


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>CARBAMAZEPINE, USP</b>
<b>PRODUCT CODE</b>	<b>0114</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 <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>USES</b>	Manufacturing and Compounding

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 4) Acute Toxicity - Dermal (Category 5) Toxic to Reproduction (Category 1A) Sensitization - Skin (Category 1B) Sensitization - Respiratory (Category 1A) Acute Aquatic Toxicity (Category 3) Eye Irritation (Category 2B)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed. May be harmful if in contact with skin. May damage fertility or the unborn child. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Harmful to aquatic life. Causes eye irritation. May cause damage to organs through prolonged or repeated exposure.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Repeated exposure may cause skin dryness or cracking.

**PRECAUTIONARY STATEMENT(S)**
**Prevention**

Wash thoroughly after handling.  
 Do not eat, drink or smoke when using this product.  
 Obtain special instructions before use.  
 Do not handle until all safety precautions have been read and understood.  
 Wear protective gloves, protective clothing, eye protection, face protection.  
 Avoid breathing dust, fume, gas, mist, vapors, spray.  
 Contaminated work clothing must not be allowed out of the workplace.  
 In case of inadequate ventilation wear respiratory protection.  
 Avoid release to the environment.

**Response**

IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth.  
 IF EXPOSED OR CONCERNED: Get medical advice/attention.  
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.  
 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional.  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

**Storage**

Store locked up.

**Disposal**

Dispose of contents and/or container in accordance with local regulations.

**HMS CLASSIFICATION**
**Health Hazard**

2

**Flammability**

0

**Reactivity**

0

**Personal Protection**

G

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**CHEMICAL NAME**

5H-Diabez [b, f] azepine-5-carboxamide

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Not applicable

**CHEMICAL FORMULA**
 $C_{15}H_{12}N_2O$ 
**CAS NUMBER**

298-46-4

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

236.273

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
CARBAMAZEPINE	298-46-4	206-062-7	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.

**NOTES**

Chemical family: Tricyclic iminostilbene derivative.

**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

**SYMPTOMS AND EFFECTS**

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****Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** 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

**SPECIFIC END USE(S)**

See Section 1

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

Chemical Name: CARBAMAZEPINE CAS #: 298-46-4

	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
GESTIS	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

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.

**NOTES**

USP: ELV: TWA (For Industrial Use): 0.2 mg/m<sup>3</sup>

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White to off-white crystalline powder. It exhibits polymorphism.

**SOLUBILITY**

Practically insoluble in water; soluble to very slightly soluble in alcohol and in acetone.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustible at high temperature

**AUTO-IGNITION TEMPERATURE**

460 °C, 860 °F

**BOILING POINT**

Not available

**DECOMPOSITION TEMPERATURE**

Not available

**EVAPORATION RATE**

Not available

**EXPLOSIVE LIMIT**

Not available

**FLASH POINT**

Not available

**log P (OCTANOL-WATER)**

2.45 (20 °C)

**LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)**

Not available

**MELTING/FREEZING POINT**

(204 - 206)°C, (399.2-402.8)°F

**ODOR THRESHOLD**

Not available

**OXIDIZING PROPERTY**

Not available

**pH**

7 (20°C)

**RELATIVE DENSITY (WATER = 1)**

Not available

**SPECIFIC GRAVITY**

1.34

**UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)**

Not available

**VAPOR DENSITY  
(AIR = 1)**

Not available

**VAPOR PRESSURE**

 1.84E-07 mm Hg  
(25° C)

**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): 1957  
 Dermal: Rabbit: LD50: (mg/kg): 2680  
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**

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

**SERIOUS EYE DAMAGE/EYE  
IRRITATION**

 Causes eye irritation.  
 Rabbit: Eye irritation; Result: Irritant; Severity: Mild.

**RESPIRATORY SENSITIZATION**

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

**SKIN SENSITIZATION**

May cause an allergic skin reaction.

**GERM CELL MUTAGENICITY**

 Based on available data, the classification criteria are not met.  
 Suspected mutagen: CAESAR Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (moderate reliability)

 Mutagenicity  
 In vitro chromosome aberration and sister chromatid exchange assay  
 Result: Dose-dependent increase.  
 Species: Human  
 Organ: Lymphocytes  
 In vivo chromosome aberration and sister chromatid exchange assay  
 Result: Increased incidence.  
 Species: Human

**CARCINOGENICITY**
**OSHA** CARBAMAZEPINE is not listed.  
**NTP** CARBAMAZEPINE is not listed.  
**IARC** CARBAMAZEPINE is not evaluated.  
**California Proposition 65** This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: CARBAMAZEPINE

**ADDITIONAL CARCINOGENICITY INFORMATION**

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

25 - 250 mg/kg/day Carcinogenicity study (dietary)

Result: Dose-related increased incidence of hepatocellular tumors in females and benign interstitial cell adenomas in the testes of males. Species: Rat; Test Duration: 2 years

**REPRODUCTIVE TOXICITY**

May damage fertility or the unborn child.

There have been reports of babies prenatally exposed to carbamazepine having small head circumference, low birth weights, craniofacial defects, fingernail hypoplasia, developmental delays, and spina bifida, with spina bifida occurring at reported rates of 1%. Use of carbamazepine in late pregnancy has been associated with a bleeding abnormality and neonatal withdrawal syndrome (vomiting, diarrhea, decreased feeding, seizures, and/or respiratory depression) in newborns.

Reproductivity

1500 mg/kg/day Reproductivity study

Result: Skeletal and soft tissue defects in offspring.

Species: Mouse

250 - 650 mg/kg Reproductivity study

Result: Offspring showed kinked ribs at the low dose and other anomalies, including cleft palate, at the high dose.

Species: Rat

Suspected toxic for reproduction: CAESAR developmental toxicity model in VEGA (Q)SAR platform predicts that the chemical is Toxicant (good reliability); Developmental/Reproductive Toxicity library (PG) in VEGA (Q)SAR platform predicts that the chemical is Toxicant (EXPERIMENTAL value); DART database in the Toolbox reports that this substance as Known developmental potential

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

May cause damage to organs through prolonged or repeated exposure.

Oral-man TDLO: 43 mg/kg: hallucinations, distorted perception - nausea or vomiting

**ASPIRATION HAZARDS**

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

**SIGNS AND SYMPTOMS OF EXPOSURE**

Symptoms related to the physical, chemical, and toxicological characteristics:

Dizziness. Drowsiness. Behavior, mood, or mental changes. Unsteadiness. Incoordination. Uncontrolled movements. Enlarged pupils. Blurred vision. Unusual eye movements. Nausea. Vomiting. Diarrhea.

Constipation. Abdominal pain. Loss of appetite. Dry mouth. Sore mouth or tongue. Joint pain. Muscle pain. Leg cramps. Skin rash. Hives. Itching. Sweating. Fever. Sore throat. Bleeding or bruising. Fast heartbeat. Irregular heartbeat. Shallow breathing. Fainting. Seizures.

Gastrointestinal disturbances. Hypersensitivity reactions. Central nervous system effects. Seizures.

Cardiovascular effects. Liver damage.

Delayed and immediate effects of exposure:

Liver damage. Coma.

Cross sensitivity

Persons sensitive to tricyclic antidepressants may be sensitive to this material also.

Medical conditions aggravated by exposure:

Seizure disorders. Active alcoholism. Behavioral disorders. Heart disease. Blood disorders. Hepatic porphyria.

Bone marrow depression. Diabetes. Glaucoma. Increased intraocular pressure. Hyponatremia. Urinary retention. Impaired kidney function. Impaired liver function. Recent or concurrent use of monoamine oxidase (MAO) inhibitors.

**POTENTIAL HEALTH EFFECTS**

**Inhalation** May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Ingestion** Harmful if swallowed.

**Skin** May be harmful if absorbed through skin. May cause an allergic skin reaction.

**Eyes** May cause eye irritation.

**NOTES**

Pharmacologically active material. Occupational exposure may cause physiological effects.

**SECTION 12: ECOLOGICAL INFORMATION**

<b>TOXICITY</b>	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 14.9* LC50: 96 Hr: Fish: (mg/L): 41.33* EC50: 96 Hr: Green Algae: (mg/L): <1*
<b>PERSISTENCE AND DEGRADABILITY</b>	Aerobic degradation half-life time: 63 days Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable
<b>BIOACCUMULATIVE POTENTIAL</b>	Weak. Log Pow: 2.45 (20° C)
<b>MOBILITY IN SOIL</b>	Practically insoluble in water. (17.7 mg/L) (25 °C) Henry's Law Constant: 1.08E-10 atm·m <sup>3</sup> /mole (25 °C)
<b>OTHER ADVERSE EFFECTS</b>	Not available  This product is not intended to be released into the environment
<b>NOTES</b>	*Danish QSAR database

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>WASTE DISPOSAL</b>	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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**SECTION 14: TRANSPORT INFORMATION**

<b>UN PROPER SHIPPING NAME</b>	Not dangerous good
<b>UN NUMBER</b>	Not applicable
<b>CLASS</b>	Not applicable
<b>PACKING GROUP</b>	Not applicable
<b>AUSTRALIA</b>	
<b>HAZCHEM</b>	Not applicable
<b>EU</b>	
<b>TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE</b>	Not Listed
<b>ENVIRONMENTAL HAZARDS</b>	Not available
<b>SPECIAL SHIPPING INFORMATION</b>	Not applicable

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

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
CARBAMAZEPINE 298-46-4	N/L	N/L	N/L	N/L	N/L	N/L	N/L	X

N/L = Not Listed; X = Listed

**AUSTRALIAN REGULATIONS**

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
CARBAMAZEPINE 298-46-4	N/L	Listed as Schedule 4	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	EC 649/2012	EC 2012/118
CARBAMAZEPINE 298-46-4	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.

**SECTION 16: OTHER INFORMATION**
**REFERENCES**

Available upon request

**ABBREVIATIONS AND ACRONYMS**

**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**

05/2022

**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.