



Material Safety Data Sheet

Kit for the Preparation of Technetium Tc 99m Pyrophosphate Injection For Diagnostic Use

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CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification

Grade: Pharmaceutical Reagent

Tradenames and Synonyms

Kit for the Preparation of Technetium Tc99m Pyrophosphate Injection For Diagnostic Use
Diphosphoric acid, Ditin (2⁺) salt
Ditin (2⁺) pyrophosphate (4⁻)

Company Identification

MANUFACTURER/DISTRIBUTOR

Pharmalucence Inc.
10 DeAngelo Drive
Bedford, MA 01730

PHONE NUMBERS

Product Information: 1-800-221-7554
Medical Emergency: 1-800-221-7554

COMPOSITION/INFORMATION ON INGREDIENTS

Components

<u>Material</u>	<u>CAS Number</u>	<u>%</u>
SODIUM PYROPHOSPHATE	7722-88-5	83.3
STANNOUS CHLORIDE, DIHYDRATE	7772-99-8	16.7

HAZARDS IDENTIFICATION

Potential Health Effects

The only adverse effects associated with parenteral administration of Kit for the Preparation of Technetium Tc99m Pyrophosphate Injection For Diagnostic Use have been hypersensitivity reactions characterized by itching, various skin rashes, hypotension, fever, chills, nausea, vomiting and dizziness.

Toxicity information on the constituents of Kit for the Preparation of Technetium Tc99m Pyrophosphate Injection For Diagnostic Use are summarized as follows:

SODIUM PYROPHOSPHATE

May be irritating to mucous membranes and upper respiratory tract. Causes eye and skin irritation.

STANNOUS CHLORIDE, DIHYDRATE

Material is extremely destructive to tissues of the mucous membranes and upper respiratory tract, eyes, and skin.

Inhalation may be fatal as a result of spasm, inflammation, and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema.

Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting.

Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

FIRST AID MEASURES

INHALATION

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SKIN CONTACT

In case of contact, wash skin with soap and water. Call a physician. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INGESTION

If swallowed, immediately give two glasses of water. Never give anything to an unconscious person. Call a physician.

FIRE FIGHTING MEASURES

Flammable Properties

Not expected to be a fire or explosion hazard.

Extinguishing Media

Water Spray, Foam, Dry Chemical, CO₂.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean up.

Spill Clean Up

Use HEPA filtered vacuum or wet mop. Do not generate dust.

If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer.

HANDLING AND STORAGE

Handling (Personnel)

Avoid breathing dust. Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling. Wash clothing after use.

Handling (Physical Aspects)

Do not generate dust.

Storage

Keep container in a cool place. Store in a dark place. Do not store or consume food, drink or tobacco in areas where they may become contaminated with this material. Store at controlled room temperature 20 – 25 C.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Handle in a laboratory fume hood, or other suitably ventilated work area.

Personal Protective Equipment

Wear safety glasses with side shields. Wear full face protection when judged that the possibility exists for eye and face contact.

Wear an appropriate NIOSH approved air purifying respirator or positive pressure air-supplied respirator in situations where a respirator is judged appropriate to prevent inhalation.

Wear impervious clothing such as gloves, lab coat, shoe covers, apron, or jumpsuit, as appropriate. Consult the site safety professional for additional guidance, as needed.

Exposure Guidelines

Applicable Exposure Limits

SODIUM PYROPHOSPHATE
PEL (OSHA): None Established
TLV (ACGIH): 5 mg/m³, 8 Hr. TWA

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Solubility in Water: Soluble.
Form: Lyophilized solid.

Kit for the Preparation of Technetium Tc99m Pyrophosphate Injection For Diagnostic Use is supplied in a 10 ml serum vial. The contents of the vial are lyophilized and stored under nitrogen. See the product package insert for further information.

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

Incompatibility with Other Materials

None reasonably foreseeable.

Decomposition

Decomposition will not occur if handled and stored properly.

Polymerization

Polymerization will not occur.

TOXICOLOGICAL INFORMATION

Animal Data

Information on the adverse effects of this material in animal studies by the inhalation, dermal, oral, or ocular route(s) of exposure is not available. Information for the constituent materials is summarized as follows:

SODIUM PYROPHOSPHATE

Oral Data

LD50: 2980 mg/kg (mouse)
LD50: 4000 mg/kg (rat)

Intravenous Data

LD50: 69 mg/kg (mouse)
LD50: 100 mg/kg (rat)

Subcutaneous Data

LD50: 400 mg/kg (mouse)

STANNOUS CHLORIDE, DIHYDRATE

Intravenous Data

LDL0: 20 mg/kg (dog)
LD50: 7.8 mg/kg (rat)

Developmental and Reproductive Toxicity Developmental fetal effects and reproductive effects were noted at very high doses which were toxic to the mother (3 gm/kg).

Mutagenicity: *In vitro* testing showed some evidence of DNA damage in hamster ovaries and in human leukocytes.

LD50 is the median dose at which lethality occurred in 50% of the animals tested following oral or dermal exposure or exposure by injection.

LDLo is the lowest dose at which lethality was noted following exposure by injection.

DISPOSAL CONSIDERATIONS

Waste Disposal

Treatment, storage, transportation, and disposal must be in accordance with applicable Federal, State/Provincial, and Local regulations.

If reconstituted with Technetium Tc-99m, notify your site Radiation Safety Officer and follow waste management procedures for radioactive material.

TRANSPORTATION INFORMATION

Shipping Information

The known properties of this material, as packaged, do not constitute a hazard as defined by the U.S. Department of Transportation.

OTHER INFORMATION

NFPA, NPCA-HMIS

NFPA Rating

Health:	1
Flammability:	0
Reactivity:	0

NPCA-HMIS Rating

Health:	1
Flammability:	0
Reactivity:	0

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

End of MSDS