

## SAFETY DATA SHEET

Preparation Date: 06/26/2015

Revision Date: 08/14/2018

Revision Number: G2

### 1. IDENTIFICATION

**Product identifier**

**Product code:** D1195  
**Product Name:** DOXEPIN HYDROCHLORIDE, USP

**Other means of identification**

**Synonyms:** N,N-dimethyldibenz(b,e)oxepin-delta(sup 11(6H),gamma)propylamine hydrochloride

1-Propanamine, 3-dibenz(b,e)oxepin-11(6H)ylidene-N,N-dimethyl-, hydrochloride  
 11-Dimethylamino propylidene 6H-dibenz(b,e)oxepin  
 11-(3-(Dimethylamino)propylidene)-6,11-dihydrodibenz(b,e)oxepin hydrochloride  
 N,N-Dimethyldibenz(b,e)oxepin-delta(sup 11(6H),gamma)-propylamine hydrochloride

**CAS #:** 1229-29-4  
**RTECS #** HQ4375000  
**CI#:** Not available

**Recommended use of the chemical and restrictions on use**

**Recommended use:** Medication. Drug.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000

**Order Online At:** <https://www.spectrumchemical.com>  
**Emergency telephone number** Chemtrec 1-800-424-9300  
**Contact Person:** Martin LaBenz (West Coast)  
**Contact Person:** lbad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)  
 Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 3
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**Label elements**

Danger
Hazard statements

Toxic if swallowed



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not available

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

**Precautionary Statements - Response**

*Precautionary Statements - Response*

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

Rinse mouth

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Doxepin Hydrochloride	1229-29-4	100

**4. FIRST AID MEASURES**

**First aid measures**

**General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.

**Skin Contact:**

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:**

Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

**Inhalation:**

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention. **WARNING!** It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**Ingestion:**

Do not induce vomiting without medical advice. Never give anything by mouth to an

**Product code:** D1195

**Product name:** DOXEPIN  
HYDROCHLORIDE, USP

**2 / 12**

unconscious person. Immediate medical attention is required. Toxic if swallowed.

**Most important symptoms and effects, both acute and delayed**

**Symptoms**

May cause gastrointestinal upset or indigestion  
Ingestion may cause nausea, vomiting, and diarrhea  
May cause constipation  
May cause anorexia  
Dryness of mouth  
May cause mydriasis (dilated pupils)  
May affect the liver  
Paresthesia (numbness and tingling of the extremities)  
Central nervous system effects  
May affect the cardiovascular system  
May cause tinnitus  
May cause taste perversion  
Blurred vision

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:**

Carbon dioxide (CO<sub>2</sub>). Dry chemical. Water spray mist or foam.

**Unsuitable Extinguishing Media:**

No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:**

Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides.  
Hydrogen Chloride Gas.

**Specific hazards:**

May be combustible at high temperatures.

**Special Protective Actions for Firefighters**

**Specific Methods:**

No information available.

**Special Protective Equipment for Firefighters:**

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

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Sensitive to light. Store in light-resistant containers.

#### **Incompatible Materials:**

Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Doxepin Hydrochloride	1229-29-4	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Doxepin Hydrochloride	1229-29-4	None	None	None	None

##### **Australia and Mexico**

Components	CAS-No.	Australia	Mexico
Doxepin Hydrochloride	1229-29-4	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

### Individual protection measures, such as personal protective equipment

#### Personal Protective Equipment

<b>Eye protection:</b>	Safety glasses with side-shields or Goggles
<b>Skin and body protection:</b>	Chemical resistant apron Gloves Long sleeved clothing
<b>Respiratory protection:</b>	Effective dust mask. or. Wear respirator with dust filter. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline. Crystals.	<b>Color:</b> White. Off-white.
<b>Odor:</b> No information available.	<b>Taste</b> No information available.	<b>Formula:</b> C <sub>19</sub> H <sub>21</sub> NO•HCl
<b>Molecular/Formula weight (g/mole):</b> 315.84	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 186°C/366.8°F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm<sup>3</sup>):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b>	<b>Partition coefficient</b>	

Product code: D1195

Product name: DOXEPIN  
HYDROCHLORIDE, USP

5 / 12

No information available

**(n-octanol/water):**  
No information available

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Soluble in Water  
Soluble in Chloroform

## 10. STABILITY AND REACTIVITY

### Reactivity

No information available

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Avoid dust formation. Incompatible materials.

**Incompatible Materials:** Strong oxidizing agents

**Hazardous decomposition products:** Carbon monoxide. Nitrogen oxides (NOx). Hydrogen chloride gas.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Eyes. Ingestion. Inhalation.

### Acute Toxicity

### Component Information

Doxepin Hydrochloride

CAS-No. | 1229-29-4

**LD50/oral/rat** = 147 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = No information available  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

### Product Information

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 147 mg/kg

**LD50/oral/mouse =**  
**Value - Acute Tox Oral =** No information available

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal =** No information available

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal =** No information available

**LC50/inhalation/rat**  
**VALUE-Vapor =** No information available  
**VALUE-Gas =** No information available  
**VALUE-Dust/Mist =** No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor =** No information available  
**VALUE - Gas =** No information available  
**VALUE - Dust/Mist =** No information available

### Symptoms

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause respiratory tract irritation.

**Ingestion** Toxic if swallowed. Ingestion of very large quantities may cause gastrointestinal upset or indigestion. Ingestion may cause nausea, vomiting, diarrhea. May cause anorexia. May cause constipation. May cause dry mouth. May cause mydriasis (dilated pupils). May affect liver. May cause tinnitus. May cause blurred or foggy vision. May affect behavior/central nervous system (hallucinations, insomnia). May affect behavior/central nervous system (convulsions, tremors, confusion). May affect the cardiovascular system (hypotension or hypertension, tachycardia). May affect behavior/central nervous system (dizziness, drowsiness). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (fatigue, weakness). May cause headache. May affect behavior/central nervous system (Hallucinations, anxiety, agitation or restlessness). It may affect the peripheral nervous system and cause paresthesias (a sensation of tickling, tingling, burning, pricking, or numbness of a person's skin. It is known as the feeling of "pins and needles" generally of the extremities (hands and feet). May cause taste perversion.

**Aspiration hazard** No information available.

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Chronic Toxicity** No information available.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances

Doxepin Hydrochloride	1229-29-4	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed
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ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available  
**Developmental Effects:** No information available  
**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility:** No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Waste from residues / unused products:**  
Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**  
Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Doxepin Hydrochloride	1229-29-4	None	None	None	None

**14. TRANSPORT INFORMATION**

**DOT**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solids, organic, n.o.s. (doxepin hydrochloride)  
**Hazard Class:** 6.1  
**Subsidiary Class** No information available  
**Packing group:** III  
**Emergency Response Guide** 154



**Number**  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.

**Description:** UN2811, Toxic solids, organic, n.o.s., 6.1, PG III

**TDG (Canada)**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**Marine Pollutant** No Information available  
**Description:** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, PG III

**ADR**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Packing Group:** III  
**Subsidiary Risk:** No information available  
**Description:** UN2811 Toxic solid, organic, n.o.s., 6.1, III

**IMO / IMDG**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**Marine Pollutant** No information available  
**EMS:** F-A

**RID**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**Description:** UN2811 Toxic solid, organic, n.o.s., 6.1, III

**ICAO**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, PG III

**IATA**

**UN-No:** UN2811  
**Proper Shipping Name:** Toxic solid, organic, n.o.s.  
**Hazard Class:** 6.1  
**Subsidiary Risk:** No information available  
**Packing Group:** III  
**ERG Code:** 6L  
**Special Provisions** No information available

**Description:** UN2811, Toxic solid, organic, n.o.s., 6.1, PG III

## 15. REGULATORY INFORMATION

### International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Doxepin Hydrochloride</i>	1229-29-4	Not Listed	Present KE-09888	Not present	Not present	Not present	Present	Present 214-966-8

### U.S. Regulations

#### California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

##### Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

##### Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
<i>Doxepin Hydrochloride</i>	1229-29-4	Not Listed	Not Listed	Not Listed	Not Listed

### CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
<i>Doxepin Hydrochloride</i>	1229-29-4	None	None	None	None	None

### U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) - Health and Safety Reporting
<i>Doxepin Hydrochloride</i>	1229-29-4	Not Applicable	Not Applicable

### Canada

#### WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

#### WHMIS 1988 Hazard Class

D1B Toxic materials

#### Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS

**Product code:** D1195

**Product name:** DOXEPIN  
HYDROCHLORIDE, USP

**10 / 12**

contains all of the information required by the CPR.

## Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Doxepin Hydrochloride	1229-29-4	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Doxepin Hydrochloride	1229-29-4	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Doxepin Hydrochloride	1229-29-4	Not listed

## EU Classification

### EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Doxepin Hydrochloride	1229-29-4	No information

### EU - CLP (1272/2008)

### R-phrase(s)

R25 - Toxic if swallowed.

### S -phrase(s)

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

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Doxepin Hydrochloride	1229-29-4		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

### Indication of danger:

T - Toxic

## 16. OTHER INFORMATION

**Preparation Date:** 06/26/2015  
**Revision Date:** 08/14/2018  
**Prepared by:** Sonia Owen

### Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. 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. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the

completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**