

SAFETY DATA SHEET



1. Identification

Product identifier	lutetium Lu 177 dotatate injection
Other means of identification	None.
Recommended use	Therapeutic radiopharmaceutical for intravenous use only.
Recommended restrictions	None known.

Manufacturer/Importer/Supplier/Distributor information

Supplier

Company name	Curium US LLC
Address	14385 Bergen BLV Noblesville, IN, 46060 United States
Telephone number	Customer Service 888-744-1414
E-mail	NuclearMedicine@curiumpharma.com
Emergency telephone number:	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.

RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL.

Precautionary statement

Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC)

This is a radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to clinical personnel and patients. Radiopharmaceuticals should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radionuclides, and whose training and experience has been approved by the appropriate government agency authorized to license the use of radionuclides.

Supplemental information

As per 29 CFR 1910.1200(b)(6)(xi), ionizing and nonionizing radiation are outside the scope and application of the Hazard Communication Standard, although the radioactive material should be considered the principle hazard of the material. This material should only be handled by trained individuals in conformance with the requirements of applicable regulations. Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

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	CAS number	%
Water	7732-18-5	96.4
Ethanol	64-17-5	2.0
Sodium Ascorbate	134-03-2	1.5
Pentetic Acid (DTPA)	67-43-6	< 0.1
DOTA-TATE (TFA)	177943-89-4	< 0.1
Lu-177 Dotatate	437608-50-9	< 0.1

Composition comments

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

The manufacturer has claimed the exact percentage as trade secret under the OSHA Hazard Communication Standard.

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

Wash off immediately with soap and plenty of water. Do not abrade skin. Always blot dry. Notify radiation safety personnel.

Eye contact

Get medical attention if irritation develops and persists. Notify radiation safety personnel.

Ingestion

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

Most important symptoms/effects, acute and delayed

Radiation-related adverse reactions are a function of the dose level received by the patient. Prolonged exposure may cause chronic effects. The most common adverse effects include: Decreased blood cell counts. Nausea and vomiting. Increased blood glucose. Decreased blood potassium levels.

Indication of immediate medical attention and special treatment needed

Treat symptomatically.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Radioactive. During fire, gases hazardous to health may be formed such as: Carbon oxides. May produce airborne radioactive materials during a fire. Avoid all exposures!

Special protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions

In case of fire and/or explosion do not breathe fumes. Ensure and follow all guidance provided in handling fire involving radioactive materials.

Specific methods

Decontaminate protective clothing and equipment before reuse or dispose of as radioactive waste.

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 license requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. 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. Following product recovery, flush area with water. Collect in containers and seal securely. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility in accordance with NRC or other applicable local, state or federal regulations. For waste disposal, see section 13 of the SDS. Shield waste containers as needed to maintain accessible dose rate ALARA and < 2 mR/hr.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

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. Label as radioactive material. 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. Change gloves frequently. Avoid contact during pregnancy/while nursing. Misuse or mishandling beyond its intended use may result in excess radiation exposure. Contact your radiation safety personnel for additional information. Use transfer pipets, spill trays and absorbent coverings to confine radioactive contamination.

All shippers and consignees, as well as handlers of this material must possess a valid radioisotope license issued by the appropriate federal or state authority. Shield waste containers as needed to maintain accessible dose rate ALARA and < 2 mR/hr.

Conditions for safe storage, including any incompatibilities

Store in a place accessible by authorized persons only. Store below 25°C. Do not freeze. Shelf life 72 hours. Keep away from heat, sparks and open flame. 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. Store in tightly closed container.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Permissible Exposure Limits (PEL) for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m3
		1000 ppm

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value
Ethanol (CAS 64-17-5)	STEL	1000 ppm

NIOSH. Immediately Dangerous to Life or Health (IDLH) Values, as amended

Components	Type	Value
Ethanol (CAS 64-17-5)	IDLH	3.3 %
		3300 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m3
		1000 ppm

Biological limit values

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

Exposure guidelines

Airborne Exposure Limit (Lu-177): NRC Occupational Concentration Limit: (3 x 10⁻⁹ µCi/ml)

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.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Double gloving is recommended.
Skin protection	
Other	Wear suitable protective clothing. Use of an impervious apron is recommended.
Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Consult with your facility's Radiation Safety Personnel or Health Physics staff for use of appropriate respiratory equipment. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. When using do not 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.

9. Physical and chemical properties**Appearance**

Physical state	Liquid.
Form	Liquid.
Color	Colorless to light yellow.

Odor Odorless.

Odor threshold Property has not been measured.

pH 5.3

Melting point/freezing point Property has not been measured.

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

Flash point > 140 °F (> 60 °C)

Evaporation rate Property has not been measured.

Flammability (solid, gas) Not applicable. Will burn if involved in a fire.

Upper/lower flammability or explosive limits

Explosive limit - lower (%) Property has not been measured.

Explosive limit - upper (%) Property has not been measured.

Vapor pressure Property has not been measured.

Vapor density Property has not been measured.

Relative density Property has not been measured.

Solubility(ies)

Solubility (water) Property has not been measured.

Partition coefficient (n-octanol/water) Not applicable, product is a mixture.

Auto-ignition temperature Property has not been measured.

Decomposition temperature Property has not been measured.

Viscosity Property has not been measured.

Other information

Density Property has not been measured.

Explosive properties Not explosive.

Kinematic viscosity Property has not been measured.

Oxidizing properties Not oxidizing.

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.
	Aqueous radioactive solutions are subject to radiolysis, the breaking apart of water molecules in solution. This occurs as a natural result of some of the higher radiation energies interacting with the solution water molecules. As a result, solutions may become concentrated over time.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid temperatures exceeding the flash point.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Exposure to radioactive materials may produce adverse effects. Prolonged inhalation may be harmful.
Skin contact	Exposure to radioactive materials may produce adverse effects. Prolonged skin contact may cause temporary irritation.
Eye contact	Exposure to radioactive materials may produce adverse effects. Direct contact with eyes may cause temporary irritation.
Ingestion	Exposure to radioactive materials may produce adverse effects. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics	The most common side effects include: Decreased blood cell counts. Nausea and vomiting. Increased blood glucose. Decreased blood potassium levels.
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Information on toxicological effects

Acute toxicity	Occupational exposure to the substance or mixture may cause adverse effects.
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Components	Species	Test Results
Ethanol (CAS 64-17-5)		
<u>Acute</u>		
Dermal		
LD50	Rat	> 2000 mg/kg
Inhalation		
<i>Vapor</i>		
LC50	Mouse	39 g/m3, 4 Hours
Oral		
LD50	Rat	7000 - 11000 mg/kg
Pentetic Acid (DTPA) (CAS 67-43-6)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Germ cell mutagenicity	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.	
Carcinogenicity	Risk of cancer cannot be excluded with prolonged 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.	

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Reproductive toxicity	Due to partial or complete lack of data the classification is not possible. 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.
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Not an aspiration hazard.
Chronic effects	Prolonged inhalation may be harmful. 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.
Further 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. Symptoms may be delayed.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
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Components		Species	Test Results
Ethanol (CAS 64-17-5)			
Aquatic			
Acute			
Crustacea	LC50	Ceriodaphnia dubia	5012 mg/l, 48 hours
		Daphnia magna	454 mg/l, 11 days
Fish	LC50	Pimephales promelas	13480 mg/l, 96 hours
Chronic			
Crustacea	NOEC	Ceriodaphnia dubia	9.6 mg/l, 10 days
Pentetic Acid (DTPA) (CAS 67-43-6)			
Aquatic			
Acute			
Crustacea	EC50	Water flea	245 mg/l, 48 Hours
Fish	LC50	Leuciscus idus	> 100 mg/l, 96 Hours

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available on bioaccumulation.
Partition coefficient n-octanol / water (log Kow)	
Ethanol (CAS 64-17-5)	-0.31
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	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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. Provide for safe disposal of radioactive waste by following institutional Waste Handling & Disposal Procedures. Avoid generating mixed waste (combinations of radioactive, biological, and chemical waste). Note that lab staff may not pour measurable quantities of radioactive material down the drain.
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. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package non-special form, non fissile or fissile-excepted
Transport hazard class(es)	
Class	7
Subsidiary hazard	-
Label(s)	7
Packing group	-
Environmental hazards	
Marine pollutant	No.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	325, A56, W7, W8
Packaging exceptions	None
Packaging non bulk	415, 418, 419
Packaging bulk	415, 418, 419

IATA

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package non-special form, non-fissile or fissile excepted
Transport hazard class(es)	
Class	7
Subsidiary hazard	-
Packing group	-
Environmental hazards	No.
ERG Code	7L
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, non-special form, non fissile or fissile - excepted
Transport hazard class(es)	
Class	7
Subsidiary hazard	-
Packing group	-
Environmental hazards	
Marine pollutant	No.
EmS	F-I, S-S
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 applicable.

15. Regulatory information

US federal regulations Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible for protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Toxic Substances Control Act (TSCA)

One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

Ethanol (CAS 64-17-5)

Low priority

US state regulations**US. Massachusetts RTK - Substance List**

Ethanol (CAS 64-17-5)

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

Ethanol (CAS 64-17-5)

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

Ethanol (CAS 64-17-5)

US. Rhode Island RTK

Ethanol (CAS 64-17-5)

California Proposition 65

For more information go to www.P65Warnings.ca.gov. California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a substance (radioactive material) known to the State of California to cause reproductive toxicity.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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 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).

16. Other information, including date of preparation or last revision**Issue date**

07-August-2024

Revision date	-
Version #	01
List of abbreviations	CAS: Chemical Abstract Service. DOT: Department of Transportation. EC50: Effective Concentration, 50%. GHS: Globally Harmonized System of Classification and Labeling of Chemicals. IBC Code: International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk. IATA: International Air Transport Association. IMDG: International Maritime Dangerous Goods. LC50: Lethal Concentration, 50%. LD50: Lethal Dose, 50%. MARPOL: International Convention for the Prevention of Pollution from Ships. NOEC: No observed effect concentration. PEL: Permissible Exposure Limit. STEL: Short-Term Exposure Limit. TWA: Time Weighted Average.
References	ECHA CHEM NRC: Nuclear Regulatory Commission,
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