

# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Technescan™ PYP™ Kit for the Preparation of Technetium Tc 99m Pyrophosphate Injection</b>
<b>Other means of identification</b>	
<b>SDS number</b>	TPYPK
<b>Synonyms</b>	Tc99m PYP * Tc99m Pyrophosphate
<b>Recommended use</b>	The content of this kit as sold is non radioactive. Technescan™ PYP™ (Kit for the Preparation of Technetium Tc 99m Pyrophosphate Injection) as supplied is a sterile, non-pyrogenic, diagnostic radiopharmaceutical suitable for intravenous administration after reconstitution with sterile sodium pertechnetate Tc 99m injection (not included in this kit) or sterile 0.9% sodium chloride injection.  Technetium Tc 99m Pyrophosphate Injection is a skeletal imaging agent used to demonstrate areas of altered osteogenesis, and a cardiac imaging agent used as an adjunct in the diagnosis of acute myocardial infarction.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Supplier</b>	
<b>Company name</b>	Curium US LLC
<b>Address</b>	2703 Wagner Place Maryland Heights, MO 63043 United States
<b>Telephone number</b>	Customer Service 888-744-1414
<b>E-mail</b>	
<b>Emergency telephone number:</b>	24 Hour Emergency 314-595-3700  Chemtrec 800-424-9300

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Acute toxicity, inhalation	Category 4
	Skin corrosion/irritation	Category 1
	Serious eye damage/eye irritation	Category 1
	Sensitization, skin	Category 1
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



<b>Signal word</b>	Danger
<b>Hazard statement</b>	Harmful if swallowed. Harmful if inhaled. Causes severe skin burns and eye damage. May cause an allergic skin reaction.
<b>Precautionary statement</b>	
<b>Prevention</b>	Do not breathe dust/fume. Use only outdoors or in a well-ventilated area. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.

<b>Response</b>	If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	This safety data sheet covers the content of the kit as sold (non radioactive) prior to reconstitution.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	CAS number	%
SODIUM PYROPHOSPHATE	7722-88-5	75.8
STANNOUS CHLORIDE	7772-99-8	24.2

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Each 10 milliliter reaction vial contains 11.9 milligrams sodium pyrophosphate, 3.2 milligrams (minimum) stannous chloride (SnCl<sub>2</sub>·2H<sub>2</sub>O) and 4.4 milligrams (maximum) total tin expressed as stannous chloride (SnCl<sub>2</sub>·2H<sub>2</sub>O) in lyophilized form under an atmosphere of nitrogen. Prior to lyophilization the pH is adjusted with hydrochloric acid. The pH of the reconstituted drug is between 4.5 and 7.5. No bacteriostatic preservative is present.

### 4. First-aid measures

<b>Inhalation</b>	If inhaled: Remove person to fresh air and keep comfortable for breathing. If breathing is difficult, give oxygen. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
<b>Eye contact</b>	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.
<b>Ingestion</b>	Rinse mouth. Call a physician immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
<b>Most important symptoms/effects, acute and delayed</b>	Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. This product is severely irritating to the skin and may cause burns. Burning pain and severe corrosive skin damage. May cause an allergic skin reaction. Dermatitis. Rash.
<b>Indication of immediate medical attention and special treatment needed</b>	Several adverse reactions due to the use of Technetium Tc 99m Pyrophosphate Injection have been reported. These were usually flushing, hypotension, fever, chills, nausea, vomiting and dizziness, as well as hypersensitivity reactions such as itching and various skin rashes. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Chemical burns must be treated by a physician.

### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.
<b>Special protective equipment and precautions for firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Ensure adequate ventilation. Do not breathe dust. Do not get in eyes and avoid contact with skin and clothing. For personal protection, see section 8 of the SDS. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect in containers and seal securely. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Provide adequate ventilation. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get this material in contact with eyes. Do not get this material in contact with skin. Do not get this material on clothing. Do not taste or swallow. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store locked up. Store in original tightly closed container. Store in a well-ventilated place. The drug should be stored at 2°C to 8°C before reconstitution with Sodium Pertechnetate Tc-99m. After reconstitution, the shielded vial should be stored at 15°C to 30°C and discarded after six (6) hours from the time of preparation. Store away from incompatible materials (see Section 10 of the SDS).  Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	PEL	2 mg/m3

#### US. ACGIH Threshold Limit Values

Components	Type	Value
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
SODIUM PYROPHOSPHATE (CAS 7722-88-5)	TWA	5 mg/m3
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Skin protection</b>	
<b>Other</b>	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and chemical properties

<b>Appearance</b>	Small, dry white crystals clinging to inside of 10 mL glass vial.
<b>Physical state</b>	Solid.
<b>Form</b>	Small, dry white crystals clinging to inside of 10 mL glass vial.
<b>Color</b>	White.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	32 °F (0 °C) reconstituted.
<b>Initial boiling point and boiling range</b>	212 °F (100 °C) reconstituted.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Will not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Carbon oxides. Hydrogen chloride.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Harmful by inhalation. Inhalation of dusts may cause respiratory irritation.
<b>Skin contact</b>	Causes skin burns. May cause an allergic skin reaction.
<b>Eye contact</b>	Causes serious eye damage.
<b>Ingestion</b>	Harmful if swallowed. Causes digestive tract burns.

### Symptoms related to the physical, chemical and toxicological characteristics

Causes serious eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. This product is severely irritating to the skin and may cause burns. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

Several adverse reactions due to the use of Technetium Tc 99m Pyrophosphate Injection have been reported. These were usually flushing, hypotension, fever, chills, nausea, vomiting and dizziness, as well as hypersensitivity reactions such as itching and various skin rashes.

### Information on toxicological effects

**Acute toxicity** Harmful if inhaled or swallowed. Causes severe skin burns and eye damage. May cause allergic skin reaction.

Components	Species	Test Results
SODIUM PYROPHOSPHATE (CAS 7722-88-5)		
<u>Acute</u>		
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
STANNOUS CHLORIDE (CAS 7772-99-8)		
<u>Acute</u>		
<b>Oral</b>		
LD50	Mouse	1200 mg/kg
	Rat	700 mg/kg

**Skin corrosion/irritation** Causes skin burns.

**Serious eye damage/eye irritation** Causes serious eye damage.

### Respiratory or skin sensitization

**Respiratory sensitization** Not available.

**Skin sensitization** May cause an allergic skin reaction.

### Germ cell mutagenicity

For the content of kit as sold prior to reconstitution (non radioactive): No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

### Carcinogenicity

For the content of kit as sold prior to reconstitution (non radioactive): This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

#### NTP Report on Carcinogens

Not listed.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

### Reproductive toxicity

For the content of kit as sold prior to reconstitution (non radioactive): Due to lack of data the classification is not possible.

For Technetium Tc 99m Pyrophosphate Injection: May cause harm to breastfed babies. Technetium Tc-99m is excreted in human milk during lactation, therefore, formula-feedings should be substituted for breast-feedings.

### Specific target organ toxicity - single exposure

Due to partial or complete lack of data the classification is not possible.

### Specific target organ toxicity - repeated exposure

Due to partial or complete lack of data the classification is not possible.

### Aspiration hazard

Due to partial or complete lack of data the classification is not possible.

**Chronic effects** For the content of kit as sold prior to reconstitution (non radioactive): Prolonged inhalation may be harmful.

## 12. Ecological information

**Ecotoxicity** There are no data on the ecotoxicity of this product.  
**Persistence and degradability** No data is available on the degradability of any ingredients in the mixture.  
**Bioaccumulative potential** No data available.  
**Mobility in soil** No data available.  
**Other adverse effects** An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

## 13. Disposal considerations

**Disposal instructions** For the content of kit as sold prior to reconstitution (non radioactive): Dispose in accordance with all applicable regulations. If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, consult local, state and federal regulations for proper disposal.  
**Local disposal regulations** Dispose in accordance with all applicable regulations.  
**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.  
**Waste from residues / unused products** Dispose of in accordance with local regulations.  
**Contaminated packaging** Dispose in accordance with all applicable regulations.

## 14. Transport information

**DOT**  
Not regulated as dangerous goods.  
**IATA**  
Not regulated as dangerous goods.  
**IMDG**  
Not regulated as dangerous goods.  
**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.  
**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**  
Not regulated.  
**CERCLA Hazardous Substance List (40 CFR 302.4)**  
Not listed.  
**SARA 304 Emergency release notification**  
Not regulated.  
**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**  
Not regulated.  
**Toxic Substances Control Act (TSCA)** All components of the mixture on the TSCA 8(b) inventory are designated "active".  
**Superfund Amendments and Reauthorization Act of 1986 (SARA)**  
**SARA 302 Extremely hazardous substance**  
Not listed.  
**SARA 311/312 Hazardous chemical** Yes  
**Classified hazard categories** Acute toxicity (any route of exposure)  
Skin corrosion or irritation  
Serious eye damage or eye irritation  
Respiratory or skin sensitization  
**SARA 313 (TRI reporting)**  
Not regulated.

## Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

### Safe Drinking Water Act (SDWA)

Not regulated.

## US state regulations

### US. Massachusetts RTK - Substance List

SODIUM PYROPHOSPHATE (CAS 7722-88-5)

STANNOUS CHLORIDE (CAS 7772-99-8)

### US. New Jersey Worker and Community Right-to-Know Act

SODIUM PYROPHOSPHATE (CAS 7722-88-5)

STANNOUS CHLORIDE (CAS 7772-99-8)

### US. Pennsylvania Worker and Community Right-to-Know Law

SODIUM PYROPHOSPHATE (CAS 7722-88-5)

### US. Rhode Island RTK

SODIUM PYROPHOSPHATE (CAS 7722-88-5)

### California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

STANNOUS CHLORIDE (CAS 7772-99-8)

## International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

Issue date	06-December-2018
Revision date	-
Version #	01

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