



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: NEUROLITE® Vial B

Version 3.0 10/20/2015

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 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 liquid

Signal Word Not Available

Hazard Statements CAUTION-SUBSTANCE NOT FULLY TESTED

Precautionary Measures Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure.

Potential Health Effects

Eyes Not Available

Skin Not Available

Ingestion Not Available

Inhalation Not Available

Target Organs Not Available

Signs and Symptoms Not Available.

Environmental Effects Not Available

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Common Name/Synonym: Sodium Phosphate, Monobasic and Dibasic; Sodium Phosphate Buffer; Rinsing Buffer; Phosphate Buffer; Kit for the Preparation of Technetium Tc99m Bicisate for Injection

Hazardous Components

Component	Concentration	CAS
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Other Components

Disodium Phosphate heptahydrate	<1%	7782-85-6
Sodium Phosphate Monobasic	<1%	10049-21-5
Water	>98%	7732-18-5

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.
Skin contact	Remove contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. If skin irritation occurs, get medical advice/attention.
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 medical imaging agent. It is combined with a radioactive material to form the solution for administration to the patient..
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: Not Available
	Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
	Hazardous Combustion Products: oxides of phosphorus
Other Information	Decontaminate protective clothing and equipment before reuse

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precaution	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat or chemical protective suit and impervious gloves. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed. If reconstituted with radioactive tracer, notify your site Radiation Officer for appropriate procedures and methods.
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). If reconstituted with radioactive tracer, notify your site Radiation Officer for appropriate procedures and methods.
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials. If reconstituted with radioactive tracer, notify your site Radiation Officer for appropriate procedures and methods.

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Avoid inhalation of vapor or mist. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage Conditions	Store at room temperature. (15 - 25°C) Protect against light. Keep away from heat, sparks and flames.
Container Requirements	Store in original primary packaging as provided.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Disodium Phosphate				
Heptahydrate	---	---	---	---
Sodium Phosphate				
Monobasic	---	---	---	---
Exposure Control Band		Not Available		

Lantheus Medical Imaging Exposure Guidelines Summary Not Available

Recommended Industrial Hygiene Monitoring Methods

A specific exposure sampling method is not available

Engineering Controls and Ventilation

When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit. This is applicable for material prior to reconstitution with radioactive tracer only.

Respiratory Protection

Respiratory protection is not required for normal use of this material. If the occupational exposure limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. This is applicable for material prior to reconstitution with radioactive tracer only.



Eye Protection

Safety glasses or chemical splash resistant goggles are recommended if eye contact is possible. Chemical splash resistant goggles should be worn when potential for splash exists. This is applicable for material prior to reconstitution with radioactive tracer only.

Hand Protection

Impervious nitrile, rubber and latex gloves are recommended. If material is handled in solution, the solvent should also be considered when selecting protective clothing material. Please note that employees who are allergic to natural rubber latex should use nitrile gloves. This is applicable for material prior to reconstitution with radioactive tracer only.

Skin and Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. This is applicable for material prior to reconstitution with radioactive tracer only.

Hygiene

Wash hands and face before breaks and immediately after handling the product. This is applicable for material prior to reconstitution with radioactive tracer only.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Liquid
Color	Colorless
Odor	Not Available

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Not Available
Flashpoint	>200F
Density	Not Available
pH	7.2-8
Boiling Point	~100C
Freezing Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available



SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	Stable under normal conditions.
Conditions to Avoid	Not Available
Incompatible Products	Not available
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions: oxides of phosphorus
Hazardous Reactions	None known.

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
Carcinogenity	Not Available
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: Ecotoxicological Information (Aquatic) Not available
Ecotoxicological Information (Terrestrial) 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. This information presented only applies to the material as supplied. If reconstituted with radioactive tracer, notify your site Radiation Officer for appropriate procedures and methods.
Other Information	Disposal by incineration is recommended.

SECTION 14: TRANSPORT INFORMATION

US DOT Transportation Classification for All Modes

Proper shipping name	N/A
This material is not a dangerous good for the purpose of transportation.	
Hazard Class	N/A
UN No.	N/A
Packing Group	N/A
Label Codes	N/A
Marine Pollutant:	No
Special Precautions	NA

SECTION 15: REGULATORY INFORMATION

United States of America

OSHA Hazard Classification No OSHA Hazards

313 Toxic Release Inventory. No components listed on the SARA 313 inventory.
Listed Chemicals/Compounds



TSCA Inventory

Ingredients present at greater than 1% are listed.

International

Canada

WHMIS

Uncontrolled product according to WHMIS classification criteria.

DSL/NDSL

Ingredients present at greater than 1% are listed.

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.

Mexico

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

SECTION 16: OTHER INFORMATION

MSDS preparation information

Prepared by

Environment, Health and Safety 1-978-671-8673

Prepared on

10/20/2015

Other Information

HMIS

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

NFPA

Health	0
Fire	0
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.