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 Ethylenediaminetetramethylene Phosphonate Injection; Sm-153 EDTMP Injection

Hazardous Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDTMP</td>
<td>&gt;1%</td>
<td>1429-50-1</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>&gt;1%</td>
<td>1310-73-2</td>
</tr>
</tbody>
</table>

Other Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration</th>
<th>CAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Samarium</td>
<td>&lt;0.0025%</td>
<td>7440-19-9</td>
</tr>
<tr>
<td>Samarium-153</td>
<td>&lt;0.01%</td>
<td>15766-00-4</td>
</tr>
<tr>
<td>Calcium Hydroxide</td>
<td>&lt;1%</td>
<td>1305-62-0</td>
</tr>
<tr>
<td>Water</td>
<td>&lt;96%</td>
<td>7732-18-5</td>
</tr>
</tbody>
</table>
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 its 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

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

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Liquid</th>
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<tbody>
<tr>
<td>Color</td>
<td>Clear, colorless to light yellow</td>
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<tr>
<td>Odor</td>
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Physical and Chemical Properties

<table>
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<th>Property</th>
<th>Value</th>
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<tbody>
<tr>
<td>Molecular Weight</td>
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<tr>
<td>Solubility</td>
<td>Soluble</td>
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<td>Flashpoint</td>
<td>&gt;200F</td>
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<tr>
<td>Density</td>
<td>~1g/ml</td>
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<tr>
<td>pH</td>
<td>7-8.5</td>
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<tr>
<td>Boiling Point</td>
<td>~100C</td>
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<tr>
<td>Freezing Point</td>
<td>Not Available</td>
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<tr>
<td>Melting Point</td>
<td>Not Available</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not Available</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Radionuclides</th>
<th>ACGIH</th>
<th>OSHA</th>
<th>NTP</th>
<th>IARC</th>
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<tbody>
<tr>
<td>EDTMP</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>1</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Samarium Ca/Na EDTMP</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Samarium-153 EDTMP</td>
<td>---</td>
<td>---</td>
<td>---</td>
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</tr>
</tbody>
</table>

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.