SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: QUADRAMET® (Samarium Sm-153 Lexidronam Injection)

Version 3.1 11/4/2015

Product Uses This material is used as a medical imaging agent. It is a radioactive isotope of Samarium (Sm-153).

COMPANY IDENTIFICATION:

Lantheus Medical Imaging
331 Treble Cove Road
Billerica, MA 01862
United States of America
1-800-299-3431

EMERGENCY PHONE:

CHEMTREC 1-800-424-9300.
For International Transportation Emergencies Call CHEMTREC @ 1-703-527-3887.
Collect Calls are accepted

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

Appearance Clear, colorless to light yellow liquid

Signal Word Danger!

Hazard Statements Radioactive, Corrosive

Precautionary Measures Avoid ingestion, inhalation, skin and eye contact. Wear eye/face protection. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing and gloves. After contact with skin, wash immediately with plenty of water. Wash hands after handling to minimize exposure. Care should be taken to minimize radiation exposure. Pregnant or nursing women should avoid exposure. Appropriate radiation shielding should be used. Keep material in a lead container. Avoid direct handling by using remote manipulation tools.

Potential Health Effects

Eyes	Corrosive
Skin	Corrosive
Ingestion	Exposure to radioactive materials may produce adverse effects.
Inhalation	Exposure to radioactive materials may produce adverse effects.
Target Organs	Bones, bone marrow, kidney.
Signs and Symptoms	Acute: severe burns, tissue destruction, blindness, corneal opacity, redness and swelling of skin and eyes, labored respiration, noisy respiration, chest pain, breathing difficulties, shortness of breath, lung inflammation, oedema, pneumonia. Chronic: Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity.

Environmental Effects Not Available

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Active Substance Samarium-153

Chemical Identity Aqueous Mixture

Common Name/Synonym: Samarium Sm-153 Lexidronam Pentasodium Injection; Samarium-153 Ethylendiaminetetramethylene Phosphonate Injection; Sm-153 EDTMP Injection

Hazardous Components

Component	**Concentration**	**CAS**
EDTMP	>1%	1429-50-1
Sodium Hydroxide	>1%	1310-73-2

Other Components

Total Samarium	<0.0025%	7440-19-9
Samarium-153	<0.01%	15766-00-4
Calcium Hydroxide	<1%	1305-62-0
Water	<96%	7732-18-5

SECTION 4: FIRST AID MEASURES

Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention. Continue rinsing eyes during transport to hospital.
Skin contact	Remove contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Wash contaminated clothing before re-use. Discard contaminated shoes. Dispose of contaminated clothing according to company procedures and governmental regulations for radioactive waste.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Do NOT induce vomiting. Call a physician or Poison Control Centre immediately. Never give anything by mouth to an unconscious person.
Note to Physicians	This material is used as a medical imaging agent. It is a radioactive isotope of Samarium (Sm-153). This product may cause: severe burns, tissue destruction, blindness, corneal opacity, redness and swelling of skin and eyes, labored respiration, noisy respiration, chest pain, breathing difficulties, shortness of breath, lung inflammation, oedema, pneumonia, Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity, decreased white blood cell count, decreased platelets, and, bone marrow suppression. Organs effected may include: bone, bone marrow, kidney. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.
Medical Surveillance	A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: a complete blood count with differential, and, a blood test for kidney function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. This exam should be overseen by a physician thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. It is recommended that the content be similar to the pre-placement exam. Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties	Material is an aqueous solution. Not expected to be flammable.
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Radioactive, Corrosive.
Protective equipment:	Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
Hazardous Combustion Products	carbon oxides (COx), nitrogen oxides (NOx), oxides of phosphorus, radioactive samarium, and, radioactive breakdown products.
Other Information	Decontaminate protective clothing and equipment before reuse. Heating can release hazardous gases.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions	Contact the company Radiation Safety Officer. Handle as radioactive spill. Care should be taken to minimize radiation exposure. Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental Precautions	Prevent release to drains and waterways. Prevent release to the environment
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

Cleanup Methods	Contact the company Radiation Safety Officer. Spill prevention procedures and a spill response procedure should be implemented. Care should be taken to minimize radiation exposure. Dispose of cleanup materials as radioactive waste. Isolate waste in sealed, clearly labeled containers and dispose of according to company procedures and governmental regulations.

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Contact the company Radiation Safety Officer. Avoid exposure - obtain special instructions before use. Care should be taken to minimize radiation exposure. Appropriate radiation shielding should be used. Handling time should be kept to a minimum. The vial containing the diagnostic agent should be kept within it's container or within heavier shielding. Store and handle in a designated area. Keep material in a lead container. Avoid direct handling by using remote manipulation tools. Use transfer pipets, spill trays and absorbent coverings to confine radioactive contamination. Obtain appropriate governmental licenses to possess and handle radioactive material. Avoid inhalation of vapor or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways. *For a complete discussion of Handling and Storage information, please consult the full prescribing information.*
Storage Conditions	Keep frozen. Store and handle in a designated area. Storage and disposal of product should be controlled in a manner compliant with applicable governmental regulations pertaining to radionuclides. Do not store near incompatible substances.
Container Requirements	Store in original primary packaging as provided. Store in lead shielded container.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Radionuclides	---	50 mSv Effective Dose, (annual) 20 mSv Effective Dose, 5 years 150 mSv (lens of eye), Annual Equivalent Dose 500 mSv (Skin), Annual Equivalent Dose 500 mSv (hands and feet), Annual Equivalent Dose 0.5 mSv (embryo/fetus), Monthly Equivalent Dose 2 mSv (abdomen of pregnant woman over course of pregnancy) 1/20, Annual Limit on Intake, as ionizing radiation, (for pregnant woman over course of pregnancy)	2.0 mCi Annual Limit (NRC - 10 CFR 20) 0.000001 µCi/ml Derived Air Concentration (NRC - 10 CFR 20) 50 mSv Effective Dose, (annual) 150 mSv (lens of eye), Annual Equivalent Dose 500 mSv (Skin), Annual Equivalent Dose 15 mg/m3 TWA total dust 5 mg/m3 TWA	---
Calcium Hydroxide	---	5mg/m^3 TWA	15mg/m^3 TWA Total 5mg/m^3	5mg/m^3 TWA
Sodium Hydroxide	---	2mg/m^3 Ceiling	2mg/m^3 TWA	2mg/m^3 Ceiling 10mg/m^3 IDLH

Exposure Control Band Not Available

Lantheus Medical Imaging Exposure Guidelines Summary Not Available

Recommended Industrial Hygiene Monitoring Methods
Contact the Lantheus Medical Imaging Radiation Protection Office at 978-671-8672 or 8673.

Engineering Controls and Ventilation
Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.

Respiratory Protection
Use and selection of respiratory protection is based upon engineering controls in use and potential for aerosol generation. When engineering controls are not sufficient to control exposure to below the exposure limit, wear an approved supplied air respirator.

Eye Protection
Chemical safety goggles and face shields are recommended. Note: Choice of eye protection may be influenced by the type of respirator which is selected.

Hand Protection
Impervious nitrile, rubber and latex gloves are recommended. Double gloving for all manufacturing personnel potentially in direct contact with the compound should be considered. If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.

Skin and Body Protection
Wear disposable coverall, polyethylene apron and sleeves, and shoe covers.

Hygiene
Follow good chemical hygiene practices. Wash hands and face before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Liquid
Color	Clear, colorless to light yellow
Odor	Not Available

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	~1g/ml
pH	7-8.5
Boiling Point	~100C
Freezing Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	Stable under normal conditions. Samarium-153 is a beta, gamma and x-ray emitting radionuclide with a half-life of 46.7 hours.
Conditions to Avoid	Heat, flames and sparks
Incompatible Products	Strong oxidizing agents
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions: carbon oxides(COx), nitrogen oxides (NOx), oxides of phosphorus, radioactive samarium, and, radioactive breakdown products
Hazardous Reactions	Hazardous polymerization does not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	Not Available
Skin Irritation	Not Available
Respiratory Irritation	Sodium Hydroxide corrosive to respiratory tract.
Sensitization	EDTMP not a dermal sensitizer.

Acute Toxicity

Acute Oral

EDTMP

LD50(rat): 6,900 mg/kg

Sodium Hydroxide

LDlo(rabbit): 500 mg/kg

Acute Dermal

EDTMP

LD50(rat): > 5,010 mg/kg

Sodium Hydroxide

LD50(rabbit): 1,350 mg/kg

Acute toxicity (other routes of administration)

Sodium Hydroxide

LD50 (mouse, Intraperitoneal): 40 mg/kg

Samarium-153 EDTMP

(dog, intravenous): Effects include: decreased white blood cell count, decreased platelets, bone marrow suppression

Repeated Dose Toxicity

EDTMP

6 months Oral dog study: NOAEL = 2 mg/kg Effects include: bone effects.

Samarium Ca/Na EDTMP

(daily) rat study: NOAEL = 20 mg/kg Effects include: changes in clinical chemistry parameters, ataxia, convulsions, decreased food consumption, decreased body weight. Microscopic changes were observed in the following organs: kidney.

(daily) dog study with recovery period (4 Weeks): LOAEL = 10 mg/kg Effects include: decreased food consumption, decreased body weight, changes in clinical chemistry parameters, increase in heart rate. Microscopic changes were observed in the following organs: kidney. After recovery, some parameters returned to normal.

(daily) Monkey study: NOAEL = 10 mg/kg Effects include: changes in clinical chemistry parameters. Microscopic changes were observed in the following organs: kidney.

Genetic Toxicity

EDTMP

Mutagenicity Assessment

This material was negative in a battery of in vivo and in vitro genotoxicity assays.

Sodium Hydroxide

Mutagenicity Assessment

This material was positive and negative in both in vitro and animal studies.

Samarium Ca/Na EDTMP

Mutagenicity Assessment

This material was negative in a battery of in vivo and in vitro genotoxicity assays.

Carcinogenicity

EDTMP

2 Years Dietary rat study: NOAEL = 100 mg/kg No treatment-related tumors were observed. No significant adverse effects were observed.

2 Years Oral rat study: LOAEL = [tumor organs: bone]

Carcinogenicity Assessment

This material has limited evidence of carcinogenic potential.

Carcinogenicity

	ACGIH	OSHA	NTP	IARC
Radionuclides	---	---	---	1
EDTMP	---	---	---	---
Sodium Hydroxide	---	---	---	---
Samarium Ca/Na EDTMP	---	---	---	---
Samarium-153 EDTMP	---	---	---	---

Reproductive Toxicity Not Available

Developmental Toxicity Not Available

Human Experience

Samarium-153 EDTMP

Intravenous injection - Pharmacological effects include: decreased white blood cell count, decreased platelets, bone marrow suppression.

Target Organs

EDTMP

bone

Samarium Ca/Na EDTMP

kidney

Samarium-153 EDTMP

bone marrow

Symptoms *Sodium Hydroxide*

Causes severe burns, tissue destruction, blindness, corneal opacity, rash, redness and swelling of eyes, rash, redness and swelling of skin, labored respiration, noisy respiration, chest pain, breathing difficulties, shortness of breath, lung inflammation, oedema, pneumonia

Other Toxicity Information Not Available

Section 12 ECOLOGICAL INFORMATION

Environmental Fate: Not available

Environmental Toxicity:

Ecotoxicological Information (Aquatic) Not available

Acute Toxicity to Fish

EDTMP

LC50 (Oncorhynchus mykiss (rainbow trout), 96 H) : 250 mg/l.
NOEC (Oncorhynchus mykiss (rainbow trout), 96 H) : 164 mg/l.
NOEC (Bluegill sunfish, 96 H) : 164 mg/l.

Sodium Hydroxide

LC50 (Oncorhynchus mykiss (rainbow trout), 96 H) : 45.4 mg/l.

Acute Toxicity to Aquatic Invertebrates

EDTMP

EC50 (Daphnia magna (Water flea), 48 H) : 510 mg/l.
NOEC (Daphnia magna (Water flea), 48 H) : 250 mg/l.
EC50 (48 H) : 7,320 mg/l.
NOEC (48 H) : 1,956 mg/l.

Toxicity to aquatic plants

EDTMP

EC50 (Selenastrum capricornutum (green algae), 96 H) : 0.42 mg/l
NOEC (Selenastrum capricornutum (green algae), 96 H) : 0.09 mg/l

Ecotoxicological Information (Terrestrial) Not available

SECTION 13: Disposal Considerations

Advice on Disposal and Packaging

Segregate and label radioactive waste. Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Other Information Disposal by incineration is recommended.

SECTION 14: TRANSPORT INFORMATION

US DOT Transportation Classification for All Modes

The classification for transportation of radioactive materials will depend on the specific activity level of the material, type of isotope, as well as the quantity shipped. Specific site procedures should be followed for shipping radioactive materials or seek advice from your site radiation safety officer.

SECTION 15: REGULATORY INFORMATION

United States of America

OSHA Hazard Classification	Corrosive, Target Organs Note: This regulation does not address hazards related to radioactivity
CERCLA/SARA RQ	Samarium-153 RQ = 1 lb Samarium-153 RQ = 0.454 kg Samarium-153 RQ = 100 Ci Samarium-153 RQ = 3.7 TBq
313 Toxic Release Inventory.	No components listed on SARA 313 inventory
TSCA Inventory	Not listed. Food, drug and cosmetic products are exempt from TSCA.

International

Canada

WHMIS Finished medicinal products are not classified under WHMIS, but using the classification criteria this material would be considered: E Corrosive Material
Note: This regulation does not address hazards related to radioactivity.

DSL/NDSL Ingredients present at greater than 1% are listed.

Europe

EINECS/ELINCS Number Calcium Hydroxide: 215-137-3
Sodium Hydroxide: 215-185-5
Water: 231-791-2

Mexico

Mexico Classification Health classification - Serious Hazard - 3 - Substances that can cause serious or permanent harm under emergency conditions
CORR Corrosive
Note: This regulation does not address hazards related to radioactivity.

Other Information Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

SECTION 16: OTHER INFORMATION

MSDS preparation information

Prepared by Environment, Health and Safety 1-978-671-8673

Prepared on 11/4/2015

Other Information:

HMIS

Health	3*
Flammability	Not Determined
Reactivity	Not Determined
Personal Protective Equipment	See Section 8

NFPA

Health	3
Fire	Not Determined
Reactivity	Not Determined
Special	CORR

The information contained in this MSDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.