

SAFETY DATA SHEET

1. Identification

Product identifier	Xenon Xe 133 Gas
Other means of identification	
SDS number	XE133
Synonyms	Xenon-133
Recommended use	Diagnostic radiopharmaceutical for inhalation.
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	
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	RADIOACTIVE MATERIAL. HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL.

Precautionary statement

Prevention	Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation. Radioactive drugs must be handled by qualified personnel only. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Observe good industrial hygiene practices.
Response	Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented. Wash hands after handling.
Storage	The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive content. Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC)	None known.
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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	%
XENON, ISOTOPE OF MASS OF 133	14932-42-4	0.5

Composition comments Gas concentrations are in percent by volume.

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 with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Not applicable. Ingestion is not a typical route of exposure for gases.

Most important symptoms/effects, acute and delayed Adverse reactions specifically attributable to Xenon Xe 133 Gas have not been reported.

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 None known.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed. Xenon is an inert gas. It does not decompose.

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 Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

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 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. 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. Isolate area until gas has dispersed. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

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

7. Handling and storage

Precautions for safe handling 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. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Special handling devices such as the Xenotron™ I Xenon Gas Dispenser, should be used. Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal and state government agency authorized to license the use of this radionuclide. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Xenon Xe 133 Gas should be stored at 15°C to 30°C (59°F to 86°F).

8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).

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

Exposure guidelines NRC occupational air concentration value is 1E-4 mC/ml.

Appropriate engineering controls Ventilation systems should vent directly to the atmosphere and should move sufficient air to dilute the Xenon-133 to permissible concentrations within the facility and outside the facility. The room in which radioactive material is handled should be at negative pressure relative to surrounding rooms within the same facility. Handle the container behind lead glass windows whenever possible.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed.

Other Wear suitable protective clothing.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations 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 Colorless gas sealed in a 2 mL unit dose glass vial.

Physical state Gas.

Form Gas.

Color Colorless.

Odor Odorless.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range -162.4 °F (-108 °C)

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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	1
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	Specific Activity: > 1 mCi/μg of Xenon gas on the date and time of calibration.
Explosive properties	Not explosive.
Half-Life	5.245 days (Radioactive)
Oxidizing properties	Not oxidizing.
Radioactivity	10 or 20 mCi/vial on the calibration date and time.

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.
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	Inert gas; does not decompose.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected. No respiratory symptoms.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	No adverse effects due to eye contact are expected.
Ingestion	Not applicable. Ingestion is not a typical route of exposure for gases.

Symptoms related to the physical, chemical and toxicological characteristics Adverse reactions specifically attributable to Xenon Xe 133 Gas have not been reported.

Information on toxicological effects

Acute toxicity	Not available.
Skin corrosion/irritation	Not classified.
Serious eye damage/eye irritation	Not classified.

Respiratory or skin sensitization

Respiratory sensitization	Not available.
Skin sensitization	This product is not expected to cause skin sensitization.

Germ cell mutagenicity No studies were conducted. The mutagenic risks associated with chronic radiation exposure are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Carcinogenicity No studies were conducted. Radioactive Xe gas emits ionizing radiation. High doses of ionizing radiation can increase the risk of cancer to those who are exposed; however radiogenic health effects have not been demonstrated for doses of less than 100 mSv (10 rem) delivered at high dose rates.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity Animal reproduction studies have not been conducted with Xenon Xe 133 Gas. It is also not known whether Xenon Xe 133 Gas can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Xenon Xe 133 Gas should be given to a pregnant woman only if clearly needed. Xenon 133 is a beta emitter with a physical half-life of 5.24 days. Because of the poor solubility of xenon Xe 133, the amount that enters the venous circulation after inhalation is negligible. The small amount of xenon Xe 133 gas that passes into the venous circulation returns rapidly to the lungs to be exhaled. Maternal Levels. Excretion of nonradioactive xenon in breastmilk was studied in 2 women who underwent about 1 hour of xenon anesthesia with a 65 to 69% inhaled xenon concentration. One mother consumed 8.3 L of xenon and the other had consumed 10 L during the procedure. Milk samples taken at 90 and 300 minutes after extubation contained no detectable xenon.

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.

12. Ecological information

Ecotoxicity There are no data on the ecotoxicity of this product.

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

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions Xenon Xe 133 Gas is Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations.

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.

Contaminated packaging Dispose in accordance with all applicable regulations.

14. Transport information

DOT

UN number UN2915

UN proper shipping name Radioactive material, Type A package

Transport hazard class(es)

Class 7

Subsidiary risk 8

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

Transport hazard class(es)

Class 7

Subsidiary risk 8

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
Transport hazard class(es)	
Class	7
Subsidiary risk	8
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	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 regulated.

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.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

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

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (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)	Yes
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 06-December-2018

Revision date -

Version # 01

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