SAFETY DATA SHEET

1. Identification

Product identifier **Thiopental**

Other means of identification

Catalog number 1661002

Chemical name 4,6(1H,5H)-Pyrimidinedione, 5-ethyldihydro-5-(1-methylbutyl)-2-thioxo-

Synonym(s) Thiopentone; Pentothiobarbital

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4
Specific target organ toxicity, single exposure Category 3 narcotic effects

OSHA hazard(s) Not classified.

Label elements

Signal word Warning

Hazard statement Harmful if swallowed. May cause drowsiness or dizziness.

Precautionary statement

Prevention Wash thoroughly after handling. Use only outdoors or in a well-ventilated area.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Thiopental	Thiopentone; Pentothiobarbital	76-75-5	100

4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Narcotic effects.

Indication of immediate medical attention and special treatment needed
Treatment of overdose should be symptomatic and supportive and may include the following: Administer charcoal as a slurry. Ipecac-induced vomiting is not recommended due to the potential for CNS depression. Consider gastric lavage after ingestion of a potentially life-threatening amount of poison if it can be performed soon after ingestion (generally within 1 hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation, controlling any seizures first. Manage patient with supportive respiratory and cardiovascular care (most patients may be safely managed this way). For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine; titrate to desired response. Forced alkaline diuresis is of no value, however, hemodialysis has been used successfully in short-acting barbiturate intoxication. Charcoal or resin hemoperfusion is more effective and should be considered in patients with hypotension not responsive to supportive care. Treat withdrawal symptoms with phenobarbital or the original addicting substance in a program of gradual reduction over 3 weeks. Monitor vital signs and level of consciousness. Monitor pulse oximetry and/or blood gasses in patients with significant CNS depression. [Meditext 2009]

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Thiopental (CAS 76-75-5)	TWA	1 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white, crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Pungent, garlic odor.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Insoluble.
Partition coefficient (n-octanol/water)	2.85
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	5,5-Disubstituted pyrimidinedione.
Molecular formula	C11H18N2O2S

Molecular weight	242.37
Solubility (other)	Soluble in dilute sodium hydroxide solution.
Specific gravity	> 1

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Barbiturates: Confusion. Drowsiness. Dizziness. Weakness. Confusion. Hallucinations. Mental depression. Unusual excitement. Decrease in or loss of reflexes. Fever. Chills. Shortness of breath. Slow heartbeat. Slurred speech. Unusual movement of the eyes. Heartburn. Indigestion. Nausea. Stomach pain. Cramps. Vomiting. Sores on lips or mouth. Swelling of face. Skin rash. Hives. Bleeding or bruising. Chest tightness.
Delayed and immediate effects of exposure	Barbiturates: Decreased blood pressure. Hypothermia. Pneumonia. Fluid in lungs. Heart failure. Kidney failure. Toxic Shock Syndrome (apnea, circulatory collapse, respiratory arrest, and death). Hypoxic damage.
Cross sensitivity	Persons sensitive to one barbiturate may be sensitive to this material also.
Medical conditions aggravated by exposure	Barbiturates: Active alcoholism. Drug dependence. Liver disease. Impaired kidney function. Respiratory disease.
Acute toxicity	Harmful if swallowed.

Product	**Species**	**Test Results**
Thiopental (CAS 76-75-5)		
Oral		
LD50	Mouse	600 mg/kg

Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible.
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity	Due to lack of data the classification is not possible. Thiopental crosses the placenta, but it is taken up by the fetal liver and is slow to reach concentrations high enough to cause depression in the fetal brain. Even though chronic barbiturate use during pregnancy has been associated with adverse effects, no such effects have been reported during the first trimester with thiopental induction anesthesia. There was no increase in frequencies of birth defects in 152 women who were administered thiopental during the first trimester of pregnancy.

Reproductivity

50 - 100 mg Reproductivity study
Result: No defective offspring were found.
Species: Rat
Reproductivity study
Result: Did not increase birth defects in studies with rats and mice treated during pregnancy with 1.5-3 times the usual human dose of thiopental.
Species: Rodent

Reproductivity

Reproductivity study
Result: No defects observed in the offspring of female mice when injected with 100 mg/kg on day 11 of pregnancy; some reduction in fetal weight was found with doses of 50 mg/kg.
Species: Mouse

Specific target organ toxicity - single exposure	Narcotic effects.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)	Schedule III - 2100
Food and Drug Administration (FDA)	Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

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)	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)	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)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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

Issue date 12-24-2009

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Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.