 5. Fire-fighting measures

#### 5.1. Extinguishing media
Water spray, carbon dioxide, dry chemical, foam

#### 5.2. Special hazards arising from the substance or mixture
Hazardous decomposition: Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, iodine.

Avoid breathing dust / fume / gas / mist / vapors / spray.

#### 5.3. Advice for fire-fighters
Wear self-contained breathing apparatus and protective clothing.

ERG Guide No. ----

### 6. Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures
Put on appropriate personal protective equipment (see section 8).

#### 6.2. Environmental precautions
Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

#### 6.3. Methods and material for containment and cleaning up
Small Spills: Wipe up with absorbent material and place in a container for disposal.

Large Spills

- Containment: Contain spill using an inert absorbent material. Do not permit spilled material to enter sewers or waterways.
- Cleanup: Wear appropriate protective clothing and equipment. Collect with an inert absorbent and place in a suitable container for disposal. Clean spill area with water and collect for proper disposal.

### 7. Handling and storage

#### 7.1. Precautions for safe handling
Wash thoroughly after handling. Avoid contact with eyes.

See section 2 for further details. - [Prevention]:

#### 7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Incompatible materials: Iodine reacts with powdered aluminum, active metals, acetylene, acetaldehyde and ammonium hydroxide.
Store in a cool, dry place < 77°F / 25°C.
See section 2 for further details.

7.3. Specific end use(s)
No data available.

8. Exposure controls and personal protection

8.1. Control parameters

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0007553-56-2</td>
<td>Iodine</td>
<td>OSHA</td>
<td>C 0.1 ppm (1 mg/m³)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACGIH</td>
<td>Ceiling: 0.1 ppm Revised 2008; 2010,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIOSH</td>
<td>C 0.1 ppm (1 mg/m³)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
<tr>
<td>0009005-25-8</td>
<td>Pregelatinized Starch</td>
<td>OSHA</td>
<td>TWA 15 mg/m³ (total) TWA 5 mg/m³ (resp)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACGIH</td>
<td>TWA: 10 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIOSH</td>
<td>TWA 10 mg/m³ (total) TWA 5 mg/m³ (resp)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
<tr>
<td>0025322-68-3</td>
<td>Polyethylene glycol</td>
<td>OSHA</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACGIH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NIOSH</td>
<td>No Established Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Supplier</td>
<td>No Established Limit</td>
</tr>
</tbody>
</table>

Carcinogen Data

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Ingredient</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0007553-56-2</td>
<td>Iodine</td>
<td>OSHA</td>
<td>Select Carcinogen: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NTP</td>
<td>Known: No; Suspected: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IARC</td>
<td>Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;</td>
</tr>
<tr>
<td>0009005-25-8</td>
<td>Pregelatinized Starch</td>
<td>OSHA</td>
<td>Select Carcinogen: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NTP</td>
<td>Known: No; Suspected: No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IARC</td>
<td>Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;</td>
</tr>
</tbody>
</table>
8.2. Exposure controls

**Respiratory**
If workers are exposed to concentrations above the exposure limit they must use the appropriate, certified respirators.

**Eyes**
Protective safety glasses recommended

**Skin**
Gloves and protective clothing are recommended.

**Engineering Controls**
Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

**Other Work Practices**
Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

### 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Gauze backing with a reddish-brown Paste</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Faint</td>
</tr>
<tr>
<td><strong>Odor threshold</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>3 - 5 @ 20°C</td>
</tr>
<tr>
<td><strong>Melting point / freezing point</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not classified as flammable or combustible</td>
</tr>
<tr>
<td><strong>Evaporation rate (Ether = 1)</strong></td>
<td>&lt; 1 (nBuAc = 1)</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not Applicable</td>
</tr>
<tr>
<td><strong>Upper/lower flammability or explosive limits</strong></td>
<td><strong>Lower Explosive Limit</strong>: Not applicable</td>
</tr>
<tr>
<td></td>
<td><strong>Upper Explosive Limit</strong>: Not applicable</td>
</tr>
<tr>
<td><strong>Vapor pressure (Pa)</strong></td>
<td>1.0 mmHg @ 38°C (iodine)</td>
</tr>
<tr>
<td><strong>Vapor Density</strong></td>
<td>8.8 (iodine) (Air = 1)</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>0.8 @ 25°C (H2O = 1)</td>
</tr>
<tr>
<td><strong>Solubility in Water</strong></td>
<td>Forms a gel</td>
</tr>
<tr>
<td><strong>Partition coefficient n-octanol/water (Log Kow)</strong></td>
<td>Not Measured</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Viscosity (cST)</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>VOC Content</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>% Volatile</strong></td>
<td>0</td>
</tr>
</tbody>
</table>

9.2. Other information
No other relevant information.
10. Stability and reactivity

10.1. Reactivity
Hazardous Polymerization will not occur.

10.2. Chemical stability
Stable under normal circumstances.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Open flames, excessive heat (> 200°F)

10.5. Incompatible materials
Iodine reacts with powdered aluminum, active metals, acetylene, acetaldehyde and ammonium hydroxide.

10.6. Hazardous decomposition products
Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, iodine.

11. Toxicological information

Acute toxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Oral LD50, mg/kg</th>
<th>Skin LD50, mg/kg</th>
<th>Inhalation Vapor LC50, mg/L/4hr</th>
<th>Inhalation Dust/Mist LC50, mg/L/4hr</th>
<th>Inhalation Gas LC50, ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregelatinized Starch - (9005-25-8)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Polyethylene glycol - (25322-68-3)</td>
<td>30,200.00, Rat - Category: NA</td>
<td>20,000.00, Rabbit - Category: NA</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Iodine - (7553-56-2)</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
### 12. Ecological information

#### 12.1. Toxicity

The preparation has been assessed following the conventional method of the Dangerous Preparations Directive 1999/45/EC and GHS and is not classified as dangerous for the environment, but contains substance(s) dangerous for the environment. See section 3 for details.

**Aquatic Ecotoxicity**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>96 hr LC50 fish, mg/l</th>
<th>48 hr EC50 crustacea, mg/l</th>
<th>ErC50 algae, mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregelatinized Starch - (9005-25-8)</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Polyethylene glycol - (25322-68-3)</td>
<td>1,000.00, Salmo salar</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Iodine - (7553-56-2)</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

#### 12.2. Persistence and degradability

There is no data available on the preparation itself.

#### 12.3. Bioaccumulative potential

Not Measured

#### 12.4. Mobility in soil

No data available.

#### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

#### 12.6. Other adverse effects

No data available.

### 13. Disposal considerations

#### 13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

### 14. Transport information

#### 14.1. UN number

Not Applicable

#### 14.2. UN proper shipping name

Not Regulated

#### 14.3. Transport hazard class(es)

**DOT Hazard Class:** Not Applicable

**IMDG:** Not Applicable

**Air Class:** Not Applicable
14.4. Packing group
Not Applicable  Not Applicable  Not Applicable

14.5. Environmental hazards
IMDG  Marine Pollutant: No

14.6. Special precautions for user
No further information

15. Regulatory information

Regulatory Overview
The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Toxic Substance Control Act (TSCA)
All components of this material are either listed or exempt from listing on the TSCA Inventory.

WHMIS Classification
Not Regulated

US EPA Tier II Hazards
   Fire: No
   Sudden Release of Pressure: No
   Reactive: No
   Immediate (Acute): Yes
   Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):
   Antimony trioxide

Proposition 65 - Developmental Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%):
   Iodine

Pennsylvania RTK Substances (>1%):
   Iodine
   Pregelatinized Starch
The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:
H312 Harmful in contact with skin.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

End of Document