SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: PHENAZOPYRIDINE HYDROCHLORIDE, USP
PRODUCT CODE: 0122
SUPPLIER: MEDISCA Inc.
Tel.: 1.800.932.1039 | Fax.: 1.855.880.5855
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.

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

HMIS CLASSIFICATION:
- Health Hazard: 1
- Flammability: 0
- Reactivity: 0
- Personal Protection: E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
## CHEMICAL NAME
2,6-Pyridinediamine, 3-(phenylazo)-, monohydrochloride

## BOTANICAL NAME
Not applicable

## SYNONYM
Phenazopyridinium chloride

## CHEMICAL FORMULA
C₁₁H₁₁N₅·HCl

## CAS NUMBER
136-40-3

## ALTERNATE CAS NUMBER
Not applicable

## MOLECULAR WEIGHT
249.70

## COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenazopyridine</td>
<td>136-40-3</td>
<td>100</td>
</tr>
<tr>
<td>Hydrochloride</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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: Pyridine derivative (Azo dye).

### 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
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, CO₂ or water spray. Large fire: dry chemical, CO₂, 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

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>OSHA PEL</td>
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<td>N/L</td>
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<td>-</td>
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<td>ACGIH TLV</td>
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<td>N/L</td>
<td>N/L</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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<tr>
<td>AIHA WEEL</td>
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<td>N/L</td>
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<td>-</td>
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<td>Safe Work Australia HSIS</td>
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<td>HSE</td>
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<td>N/L</td>
<td>-</td>
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<td>-</td>
</tr>
</tbody>
</table>

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
<table>
<thead>
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<th>Property</th>
<th>Value</th>
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<tbody>
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<td><strong>ODOR THRESHOLD</strong></td>
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<td><strong>pH</strong></td>
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<td><strong>BOILING POINT</strong></td>
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<tr>
<td><strong>FREEZING POINT</strong></td>
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<tr>
<td><strong>FLASH POINT</strong></td>
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<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
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<tr>
<td><strong>EVAPORATION RATE</strong></td>
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<td><strong>EXPLOSIVE LIMIT</strong></td>
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<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
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</tr>
<tr>
<td><strong>LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
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</tr>
<tr>
<td><strong>VAPOR PRESSURE</strong></td>
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<td><strong>RELATIVE DENSITY (WATER = 1)</strong></td>
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</tr>
<tr>
<td><strong>log P (OCTANOL-WATER)</strong></td>
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</tr>
<tr>
<td><strong>VISCOITY</strong></td>
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<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>235 °C, 455 °F</td>
</tr>
</tbody>
</table>

**SECTION 10: STABILITY AND REACTIVITY**

- **REACTIVITY**: Not established
- **STABILITY**: Stable under recommended storage conditions
- **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
  - Dermat: 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/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

Not expected to present a significant hazard under anticipated conditions of normal use.

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

Delayed and immediate effects of exposure:

Medical conditions aggravated by exposure:

SIGNS AND SYMPTOMS OF EXPOSURE

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

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

### SECTION 13: DISPOSAL CONSIDERATIONS

**WASTE DISPOSAL**
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

### 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

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>PHENAZOPYRIDINE HCl, 136-40-3</td>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>X</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed
PHENAZOPYRIDINE HCl, 136-40-3

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. MEDIISCA® 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.