

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION	
<i>Product Information</i>	
Product name	NEUROLITE® Vial A (For the Preparation of Technetium Tc-99m Bicisate for Injection)
Version	2.0, 11/21/2007
Chemical Name	Not applicable
Active substance	Bicisate Dihydrochloride
Synonyms	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
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.
<i>Company/Undertaking Identification</i>	
Address	Lantheus Medical Imaging 331 Treble Cove Road Billerica, MA 01862 United States of America 1-800-299-3431
Emergency Phone Number	CHEMTREC 1-800-424-9300. For all international transportation emergencies call CHEMTREC at 1-703-527-3887. Collect calls accepted.

2. COMPOSITION/INFORMATION ON INGREDIENTS		
Components	Concentration	CAS-No.
<i>Hazardous components</i>		
Bicisate Dihydrochloride	3.5 %	14344-58-2
Disodium EDTA Dihydrate	> 1 %	6381-92-6
<i>Other ingredients</i>		
Mannitol	> 1 %	69-65-8
Stannous Chloride Dihydrate	<1 %	10025-69-1
Other information: Contents are lyophilized and stored under nitrogen.		

3. HAZARDS IDENTIFICATION	
<i>Emergency Overview</i>	
Appearance	solid : white ; powder, (lyophilized)
Signal Word	Warning!
Hazard Statements	Toxic May cause serious health effects if swallowed. Severe eye irritant Skin irritant Target Organs: kidney.

3. HAZARDS IDENTIFICATION

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.
<i>Potential Health Effects</i>	
Eyes	Severely irritating to eyes.
Skin	Skin irritant
Ingestion	May cause serious health effects if swallowed.
Inhalation	Not available
Target Organs	kidney
Signs and Symptoms	Acute: redness and swelling of skin and eyes
<i>Environmental Effects</i>	Not available

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	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
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.
Notes to Physician	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	<p>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 pre-placement exam.</p> <p>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.</p>

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not available
Extinguishing Media	<p>Suitable extinguishing media: Dry chemical, Water spray, Foam</p> <p>Unsuitable extinguishing media: Do NOT use water jet.</p>

5. FIRE-FIGHTING MEASURES

Protection of Firefighters	<p>Specific hazards: Toxic Severe eye irritant Skin irritant</p> <p>Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.</p> <p>Hazardous Combustion Products: carbon oxides, nitrogen oxides (NOx), Gaseous hydrogen chloride (HCl), sulphur compounds, Tin oxide fumes.</p> <p>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.</p>
Other information:	Decontaminate protective clothing and equipment before reuse. Heating can release hazardous gases.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, disposable lab coat of low permeability with cuffs, double gloves and shoe covers. 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. .

7. HANDLING AND STORAGE

Handling Precautions	Avoid exposure - obtain special instructions before use. 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. .
Storage Conditions	Store at room temperature. (15 - 25°C) Protect against light. Keep away from heat, sparks and flames.
Container Requirements	Store in the original primary packaging as provided.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Bicisate Dihydrochloride	--	--	--	--
Disodium EDTA Dihydrate	--	--	--	--
Mannitol	--	--	--	--

8. EXPOSURE CONTROLS / PERSONAL PROTECTION				
Stannous Chloride Dihydrate	--	2 mg/m ³ TWA air, as Sn	2 mg/m ³ air, as Sn	100 mg/m ³ IDLH as Sn 2 mg/m ³ TWA as Sn
Exposure Control Band	<u>Bicisate Dihydrochloride</u> 4 -- Material is assigned to Exposure Control Band 4 (range 1 - 20 µg/m ³).			
Lantheus MI Exposure Guidelines Summary	<u>Bicisate Dihydrochloride</u> 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	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.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	solid
Color	white
Form	powder, (lyophilized)

Descriptive properties

Molecular Weight	Not available
Molecular formula	Not applicable
Bulk density	Not available
Chemical Name	Not applicable
Evaporation rate	Not available
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
Odor	Not available
Odor Threshold	Not available
pH	2.7; before lyophilization
pKa	Not available
Particle Size	Not available
Solubility, Water	Not available
Specific Gravity/ Relative density	Not available
Viscosity	Not available

Thermal/Stability properties

Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, LEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available

Vapor Properties

Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. STABILITY AND REACTIVITY

Stability

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.

Continued

10. STABILITY AND REACTIVITY

Sensitivity to static discharge/Dust exp.

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.).
--------------------	--

11. TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye Irritation	<u>Bicisate Dihydrochloride</u> Severely irritating to eyes.
Skin Irritation	<u>Bicisate Dihydrochloride</u> Irritating to skin.
Respiratory Irritation	Not available
Sensitisation	<u>Bicisate Dihydrochloride</u> Not a dermal sensitizer
Acute Toxicity Study	<p>Acute Oral <u>Bicisate Dihydrochloride</u> LD50(rat, males): 94 mg/kg LD50(rat, females): 194 mg/kg LD50(mouse, males and females): 110 mg/kg</p> <p>Acute Dermal <u>Bicisate Dihydrochloride</u> LD50(rabbit, males): > 1,000 mg/kg</p> <p>Acute toxicity (other routes of administration) <u>Bicisate Dihydrochloride</u> LD50 (rat, intravenous): 26 mg/kg males LD50 (rat, intravenous): 55 mg/kg females</p>
Repeated dose toxicity	<p><u>Bicisate Dihydrochloride</u> 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.</p>
Genetic Toxicity	<p><u>Bicisate Dihydrochloride</u> in vitro Ames reverse-mutation assay -- positive in vivo intravenous, Mutagenicity (micronucleus test) (mouse) -- negative</p>

Continued

11. TOXICOLOGICAL INFORMATION

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.

Carcinogenicity 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
kidney

Symptoms Bicisate Dihydrochloride
redness and swelling of skin and eyes

Other Toxicity Information Not available

12. ECOLOGICAL INFORMATION

Ecotoxicological Information (Aquatic) Not available

Ecotoxicological Information (Terrestrial) Not available

Chemical fate information Not available

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.

14. TRANSPORT INFORMATION

This material is not a dangerous good for the purpose of transportation.

15. REGULATORY INFORMATION

United States of America

OSHA Hazard Classification	Toxic, Eye irritant., Skin irritant, Target Organs.
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.

International

Canada	
WHMIS	D1B Toxic Material Causing Immediate and Serious Toxic Effects D2B Toxic Material Causing Other Toxic Effects
DSL/NDSL	Not listed.
Mexico	
Mexico Classification	Health classification - Moderate Hazard 2 - Substances that may cause temporary disability or residual harm under emergency conditions
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.

16. OTHER INFORMATION

MSDS preparation information

Prepared by	Environmental Health & Safety 1-978-671-8673
Prepared on	11/21/2007
	This Safety Data Sheet has been revised. This MSDS has been reformatted in a new electronic system. This data sheet contains changes from the previous version in section(s): All.

Other information

HMIS	Health	3*	
	Flammability	1	
	Reactivity	Not Determined (ND)	
	Personal protective equipment	See Section 8.	
NFPA	Health	2	
	Fire	ND	
	Reactivity	ND	
	Special	ND	

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.