SAFETY DATA SHEET

1. Identification

<table>
<thead>
<tr>
<th>GHS product identifier</th>
<th>OPTIRAY® IOVERSOL INJECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version #</td>
<td>01</td>
</tr>
<tr>
<td>Issue date</td>
<td>03-27-2012</td>
</tr>
<tr>
<td>CAS #</td>
<td>Mixture</td>
</tr>
<tr>
<td>Recommended use</td>
<td>Diagnostic imaging agent.</td>
</tr>
<tr>
<td>Recommended Restrictions</td>
<td>Not available.</td>
</tr>
<tr>
<td>Synonym(s)</td>
<td>OPTIRAY® 160 Ioversol Injection 34% * OPTIRAY® 240 Ioversol Injection 51% * OPTIRAY® 300 Ioversol Injection 64% * OPTIRAY® 320 Ioversol Injection 68% * OPTIRAY® 350 Ioversol Injection 74% * N,N'-bis(2,3-dihydroxypropyl)-5-[N-(2-hydroxyethyl-gl yolamido]-2,4,6-triiodoisophthalamide</td>
</tr>
</tbody>
</table>

Manufacturer information

Mallinckrodt
675 McDonnell Blvd.
Hazelwood, MO
63042
United States
24 Hour Emergency 1-314-654-1600
Chemtrec 1-703-527-3887
Customer Service 1-888-744-1414

2. Hazards identification

<table>
<thead>
<tr>
<th>GHS classification</th>
<th>Physical hazards</th>
<th>Health hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Classification not possible</td>
<td>Acute toxicity, oral</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>Acute toxicity, dermal</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>Acute toxicity, inhalation</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>Skin corrosion/irritation</td>
</tr>
<tr>
<td></td>
<td>Classification not possible</td>
<td>Serious eye damage/eye irritation</td>
</tr>
<tr>
<td></td>
<td>Classification not possible</td>
<td>Sensitization, respiratory</td>
</tr>
</tbody>
</table>

Material name: OPTIRAY® IOVERSOL INJECTION
MSDS ID: IOVER   Version #: 01   Revision date: 03-27-2012
Classification not possible

Environmental hazards
- Hazardous to the aquatic environment, acute hazard
- Hazardous to the aquatic environment, long-term hazard
- Hazardous to the ozone layer

Emergency overview
The hazard warnings associated with this product are based on the individual ingredients included in the finished dosage form of the pharmaceutical product. The supplied package insert (approved labeling) provides the necessary drug safety information.

Avoid any exposure. Handle in accordance with good industrial hygiene and safety practice.

### 3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Non-hazardous components</th>
<th>CAS #</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOVERSOL</td>
<td>87771-40-2</td>
<td>34 - &lt; 74</td>
</tr>
<tr>
<td>EDETATE CALCIUM DISODIUM</td>
<td>62-33-9</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>TRIS (HYDROXYMETHYL) AMINOMETHANE</td>
<td>77-86-1</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Other components below reportable levels</td>
<td></td>
<td>40 - &lt; 50</td>
</tr>
</tbody>
</table>

### 4. First aid measures

First aid procedures
- **Inhalation**: Not likely, due to the form of the product.
- **Skin**: Rinse skin with water/shower. Get medical attention if irritation develops and persists.
- **Eye**: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
- **Ingestion**: If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

**Notes to physician**: Not available.

### 5. Fire-fighting measures

**Suitable extinguishing media**: Use any media suitable for the surrounding fires.

**Specific hazards arising from the chemical**: Not available.

**Protective equipment and precautions for firefighters**: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

### 6. Accidental release measures

**Personal precautions**: No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the MSDS for additional personal protection advice when handling this product.

**Environmental precautions**: No special environmental precautions required.
Methods for containment

Not available.

Methods for cleaning up

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece).

Large Spills: Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the MSDS.

7. Handling and storage

Handling

Handle and open container with care. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes. Avoid contact with skin. Do not ingest. When using, do not eat, drink or smoke. Wash thoroughly after handling.

Storage

Keep container tightly closed. Keep from freezing. Storage temperature: between 15°C (59°F) and 30°C (86°F). Protect from light. Use care in handling/storage. Store in accordance with local/regional/national/international regulation.

8. Exposure controls / personal protection

Recommended monitoring procedures

Additional exposure data

Not available.

Recommended monitoring procedures

Not available.

Engineering controls

General ventilation normally adequate.

Personal protective equipment

Eye/face protection

Safety glasses. Provide eyewash station and safety shower.

Skin protection

Wear appropriate chemical resistant clothing. Wear protective gloves.

Respiratory protection

No personal respiratory protective equipment normally required.

Hand protection

Wear protective gloves.

9. Physical and chemical properties

Appearance

Clear.

Physical state

Liquid.

Color

Colourless to light yellow.

Form

Liquid.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/Freezing point

Not available.

Boiling point

212 °F (100 °C) estimated

Flash point

Not available.

Evaporation rate

Not available.

Flammability (Train fire)

Not available.

Flammability limits in air, lower, % by volume

Not available.

Flammability limits in air, upper, % by volume

Not available.

Vapor pressure

0 hPa estimated

Vapor density

Not available.

Relative density

Not available.

Solubility (H2O)

Complete

Octanol/H2O coeff

Not available.
Auto-ignition temperature: Not available.
Decomposition temperature: Not available.
Viscosity: Not available.
Specific gravity: 1.18 - 1.4
VOC (Weight %): 45.78%
Percent volatile: 45.78% estimated

10. Stability and reactivity

Chemical stability: Material is stable under normal conditions. Instability caused by exposure to light.
Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
Conditions to avoid: None under normal conditions.
Incompatible materials: None known.

11. Toxicological information

Toxicological data

<table>
<thead>
<tr>
<th>Product</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPTIRAY® IOVERSOL INJECTION (Mixture)</td>
<td>Acute Other LD50 Rat: 15 g/kg Intravenous (68% Injection)</td>
</tr>
</tbody>
</table>

Components

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDETATE CALCIUM DISODIUM (62-33-9)</td>
<td>Acute Oral LD50 Rat: 10 g/kg</td>
</tr>
<tr>
<td>TRIS (HYDROXYMETHYL) AMINOMETHANE (77-86-1)</td>
<td>Acute Oral LD50 Rat: 5900 mg/kg</td>
</tr>
</tbody>
</table>

Routes of exposure: Ingestion. Skin contact. Eye contact.
Sensitization: Not a skin sensitizer.
Local effects: May cause eye irritation. Mild skin irritation. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Chronic effects: None known through occupational exposure.
Carcinogenicity: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Mutagenicity: Due to lack of data the classification is not possible.
Reproductive effects: Due to lack of data the classification is not possible.
Skin corrosion/Irritation: Due to lack of data the classification is not possible.
Serious eye damage/eye irritation: Due to lack of data the classification is not possible.
Other information: Not available.

12. Ecological information

Ecotoxicity: This product has no known eco-toxicological effects.
Environmental effects: Not classified as an environmental hazard. Ecological injuries are not known or expected under normal use.
Persistence / degradability: No data is available on the degradability of this product.
Aquatic toxicity: Not classified.

13. Disposal considerations

Disposal methods: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations. Disposal recommendations are based on uncontaminated material.

Waste from residues / unused products: Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
14. Transport information

ADR
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.

RID
Not regulated as dangerous goods.

15. Regulatory information

Regulatory information
Mallinckrodt finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labeling) which provides necessary drug safety information.

Inventory status

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information

Disclaimer
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Revision date
03-27-2012