

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	PHENAZOPYRIDINE HYDROCHLORIDE, USP
PRODUCT CODE	0122
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	Analgesic

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 4) Carcinogenicity (Category 1A)				
PICTOGRAM					
SIGNAL WORD	Warning				
HAZARD STATEMENT(S)	Harmful if swallowed May cause cancer				
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. 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.	Response IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth. IF EXPOSED OR CONCERNED: Get medical advice/attention.	Storage Store locked up.		
HMIS CLASSIFICATION	Disposal Dispose of contents and/or container in accordance with local regulations.	Health Hazard <table border="1" data-bbox="760 1747 906 1780"> <tr> <td>1</td> </tr> </table>	1	Flammability <table border="1" data-bbox="1269 1747 1416 1780"> <tr> <td>0</td> </tr> </table>	0
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	Reactivity <table border="1" data-bbox="760 1797 906 1831"> <tr> <td>0</td> </tr> </table>	0	Personal Protection <table border="1" data-bbox="1269 1797 1416 1831"> <tr> <td>E</td> </tr> </table>	E	
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	2,6-Pyridinediamine, 3-(phenylazo)-, monohydrochloride						
BOTANICAL NAME	Not applicable						
SYNONYM	Phenazopyridinium chloride						
CHEMICAL FORMULA	C ₁₁ H ₁₁ N ₅ · HCl						
CAS NUMBER	136-40-3						
ALTERNATE CAS NUMBER	Not applicable						
MOLECULAR WEIGHT	249.70						
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>PHENAZOPYRIDINE HYDROCHLORIDE</td> <td>136-40-3</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	PHENAZOPYRIDINE HYDROCHLORIDE	136-40-3	100
CHEMICAL NAME	CAS NUMBER	% BY WEIGHT					
PHENAZOPYRIDINE HYDROCHLORIDE	136-40-3	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: Pyridine derivative (Azo dye).</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, 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. Preserve in tight containers.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: PHENAZOPYRIDINE HYDROCHLORIDE CAS #: 136-40-3

	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: TWA 0.3 mg/m³, Skin

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

Light or dark red to dark violet, crystalline powder. Is odorless, or has a slight odor.

SOLUBILITY

Slightly soluble in water, in alcohol, and in chloroform.

ODOR

Is odorless, or has a slight odor.

FLAMMABILITY

May be combustible at high temperature

ODOR THRESHOLD	Not available	pH	Not available	MELTING POINT	235 °C, 455 °F (decomposes)
BOILING POINT	Not available	FREEZING POINT	235 °C, 455 °F	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	Not available
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	Not available
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	235 °C, 455 °F	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	Strong oxidizing agents. Peroxides. Isocyanates. Amides. Phenols.
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): 472 Dermal: Rabbit: LD50: (mg/kg): Not available Inhalation: Rat: LD50: (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 OR 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.
 Data from germ cell mutagenicity tests were not found.
 Mutagenicity
 Chromosome aberrations in Chinese hamster ovary cells
 Result: Positive.
 Forward mutation in mouse lymphoma cells
 Result: Positive with activation, negative without activation.
 Salmonella mutagenicity tests
 Result: Equivocal and positive.
 Sex-linked recessive lethal mutation studies in Drosophila
 Result: Equivocal.
 Sister chromatid exchange in Chinese hamster ovary cells
 Result: Positive.

CARCINOGENICITY

OSHA PHENAZOPYRIDINE HYDROCHLORIDE is listed.
NTP PHENAZOPYRIDINE HYDROCHLORIDE is reasonably anticipated to be a human carcinogen.
IARC PHENAZOPYRIDINE HYDROCHLORIDE 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: PHENAZOPYRIDINE HYDROCHLORIDE.

ADDITIONAL CARCINOGENICITY INFORMATION

3700 - 7500 ppm Long-term carcinogenicity study, administered orally in feed.
 Result: Increased incidence of adenomas and carcinomas of the colon and rectum.
 Species: Rat
 Test Duration: 78 weeks
 600 - 1200 ppm Long-term carcinogenicity study, administered orally in feed.
 Result: Increased incidence of hepatocellular adenomas and carcinomas in females but not in males.
 Species: Mouse
 Test Duration: 80 weeks

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.
 Human epidemiological studies have not identified abnormalities caused by therapeutic use of this material during pregnancy.
 Reproductivity
 50 mg/kg/day Reproductivity studies
 Result: No impairment of fertility. No harm to the fetus. Not teratogenic.
 Species: Rat

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

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

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

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

ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.
 Symptoms related to the physical, chemical, and toxicological characteristics:
 Nausea. Vomiting. Diarrhea. Blue or pale lips, fingernails, or skin. Difficulty breathing. Dizziness. Headache. Weakness. Tiredness. Fever. Yellow eyes and/or skin. Orange-red colored urine. Swelling of extremities.
 Delayed and immediate effects of exposure:
 Increase in blood pressure. Methemoglobinemia. Liver toxicity. Kidney stones. Hemolytic anemia.
 Medical conditions aggravated by exposure:
 Glucose-6-phosphate dehydrogenase deficiency. Kidney impairment. Hepatitis.

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

TOXICITY	EC50: 48 Hr: Daphnia magna: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available IC50: 72 Hr: Algae: (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Not available
MOBILITY IN SOIL	Slightly soluble in water
OTHER ADVERSE EFFECTS	Not available This product is not intended to be released into the environment

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	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable
HAZCHEM	Not applicable

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		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
PHENAZOPYRIDINE HCl, 136-40-3	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
PHENAZOPYRIDINE HCl, 136-40-3	N/L	Listed as Schedule 4*	N/L

NOTES

*Listed as the base only

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

03/2016

SUPERSEDES

07/2013

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.