

MATERIAL SAFETY DATA SHEET

OCTREOSCAN®

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: OctreoScan®
Synonyms: Indium In-111 labeled Pentetreotide

Manufacturer: Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

Revision Date: April 5, 2011
Information Telephone Number: (888) 744-1414
Emergency Telephone Number: (314)-654-7860
CHEMTREC: 1-800-424-9300
CANUTEC: 613-996-6666

SECTION 2. COMPOSITION. INFORMATION ON INGREDIENTS

Chemical Ingredients:

<u>Component</u>	<u>CAS #</u>	<u>Wt%</u>
Lyophilized Material:		
Pentetreotide	138661-02-6	0.06%
Inositol	87-89-8	57.8%
Trisodium Citrate Dihydrate	6132-04-3	28.4%
Gentisic Acid	490-79-9	11.6%
Citric Acid Monohydrate	5949-29-1	2.1%
Indium Chloride In-111 Sterile Solution-0.2M		
Indium Chloride In-111	50800-85-6	< 1%
Hydrogen Chloride	7647-01-0	< 1%
Ferric Chloride	7705-08-0	< 1%
Water	7732-18-5	> 99%

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Radioactive drugs must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

POTENTIAL HEALTH EFFECTS

The hazardous ingredients found in OctreoScan are skin and eye irritants, but due to the form of the material (lyophilized pellet) no adverse health effects are expected to occur from exposure. The following information applies to the radioactive Indium (In-111) in the kit:

Inhalation:

Indium Chloride does not easily become airborne. Not expected to be a health hazard via inhalation.

Ingestion:

May cause asymptomatic physiological uptake by specific target organs or tissues.

Eye Contact:

No adverse affect expected, but may cause mechanical irritation.

Chronic Exposure:

The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Aggravation of Pre-existing Conditions:

No information found.

SECTION 4. FIRST AID MEASURES

Minimal first aid is expected to be required as a result of exposure to the lyophilized material. Wash exposed skin with soap and water and wash exposed eyes thoroughly with running water. In both instances, seek medical attention if irritation develops.

The following information applies to the radioactive Indium (In-111) in the kit.

Inhalation:

Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented.

Ingestion:

Notify radiation safety personnel immediately. The amount of material ingested should be assessed and documented.

Skin Exposure:

If skin contact occurs, wash the affected area thoroughly with soap and water until no more radioactivity can be removed. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye Exposure:

If a splash occurs, wash eyes with water for at least 15 minutes or until no more radioactivity can be removed. Notify radiation safety personnel.

SECTION 5. FIRE FIGHTING MEASURES

Fire: Not considered to be a fire hazard.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

If the product is received in a leaking condition or any loss or release of the radioactive contents occurs, notify your Radiation Safety Department and Mallinckrodt at (314) 654-7860. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state or federal regulations.

SECTION 7. HANDLING AND STORAGE

Protect from light. Store at 2-8°C (36-46°F). After reconstitution, store at or below 25°C (77°F). Discard after six (6) hours from the time of preparation. After reconstitution, handling time should be kept to a minimum and appropriate shielding should be used. Handling devices such as syringe shields and tongs should be used. Storage and disposal of product should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

SECTION 8. EXPOSURE CONTROLS. PERSONAL PROTECTION

Airborne Exposure Limits:

-NRC Occupational concentration limit is 3×10^{-6} $\mu\text{Ci}/\text{mL}$ of air.

Engineering Controls:

Properly sealed containers are not expected to require any special ventilation.

Respiratory Protection:

Not expected to require personal respirator usage.

Skin Protection:

Disposable plastic, latex, or rubber gloves; labcoat.

Eye/Face Protection:

Safety glasses.

Precautions:

No smoking, eating, or drinking should be allowed in any area where radioactive materials are handled or stored.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Lyophilized white pellet in a 10 mL vial. Clear, colorless liquid in a 10 mL vial (Indium 111).

Odor: Odorless.

Solubility: Somewhat soluble in water.

Boiling Point: ca. 100 °C (212°F).

Melting Point: ca. 0 °C (32°F).

Radioactivity: 3.3 mCi at the time of calibration (Indium 111).

Concentration: 3.0 mCi/mL minimum on the calibration date and time (Indium 111)

Half Life: 6.02 hours

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products: When heated to decomposition, lyophilized material may emit carbon dioxide and carbon monoxide; solution may emit radioactive fumes containing In-111.

Hazardous Polymerization: Will not occur.

Incompatibilities: Protect from light, strong oxidizers and reducing agents.

SECTION 11. TOXICOLOGICAL INFORMATION

It is widely accepted by the scientific community that exposure to sufficient quantities of ionizing radiation can potentially cause harmful biological effects which include cancer, leukemia, and genetic and teratogenic effects. For detailed toxicological information on specific components, write to the address listed in Section 1 - Attn: Regulatory Compliance Department.

SECTION 12. ECOLOGICAL INFORMATION

Because this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13. DISPOSAL CONSIDERATIONS

OctreoScan® reconstituted with Indium Chloride In-111 is Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations.

If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a Biohazard and disposed of accordingly.

If not radioactive or a biohazard, waste OctreoScan® is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

IATA (International Air Transport Association):

Proper Shipping Name: Radioactive Material, Type A Package

Hazard Class: 7

Identification Number: UN2915

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantities:

In-111 = 100 Ci (3.7 E 12 Bq)

Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported to the National Response Center at 800-424-8802.

SARA Title III:

302 Extremely Hazardous Substances: None

311 / 312 Hazard Categories: Chronic

313 Toxic substances subject to annual release reporting requirements: None

RCRA Hazardous Waste Status:

Non-hazardous (See Section 13 for additional details)

California Proposition 65 Warning:

This product contains a substance known to the State of California to cause cancer.

Australian Hazchem Code: None allocated.

Australian Poison Schedule: None allocated.

WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

SECTION 16. OTHER INFORMATION

MSDS Status: Revised in accordance with ANSI Guideline Z400.1-1998

NFPA Ratings: Health: 1 Flammability: 0 Reactivity: 0

Product Use: Diagnostic Imaging Agent.

Revision Information: Section 7

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