

SAFETY DATA SHEET

Version 3.2 12/1/2022

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: NEUROLITE® Vial B (For the Preparation of Technetium Tc-99m

Bicisate for Injection)

Synonyms Sodium Phosphate, Monobasic and Dibasic; Sodium Phosphate Buffer;

Rinsing Buffer; Phosphate Buffer; Kit for the Preparation of Technetium

Tc99m Bicisate for Injection

Product Uses This material is used as a medical imaging agent. It is combined with a

radioactive material to form the solution for administration to the patient.

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)

None identified



SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Component	Concentration	CAS
Water	>98%	7732-18-5
Disodium Phosphate Heptahydrate	<1%	7782-85-6
Sodium Phosphate Monobasic	<1%	10049-21-5

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 medical imaging agent. It is combined with a radioactive material to form the solution for administration to the patient.

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.

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

Store at room temperature. Protect against light. Keep away from heat, sparks and flames.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Engineering Controls and Ventilation

Ensure adequate ventilation, especially in confined areas. 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.

Eve/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 Colorless
Odor Not Available

pH 7.2-8

Molecular Weight Not Available Solubility Not Available

Flashpoint >200F

DensityNot AvailableBoiling PointNot AvailableMelting PointNot AvailableMelting PointNot AvailableVapor DensityNot AvailableVapor PressureNot Available

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

Carcinogenicity Not Available

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Reproductive Toxicity Not Available

Developmental Toxicity Not Available

Human Experience Not Available

Target Organs Not Available

Symptoms Not Available

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

Not Regulated

IATA

Not Regulated

SECTION 15: REGULATORY INFORMATION

United States of America

OSHA Hazard Classification Not applicable

313 Toxic Release Inventory. No components listed on the SARA 313 inventory.

TSCA Inventory Not listed. Food, drug and cosmetic products are exempt

from TSCA.

<u>International</u>

Canada



WHMIS Product is not according to Control Products Regulations.

DSL/NDSL Not Listed

Mexico

Health classification - Minimal hazard - 0 - Substances that do not pose a hazard under emergency conditions other than that of ordinary combustible materials.

Europe

EINECS/ELINCS Number Water: 231-791-2

Other Information: Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.

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.