



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: NEUROLITE® Vial A (For the Preparation of Technetium Tc-99m Biscisate for Injection)

Version 3.1 11/4/2015

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 White powder (lyophilized)

Signal Word Warning!

Hazard Statements Toxic
May cause serious health effects if swallowed.
Severe eye irritant
Skin irritant
Target Organs: kidney

Precautionary Measures Avoid ingestion, inhalation, skin and eye contact. Wear eye/face protection. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing and gloves. Wash hands after handling to minimize exposure.

**Potential Health Effects**

Eyes	Severely irritating to eyes.
Skin	Skin irritant.
Ingestion	May cause serious health effects if swallowed.
Inhalation	Not Available
Target Organs	Kidneys.
Signs and Symptoms	Acute: Redness and swelling of skin and eyes.

Environmental Effects Not Available

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Active Substance	Bicisate Dihydrochloride
Common Name/Synonym:	NEUROLITE® Ligand; Bicisate Dihydrochloride; DUP 198; Kit for the Preparation of Technetium Tc-99m Bicisate for Injection; Technetium Tc-99m Bicisate; Tc-99m Bicisate; Tc 99m Bicisate

Hazardous Components

Component	Concentration	CAS
Bicisate Dihydrochloride	<4%	14344-58-2
Disodium EDTA Dihydrate	>1%	6381-92-6

Other Components

Mannitol	>93%	69-65-8
Stannous Chloride Dihydrate	<1%	10025-69-1

Other Information Contents are lyophilized and stored under nitrogen.

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. This product may cause: redness and swelling of skin and eyes, Organs effected may include: kidney. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.

Medical Surveillance A pre-placement physical examination and history for employees with potential exposure to this compound is recommended. Baseline testing would include: a blood test for kidney function. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. This exam should be overseen by a physician thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. It is recommended that the content be similar to the preplacement exam.

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	Not Available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Toxic Severe eye irritant Skin irritant Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus. Hazardous Combustion Products: carbon oxides, nitrogen oxides (NO _x), Gaseous hydrogen chloride (HCl)., sulphur compounds, Tin oxide fumes. 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

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	Wet down any dust to prevent generation of aerosols, if appropriate. Cover with suitable material. 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). Clean spill area with a deactivating solution (if available) followed by detergent and water after spill pick-up. 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 exposure. Avoid formation of dust and aerosols. Keep away from heat and sources of ignition. Prevent release to drains and waterways. If reconstituted with radioactive tracer, notify your site Radiation Officer for appropriate procedures and methods. <i>For a complete discussion of Handling and Storage information, please consult the full prescribing information.</i>
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
Bicisate Dihydrochloride	---	---	---	---
Disodium EDTA Dihydrate	---	---	---	---
Mannitol	---	---	---	---
Stannous Chloride Dihydrate	---	2mg/m ³ TWA except tin hydride	2 mg/m ³ TWA except tin hydride	100mg/m ³ IDLH as tin 2mg/m ³ as tin except oxides

Exposure Control Band Bicisate Dihydrochloride
4 -- Material is assigned to Exposure Control Band 4 (range 1 – 20 µg/m³).

Lantheus Medical Imaging Exposure Guidelines Summary

Bicisate Dihydrochloride: A specific exposure guideline has not been established. Materials require particular care and handling.

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 dust 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

Wear a laboratory coat when handling quantities up to 2 kilograms. For quantities over 2 kilogram, wear laboratory coat or coverall of low permeability. For manufacturing operations, wear coverall of low permeability. 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	Solid
Color	White powder (lyophilized)
Odor	Not Available

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Not Available
Flashpoint	N/A
Density	Not Available
pH	2.7 (before lyophilization)
Boiling Point	N/A
Freezing Point	N/A
Melting Point	N/A
Vapor Density	N/A
Vapor Pressure	N/A

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: carbon oxides, nitrogen oxides (NOx), Gaseous hydrogen chloride (HCl), Sulphur compounds, Tin oxide fumes.
Hazardous Reactions	None known.
Summary Statements	Although material has not been specifically tested, fine dust suspended in air in sufficient concentration and in the presence of an ignition source may pose a potential explosion hazard. Provide appropriate bonding and grounding protection to control static charge. Powder handling equipment such as dust collectors, dryers, and mills may require additional protective measures (e.g. explosion venting, inerting, etc.).

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	Bicisate Dihydrochloride : Severely irritating to eyes
Skin Irritation	Bicisate Dihydrochloride : Irritating to skin
Respiratory Irritation	Not Available
Sensitization	Bicisate Dihydrochloride :Not a dermal sensitizer
Acute Toxicity	<p>Acute Oral <i>Bicisate Dihydrochloride</i> LD50(rat, males): 94 mg/kg LD50(rat, females): 194 mg/kg LD50(mouse, males and females): 110 mg/kg</p> <p>Acute Dermal <i>Bicisate Dihydrochloride</i> LD50(rabbit, males): > 1,000 mg/kg</p> <p>Acute toxicity (other routes of administration) <i>Bicisate Dihydrochloride</i> LD50 (rat, intravenous): 26 mg/kg males LD50 (rat, intravenous): 55 mg/kg Females</p>

Repeated Dose Toxicity

Bicisate Dihydrochloride

14 Days intravenous rat study : NOAEL = 0.9 mg/kg (males).
No significant adverse effects were observed.

15 Days intravenous dog study : NOAEL = 0.21 mg/kg
(males). Effects include: abnormal penile discharge.

Microscopic changes were observed in the following organs:
lungs.

Genetic Toxicity

Bicisate Dihydrochloride

in vitro

Ames reverse-mutation assay -- positive

in vivo

intravenous, Mutagenicity (micronucleus test) (mouse) –
negative

Mutagenicity Assessment

In vitro tests showed mutagenic effects Did not show
mutagenic effects in animal experiments. Not considered a
mutagen according to 29 CFR 1910, 67/348/EC or
Canadian Controlled Products Regulations.

Disodium EDTA Dihydrate

in vitro

Chromosome aberration test in vitro -- positive

Mutagenicity Assessment

Not considered a mutagen according to 29 CFR 1910,
67/348/EC or Canadian Controlled Products Regulations.

Carcinogenitiy

Not Available

Carcinogenicity

	ACGIH	OSHA	NTP	IARC
Bicisate Dihydrochloride	---	---	---	---
Disodium EDTA Dihydrate	---	---	---	---

Reproductive Toxicity

Not Available

Developmental Toxicity

Not Available

Human Experience

Not Available

Target Organs

Disodium EDTA Dihydrate: Kidneys

Symptoms

Bicisate Dihydrochloride: Redness and swelling of skin and
eyes

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.

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 Toxic, Eye irritant, Skin irritant, Target Organs

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

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

International

Canada	
WHMIS	D1B Toxic Material Causing Immediate and Serious Toxic Effects D2B Toxic Material Causing Other Toxic Effects
DSL/NDSL	Not listed
Europe	
EINECS/ELINCS Number	Mannitol: 200-711-8
Other Information	Medicinal products are exempt from classification and labeling requirements under EU Preparations Directive 1999/45/EC.
Mexico	Health classification - Moderate Hazard 2 - Substances that may cause temporary disability or residual 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	3*
Flammability	1
Reactivity	Not Determined
Personal Protective Equipment	See Section 8

NFPA

Health	2
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.