

**Product Name:** Clorazepate Dipotassium (Tranxene)  
**Issued:** Dec-30-2004



# MATERIAL SAFETY DATA SHEET

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Manufacturer Name and Address:** Abbott Laboratories  
Specialty Products Division  
1401 N. Sheridan Rd.  
North Chicago, IL 60064-4000

**Emergency Telephone:** EMERGENCY INFORMATION  
1 (800) 424-9300 CHEMTREC (USA)  
1 (703) 527 3887 CHEMTREC (INTERNATIONAL)

**Product Name:** Clorazepate Dipotassium (Tranxene)

**Synonyms:** Clorazepate Dipotassium: Clorazepate Dipotassium (Tranxene), USP:  
Chlorazepate Dipotassium: 7-Chloro-2,3-dihydro-2,2-dihydroxy-5-phenyl-1H-1,4-benzodiazepine-3-carboxylic Acid, Dipotassium salt: A-35616

**Product Use:** Tranquilizer

**Drug Code Number:** 72474

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Clorazepate Dipotassium 57109-90-7	100	Not Listed	Not Listed	Not Applicable	25 mcg/m <sup>3</sup> TWA	None

**Notes:** OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.  
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.  
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.  
Abbott EEL: Abbott Laboratories Employee Exposure Limit.  
TWA: 8-hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.  
C: Ceiling Limit.

## 3. HAZARDS IDENTIFICATION

**Emergency Overview:**  
Light yellow crystalline powder.  
Odorless.  
Reproductive hazard. Harmful if swallowed. Fine dust clouds may form explosive mixtures with air.

**Routes of Exposure:**  
**Oral:** Clinical Route  
**Dermal:** Not determined.  
**Inhalation:** Yes

**Hazard Information:**  
**Ingestion Rating:** None.  
**Skin Absorption Rating:** Not determined.  
**Inhalation Rating:** Not determined.

**Product Name:** Clorazepate Dipotassium (Tranxene)  
**Issued:** Dec-30-2004

**Corrosiveness Rating:** Not determined.  
**Skin Contact Rating:** Not determined.  
**Skin Sensitization Rating:** Not determined.  
**Eye Contact Rating:** Not determined.  
**Target Organs:** Digestive System , Nervous System , Liver , Reproductive System.

**Carcinogenicity Rating:**

<b>Ingredients</b>	<b>Percent</b>	<b>OSHA:</b>	<b>NTP:</b>	<b>IARC:</b>	<b>ACGIH:</b>
Clorazepate Dipotassium	100	Not Listed	Not Listed	Not Listed	Not Listed

**NFPA Rating:**

Health: 1  
Fire: 1  
Reactivity: 0

**Signs and Symptoms:** Increased effect of alcohol if consumed. Clinical data suggests the following: drowsiness, nausea, vomiting, incoordination, headaches, sedation, visual impairment, coma.

**Medical Conditions Aggravated by Exposure:** Clinical data suggests any pre-existing ailments of the following organs: nervous system, liver, gastrointestinal system, eyes. Hypersensitivity to the material and/or similar materials.

**4. FIRST AID MEASURES**

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

**FLAMMABILITY:**

**Autoignition Temp. (°C):** Not determined.

**FIRE-FIGHTING INFORMATION:**

**Suitable Extinguishing Media:** Use appropriate medium for the underlying cause of the fire.

**Special Protective Equipment:** Wear protective clothing and self-contained breathing apparatus.

**Product Name:** Clorazepate Dipotassium (Tranxene)  
**Issued:** Dec-30-2004

**Special Exposure Hazards:** Avoid inhalation of combustion products.

**Explosivity:** Not determined. Fine dust clouds may form explosive mixtures with air.

## 6. ACCIDENTAL RELEASE MEASURES

**Methods of Cleaning and Collecting:** Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

**Personal Precautions:** Use personal protective equipment identified in Section 8.

**Environmental Precautions:** Not determined.

**Incompatibilities:** Oxidizers.

## 7. HANDLING AND STORAGE

**Handling:** Use appropriate personal protective equipment. Avoid breathing dust and contact with the skin or eyes. Do not consume food, drink or smoke while handling this material. Bond and ground containers during transfer operations.

**Storage:** Tight container.

**Special Precautions:** Wash hands and face after handling this compound.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Controls:** Utilize appropriate engineering controls ( i.e. hood, glovebox, or process enclosure) when handling open containers of this compound.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits. Production-scale activities in our facilities have required the use of:  
Full-face supplied-air (airline) respirator.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Wear 2 pair; latex inner and thicker glove outside.

**Other PPE Data:** Wear appropriate body coverings if contact may occur. Recommended for production processes: Full body tyvek coveralls with hood and shoe covers.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Light yellow crystalline powder.

**Odor:** Odorless.

**Boiling Pt. @ 760 mm Hg (°C):** Not determined.

**Melting/Freezing Point:** Not determined.

**Vapor Pressure (mm Hg)** Not determined.

**Bulk Density at 20°C:** 5-11 g/in<sup>3</sup>

**Solubility:** Soluble in: water (11.2 grams/l) and Not soluble in: ether, chloroform.

**Specific Gravity:** Not determined.

**pH:** Not determined.

**Product Name:** Clorazepate Dipotassium (Tranxene)  
**Issued:** Dec-30-2004

**Viscosity (centipoise):** Not determined.

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Not determined.

**Self-Heating Tendency:** Not determined.

**Materials to Avoid:** Strong acids and oxidizers.

**Hazardous Decomposition Products:** Not determined.

**Hazardous Polymerization:** Not determined.

**Conditions to Avoid:** Not determined.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity - Oral:** Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Clorazepate Dipotassium	100	LD50 =	700 - 1600	mg/kg	Rats Mice Monkeys

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Target Organ Effects:** In clinical use target organ effects include: central nervous system. In animal testing, target organs include: liver.

Use of this material can lead to dependence.

**Reproductive Effects:** In animal and human data, adverse reproductive effects included : fetal behavior abnormalities.

Clorazepate use during pregnancy can cause fetal dependence and withdrawal. There is an increased risk of congenital malformation associated with the use of minor tranquilizers during the first trimester of pregnancy.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Not determined.

### Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

**Product Name:** Clorazepate Dipotassium (Tranxene)  
**Issued:** Dec-30-2004

## 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity:** Not determined.

**Biodegradation:** Not determined.

**General Notes:** Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Methods:** All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices.

## 14. TRANSPORT INFORMATION

**DOT:**  
**Status:** Not Regulated.

**ICAO/IATA:**  
**Status:** Not Regulated.

**IMDG:**  
**Status:** Not Regulated.

**TDG (Canada):**  
**Status:** Not Regulated.

## 15. REGULATORY INFORMATION

### SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Clorazepate Dipotassium	100	No	Not Applicable	Not applicable

### SARA 311/312 Hazard Categories:

**Immediate Health:** Yes  
**Delayed Health:** Yes  
**Fire:** No  
**Sudden Pressure:** No  
**Reactivity:** No

**Product Name:** Clorazepate Dipotassium (Tranxene)  
**Issued:** Dec-30-2004

**TSCA Inventory Status:** Exempt.

**CERCLA Status:** Not determined.

**RCRA Status:** Not determined.

**Proposition 65 Status:** Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Ingredients	Percent	Proposition 65 Listed Materials
Clorazepate Dipotassium	100	developmental toxicity; initial date 8/20/99.

#### EC HAZARD CLASSIFICATION:

**Category of Danger:** Toxic  
Repr. cat. 1

**Indication of danger:** Xn - Harmful.

**Risk Phrases:** R61 - May cause harm to the unborn child. R22 - Harmful if swallowed.

**Safety Phrases:** S22 - Do not breathe dust.

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).

**ICH Classification:** Class 4 - Minimum Hazard.

#### CANADIAN REGULATIONS:

**Canadian Inventory:** Not determined.

**Canadian NDSL:** Not determined.

**WHMIS Hazard Class:** Not determined.

#### Notes:

1. SARA = Superfund Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

## 16. OTHER INFORMATION

**Document Authored By:** Dale Smrz

#### Disclaimer:

*The information and recommendations contained herein are based upon tests believed to be reliable. However, Abbott Laboratories does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.*