SAFETY DATA SHEET

Version 4.2 12/1/2022

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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

Synonyms UTK-FM Generator; Tc-99m; Tc 99m; Sodium Pertechnetate Tc 99m Injection

Product Uses diagnostic radiopharmaceutical

COMPANY IDENTIFICATION:
Lantheus
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

Classification
This material is not considered hazardous under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements
None Required

Hazards not otherwise classified (HNOC)
Technelite is a diagnostic radiopharmaceutical for intravenous use only. It emits radiation and must be handled with appropriate safety measures to minimize radiation exposure to household contacts consistent with institutional good radiation safety practices and patient management procedures.

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Component	Concentration	CAS
Water	99%	7732-18-5

Sodium Chloride	0.9%	7647-14-5
Sodium Molybdate MO-99	<0.1%	38848-45-2
Sodium Pertechnecate	<0.1%	23288-60-0

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 if symptoms occur.

Skin contact
Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if symptoms occur.

Inhalation
Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention if symptoms occur.

Ingestion
Do not induce vomiting. Obtain medical attention if symptoms occur.

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.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties
Material is an aqueous solution. Not expected to be flammable.

Suitable Extinguishing Media
Use agent most appropriate to extinguish surrounding fire.

Protection of Firefighters
In the event of fire, wear self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precaution
Use personal protective equipment as required. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing

Environmental Precautions
Avoid release to the environment

Methods for Containment and Clean Up
Soak up with inert absorbent material. Keep in suitable, closed container for disposal.

Other Information
If loss or release of the radioactive contents occurs, notify your Radiation Safety Department

SECTION 7: HANDLING AND STORAGE

Handling Precautions
Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

Storage Conditions
Keep container tightly closed in a dry and well ventilated place. Store and handle in a designated area. Keep away from heat, sparks and flames.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)

Component	ACGIH	OSHA	NIOSH
Molybdenum-99	TWA 10mg/m^3	---	IDLH 5000mg/m^3

Engineering Controls and Ventilation
Use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. Ensure that eye wash stations and safety showers are close to the workstation location.

Respiratory Protection
Follow the OSHA respirator regulations found in 29 CFR 1910.134. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Eye/Face Protection
Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133

Skin and Body Protection
Wear appropriate protective gloves and clothing to prevent skin exposure

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Liquid
Appearance	Clear, translucent
Odor	Odorless
pH	4.5-7.5
Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	Not Available
Boiling Point	Not Available
Melting Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available

Radioactivity

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 10: STABILITY AND REACTIVITY

Stability	Stable under normal conditions.
Conditions to Avoid	Not Available
Incompatible Products	Not Available
Hazardous Decomposition Products	None under normal use conditions
Hazardous Reactions	None under normal processing

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

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Carcinogenicity

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: Not Available

SECTION 13: DISPOSAL CONSIDERATIONS

Advice on Disposal and Packaging
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.

SECTION 14: TRANSPORT INFORMATION

DOT and IATA
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
DSL/NDSL	Not Listed

Mexico

Health classification - Moderate Hazard - 2 - Substances that can cause serious or permanent harm under emergency conditions.

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).

SECTION 16: OTHER INFORMATION

SDS preparation information

Prepared by	Environment, Health and Safety 1-978-671-8673
Prepared on	12/1/2022

The information contained in this SDS 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.