

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	METRONIDAZOLE, USP
PRODUCT CODE	0146
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. 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 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Antiprotozoal; Antimicrobial; Antibacterial

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Carcinogenicity (Category 1B) Toxic to Reproduction (Category 2) - Effects on or via lactation Acute Aquatic Toxicity (Category 3) Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (nervous system)
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PICTOGRAM

SIGNAL WORD

Danger

HAZARD STATEMENT(S)

May be harmful if swallowed.
 Suspected of damaging fertility or the unborn child.
 Suspected of causing genetic defects
 May cause harm to breast-fed children.
 Suspected of causing cancer.
 May cause damage to organs through prolonged or repeated exposure.
 Harmful to aquatic life.

AUSTRALIA-ONLY HAZARDS

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. Do not breathe dusts or mists. Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye protection, face protection. Avoid release to the environment.
Response	IF EXPOSED OR CONCERNED: Get medical advice/attention. Get medical advice/attention if you feel unwell.

HMIS CLASSIFICATION	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	Health Hazard	2	Flammability	0
	Reactivity	0	Personal Protection	I

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	1H-Imidazole-1-ethanol, 2-methyl-5-nitro						
BOTANICAL NAME	Not applicable						
SYNONYM	Not available						
CHEMICAL FORMULA	C ₆ H ₉ N ₃ O ₃						
CAS NUMBER	443-48-1						
ALTERNATE CAS NUMBER	Not applicable						
MOLECULAR WEIGHT	171.1551						
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>METRONIDAZOLE</td> <td>443-48-1</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	METRONIDAZOLE	443-48-1	100
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT					
METRONIDAZOLE	443-48-1	100					
NOTES	<p>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.</p> <p>Chemical family: Nitroimidazole.</p>						

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.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , 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.

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.

STORAGE CONDITIONS

Store in original container, tightly sealed container, protected from direct sunlight, in a dry, and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. 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.

Preserve in well-closed, light-resistant containers and store at controlled room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: METRONIDAZOLE CAS #: 443-48-1

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

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.

SPECIFIC ENGINEERING CONTROLS

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

NOTES

 USP: ELV: Industrial: TWA 0.1 mg/m³
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	Solid				
DESCRIPTION	White to pale yellow, odorless crystals or crystalline powder. Is stable in air, but darkens on exposure to light.				
SOLUBILITY	Soluble in dilute hydrochloric acid (1 in 2); sparingly soluble in water and in alcohol; slightly soluble in ether and in chloroform.				
ODOR	Odorless or slight odor.				
FLAMMABILITY	May be combustible at high temperature				
ODOR THRESHOLD	Not available	pH	5.5 - 7.5 (10g/L H ₂ O)	MELTING POINT	(158-163)°C, (316.4-325.4)°F
BOILING POINT	Not available	FREEZING POINT	(158-163)°C, (316.4-325.4)°F	FLASH POINT	Not available
SPECIFIC GRAVITY	1.426	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25°C)
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	0.9	log P (OCTANOL-WATER)	-0.02 (20°C)
AUTO-IGNITION TEMPERATURE	155/185°C	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	Strong oxidants. Acids. Alkalis. Aluminum.
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): 3000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LD50: (mg/L/4hr): Not available
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SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met.
SERIOUS EYE DAMAGE/EYE IRRITATION	Due to lack of data the classification is not possible.
RESPIRATORY OR SKIN SENSITIZATION	Respiratory sensitization: Due to lack of data the classification is not possible. Skin sensitization: Based on available data, the classification criteria are not met. Suspected skin sensitizer.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible. Suspected mutagen: The Toolbox profiler 'DNA alerts for AMES, MN and CA by OASIS v.1.3' gives an alert for mutagenicity; The Toolbox profiler 'in vitro mutagenicity (Ames test) alerts by ISS' gives an alert for mutagenicity; CAESAR Mutagenicity model in VEGA (Q)SAR platform predicts that the chemical is Mutagen (experimental value).
CARCINOGENICITY	OSHA METRONIDAZOLE is listed. NTP METRONIDAZOLE is listed. IARC METRONIDAZOLE is listed in group 2b (possibly carcinogenic to humans). California Proposition 65 This product contains the following chemical known to the State of California to cause cancer: METRONIDAZOLE.
ADDITIONAL CARCINOGENICITY INFORMATION	500 mg/kg/day Carcinogenicity study Result: Increased incidence of malignant liver tumors in males. Species: Mouse >= 225 mg/kg/day Carcinogenicity study Result: Increased incidence of pulmonary tumors and lymphomas. Species: Mouse
REPRODUCTIVE TOXICITY	Metronidazole is mutagenic in bacteria and carcinogenic in rodents. It readily crosses the placenta achieving similar concentrations in the placental cord and maternal plasma and its use in pregnancy is controversial. Metronidazole is distributed into breast milk giving it a bitter taste which may impair feeding. The American Academy of Pediatrics considers that although the effects of metronidazole on breast-fed infants are unknown they may be of concern. It recommends that breast feeding should be stopped for 12 to 24 hours when single-dose therapy is used; no specific recommendations are given for long-term treatment.
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 (nervous system) through prolonged or repeated exposure.
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. Headache. Trembling. Weakness. Numbness, pain, tingling, or weakness in hands or feet. Incoordination. Diarrhea. Loss of appetite. Nausea. Vomiting. Cramps. Dry mouth. Unpleasant taste. Dark urine. Delayed and immediate effects of exposure Peripheral neuropathy. Neutropenia. Candida overgrowth. Cancer. Cross sensitivity Persons sensitive to one nitroimidazole derivative may be sensitive to this material also. Medical conditions aggravated by exposure Active alcoholism. Epilepsy. Central nervous system disorders. Blood dyscrasias. Candidiasis. Impaired liver function.
POTENTIAL HEALTH EFFECTS	Inhalation May be harmful if inhaled. May cause respiratory tract irritation. Ingestion May be harmful if swallowed. Skin May be harmful if absorbed through skin. May cause skin irritation Eyes May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	EC50: 48 Hr: Crustacea (Daphnia): (mg/L): 12.07* LC50: 96 Hr: Fish: (mg/L): > 100 IC50: 72 Hr: Algae: (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Sparingly soluble in water Water solubility: 9500mg/L (25°C) Henry's Law Constant: 1.69E-11 atm-m ³ /mole (25°C)
OTHER ADVERSE EFFECTS	Not available
NOTES	This product is not intended to be released into the environment *Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

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

UNITED STATES & CANADA

UN PROPER SHIPPING NAME	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
UN NUMBER	3077
CLASS	9
PACKING GROUP	III

AUSTRALIA

UN PROPER SHIPPING NAME	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
UN NUMBER	3077
CLASS	9
PACKING GROUP	III
HAZCHEM	2Z

ENVIRONMENTAL HAZARDS	Not available
SPECIAL SHIPPING INFORMATION	Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
METRONIDAZOLE 443-48-1	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
METRONIDAZOLE 443-48-1	N/L	Listed as Schedule 4	N/L

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** - Mine Safety and Health Administration; **ACGIH** - American Conference of Governmental Industrial Hygienists; **IDHL** - Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** - Recommended Exposure Limit

LAST REVISION

04/2017

SUPERSEDES

06/2015

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.