

SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Xenon Xe-133 Gas

Version 4.0 11/4/2015

Product Uses Xenon-133 gas is a radiopharmaceutical that is used to evaluate pulmonary function and cerebral blood flow, and for imaging the lungs. It is administered by inhalation from closed respirator systems and spirometers. Xenon-133 gas is a readily diffusible gas which is neither utilized nor produced by the body. Most of the Xenon-133 gas that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation. It is essentially an inert gas. Overexposure manifests as asphyxiation.

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 Colorless Gas

Signal Word Danger!

Hazard Statements Radioactive.

Precautionary Measures Avoid ingestion, inhalation, skin and eye contact. Care should be taken to minimize radiation exposure. Appropriate radiation shielding should be used. Keep material in a lead container. Avoid direct handling by using remote manipulation tools. Wash hands after handling to minimize exposure. Pregnant or nursing women should avoid exposure.

Potential Health Effects

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| Eyes | Exposure to ionizing radiation may produce adverse effects. |
| Skin | Exposure to ionizing radiation may produce adverse effects. |
| Ingestion | Exposure to ionizing radiation may produce adverse effects. |
| Inhalation | Exposure to ionizing radiation may produce adverse effects. |
| Target Organs | Lung; bone; fatty tissue |
| Signs and Symptoms | Acute: diarrhea, nausea, vomiting, abdominal pain, thirst, fever, difficulty sleeping, tremors, delirium, confusion, convulsions, coma, death. Chronic: Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity, hair loss, rash, skin effects, nail changes, pain, weakness, |

Environmental Effects Refer to Section 12

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| SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS |
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Substance Xenon-133 Gas

Common Name/Synonym: Xenon gas, Xenon-133, Xe-133 Gas

Hazardous Components

| Component | Concentration | CAS |
|------------------|----------------------|------------|
| Xe-133 Gas | <0.1% | 14932-42-4 |

Mixture Concentration

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|----------------|-----|-----------|
| Carbon Dioxide | 5% | 124-38-9 |
| Xenon | 95% | 7440-63-3 |

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| SECTION 4: FIRST AID MEASURES |
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| Eye contact | Not Applicable |
| Skin contact | Not Applicable |
| Inhalation | Move to fresh air. Obtain medical attention. |
| Ingestion | Not Applicable |

Note to Physicians Xenon-133 gas is a radiopharmaceutical that is used to evaluate pulmonary function and cerebral blood flow, and for imaging the lungs. It is administered by inhalation from closed respirator systems and spirometers. Xenon-133 gas is a readily diffusible gas which is neither utilized nor produced by the body. Most of the Xenon-133 gas that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation. It is essentially an inert gas. Overexposure manifests as asphyxiation.

Medical Surveillance A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: EKG, a blood test for liver 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 a non-flammable gas.

Extinguishing Media Suitable extinguishing media: Dry chemical, Water spray, Foam

Protection of Firefighters Specific hazards: Radioactive.
Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
Hazardous Combustion Products: None

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions Evacuate affected rooms. Contact the company Radiation Safety Officer.
Care should be taken to minimize radiation exposure. Handle as radioactive gas release. Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Depending on the nature of the spill (quantity and extent of release) a self-contained breathing apparatus may be needed. .

Environmental Precautions Prevent release to the environment.



Containment Methods Seal leaking containers.

Cleanup Methods Allow released gas to clear from the affected area through the building ventilation.

SECTION 7: HANDLING AND STORAGE

Handling Precautions Avoid exposure. Contact the company/institution Radiation Safety Officer. Care should be taken to minimize radiation exposure. Handling time should be kept to a minimum. Appropriate radiation shielding should be used. Use of syringe shields and tongs are recommended. Keep material in a lead container. Avoid direct handling by using remote manipulation tools. Obtain appropriate governmental licenses to possess and handle radioactive material. Keep away from heat and sources of ignition. *For a complete discussion of Handling and Storage information, please consult the full prescribing information.*

Storage Conditions Store at controlled room temperature of 15 - 30°C. Storage and disposal of product should be controlled in a manner compliant with applicable governmental regulations pertaining to radionuclides. Store and handle in a designated area. Keep away from heat, sparks and flames.

Container Requirements Store in sturdy containers appropriate to maintain the integrity of this material for its intended use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

| Exposure Limit(s) | NCR | ICRP/ACGIH | OSHA | NIOSH |
|-------------------|-----------------------------|---|--|-------|
| Radionuclides | 5 rem Whole Body (annual) | 20 mSv Effective Dose (annual) | 2.0 mCi Annual Limit (NRC - 10 CFR 20) | --- |
| | 15 rem Lens of eye Annual | 150 mSv (lens of eye) annual equivalent dose | 0.000001 µCi/ml Derived Air (annual) Concentration (NRC - 10 CFR 20) | |
| | 50 rem skin of whole body | 500 mSv (skin) annual equivalent dose | 50 mSv Effective dose Annual | |
| | 50 rem Extremities (annual) | 500 mSv (hands & feet) 0.5 mv Equivalent Dose annual equivalent dose | 150 mSv (lens of eye) Annual Equivalent Dose | |
| | 0.5 rem Embry/fetus | Term of pregnancy 2 mSv Embryo/Fetus (abdomen of pregnant woman over course of pregnancy) | 500mSv (skin) Annual Equivalent Dose | |



| Exposure Limit(s) (continued) | NCR | ICRP/ACGIH | OSHA | NIOSH |
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| Xenon | --- | ---- | --- | --- |
|-------|-----|------|-----|-----|

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| Exposure Control Banding | Not Available |
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| Lantheus MI Exposure Guidelines Summary | Not Available |
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Recommended Industrial Hygiene Monitoring Methods

Contact the Lantheus Medical Imaging Radiation Protection Office at 978-671-8672 or 978-671-8673

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 control exposure, wear an approved 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. Please note that employees who are allergic to natural rubber latex should use nitrile gloves.

Skin and Body Protection

Wear a disposable coverall, polyethylene apron and sleeves, and shoe covers.

Hygiene

Wash hands and face before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

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| Physical State | Gas |
| Color | Colorless |
| Odor | Odorless |

Physical and Chemical Properties

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| Molecular Weight | Not Available |
| Solubility | Soluble |
| Flashpoint | NA |
| Density | Not Available |
| pH | NA |
| Boiling Point | NA |
| Melting Point | NA |
| Vapor Density | Not Available |
| Vapor Pressure | Not Available |

SECTION 10: STABILITY AND REACTIVITY

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| Chemical Stability | Stable under recommended storage conditions. |
| Conditions to Avoid | Heat, sparks, flame |
| Incompatible Products | Not Available |
| Hazardous Decomposition Products | Not Available |
| Hazardous Reactions | Hazardous polymerization does not occur. |

SECTION 11: TOXICOLOGICAL INFORMATION

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| Routes of Entry | Inhalation |
| Eye Irritation | Not expected |
| Skin Irritation | Not expected |
| Respiratory Irritation | Not expected |
| Sensitization | Not expected |
| Acute Toxicity | Xenon/Carbon dioxide: asphyxiation if oxygen displaced. Carbon dioxide: In high concentrations causes rapid circulatory insufficiency. |
| Carcinogenicity | Ionizing radiation: exposure known to increase risk of cancer. Xenon/carbon dioxide: not listed by IARC, NTP, OSHA, ACGIH |



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| Reproductive Toxicity | Ionizing radiation: exposure known to increase risk of reproductive and developmental effects. |
| Developmental Toxicity | Ionizing radiation: exposure known to increase risk of reproductive and developmental effects. |
| Target Organs | Carbon dioxide: cardiovascular system. |
| Symptoms | Carbon dioxide: headache, nausea and vomiting, which may lead to unconsciousness. |

Section 12 ECOLOGICAL INFORMATION

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| Environmental Fate: | Not available. Hazardous component, Xe-133 will undergo radiological decay to Cs-133, a non-radioactive isotope of Cesium. |
| Environmental Toxicity: | Ecotoxicological Information (Aquatic) Not Available Ecotoxicological Information (Terrestrial) Not Available |

SECTION 13: Disposal Considerations

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| 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. After use follow local procedures for radioactive waste. |
| Other Information | This information presented below only applies to the material as supplied. |

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

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| OSHA Hazard Classification | No OSHA Hazards. Note: This regulation does not address radiation hazards. |
| CERCLA/SARA RQ | Not Listed |
| 313 Toxic Release Inventory. Listed Chemicals/Compounds | No components listed on the SARA 313 inventory. |
| TSCA Inventory | Not listed. Food, drug and cosmetic products are exempt from TSCA. |

International

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| Canada WHMIS | Finished medicinal products are exempt from classification and labeling requirements under the Canadian Hazardous Products Act and Controlled Products Regulations. Note: This regulation does not address hazards related to radioactivity. |
| DSL/NDSL | Not listed |
| Europe EINECS/ELINCS Number | Xenon: 231-172-7, Carbon Dioxide: 204-696-9 |
| Other Information | Medicinal product are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC. |
| Mexico | Health classification - Minimal hazard -0 - Substances that do not pose a hazard under emergency conditions other than that of ordinary combustible materials. Note: This regulation does not address hazards related to radioactivity. |

SECTION 16: OTHER INFORMATION

MSDS preparation information

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| Prepared by | Environment, Health and Safety 1-978-671-8673 |
| Prepared on | 11/4/2015 |



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.