SAFETY DATA SHEET

1. Identification

Product identifier **Octreoscan™ Kit for the Preparation of Indium In 111 Pentetreotide**

Other means of identification

SDS number OCKIP

Synonyms Indium In-111 labeled Pentetreotide

Recommended use The content of this kit as sold is radioactive.

Octreoscan™ is a kit for the preparation of indium In-111 pentetreotide, a diagnostic radiopharmaceutical. Indium In 111 pentetreotide is an agent for the scintigraphic localization of primary and metastatic neuroendocrine tumors bearing somatostatin receptors.

It is used as a diagnostic radiopharmaceutical.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Supplier

Company name Curium Canada Inc.

Address 2572 Daniel-Johnson Boulevard
Offices 245-249, 2nd Floor
Laval, QC H7T 2R3
Canada

Telephone number Customer Service phone number: 866-885-5988

E-mail NuclearMedicine@curiumpharma.com

Emergency telephone number: 24 Hour Emergency 314-595-3700

Chemtrec 800-424-9300

2. Hazard identification

Physical hazards Not classified.

Health hazards

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Sensitization, skin	Category 1

Label elements

Signal word Warning

Hazard statement Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.

Precautionary statement

Prevention Avoid breathing dust. Wear protective gloves/eye protection/face protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

Response IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Storage Store away from incompatible materials.

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

Other hazards None known.

Supplemental information 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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Inositol		87-89-8	57.8
Sodium citrate dihydrate		6132-04-3	28.4
Gentisic Acid		490-79-9	11.6
Citric acid (hydrated form)		5949-29-1	2.1
Ferric chloride		7705-08-0	< 1
Hydrochloric acid		7647-01-0	< 1
INDIUM CHLORIDE IN-111		50800-85-6	< 1
Pentetreotide		138661-02-6	0.06

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

The kit is consisting of two components:
1) A 10-mL Octreoscan Reaction Vial which contains a lyophilized mixture of: (i) 10 µg pentetreotide [N-(diethylenetriamine-N,N,N',N"- tetraacetic acid-N"-acetyl)-D-phenylalanyl-L-hemicystyl-Lphenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-L-hemicystyl-Lthreoninol cyclic (2 to 7) disulfide], (also known as octreotide DTPA), (ii) 2.0 mg gentisic acid [2, 5-dihydroxybenzoic acid], (iii) 4.9 mg trisodium citrate, anhydrous, (iv) 0.37 mg citric acid, anhydrous, and (v) 10.0 mg inositol.

2) A 10-mL vial of Indium In 111 Chloride Sterile Solution, which contains: 1.1 mL or 111 MBq/mL (3.0 mCi/mL) indium In-111 chloride in 0.02N HCl at time of calibration. The vial also contains ferric chloride at a concentration of 3.5 µg/mL (ferric ion, 1.2 µg/ mL). The vial contents are sterile and nonpyrogenic. No bacteriostatic preservative is present.

4. First-aid measures

Inhalation Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Evaluate and document the amount of material inhaled and seek medical attention for radiation intake.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. Always blot dry. Do not abrade skin. Get medical attention if irritation develops and persists. Notify radiation safety personnel.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists. Notify radiation safety personnel.

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

Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin. Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is sub therapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/ discomfort, loose stools, and vomiting. Hypertension and hyper- and hypogly cemia have also been reported with the use of octreotide.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. When heated to decomposition, lyophilized material may emit carbon dioxide and carbon monoxide; solution may emit radioactive fumes containing In-111.
Special 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.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Follow all guidances provided by NRC or equivalent authority. In the case of a leak/release of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. If on site, follow the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate the area, allowing sufficient time for several air exchanges. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Follow all guidances provided by the US Nuclear Regulatory Commission in the US or equivalent authority in your country and your radiation safety personnel. Maintain radioactive exposures as low as reasonably achievable. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Should be handled in closed systems, if possible. When using, do not eat, drink or smoke. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices. All shippers and consignees, as well as handlers of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Keep container tightly closed. Protect from light. The drug should be stored at 2°C to 8°C both prior to and following reconstitution with Indium Chloride In-111 and discarded after six (6) hours from the time of preparation. Store away from incompatible materials (see section 10 of the SDS).

Storage should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

8. Exposure controls/personal protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	3 mg/m3
		2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	STEL	2 mg/m3
	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	TWA	1 mg/m3

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety)

Components	Type	Value
Hydrochloric acid (CAS 7647-01-0)	Ceiling	7.5 mg/m3
		5 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	TWA	0.1 mg/m3

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21)

Components	Type	Value
Ferric chloride (CAS 7705-08-0)	15 minute	3 mg/m3
	8 hour	1 mg/m3
Hydrochloric acid (CAS 7647-01-0)	Ceiling	2 ppm
INDIUM CHLORIDE IN-111 (CAS 50800-85-6)	15 minute	0.3 mg/m3
	8 hour	0.1 mg/m3

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

Appropriate engineering controls Good general ventilation 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. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Chemical resistant gloves.

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

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

Physical state Liquid.

Form Pellets. Solution.

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

Odour Odourless.

Odour threshold Not available.

pH Not available.

Melting point/freezing point 0 °C (32 °F)

Initial boiling point and boiling range 100 °C (212 °F)

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1
Solubility(ies)	
Solubility (water)	Somewhat soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Concentration	3.0 mCi/mL minimum on the claibration date and time (Indium 111).
Half-Life	67.32 hours (Radioactive)
Radioactivity	3.3 mCi at the time of calibration (Indium 111).

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Light. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents. Reducing Agents.
Hazardous decomposition products	When heated to decomposition, lyophilized material may emit carbon dioxide and carbon monoxide; solution may emit radioactive fumes containing In-111.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected. No respiratory symptoms. Indium Chloride does not easily become airborne.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	May cause asymptomatic physiological uptake by specific target organs or tissues.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash. The following adverse effects were observed in clinical trials at a frequency of less than 1% of 538 patients: dizziness, fever, flush, headache, hypotension, changes in liver enzymes, joint pain, nausea, sweating, and weakness. These adverse effects were transient. Also in clinical trials, there was one reported case of bradycardia and one case of decreased hematocrit and hemoglobin. Pentetreotide is derived from octreotide which is used as a therapeutic agent to control symptoms from certain tumors. The usual dose for indium In-111 pentetreotide is approximately 5 to 20 times less than for octreotide and is sub therapeutic. The following adverse reactions have been associated with octreotide in 3% to 10% of patients: nausea, injection site pain, diarrhea, abdominal pain/ discomfort, loose stools, and vomiting. Hypertension and hyper- and hypogly cemia have also been reported with the use of octreotide.

Information on toxicological effects

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

Components	Species	Test Results
Ferric chloride (CAS 7705-08-0)		
Acute		
Oral		
LD50	Rat	1 g/kg
Hydrochloric acid (CAS 7647-01-0)		
Acute		
Dermal		
LD50	Rabbit	> 5100 mg/kg
Inhalation		
Gas		
LC50	Rat	4.2 mg/l, 1 hours
Oral		
LD50	Rat	238 - 277 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitisation

Canada - Alberta OELs: Irritant

Ferric chloride (CAS 7705-08-0)	Irritant
Hydrochloric acid (CAS 7647-01-0)	Irritant

Respiratory sensitisation Not available.

Skin sensitisation May cause an allergic skin reaction.

Germ cell mutagenicity PENTETREOTIDE was evaluated for mutagenic potential in an in vitro mouse lymphoma forward mutation assay and an in vivo mouse micronucleus assay; evidence of mutagenicity was not found.

Carcinogenicity Studies have not been performed with indium In-111 pentetreotide to evaluate carcinogenic potential or effects on fertility. Gamma radiation is carcinogenic to humans. The health risks associated with chronic radiation exposure (cancer, leukaemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally. Risk of cancer cannot be excluded with prolonged exposure.

ACGIH Carcinogens

Hydrochloric acid (CAS 7647-01-0)	A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Hydrochloric acid (CAS 7647-01-0)	Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Hydrochloric acid (CAS 7647-01-0)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Animal reproduction studies have not been conducted with indium In-111 pentetreotide. It is not known whether indium In-111 pentetreotide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Therefore, indium In-111 pentetreotide should not be administered to a pregnant woman unless the potential benefit justifies the potential risk to the fetus. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when indium In-111 pentetreotide is administered to a nursing woman.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure May cause damage to organs (immune system, blood) through prolonged or repeated exposure. Due to inconclusive data the classification criteria are not met.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

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

12. Ecological information

Ecotoxicity There are no data on the ecotoxicity of this product.

Components		Species	Test Results
Ferric chloride (CAS 7705-08-0)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	9.6 mg/l, 48 Hours
Fish	LC50	Bluegill (Lepomis macrochirus)	20.26 mg/l, 96 Hours
Hydrochloric acid (CAS 7647-01-0)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	0.492 mg/l, 48 Hours
Fish	LC50	Oncorhynchus mykiss	7.45 mg/l, 96 Hours

Persistence and degradability No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential No data available.

Mobility in soil No data available.

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

13. Disposal considerations

Disposal instructions 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 a biohazard, consult local, state and federal regulations for proper disposal.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

TDG

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class 7

Subsidiary risk -

Packing group Not available.

Environmental hazards Not available.

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IATA

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class 7

Subsidiary risk -

Label(s) 7

Packing group Not available.

Environmental hazards No.

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

IMDG

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class 7

Subsidiary risk -

Label(s) 7

Packing group Not available.

Environmental hazards

Marine pollutant No.

EmS Not available.

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established. This substance/mixture is not intended to be transported in bulk.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Hydrochloric acid (CAS 7647-01-0)

Precursor Control Regulations

Hydrochloric acid (CAS 7647-01-0) Class B

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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
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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies 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).

16. Other information

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Revision date -

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