

SAFETY DATA SHEET

1. Identification

Product identifier copper Cu 64 dotatate injection
Other means of identification None.
Recommended use Not available.
Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Supplier

Company name Curium US LLC
Address 2703 Wagner Place
Maryland Heights, MO 63043
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 Reproductive toxicity Category 1
OSHA defined hazards Not classified.
Label elements



Signal word Danger
Hazard statement May damage fertility or the unborn child.

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

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response If exposed or concerned: Get medical advice/attention.
Storage Store locked up.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

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	> 89%
Sodium Ascorbate	134-03-2	< 6%
Ethanol	64-17-5	< 5%
Dotatate	177943-88-3	< 0.1%
copper Cu 64 dotatate	1426155-87-4	< 0.1%

Composition comments

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

The total activity of Cu-64 < 166.5 MBq (4.5 mCi) at product calibration.

The exact percentage (concentration) of composition has been withheld as a trade secret.

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. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.

Ingestion

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

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Prolonged exposure may cause chronic effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. 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.

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

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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. Move containers from fire area if you can do so without risk. Water runoff can cause environmental damage.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials. Decontaminate protective clothing and equipment before reuse or dispose of as radioactive waste.

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. Collect in containers and seal securely. Following product recovery, flush area with water. 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. Provide adequate ventilation. Avoid prolonged exposure. Misuse or mishandling beyond its intended use may result in excess radiation exposure. Use transfer pipets, spill trays and absorbent coverings to confine radioactive contamination. Pregnant or breastfeeding women must not handle this product. 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. Shield waste containers as needed to maintain accessible dose rate ALARA and < 2 mR/hr.

Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store below 25°C. Do not freeze. Store away from incompatible materials (see Section 10 of the SDS).

Storage and disposal of product 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. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
Ethanol (CAS 64-17-5)	PEL	1900 mg/m ³ 1000 ppm

US. ACGIH Threshold Limit Values

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

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Ethanol (CAS 64-17-5)	TWA	1900 mg/m ³ 1000 ppm

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.

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 appropriate chemical resistant 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.
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. No smoking, eating or drinking should be allowed in any area where radioactive materials are handled or stored. 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	Clear to yellow.
Odor	Slight alcohol odor may be present.
Odor threshold	Not available.
pH	5.5 - 7.5
Melting point/freezing point	28.4 °F (-2 °C)
Initial boiling point and boiling range	204.8 °F (96 °C)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Non-Flammable.
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.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Completely soluble (100%).
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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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	Contact with incompatible materials.
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 Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Ethanol (CAS 64-17-5)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Inhalation		
<i>Vapor</i>		
LC50	Mouse	39 g/m3, 4 Hours
Oral		
LD50	Rat	7000 - 11000 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 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.

Carcinogenicity Risk of cancer cannot be excluded with prolonged exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer.

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	May damage fertility or the unborn child. 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	Due to partial or complete lack of data the classification is not possible.
Chronic effects	Prolonged exposure may cause chronic effects. 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 Due to lack of data the classification is not possible.

Components	Species	Test Results
Ethanol (CAS 64-17-5)		
Aquatic		
<i>Acute</i>		
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
<i>Chronic</i>		
Crustacea	NOEC	Ceriodaphnia dubia 9.6 mg/l, 10 days

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

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

Ethanol (CAS 64-17-5) -0.31

Mobility in soil No data available.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions	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 (see: Disposal instructions).
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 (copper Cu 64 dotatate injection)
Transport hazard class(es)	
Class	7
Subsidiary risk	-
Label(s)	7
Packing group	Not available.
Special precautions for user	Read safety instructions, SDS and emergency procedures before handling.
Special provisions	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 (copper Cu 64 dotatate injection)
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 (copper Cu 64 dotatate injection)
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 This substance/mixture is not intended to be transported in bulk.

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 Yes
Classified hazard categories Reproductive toxicity
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

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. For more information go to www.P65Warnings.ca.gov.

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, including date of preparation or last revision

Issue date 15-March-2020
Revision date -
Version # 01

Disclaimer

Curium US LLC cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.