


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>TERBINAFINE HYDROCHLORIDE, USP</b>
<b>PRODUCT CODE</b>	<b>3253</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 5) Acute Toxicity - Dermal (Category 5) Skin Irritation (Category 2) Eye Irritation (Category 2A) Specific Target Organ Toxicity - Single Exposure (Category 3) Chronic Aquatic Toxicity (Category 1)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Warning
<b>HAZARD STATEMENT(S)</b>	May be harmful if swallowed. May be harmful if in contact with skin. Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Available.

<b>PRECAUTIONARY STATEMENT(S)</b>	<b>Prevention</b>	Wash hands thoroughly after handling. Do not touch eyes. Wear protective gloves/protective clothing/eye protection/face protection. Do not eat, drink or smoke when using this product. Avoid breathing dust, fume, gas, mist, vapors and spray. Use only outdoors or in a well-ventilated area. Avoid release to the environment.		
	<b>Response</b>	IF SWALLOWED: Get medical help. IF ON SKIN: Wash with plenty of water. If skin irritation occurs, get medical help. Take off contaminated clothing and wash it before reuse. 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. 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. COLLECT SPILLAGE		
	<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.		
	<b>Disposal</b>	Dispose of contents and/or container in accordance with local regulations.		
	<b>HMIS CLASSIFICATION</b>	<b>Health Hazard</b>	0	<b>Flammability</b>
	<b>Reactivity</b>	0	<b>Personal Protection</b>	E

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<b>CHEMICAL NAME</b>	(E)-N,6,6-trimethyl-N-(naphthalen-1-ylmethyl)hept-2-en-4-yn-1-amine;hydrochloride								
<b>BOTANICAL NAME</b>	Not applicable								
<b>SYNONYM</b>	Not available								
<b>CHEMICAL FORMULA</b>	C <sub>21</sub> H <sub>25</sub> N • HCl								
<b>CHEMICAL FAMILY</b>	Naphthalene methanamine derivative								
<b>CAS NUMBER</b>	78628-80-5								
<b>ALTERNATE CAS NUMBER</b>	Not applicable								
<b>MOLECULAR WEIGHT</b>	327.8964								
<b>COMPOSITION</b>	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>TERBINAFINE HCl</td> <td>78628-80-5</td> <td>616-640-4</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	TERBINAFINE HCl	78628-80-5	616-640-4	100
CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT						
TERBINAFINE HCl	78628-80-5	616-640-4	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**

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.

Store at controlled room temperature. Controlled room temperature indicates a temperature 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (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°C (104°F) are permitted as long as they do not exceed 24 hours

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

Chemical Name: TERBINAFINE HCl CAS #: 78628-80-5

	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

**NOTES**

USP: ELV: Industrial TWA: 2 mg/m<sup>3</sup>

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

Solid

**DESCRIPTION**

White or almost white powder.

<b>SOLUBILITY</b>	Very slightly or slightly soluble in water; freely soluble in anhydrous ethanol and in methanol, slightly soluble in acetone.				
<b>ODOR</b>	Odorless				
<b>FLAMMABILITY</b>	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>	5.2 (approx. 22°C)	<b>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(195-198;203-207)°C,(383-388.4; 397.4-404.6)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	3.5 (0.24% solution)
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	Negligible	<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, acids and alkali
<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

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): > 4000 Dermal: Rat: LD50: (mg/kg): > 2000 Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Causes skin irritation.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Causes serious eye irritation.

<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.
<b>GERM CELL MUTAGENICITY</b>	Due to lack of data the classification is not possible.
<b>CARCINOGENICITY</b>	<b>OSHA</b> TERBINAFINE HYDROCHLORIDE is not listed. <b>NTP</b> TERBINAFINE HYDROCHLORIDE is not listed. <b>IARC</b> TERBINAFINE HYDROCHLORIDE is not evaluated. <b>California Proposition</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	Due to lack of data the classification is not possible.
<b>REPRODUCTIVE TOXICITY</b>	Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	May cause respiratory irritation.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Based on available data, the classification criteria are not met.
<b>ASPIRATION HAZARDS</b>	Based on available data, the classification criteria are not met.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	ROUTES OF EXPOSURE: Oral, Dermal, Inhalation, Eye contact EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available DELAYED HEALTH EFFECT FROM EXPOSURE: Not available  Symptoms related to the physical, chemical, and toxicological characteristics: Gastrointestinal disturbances; dizziness, headache, nausea and loss of coordination. Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Ptosis. Behavioral: Ataxia; Blood: Changes in spleen.
<b>POTENTIAL HEALTH EFFECTS</b>	<b>Inhalation</b> May be harmful if inhaled. May cause respiratory tract irritation. <b>Ingestion</b> May be harmful if swallowed. <b>Skin</b> May be harmful if absorbed through skin. Causes skin irritation. <b>Eyes</b> Causes serious eye irritation.
<b>NOTES</b>	Pharmacologically active material. Occupational exposure may cause physiological effects.

## SECTION 12: ECOLOGICAL INFORMATION

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 Hr: Algae: (mg/L): 0.029
<b>PERSISTENCE AND DEGRADABILITY</b>	Not readily biodegradable.
<b>BIOACCUMULATIVE POTENTIAL</b>	Has the potential to bioaccumulate. LogPow: 5.2 (approx. 22°C)
<b>MOBILITY IN SOIL</b>	Very slightly or slightly soluble in water.
<b>OTHER ADVERSE EFFECTS</b>	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

### UN PROPER SHIPPING NAME

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

### UN NUMBER

3077

### CLASS

9

### PACKING GROUP

III

### AUSTRALIA

#### HAZCHEM

2Z

### 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
TERBINAFINE HCl 78628-80-5	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
TERBINAFINE HCl 78628-80-5	N/L	Listed as Schedule 4*	N/L	Listed*	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
TERBINAFINE HCl 78628-80-5	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

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

10/2023

### SUPERSEDES

01/2022

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.