

1 Identification

- **Product identifier**
- **Trade name:** "Thiotepa"; Tris(1-aziridinyl)phosphine-sulphide
- **Article number:** 89730026
- **CAS Number:**
52-24-4
- **EC number:**
200-135-7
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **Manufacturer/Supplier:**
Heraeus Precious Metals GmbH & Co. KG
Chemicals Division - Pharmaceutical Ingredients
Heraeusstr. 12-14, D-63450 Hanau
Germany/ Deutschland
- **Information department:**
Dr. Guido Pantkowski
Phone: +49 (0)6181 35-3176
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E-Mail: guido.pantkowski@heraeus.com
- **Emergency telephone number:**
Emergency Contact (24-Hour-Phone Number)
GBK-GmbH, Ingelheim: (international) +49 (0)6132-84463
GBK/ Infotrac ID 105241a: (China domestic) 4001 200 761

2 Hazard(s) identification

- **Classification of the substance or mixture**
Acute Tox. 2 H300 Fatal if swallowed.
Acute Tox. 1 H310 Fatal in contact with skin.
Acute Tox. 2 H330 Fatal if inhaled.
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Muta. 1B H340 May cause genetic defects.
Carc. 1A H350 May cause cancer.
Repr. 1B H360 May damage fertility or the unborn child.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Very toxic
Very toxic by inhalation, in contact with skin and if swallowed.
Toxic
May cause cancer. May cause heritable genetic damage. May impair fertility. May cause harm to the unborn child.
Irritant
Irritating to eyes, respiratory system and skin. May cause sensitisation by inhalation and skin contact.
- **Label elements**
- **GHS label elements**
The substance is classified and labeled according to the Globally Harmonized System (GHS).

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· Hazard pictograms



GHS06 GHS08

· Signal word *Danger*

· Hazard statements

Fatal if swallowed, in contact with skin or if inhaled.
Causes skin irritation.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause genetic defects.
May cause cancer.
May damage fertility or the unborn child.
May cause respiratory irritation.

· Precautionary statements

Obtain special instructions before use.
Wear protective gloves/protective clothing/eye protection/face protection.
Avoid release to the environment.
Do not eat, drink or smoke when using this product.
IF exposed or concerned: Get medical advice/attention.

· Classification system:

· NFPA ratings (scale 0 - 4)



Health = 4
Fire = 0
Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = *4
Fire = 0
Reactivity = 0

· Other hazards

· Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

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3 Composition/information on ingredients

- Chemical characterization: Substances
- CAS No. Description
52-24-4 Tris(1-aziridinyl)phosphine-sulphide
- Identification number(s)
- EC number: 200-135-7

4 First-aid measures

· Description of first aid measures

· General information:

In case of accident or if you feel unwell, seek medical advice immediately.
Immediately remove any clothing soiled by the product.
Remove breathing apparatus only after contaminated clothing have been completely removed.
In case of irregular breathing or respiratory arrest provide artificial respiration.

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- **After inhalation:**
Supply fresh air.
Call a doctor immediately.
- **After skin contact:**
Immediately rinse with water.
Call a doctor immediately.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Induce vomiting, if person is conscious. Seek medical help.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** Cytostatic drug

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Carbon monoxide (CO)
Nitrogen oxides (NO_x)
Sulphur dioxide (SO₂)
Phosphorus oxides (e.g. P₂O₅)
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.
- **Additional information -**

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Mount respiratory protective device.
Avoid formation of dust.
Avoid contact with the eyes and skin.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Wear protective equipment. Keep unprotected persons away.
Work only in fume cabinet.
Prevent formation of dust.

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Store under lock and key and with access restricted to technical experts or their assistants only.

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

· **Information about protection against explosions and fires:**

see chapter 5

Keep respiratory protective device available.

· **Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:**

Store in dry conditions.

Store in a cool location.

· **Information about storage in one common storage facility:**

Store away from flammable substances.

Store away from foodstuffs.

· **Further information about storage conditions:**

Protect from exposure to the light.

Keep receptacle tightly sealed.

· **Recommended storage temperature:** < 5 °C

· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical systems:**

Work only in fume cabinet.

Ensure good ventilation/exhaustion at the workplace.

Waste air is to be released into the atmosphere only via suitable separators.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

The pharmaceutical industry recommends the reference point of 0.05 µg/m³ for cytostatic drugs which show acute very toxic effects.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Work only in fume cabinet.

Do not eat or drink while working.

Shower or take a bath at the end of work.

Immediately remove all soiled and contaminated clothing.

Store protective clothing separately.

Avoid contact with the eyes and skin.

· **Breathing equipment:**

If dust or aerosol is present use respiratory protection filter P3 (push on filter EN 143 or screwed filter EN 149).

· **Protection of hands:**

Long cuffed gloves

Only use chemical-protective gloves with CE-labeling of category III.

Use 2 pairs of this special high risk gloves (wear one upon the other).

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Natural rubber, NR

PVC gloves

· **Eye protection:**



Tightly sealed goggles

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· **Body protection:** Protective work clothing**9 Physical and chemical properties**· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form: Powder

Color: White

· **Odor:** Recognizable· **pH-value (10 g/l) at 20 °C (68 °F):** 5-7.5· **Change in condition**

Melting point/Melting range: 52-57 °C (126-135 °F)

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.· **Flammability (solid, gaseous):** Undetermined.· **Danger of explosion:** Product does not present an explosion hazard.· **Vapor pressure:** Undetermined.· **Density:**

Bulk density: Not determined.

· **Solubility in / Miscibility with**

Water at 20 °C (68 °F): 190 g/l

· **Other information** No further relevant information available.**10 Stability and reactivity**· **Reactivity**· **Chemical stability**· **Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

Protect from exposure to the light.

· **Possibility of hazardous reactions** No dangerous reactions known.· **Conditions to avoid** No further relevant information available.· **Incompatible materials:** Reacts with acids.**11 Toxicological information**· **Information on toxicological effects**· **Acute toxicity:**· **LD/LC50 values that are relevant for classification:**

52-24-4 thiotepa

Oral LD50 23 mg/kg (rat)

· **Primary irritant effect:**· **on the skin:** Irritant to skin and mucous membranes.· **on the eye:** Irritating effect.· **Subacute to chronic toxicity:**

The substance effects in a genotoxic way. Therefore it may be carcinogenic, mutagenic or/and reproductive toxic.

Cytostatic drugs are classified in category 1 or 2 concerning the carcinogenic potential under german regulation (TRGS 905). This means the substance is carcinogenic for human or animal.

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· **Additional toxicological information:**· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

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· **NTP (National Toxicology Program)**

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12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** No data available.
- **Additional ecological information:**
- **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information· **UN-Number**· **DOT, ADR, IMDG, IATA**

UN2811

· **UN proper shipping name**· **DOT**

Toxic solids, organic, n.o.s. (Thiotepa)

· **ADR**

2811 Toxic solids, organic, n.o.s. (Thiotepa)

· **IMDG, IATA**

TOXIC SOLID, ORGANIC, N.O.S. (Thiotepa)

· **Transport hazard class(es)**· **DOT**· **Class**

6.1 Toxic substances.

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· Label	6.1
· ADR, IMDG, IATA	
	
· Class	6.1 Toxic substances
· Label	6.1
· Packing group	
· DOT, ADR, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Toxic substances
· Danger code (Kemler):	60
· EMS Number:	F-A,S-A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	UN2811, Toxic solids, organic, n.o.s. (thiotepa), 6.1, II

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara
- Section 355 (extremely hazardous substances): Substance is not listed.
- Section 313 (Specific toxic chemical listings): Substance is not listed.
- TSCA (Toxic Substances Control Act):
Medical devices are exempted from TSCA.

Substance is not listed.

- Proposition 65
- Chemicals known to cause cancer: Substance is listed.
- Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- Chemicals known to cause developmental toxicity: Substance is not listed.
- Cancerogenity categories
- EPA (Environmental Protection Agency) Substance is not listed.
- TLV (Threshold Limit Value established by ACGIH) Substance is not listed.
- NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.
- GHS label elements
The substance is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms



GHS06 GHS08

- Signal word Danger
- Hazard statements
Fatal if swallowed, in contact with skin or if inhaled.
Causes skin irritation.
Causes serious eye irritation.

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May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause genetic defects.

May cause cancer.

May damage fertility or the unborn child.

May cause respiratory irritation.

• **Precautionary statements**

Obtain special instructions before use.

Wear protective gloves/protective clothing/eye protection/face protection.

Avoid release to the environment.

Do not eat, drink or smoke when using this product.

IF exposed or concerned: Get medical advice/attention.

• **National regulations:**

• **Information about limitation of use:**

Employment restrictions concerning young persons must be observed.

Employment restrictions concerning pregnant and lactating women must be observed.

• **Disturbance regulations:**

Critical quantity values according to the regulations on accidents should be adhered to.

• **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

• **Department issuing MSDS:** HH-US

• **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Acute Tox. 2: Acute toxicity, Hazard Category 2

Acute Tox. 1: Acute toxicity, Hazard Category 1

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Muta. 1B: Germ cell mutagenicity, Hazard Category 1B

Carc. 1A: Carcinogenicity, Hazard Category 1A

Repr. 1B: Reproductive toxicity, Hazard Category 1B

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

• *** Data compared to the previous version altered.**