

SAFETY DATA SHEET

1. Identification

Product identifier	Technescan™ HDP Kit for the Preparation of Technetium Tc 99m Oxidronate	
Other means of identification		
SDS number	THDPK	
Synonyms	Tc99m HDP * Tc99m Oxidronate	
Recommended use	The content of this kit as sold is non radioactive. Technescan™ HDP is supplied as a lyophilized powder, packaged under nitrogen in vials for intravenous administration after reconstitution with ADDITIVE-FREE sodium pertechnetate Tc 99m (not included in this kit). Once mixed together the content becomes radioactive.	
	TechneScan HDP Tc 99m is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis in adult and pediatric patients.	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Supplier		
Company name	Curium US LLC	
Address	2703 Wagner Place Maryland Heights, MO 63043 United States	
Telephone number	Customer Service 888-744-1414	
E-mail		
Emergency telephone number:	24 Hour Emergency 314-595-3700 Chemtrec 800-424-9300	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Warning	
Hazard statement	Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.	
Precautionary statement		
Prevention	Avoid breathing dust. Wear protective gloves/eye protection/face protection. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace.	
Response	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.	
Storage	Store away from incompatible materials.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
SODIUM CHLORIDE	7647-14-5	87.5
OXIDRONATE SODIUM	14255-61-9	9.2
Gentisic Acid	490-79-9	2.4
STANNOUS CHLORIDE	7772-99-8	0.9

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

Technescan™ HDP is supplied as a lyophilized powder, packaged under nitrogen in vials for intravenous administration after reconstitution with ADDITIVE-FREE sodium pertechnetate Tc 99m. Each vial contains 3.15 mg oxidronate sodium and 0.258 mg, minimum, stannous chloride (SnCl₂•2H₂O), 0.297 mg, theoretical, stannous chloride (SnCl₂•2H₂O) with 0.343 mg, maximum, tin chloride [stannous and stannic] dihydrate as SnCl₂•2H₂O as active ingredients. In addition, each vial contains 0.84 mg gentisic acid as a stabilizer and 30.0 mg sodium chloride. The pH is adjusted with hydrochloric acid and/or sodium hydroxide. The pH of the reconstituted drug is between 4.0 and 5.5. The contents of the vial are sterile and nonpyrogen.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

Some hypersensitivity reactions, as well as nausea and vomiting, have been infrequently associated with Technetium Tc 99m Oxidronate.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information 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.

5. Fire-fighting measures

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical When heated to decomposition, substance may emit oxides of carbon and corrosive fumes of hydrochloric acid.

Special protective equipment and precautions for firefighters As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Do not handle until all safety precautions have been read and understood. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. 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.

Discard after eight (8) hours from the time of preparation. After reconstitution, handling time should be kept to a minimum and appropriate shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs.

Conditions for safe storage, including any incompatibilities

Store at controlled room temperature 20-25°C (68-77°F) both prior to and following reconstitution. Discard after eight (8) hours from the time of preparation. Store locked up. Store in original tightly closed container. Keep container tightly closed. Store in a well-ventilated place. 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
STANNOUS CHLORIDE (CAS 7772-99-8)	TWA	2 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Chemical resistant gloves. Suitable gloves can be recommended by the glove supplier.

Skin protection

Other

Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection

No personal respiratory protective equipment normally required.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

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

Appearance

Small, dry white crystals clinging to inside of 6 mL glass vial.

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

10. Stability and reactivity

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

11. Toxicological information

Information on likely routes of exposure

Inhalation	Inhalation of dusts may cause respiratory irritation.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	May cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis. Rash.

Some hypersensitivity reactions, as well as nausea and vomiting, have been infrequently associated with Technetium Tc 99m Oxidronate.

Information on toxicological effects

Acute toxicity Causes skin irritation. Causes serious eye irritation. May cause an allergic skin reaction.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
Acute		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Other		
LD50	Mouse	2602 mg/kg
STANNOUS CHLORIDE (CAS 7772-99-8)		
Acute		
Oral		
LD50	Mouse	1200 mg/kg
	Rat	700 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

For TechneScan HDP Reconstituted with Sodium Pertechnetate Tc-99m: The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally. Gamma radiation is a potential mutagen to human.

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 TechneScan HDP Reconstituted with Sodium Pertechnetate Tc-99m: 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.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
Aquatic		
Crustacea	EC50	Water flea (Daphnia magna) 340.7 - 469.2 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas) 6020 - 7070 mg/l, 96 hours
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)	One or more components of the mixture are not on the TSCA 8(b) inventory or are designated "inactive".
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
Classified hazard categories	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**

STANNOUS CHLORIDE (CAS 7772-99-8)

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

STANNOUS CHLORIDE (CAS 7772-99-8)

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

Not listed.

US. Rhode Island RTK

Not regulated.

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.

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)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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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