MATERIAL SAFETY DATA SHEET

1. Product and Company Identification

Material name IOVERSOL

Version # 01

CAS # 12-05-2014 87771-40-2

Product use Diagnostic imaging agent.

Synonym(s) OPTIRAY * N,N'-bis(2,3-dihydroxypropyl)-5-[N-(2-hydroxyethyl)-

glycolamido]-2,4,6-triiodoisophthalamide

Manufacturer information Mallinckrodt

675 McDonnell Blvd. Hazelwood, MO 63042

 Customer Service
 888-744-1414

 24 Hour Emergency
 314-654-1600

 Chemtrec
 800-424-9300

Item code 0946, 7888, 7957, 8327, 8777

2. Hazards Identification

Emergency overview DANGER

May form combustible dust concentrations in air.

HIGHLY FLAMMABLE SOLID.

Will be easily ignited by heat, spark or flames. High concentrations of dust may form explosive

mixture with air.

Exposure to powder or dusts may be irritating to eyes, nose and throat. Dust may form explosive

mixture with air.

OSHA regulatory status NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. This product is considered

hazardous under 29 CFR 1910.1200 (Hazard Communication). This substance is not classified as

dangerous according to Directive 67/548/EEC.

Potential health effects

Routes of exposure Inhalation.

Eyes Dust in the eyes will cause irritation.

Skin Dust or powder may irritate the skin.

Inhalation Dust may irritate respiratory system. Prolonged inhalation may be harmful. Inhalation of dusts may

cause respiratory irritation. Coughing. Difficulty in breathing.

Ingestion May cause irritation.

Chronic effects Inhalation of powder/dust may cause lung edema.

aquatic organisms.

3. Composition / Information on Ingredients

Components	CAS#	Percent	
IOVERSOL	87771-40-2	100	

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4. First Aid Measures

First aid procedures

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Get medical attention if irritation develops and persists.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Inhalation If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a physician if

symptoms develop or persist.

Ingestion Get medical attention if any discomfort continues. If ingestion of a large amount does occur, call a

poison control center immediately. Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions. If

vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Notes to physician Provide general supportive measures and treat symptomatically.

General advice In the case of accident or if you feel unwell, seek medical advice immediately (show the label

where possible). If you feel unwell, seek medical advice (show the label where possible). Show

this safety data sheet to the doctor in attendance.

5. Fire Fighting Measures

Flammable properties No unusual fire or explosion hazards noted.

Extinguishing media

Suitable extinguishing

media

Unsuitable extinguishing

media

Water. Use any media suitable for the surrounding fires.

Do not use a solid water stream as it may scatter and spread fire.

Protection of firefighters

Specific hazards arising from the chemical

Decomposition of this product may emit oxides of nitrogen. Iodine.

Protective equipment and precautions for firefighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Structural firefighters protective

clothing will only provide limited protection.

Fire fighting

equipment/instructions

In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. Cool containers exposed to flames with water until well after the fire is out. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or

equivalent) and full protective gear.

Specific methods Cool containers exposed to flames with water until well after the fire is out. Wear full protective

clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask. In the event of fire, cool tanks with water spray.

Move container from fire area if it can be done without risk.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions Ensure adequate ventilation. Keep unnecessary personnel away. Avoid inhalation of dust from the

spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with spilled material. Ventilate closed spaces before entering

them. Wear appropriate protective equipment and clothing during clean-up.

Environmental precautions Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or

onto the ground.

Methods for containment ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Stop the

flow of material, if this is without risk. If sweeping of a contaminated area is necessary use a dust

suppressant agent which does not react with the product.

Methods for cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust

formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product

recovery, flush area with water. For waste disposal, see section 13 of the MSDS.

Other information Clean up in accordance with all applicable regulations.

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7. Handling and Storage

Handling DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect

material from direct sunlight. Do not smoke. Avoid dust formation. Guard against dust accumulation of this material. Provide appropriate exhaust ventilation at places where dust is formed. All equipment used when handling the product must be grounded. Do not breathe dust from this material. Avoid contact with skin and eyes. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Practice good

housekeeping. Avoid contact with eyes. Avoid breathing dust. Keep formation of airborne dusts to a minimum. Do not use in areas without adequate ventilation. Do not ingest. Wash hands thoroughly after handling. When using, do not eat, drink or smoke. Use personal protective

equipment as required. Wash thoroughly after handling.

Storage Store in a well-ventilated place. Keep container tightly closed. Guard against dust accumulation of

this material. Use care in handling/storage. The pressure in sealed containers can increase under the influence of heat. Keep away from heat and sources of ignition. This material can accumulate static charge which may cause spark and become an ignition source. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Avoid dust formation. Store in a cool, dry place. Store in accordance with local/regional/national/international regulation.

8. Exposure Controls / Personal Protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates

should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. Ensure adequate ventilation,

especially in confined areas.

Personal protective equipment

Eye / face protection Use tight fitting goggles if dust is generated. Safety glasses with side-shields. Provide eyewash

station and safety shower.

Skin protection Wear appropriate chemical resistant clothing.

Respiratory protection Wear respirator with dust filter. Use a NIOSH/MSHA approved respirator if there is a risk of

exposure to dust/fume at levels exceeding the exposure limits. In the case of respirable dust

and/or fumes, use self-contained breathing apparatus.

General hygiene considerations

Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after

handling the product. Avoid contact with skin. Avoid breathing dust.

9. Physical & Chemical Properties

Appearance Powder.

Physical state Solid.

Powder. **Form** White. Color Odor Odorless. Odor threshold Not available. pН Not available. Vapor pressure Not available. Not available. Vapor density Not available. **Boiling point**

Melting point/Freezing pointNot available.Solubility (water)Complete

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Specific gravity 1.18 - 1.37

Relative density 1.18 - 1.37 g/cm3 **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.

Molecular weight 807.13

Molecular formula C18-H24-I3-N3-O9

10. Chemical Stability & Reactivity Information

Chemical stability Material is stable under normal conditions. The substance is hygroscopic and will absorb water by

contact with the moisture in the air.

Conditions to avoid Avoid spread of dust. Exposure to moisture. Exposure to light.

Incompatible materials Not available.

Hazardous decomposition

products

reactions

May include oxides of iodine. Nitrogen oxides (NOx).

Possibility of hazardousNo dangerous reaction known under conditions of normal use.

11. Toxicological Information

Toxicological data

Product Species Test Results

IOVERSOL (CAS 87771-40-2)

AcuteOther

LD50 Rat 15 g/kg Intravenous (68% injection)

Local effects Inhalation of dusts may cause respiratory irritation.

Chronic effects Not expected to be hazardous by WHMIS criteria. None known through occupational exposure.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Skin corrosion/irritation

Due to lack of data the classification is not possible.

Epidemiology

No epidemiological data is available for this product.

Mutagenicity Due to lack of data the classification is not possible. No data available to indicate product or any

components present at greater than 0.1% are mutagenic or genotoxic.

Reproductive effectsDue to lack of data the classification is not possible.

Further information This product has no known adverse effect on human health.

12. Ecological Information

EcotoxicityThis product has no known eco-toxicological effects. No data on possible environmental effects

have been found. Not expected to be harmful to aquatic organisms.

Environmental effects Not classified as an environmental hazard.

Aquatic toxicity Not available.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulation / accumulation Not established.

Mobility in environmental media This product is miscible in water.

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

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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. Dispose of contents/container in accordance with local/regional/national/international regulations. Contract

with a disposal operator licensed by the Law on Disposal and Cleaning.

Waste from residues / unused

products

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

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 regulationsThis product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard

Communication Standard, 29 CFR 1910.1200.

CERCLA/SARA Hazardous Substances - Not applicable.

TSCA exempt status.

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

Not listed.

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.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

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

Not listed.

SARA 311/312 Hazardous

Yes

chemical

International Inventories

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

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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
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)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

US state regulations

Country(s) or region

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm. 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.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed

US. Pennsylvania Worker and Community Right-to-Know Law

Inventory name

Not listed.

US. Rhode Island RTK

Not regulated.

16. Labeling Info

Label Hazard Warning	Health injuries are not known or expected under normal use. Handle in accordance with good
	industrial hygiene and safety practice.

Label Precautions Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Keep container closed. Wash

thoroughly after handling.

Label First Aid Immediately flush eyes with plenty of water for at least 15 minutes. Flush skin thoroughly with

water. If gas/fume/vapor/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. Get medical attention if irritation develops or persists. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions. Rinse mouth thoroughly. If vomiting occurs, keep head low so that stomach

content doesn't get into the lungs.

17. Other Information

NFPA ratings Health: 0

Flammability: 0 Instability: 0

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On inventory (yes/no)*

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This data sheet contains changes from the previous version in section(s):

This document has undergone significant changes and should be reviewed in its entirety.

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