

1. Product and Company Identification

Material name	OPTIRAY® IOVERSOL INJECTION
Version #	01
Revision date	03-16-2012
CAS #	Mixture
Synonym(s)	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-glucolamido)-2,4,6-triiodoisophthalamide
Manufacturer information	Mallinckrodt 675 McDonnell Blvd. Hazelwood, MO 63042 United States 24 Hour Emergency 314-654-1600 Chemtrec 800-424-9300 Customer Service 888-744-1414

2. Hazards Identification

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.
OSHA regulatory status	<p>Avoid any exposure. Handle in accordance with good industrial hygiene and safety practice.</p> <p>As per 29 CFR 1910.1200(b)(5)(iii), any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements under that Act by the Food and Drug Administration are exempted from the requirements of the Hazard Communication Standard.</p> <p>All 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.</p>
Potential health effects	
Routes of exposure	Ingestion. Skin contact. Eye contact.
Eyes	Direct contact may irritate.
Skin	The hazardous properties of the product are considered limited. May cause minor irritation on skin contact.
Inhalation	Health injuries are not known or expected under normal use.
Ingestion	Ingestion of large amounts may produce gastrointestinal disturbances including irritation, nausea, and diarrhea. Allergic reactions are possible.
Chronic effects	None known.
Potential environmental effects	Ecological injuries are not known or expected under normal use.

3. Composition / Information on Ingredients

Non-hazardous components	CAS #	Percent
IOVERSOL	87771-40-2	34 - 74
EDETATE CALCIUM DISODIUM	62-33-9	0 - <1

TRIS (HYDROXYMETHYL) AMINOMETHANE	77-86-1	0 - <1
Other components below reportable levels		40 - 60

4. First Aid Measures

First aid procedures

Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Inhalation	Not likely, due to the form of the product.
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. Rinse mouth.
General advice	If you feel unwell, seek medical advice (show the label where possible).

5. Fire Fighting Measures

Flammable properties	Not flammable by OSHA criteria.
Extinguishing media	
Suitable extinguishing media	Use any media suitable for the surrounding fires.
Fire fighting equipment/instructions	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 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

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.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

Appearance	Clear.
Physical state	Liquid.
Form	Liquid.
Color	Colourless to light yellow.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Vapor pressure	0 hPa estimated
Vapor density	Not available.
Boiling point	212 °F (100 °C) estimated
Melting point/Freezing point	Not available.
Solubility (water)	Complete
Specific gravity	1.18 - 1.4
Relative density	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
VOC	45.7838 % estimated
Percent volatile	45.7838 % estimated

10. Chemical Stability & Reactivity Information

Chemical stability	Material is stable under normal conditions. Instability caused by exposure to light.
Conditions to avoid	None under normal conditions.
Incompatible materials	Not available.
Hazardous decomposition products	Toxic gas. Nitrogen oxides (NOx). Iodine.

11. Toxicological Information

Toxicological data	
Product	Test Results
OPTIRAY® IOVERSOL INJECTION (Mixture)	Acute Other LD50 Rat: 15 g/kg Intravenous (68% Injection)
Components	Test Results
EDETATE CALCIUM DISODIUM (62-33-9)	Acute Oral LD50 Rat: 10 g/kg
TRIS (HYDROXYMETHYL) AMINOMETHANE (77-86-1)	Acute Oral LD50 Rat: 5900 mg/kg
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.

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 and degradability

No data is available on the degradability of this product.

13. Disposal Considerations

Disposal instructions

This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations. Disposal recommendations are based on uncontaminated material.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. Regulatory Information

US federal regulations

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(iii).
TSCA exempt status.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2))

Not regulated

DEA Essential Chemical Code Number

Not regulated

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated

DEA Exempt Chemical Mixtures Code Number

Not regulated

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance

No

Section 311 hazardous chemical

No

Inventory status**Country(s) or region****Inventory name****On inventory (yes/no)***

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

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

State regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

16. Labeling Info

Label Hazard Warning	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.
Label Precautions	-
Label First Aid	-

17. Other Information

Recommended use	Diagnostic imaging agent.
NFPA ratings	Health: 0 Flammability: 0 Instability: 0
Disclaimer	Mallinckrodt (D/B/A Covidien) provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.
Issue date	03-16-2012