



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Technelite® (Technetium Tc-99m Generator)

Version 4.1 11/4/2015

Product Uses This material is used as a radioactive tracer. It is a radioactive isotope of Technetium (Tc-99m).

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, odorless liquid

Signal Word Danger!

Hazard Statements Radioactive

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

Potential Health Effects

Eyes Not Available

Skin Not Available

Ingestion Exposure to radioactive materials may produce adverse effects.

Inhalation Exposure to radioactive materials may produce adverse effects.



Target Organs	Not Available
Signs and Symptoms	Acute: allergic reactions, anaphylaxis, tearing. Chronic: Radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity.
Environmental Effects	Not Available

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Active Substance	Sodium Pertechnetate Tc-99m
Common Name/Synonym:	UTK-FM Generator; Tc-99m; Tc 99m; Sodium Pertechnetate Tc 99m Injection;

Hazardous Components

Component	Concentration	CAS
Sodium Molybdate MO-99	<0.1%	38848-45-2
Sodium Pertechnecate	<0.1%	23288-60-0

Other Components

Sodium Chloride	0.9%	7647-14-5
Water	99%	7732-18-5

Other Information Molybdenum-99 (Mo-99) is a beta and gamma emitter with maximum energies of 1.214 MeV and 0.778 MeV, respectively. Mo-99 has a gamma ray constant of 1.8 R/hr per mCi at 1 cm. Technetium-99m (Tc-99m) is a gamma emitter with a maximum energy of 0.140 MeV. Tc-99m has a gamma ray constant of 0.63 R/hr per mCi at 1 cm. The physical half-lives of Mo-99 and Tc-99m are 65.94 hours and 6.02 hours, respectively.

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.
Skin contact	Remove contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention. Dispose of contaminated clothing according to company procedures and governmental regulations for radioactive waste or alternately hold contaminated clothing for radioactive decay 10 half-lives or 1 month.

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Obtain medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
Note to Physicians	This material is used as a radioactive tracer. It is a radioactive isotope of Technetium (Tc-99m). This product can cause: allergic reactions, anaphylaxis, tearing, radioactive material: may cause cancer, adverse reproductive effects, embryo/fetal toxicity, gout. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.
Medical Surveillance	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. Heating can release hazardous gases. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: Radioactive molybdenum and technetium, radioactive breakdown products, light metal compounds., Hydrogen halides Further Information: HCl gas can form flammable or explosive mixtures with alcohols or metals. In the event of fire and/or explosion do not breathe fumes.
Other Information	Decontaminate protective clothing and equipment before reuse, or dispose of as radioactive waste. See Section 6.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions	If the generator container is damaged maintain a distance of 130 feet until radiation measurements can be made by a knowledgeable person. Contact the company Radiation Safety Officer. 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
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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. Dispose of cleanup materials as radioactive waste. Isolate waste in sealed, clearly labeled containers and dispose of according to company procedures and governmental regulations. Spill prevention procedures and a spill response procedure should be implemented. Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up.

SECTION 7: HANDLING AND STORAGE

Handling Precautions

Contact the company Radiation Safety Officer. Label as radioactive material. 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. Highly potent material. Avoid exposure - obtain special instructions before use. Handling time should be kept to a minimum. Appropriate radiation shielding should be used. 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

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. Store at room temperature. 20 - 25°C 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)	Company Guideline	ACGIH	OSHA	NIOSH
Sodium Molybdate Mo-99	---	---	---	---
Sodium Pertechnetate Tc-99m	---	---	---	---
Sodium Chloride	---	---	---	---
Technetium-99m	---	---	---	---
Molybdenum-99	---	10mg/m ³ TWA 3 mg/m ³ TWA Respirable	---	5000mg/m ³ IDLH

Exposure Control Band Not Available

Lantheus Medical Imaging Exposure Guidelines Summary

Sodium Pertechnetate Tc-99m: A specific exposure guideline has not yet been established. Materials require particular care and handling.

Recommended Industrial Hygiene Monitoring Methods

Contact the Lantheus Medical Imaging 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 to control exposure to below the exposure limit, wear an approved supplied air respirator. Note: Exposure to radioactive materials may produce adverse effects.

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. 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

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
Appearance

Physical State	Liquid
Color	Colorless
Odor	Odorless

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	Not Available
pH	4.5-7.5
Boiling Point	100 °C @ 1.33 hPa
Melting Point	0 °C
Vapor Density	Not Available
Vapor Pressure	Not Available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	Stable under recommended storage conditions. Molybdenum-99 (Mo-99) is a beta and gamma emitter with maximum energies of 1.214 MeV and 0.778 MeV, respectively. Mo-99 has a gamma ray constant of 1.8 R/hr per mCi at 1 cm. Technetium-99m (Tc-99m) is a gamma emitter with a maximum energy of 0.140 MeV. Tc-99m has a gamma ray constant of 0.63 R/hr per mCi at 1 cm. The physical half-lives of Mo-99 and Tc-99m are 65.94 hours and 6.02 hours, respectively.
Conditions to Avoid	Heat, flames and sparks
Incompatible Products	Not Available
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions: Radioactive molybdenum and technetium, radioactive breakdown products, light metal compounds, Hydrogen halides
Hazardous Reactions	Hazardous polymerization does not occur. HCl gas can form flammable or explosive mixtures with alcohols or metals.

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry Ingestion, Inhalation, Eye Contact, Skin Contact

Eye Irritation Not Available

Skin Irritation Not Available

Respiratory Irritation Not Available

Sensitization Not Available

Acute Toxicity Not Available

Repeated Dose Toxicity Not Available

Genetic Toxicity Not Available

Carcinogeni

Molybdenum-99

Carcinogenicity Assessment

Gamma radiation is carcinogenic to humans.

Technetium-99m

Carcinogenicity Assessment

Gamma radiation is carcinogenic to humans.

Carcinogenicity

	ACGIH	OSHA	NTP	IARC
Sodium Molybdate Mo-99	---	---	---	1
Molybdenum-99	---	---	---	1
Sodium Pertechnetate Tc-99m	---	---	---	1
Technetium-99m	---	---	---	1

Reproductive Toxicity

Molybdenum-99

Assessment Reproductive Toxicity

This material has been shown to cross the placenta. Exposure to radioactive materials may produce adverse effects.

Technetium-99m

Assessment Reproductive Toxicity

This material has been shown to cross the placenta. Exposure to radioactive materials may produce adverse effects.

Developmental Toxicity

Sodium Pertechnetate Tc-99m

intravenous (daily) Study of Pre- and Postnatal Development (mouse): LOAEL = 5 microcurie (parent, females). Offspring effects include: decreased weight gain, decreased fertility, death. Maternal effects include: hair loss, decreased fertility, Hypofunction of thyroid

gland. The developmental changes reported are believed to be a result of altered maternal metabolism and homeostasis during gestation. This study(s) was conducted on a different salt form.

Developmental Toxicity Assessment

Limited data are available. This material has been shown to cross the placenta. This compound and/or its metabolites may be excreted into the milk. See "Human Experience". Exposure to radioactive materials may produce adverse effects

Human Experience

Experiences with Human Exposure

Sodium Pertechnetate Tc-99m

General effects therapeutic use - Symptoms: allergic reactions, anaphylaxis, tearing.

Target Organs

Sodium Pertechnetate Tc-99m
embryo/fetus

Symptoms

Sodium Pertechnetate Tc-99m
See "Human Experience".

Other Toxicity Information Not Available

Section 12 ECOLOGICAL INFORMATION

Environmental Fate: Not Available

Environmental Toxicity: Ecotoxicological Information (Aquatic) Not available

Ecotoxicological Information (Terrestrial) Not available

SECTION 13: Disposal Considerations

Advice on Disposal Packaging Segregate and label radioactive waste. Disposal should be in and 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

OSHA Hazard Classification	No OSHA Hazards, Radioactive—This regulation does not address hazards related to radioactivity.	
CERCLA/SARA RQ	Molybdenum-99	RQ = 100 Ci
	Molybdenum-99	RQ = 3.7 TBq
	Molybdenum-99	RQ = 1 lb
	Molybdenum-99	RQ = 0.454 kg
	Technetium-99m	RQ = 100 Ci
	Technetium-99m	RQ = 3.7 TBq
311/312 SARA Hazard Classes	Technelite® (Technetium Tc-99m Generator) Health Hazard -- Chronic	
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.	
California Prop 65	Carcinogen	Radionuclides

International

Canada WHMIS	Not Rated Note: This regulation does not address hazards related to radioactivity.	
DSL/NDSL	Not listed	
Europe EINECS/ELINCS Number	Sodium Chloride: 231-598-3 Water: 231-791-2	

R-phrase(s)	C-snft: Caution - substance not yet fully tested. Note: This regulation does not address hazards related to radioactivity.
S-phrase(s)	S23: Do not breathe gas/fumes/vapour/spray. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection. S38: In case of insufficient ventilation, wear suitable respiratory equipment. S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
Mexico	Health classification - Moderate Hazard - 2 - Substances that can cause serious or permanent harm under emergency conditions.

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	0
Flammability	Not Determined
Reactivity	Not Determined
Personal Protective Equipment	See Section 8

NFPA

Health	0
Fire	Not Determined
Reactivity	Not Determined
Special	Not Determined

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.