



SAFETY DATA SHEET

Version 3.2 12/1/2022

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

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

Synonyms NEUROLITE® Ligand; Bicisate Dihydrochloride; DUP 198; Kit for the Preparation of Technetium Tc-99m 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
Mannitol	>93%	69-65-8



Bicisate Dihydrochloride	<4%	14344-58-2
Disodium EDTA Dihydrate	>1%	6381-92-6
Stannous Chloride Dihydrate	<1%	10025-69-1

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. This product may cause: redness and swelling of skin and eyes. Organs affected may include: kidney. Material not fully tested.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties

May form combustible dust concentrations in air (during processing).

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)

Component	ACGIH	OSHA	NIOSH
Stannous Chloride Dihydrate	TWA: 2 mg/m ³	TWA: 2 mg/m ³	TWA: 2 mg/m ³

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.

Eye/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	Solid
Appearance	White powder (lyophilized)
Odor	Not Available
pH	Not Available
Molecular Weight	Not Available
Solubility	Not Available
Flashpoint	Not Available
Density	Not Available
Boiling Point	Not Available
Melting Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not 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	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	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

Acute Dermal

Bicisate Dihydrochloride

LD50(rabbit, males): >1,000 mg/kg

Acute toxicity (other routes of administration)

Bicisate Dihydrochloride

LD50 (rat, intravenous): 26 mg/kg males

LD50 (rat, intravenous): 55 mg/kg Females

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.

Carcinogenicity

Not Available

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: 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.

International

Canada

WHMIS Product is not according to Control Products Regulations.
DSL/NDSL Not Listed

Mexico

Mexico Classification Health classification – Slight Risk, Grade 1



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.

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.