

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Substance

Product Name: Thiotepa for Injection

CAS-No.: 52-24-4

1.2. Intended Use of the Product

Thiotepa for injection is an alkylating drug indicated for treatment of adenocarcinoma of the breast or ovary, for controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities, and for treatment of superficial papillary carcinoma of the urinary bladder.

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

Manufacturer

Gland Pharma, Ltd.

143 – 148, 150 & 151, Near Gandimaisamma Cross Roads

D.P. Pally, Quthubullapur Mandal – Ranga Reddy District

Hyderabad, Andhra Pradesh 500 043

India

+91-40-30510999

+91-40-30510810

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Acute Tox. 2 (Oral) H300

Muta. 1B H340

Carc. 1A H350

Repr. 1B H360

STOT SE 2 H371

STOT RE 1 H372

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA)



Signal Word (GHS-US/CA)

: Danger

Hazard Statements (GHS-US/CA)

: H300 - Fatal if swallowed.

H340 - May cause genetic defects.

H350 - May cause cancer (oral).

H360 - May damage fertility or the unborn child.

H371 - May cause damage to organs (systemic toxicity).

H372 - Causes damage to organs (bone marrow, kidney, systemic toxicity) through prolonged or repeated exposure.

Precautionary Statements (GHS-US/CA) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe dust.

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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Name : Thiotepa for Injection
CAS-No. : 52-24-4

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Tris(1-aziridinyl)phosphine sulfide	Aziridine, 1,1',1''-phosphinothiolidynetris- / Phosphine sulfide, tris(1-aziridinyl)- / 1,1',1''-Phosphinothiolidynetrisaziridine / Phosphorothioic acid triethylenetriamide / Phosphorothioic triamide, N,N',N''-tri-1,2-ethanediy- / Thiophosphamide / Thiophosphoramidate, N,N',N''-triethylene- / Thiophosphoramidate, N,N',N''-tri-1,2-ethanediy- / Tri(ethyleneimino)thiophosphoramidate / Triaziridinylphosphine sulfide / N,N',N''-Triethylenethiophosphoramidate / Triethylenethiophosphoramidate / Triethylenethiophosphorotriamide / Tris(1-aziridinyl)phosphine sulphide / TSPA / 4,5,6,7,7-Pentamethyloctan-3-ol / Thiotepa / Phosphorothioic tri(ethyleneamide)	(CAS-No.) 52-24-4	100	Acute Tox. 2 (Oral), H300 Muta. 1B, H340 Carc. 1A, H350 Repr. 1B, H360 STOT SE 2, H371 STOT RE 1, H372

Full text of H-statements: see section 16

3.2. Mixture

Not applicable

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

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Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Do NOT induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: May cause damage to organs (systemic toxicity). May cause cancer (oral). May cause genetic defects. May damage fertility. May damage the unborn child. Fatal if swallowed. Causes damage to organs (bone marrow, kidney, systemic toxicity) through prolonged or repeated exposure.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: This material is fatal through the oral route in small amounts. This material can cause serious health effects and death. May cause damage to organs.

Chronic Symptoms: Causes damage to organs (bone marrow, kidney, systemic toxicity) through prolonged or repeated exposure. May cause genetic defects. May damage fertility or the unborn child. May cause cancer (oral).

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Nitrous fumes. Sulfur compounds. Phosphorous oxide.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Do not handle until all safety precautions have been read and understood.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accidental injection may cause pain and swelling at the injection site. Sharps should be handled appropriately to minimize risk of accidents.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Avoid contact with eyes, skin and clothing. Handle empty containers with care because they may still present a hazard.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Acids. Oxidizing materials. Heat sources.

Maximum Storage Period: 18 months

Storage Temperature: 2 – 8 °C

7.3. Specific End Use(s)

Thiotepa for injection is an alkylating drug indicated for treatment of adenocarcinoma of the breast or ovary, for controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities, and for treatment of superficial papillary carcinoma of the urinary bladder.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection. Face shield.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles and face shield.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: White lyophilized cake or powder
Odor	: Odorless

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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Odor Threshold	: No data available
pH	: 5.5 – 7.5 (0.02% solution)
Evaporation Rate	: No data available
Melting Point	: 52 – 57 °C (125.6 – 134.6 °F)
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: > 50 °C (122 °F)
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Density	: 0.97 – 1.07 g/ml
Specific Gravity	: No data available
Solubility	: Water: 190 g/l Ethanol: Freely soluble Ether: Freely soluble Acetone: Freely soluble Organic solvent: Freely soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Polymerization will occur at an acidic pH when exposed to heat or moisture.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Acids. Oxidizing materials. Heat sources.

10.6. Hazardous Decomposition Products:

Thermal decomposition will occur at > 50 °C (122 °F) producing Nitrous fumes, Sulfur compounds and Phosphorus oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Fatal if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

Thiotepa for Injection (52-24-4)	
ATE US/CA (oral)	23.00 mg/kg body weight

Skin Corrosion/Irritation: Not classified

pH: 5.5 – 7.5 (0.02% solution)

Eye Damage/Irritation: Not classified

pH: 5.5 – 7.5 (0.02% solution)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects.

Carcinogenicity: May cause cancer (oral).

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Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs (bone marrow, kidney, systemic toxicity) through prolonged or repeated exposure.

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): May cause damage to organs (systemic toxicity).

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is fatal through the oral route in small amounts. This material can cause serious health effects and death. May cause damage to organs.

Chronic Symptoms: Causes damage to organs (bone marrow, kidney, systemic toxicity) through prolonged or repeated exposure. May cause genetic defects. May damage fertility or the unborn child. May cause cancer (oral).

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Tris(1-aziridinyl)phosphine sulfide (52-24-4)	
LD50 Oral Rat	23 mg/kg
Tris(1-aziridinyl)phosphine sulfide (52-24-4)	
IARC Group	1
National Toxicology Program (NTP) Status	Known Human Carcinogens, Evidence of Carcinogenicity.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

12.2. Persistence and Degradability

Thiotepa for Injection (52-24-4)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Thiotepa for Injection (52-24-4)	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.

Hazard Class : 6.1

Identification Number : UN3249

Label Codes : 6.1

Packing Group : II

ERG Number : 151

14.2. In Accordance with IMDG

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.



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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1
Packing Group : II
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-A



14.3. In Accordance with IATA

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.
Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1
Packing Group : II
ERG Code (IATA) : 6L



14.4. In Accordance with TDG

Proper Shipping Name : MEDICINE, SOLID, TOXIC, N.O.S.
Hazard Class : 6.1
Identification Number : UN3249
Label Codes : 6.1
Packing Group : II



SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Thiotepa for Injection (52-24-4)	
SARA Section 311/312 Hazard Classes	Health hazard - Carcinogenicity Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Germ cell mutagenicity Health hazard - Reproductive toxicity Health hazard - Acute toxicity (any route of exposure)

15.2. US State Regulations

Thiotepa for Injection(52-24-4)
State or local regulations

California Proposition 65

 **WARNING:** This product can expose you to Tris(1-aziridinyl)phosphine sulfide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Tris(1-aziridinyl)phosphine sulfide (52-24-4)	X			

Tris(1-aziridinyl)phosphine sulfide (52-24-4)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Special Hazardous Substances U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

This product or its components are not listed on the Canadian Domestic Substances List (DSL) or the Non-Domestic Substances List (NDSL), or are not required to be disclosed.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 02/24/2022

Thiotepa for Injection

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According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Other Information

: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Carc. 1A	Carcinogenicity Category 1A
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 2	Specific target organ toxicity (single exposure) Category 2
H300	Fatal if swallowed
H340	May cause genetic defects
H350	May cause cancer
H360	May damage fertility or the unborn child
H371	May cause damage to organs
H372	Causes damage to organs through prolonged or repeated exposure

NFPA Health Hazard

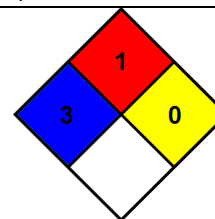
: 3 - Materials that, under emergency conditions, can cause serious or permanent injury.

NFPA Fire Hazard

: 1 - Materials that must be preheated before ignition can occur.

NFPA Reactivity Hazard

: 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health

: 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given
* Chronic - Chronic (long-term) health effects may result from repeated overexposure

Flammability

: 1 Slight Hazard

Physical

: 0 Minimal Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)