



## 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

<b>Exposure Limit(s)</b>	<b>Company Guideline</b>	<b>ACGIH</b>	<b>OSHA</b>	<b>NIOSH</b>
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***

<b>Physical State</b>	Liquid
<b>Color</b>	Colorless
<b>Odor</b>	Not Available

### ***Physical and Chemical Properties***

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

**SECTION 10: STABILITY AND REACTIVITY**

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

**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>Routes of Entry</b>	Ingestion, Inhalation, Eye Contact, Skin Contact
<b>Eye Irritation</b>	Not Available
<b>Skin Irritation</b>	Not Available
<b>Respiratory Irritation</b>	Not Available
<b>Sensitization</b>	Not Available
<b>Acute Toxicity</b>	Not Available
<b>Repeated Dose Toxicity</b>	Not Available
<b>Genetic Toxicity</b>	Not Available
<b>Carcinogenitiy</b>	Not Available
<b>Reproductive Toxicity</b>	Not Available
<b>Developmental Toxicity</b>	Not Available
<b>Human Experience</b>	Not Available
<b>Target Organs</b>	Not Available
<b>Symptoms</b>	Not Available
<b>Other Toxicity Information</b>	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.

<b>SECTION 16: OTHER INFORMATION</b>
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**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.