


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>MIRTAZAPINE, USP (Hemihydrate)</b>
<b>PRODUCT CODE</b>	<b>3076</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) Chronic Aquatic Toxicity (Category 2) Specific Target Organ Toxicity - Repeated Exposure (Category 1) - Endocrine System Toxic to Reproduction (Category 2) - Effects on or via lactation Specific Target Organ Toxicity - Single Exposure (Category 1) - Cardiovascular System Specific Target Organ Toxicity - Single Exposure (Category 3) - Narcotic effects
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	Harmful if swallowed. Toxic to aquatic life with long lasting effects. Causes damage to organs through prolonged or repeated exposure - Endocrine System. Suspected of damaging fertility or the unborn child. Causes damage to organs - Cardiovascular System. May cause harm to breast-fed children. May cause drowsiness or dizziness - Narcotic effects.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

**PRECAUTIONARY STATEMENT(S)**

<b>Prevention</b>	Do not eat, drink or smoke when using this product. Avoid release to the environment. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy and while nursing. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Do not breathe dust, fume, gas, mist, vapors and spray. Wash hands thoroughly after handling. Use only outdoors or in a well-ventilated area.								
<b>Response</b>	IF SWALLOWED: Immediately call a poison center. Get medical help. Rinse mouth. COLLECT SPILLAGE. Get medical help, if you feel unwell. IF EXPOSED OR CONCERNED: Get medical advice. IF EXPOSED: Get emergency medical help immediately. Call a poison center or doctor. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or doctor. Get medical help if you feel unwell.								
<b>Storage</b>	Store locked up. Store in a well-ventilated place. Keep container tightly closed.								
<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.								
<b>HMIS CLASSIFICATION</b>	<table border="0"> <tr> <td style="vertical-align: top;"><b>Health Hazard</b></td> <td style="text-align: center;">4</td> <td style="vertical-align: top;"><b>Flammability</b></td> <td style="text-align: center;">0</td> </tr> <tr> <td style="vertical-align: top;"><b>Reactivity</b></td> <td style="text-align: center;">0</td> <td style="vertical-align: top;"><b>Personal Protection</b></td> <td style="text-align: center;">J</td> </tr> </table>	<b>Health Hazard</b>	4	<b>Flammability</b>	0	<b>Reactivity</b>	0	<b>Personal Protection</b>	J
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<b>Reactivity</b>	0	<b>Personal Protection</b>	J						

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

<b>CHEMICAL NAME</b>	Pyrazino[2,1-a]pyrido[2,3-c][2]benzazepine, 1,2,3,4,10,14b-hexahydro-2-methyl-
<b>BOTANICAL NAME</b>	Not applicable
<b>SYNONYM</b>	Not applicable
<b>CHEMICAL FORMULA</b>	C <sub>17</sub> H <sub>19</sub> N <sub>3</sub>
<b>CHEMICAL FAMILY</b>	Piperazinoazepine
<b>CAS NUMBER</b>	85650-52-8
<b>ALTERNATE CAS NUMBER</b>	61337-67-5
<b>MOLECULAR WEIGHT</b>	265.3581

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
MIRTAZAPINE (Anhydrous)	85650-52-8	288-060-6	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**

<b>IN CASE OF EYE CONTACT</b>	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
<b>IN CASE OF SKIN CONTACT</b>	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
<b>IF SWALLOWED</b>	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
<b>IF INHALED</b>	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**

Refer to Section 11.

**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, at controlled room temperature protected from light and moisture.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25° (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°; and that allows for excursions between 15° and 30° (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40° are permitted as long as they do not exceed 24 hours.

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

Chemical Name: MIRTAZAPINE (Anhydrous) CAS #: 85650-52-8

	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	Add Country	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.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

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

Solid

**DESCRIPTION**

White to creamy white, crystalline powder. Slightly hygroscopic to hygroscopic.

**SOLUBILITY**

Freely soluble in methanol and in toluene; soluble in ethyl ether; sparingly soluble in n-hexane; practically insoluble in water.

**ODOR**

Odorless.

**FLAMMABILITY**

May be combustible at high temperature

<b>AUTO-IGNITION TEMPERATURE</b>	Not available	<b>BOILING POINT</b>	Not available	<b>DECOMPOSITION TEMPERATURE</b>	Not available
<b>EVAPORATION RATE</b>	Not available	<b>EXPLOSIVE LIMIT</b>	Not available	<b>FLASH POINT</b>	Not available
<b>log P (OCTANOL-WATER)</b>	3.09 (20°C)	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(112 - 124)°C, (233.6-255.2)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	7 (0.3 g/L; 25°C)
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	1.23 (20°C)	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available	<b>VISCOSITY</b>	Not available

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

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants, strong acids and strong bases.
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures. Light sensitive - avoid exposure to light Hygroscopic - avoid exposure to moisture

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): 320 mg/L Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Due to lack of data the classification is not possible.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Due to lack of data the classification is not possible.
<b>RESPIRATORY SENSITIZATION</b>	Due to lack of data the classification is not possible.
<b>SKIN SENSITIZATION</b>	Due to lack of data the classification is not possible. Exposure may produce an allergic reaction.

**GERM CELL MUTAGENICITY**

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

**CARCINOGENICITY**

**OSHA** MIRTAZAPINE is not listed.

**NTP** MIRTAZAPINE is not listed.

**IARC** MIRTAZAPINE is not evaluated.

**California Proposition 65** 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.

**REPRODUCTIVE TOXICITY**

Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

**SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE**

Causes damage to organs - Cardiovascular system.

May cause drowsiness or dizziness - Narcotic effects.

**SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE**

Causes damage to organs (Endocrine system) through prolonged or repeated exposure.

**ASPIRATION HAZARDS**

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

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

Oral, Dermal, Inhalation, Eye contact

**EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:**

Not available

**DELAYED HEALTH EFFECT FROM EXPOSURE:**

High blood pressure. Low blood pressure. Vertigo.

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

Shortness of breath. Swelling. Flu symptoms. Mental status changes. Skin rash. Constipation.

Dizziness. Drowsiness. Dry mouth. Increased appetite. Weight gain. Abdominal pain. Abnormal thoughts or dreams. Weakness. Back pain. Thirst. Muscle pain. Nausea. Trembling. Increased urination. Vomiting. Disorientation. Fast heartbeat.

**POTENTIAL HEALTH EFFECTS**

**Inhalation** Harmful if inhaled. May cause respiratory tract irritation.

**Ingestion** Harmful if swallowed.

**Skin** 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): 19.5

LC50: 96 Hr: Fish: (mg/L): 6.92

EC50: 96 Hr: Algae: Green Algae: (mg/L): 5.7

**PERSISTENCE AND DEGRADABILITY**

Not rapidly degradable.

**BIOACCUMULATIVE POTENTIAL**

Log Pow: 3.09 (20°C)

**MOBILITY IN SOIL**

Practically insoluble in water.

**OTHER ADVERSE EFFECTS**

Not available

This product is not intended to be released into the environment

## 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**

<b>UN PROPER SHIPPING NAME</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
<b>UN NUMBER</b>	3077
<b>CLASS</b>	9
<b>PACKING GROUP</b>	III
<b>AUSTRALIA</b>	
<b>HAZCHEM</b>	2Z
<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		Right-to-know		
			Appendix A	Appendix B	Pennsylvania	New Jersey	Massachusetts
MIRTAZAPINE 85650-52-8	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 Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Work Health and Safety Regulations	Inventory of Industrial Chemicals
MIRTAZAPINE 85650-52-8	N/L	Listed as Schedule 4 (Appendix A)	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	PIC - Prior Informed Consent Regulation	EC 2012/18
MIRTAZAPINE 85650-52-8	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

## 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

03/2026

## SUPERSEDES

05/2023

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.