


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>TRAZODONE HYDROCHLORIDE, USP</b>
<b>PRODUCT CODE</b>	<b>0559</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Pharmaceutical Manufacturing
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 4) Acute Aquatic Toxicity (Category 2)	
<b>PICTOGRAM</b>		
<b>SIGNAL WORD</b>	Warning	
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed. Toxic to aquatic life. May cause drowsiness and/or dizziness. Repeated exposure may cause skin dryness or cracking.	
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment.
	<b>Response</b>	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth.
	<b>Storage</b>	Not applicable
	<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION	Health Hazard	1	Flammability	0
	Reactivity	0	Personal Protection	E

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	1, 2, 4-Triazolo [4, 3- $\alpha$ ] pyridin-3(2H)-one, 2-[3-[4-(3-chlorophenyl)-1-piperazinyl]propyl]-, monohydrochloride
BOTANICAL NAME	Not applicable
SYNONYM	Not available
CHEMICAL FORMULA	C <sub>19</sub> H <sub>22</sub> ClN <sub>5</sub> O · HCl
CHEMICAL FAMILY	Triazolopyridine derivative.
CAS NUMBER	25332-39-2
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	408.3307

COMPOSITION	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
	TRAZODONE HCl	25332-39-2	246-855-5	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

## SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

## SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
SUITABLE & UNSUITABLE EXTINGUISHING MEDIA	<b>Small fire:</b> dry chemical, CO <sub>2</sub> or water spray. <b>Large fire:</b> dry chemical, CO <sub>2</sub> , alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND  
PRECAUTIONS FOR  
FIREFIGHTERS**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**
**PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR  
CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**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.

**SECTION 7: HANDLING AND STORAGE**
**PRECAUTIONS FOR SAFE  
HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE  
STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

Chemical Name: TRAZODONE HCl CAS #: 25332-39-2

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

<b>GESTIS</b>	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
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N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

## EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>

## PERSONAL PROTECTIVE EQUIPMENT

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

## SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

## BIOLOGICAL MONITORING

Not available

## CONTROL BANDING

Not available

## NOTES

Manufacturer's OEL:  $\geq 100 \mu\text{g}/\text{m}^3$   
 USP: ELV: Industrial: TWA: 20 micrograms/m<sup>3</sup>

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### PHYSICAL STATE

Solid

### DESCRIPTION

White to off-white, crystalline powder.

### SOLUBILITY

Sparingly soluble in chloroform and in water.

### ODOR

Odorless

### FLAMMABILITY

May be combustible at high temperature

### AUTO-IGNITION TEMPERATURE

Not available

### BOILING POINT

Not available

### DECOMPOSITION TEMPERATURE

Not available

### EVAPORATION RATE

Not available

### EXPLOSIVE LIMIT

Not available

### FLASH POINT

Not available

### log P (OCTANOL-WATER)

1.8

### LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

### MELTING/FREEZING POINT

(223 - 225)<sup>°C</sup>,  
(433.4-437)<sup>°F</sup>

### PARTICLE CHARACTERISTICS

Not available

### OXIDIZING PROPERTY

Not available

### pH

Not available

### RELATIVE DENSITY (WATER = 1)

Not available

### SPECIFIC GRAVITY

Not available

### UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

**VAPOR DENSITY (AIR = 1)**

Not available

**VAPOR PRESSURE**

Negligible

**VISCOSITY**

Not available

The physical data presented above are typical values and should not be construed as a specification.



## SECTION 10: STABILITY AND REACTIVITY

**REACTIVITY**

Not established

**CHEMICAL STABILITY**

Stable under recommended storage conditions

**INCOMPATIBLE MATERIALS**

Strong oxidants

**HAZARDOUS DECOMPOSITION PRODUCTS**

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

**HAZARDOUS POLYMERIZATION**

Will not occur

**POSSIBILITY OF HAZARDOUS REACTION**

Not established

**CONDITIONS TO AVOID**

Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

**ACUTE TOXICITY**

 Oral: Rat: LD50: (mg/kg): 690  
 Dermal: Rabbit: LD50: (mg/kg): Not available  
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

**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**
**OSHA** TRAZODONE HYDROCHLORIDE is not listed.

**NTP** TRAZODONE HYDROCHLORIDE is not listed.

**IARC** TRAZODONE HYDROCHLORIDE is not evaluated.

**California Proposition** This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

**ADDITIONAL CARCINOGENICITY INFORMATION**

Based on available data, the classification criteria are not met.

300 mg/kg/day Carcinogenicity study; Species: Rat; Test Duration: 18 months; Result: No evidence of carcinogenicity.

Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and nongenotox) alerts by ISS gives an alert for carcinogenicity

**REPRODUCTIVE TOXICITY**

Based on available data, the classification criteria are not met.  
Epidemiological studies have not shown an association between therapeutic use of this material during pregnancy and an increased incidence of birth defects.  
15 - 450 mg/kg/day Reproductivity and development studies in rats and rabbits, administered during gestation:  
Result: No teratogenicity.  
30 - 300 mg/kg Reproductivity and development study in rats, administered orally during organogenesis:  
Result: Maternal toxicity at all doses; fetotoxicity at highest dose; no teratogenicity.

**SPECIFIC TARGET ORGAN  
TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN  
TOXICITY - REPEATED  
EXPOSURE**

Due to lack of data the classification is not possible.

**ASPIRATION HAZARDS**

Due to lack of data the classification is not possible.

**SIGNS AND SYMPTOMS OF  
EXPOSURE**
**ROUTES OF EXPOSURE:**

Ingestion

**EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:**

Suicidal thoughts. Dizziness. Drowsiness Lethargy. Headache. Excitement. Insomnia. Confusion. Nervousness. Abnormal thoughts or dreams. Blurred vision. Incoordination. Tremor. Seizures. Muscle pain. Weakness. Nausea. Vomiting. Diarrhea. Constipation. Dry mouth. Unpleasant taste. Prolonged or painful erection in men. Fever. Sore throat.

**DELAYED HEALTH EFFECT FROM EXPOSURE:**

Drop in blood pressure. Faint or slow heart beat or pulse. Sedation

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:**

Active alcoholism. Recent myocardial infarction. Liver impairment. Kidney impairment. Heart disease. Epilepsy. Recent or concurrent use of monoamine oxidase (MAO) inhibitors. Hypokalemia. Hypomagnesemia. Bipolar disorder. Psoriasis.

**POTENTIAL HEALTH EFFECTS**

**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** Harmful if swallowed.

**Skin** May be harmful if absorbed through skin. May cause skin irritation.

**Eyes** May cause eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

**ECOTOXICITY**

EC50: 48 Hr: Crustacea:Daphnia: (mg/L): 1.57\*  
LC50: 96 Hr: Fish: (mg/L): 1.32\*  
EC50: 96 Hr: Green Algae: (mg/L): <1 \*

**PERSISTENCE AND  
DEGRADABILITY  
BIOACCUMULATIVE POTENTIAL**

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable  
Expected to bioaccumulate (LogPow: 1.8)

**MOBILITY IN SOIL**

Solubility in water: Sparingly soluble to immiscible  
Persistence in water and soil: High

**OTHER ADVERSE EFFECTS**

Not available

**NOTES**

This product is not intended to be released into the environment

\*Danish QSAR database

**SECTION 13: DISPOSAL CONSIDERATIONS**
**DISPOSAL METHODS**

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

**SECTION 14: TRANSPORT INFORMATION**
**UN PROPER SHIPPING NAME**

Not dangerous good

**UN NUMBER**

Not applicable

**CLASS**

Not applicable

**PACKING GROUP**

Not applicable

**AUSTRALIA**
**HAZCHEM**

Not Applicable

**EU**
**TRANSPORT IN BULK ACCORDING  
TO ANNEX II OF MARPOL 73/78  
AND THE IBC CODE**

Not Listed

**ENVIRONMENTAL HAZARDS**

Not available

**SPECIAL SHIPPING  
INFORMATION**

Not applicable

**SECTION 15: REGULATORY INFORMATION**
**UNITED STATES REGULATIONS**

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
TRAZODONE HCl, 25332-39-2	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
TRAZODONE HCl, 25332-39-2	N/L	Listed as Schedule 4*	N/L	N/L	N/L	N/L

N/L = Not Listed

**EU REGULATIONS**

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
TRAZODONE HCl, 25332-39-2	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

NOTES \*Listed as the base

## SECTION 16: OTHER INFORMATION

### REFERENCES

### ABBREVIATIONS AND ACRONYMS

Available upon request

**ACGIH** - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

### LAST REVISION

12/2022

### SUPERSEDES

04/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at [www.medisca.com](http://www.medisca.com)

### DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

### SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.