SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: HYDROXYUREA, USP  
PRODUCT CODE: 1354  
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: Anti-neoplastic agent

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION:  
Eye Irritation (Category 2B)  
Germ Cell Mutagenicity (Category 2)  
Toxic to Reproduction (Category 1B)  
Carcinogenicity (Category 2)  
Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (Bone Marrow)

PICTOGRAFM

SIGNAL WORD: Danger  
HAZARD STATEMENT(S):  
Causes eye irritation.  
Suspected of causing genetic defects  
May damage fertility or the unborn child.  
Suspected of causing cancer.  
Causes damage to organs (bone marrow) through prolonged or repeated exposure.

AUSTRALIA-ONLY HAZARDS:  
Repeated exposure may cause skin dryness or cracking.

PRECAUTIONARY STATEMENT(S):  
Prevention: Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Do not breathe dust/fume/gas/mist/ vapors/spray.  
Do not eat, drink or smoke when using this product.  
Wear protective gloves, protective clothing, eye protection, face protection.  
Wash thoroughly after handling.

Response: 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 EXPOSED OR CONCERNED: Get medical advice/attention.  
Get medical advice/attention if you feel unwell.

Storage: Store locked up.
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME | Hydroxycarbamide
BOTANICAL NAME | Not applicable
SYNONYM | Not applicable
CHEMICAL FORMULA | CH₃N₂O₂
CAS NUMBER | Not applicable
ALTERNATE CAS NUMBER | 127-07-1
MOLECULAR WEIGHT | 76.05

COMPOSITION

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROXYUREA</td>
<td>127-07-1</td>
<td>100</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

An antineoplastic agent that may inhibit DNA synthesis through the inhibition of ribonucleotide reductase.

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
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

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.
Dust explosion properties:
Kst: 78 bar.m/s
St class: 1
Minimum ignition energy (MIE) – dust cloud > 500 mJ

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, in a dry atmosphere. Protect from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Chemical Name: HYDROXYUREA  CAS #: 127-07-1</th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<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.
### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PHYSICAL STATE</strong></td>
<td>Solid</td>
</tr>
<tr>
<td><strong>DESCRIPTION</strong></td>
<td>White to off-white powder. Is somewhat hygroscopic, decomposing in the presence of moisture.</td>
</tr>
<tr>
<td><strong>SOLUBILITY</strong></td>
<td>Freely soluble in water and in hot alcohol.</td>
</tr>
<tr>
<td><strong>ODOR</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>FLAMMABILITY</strong></td>
<td>May be combustible at high temperature</td>
</tr>
<tr>
<td><strong>ODOR THRESHOLD</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>BOILING POINT</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>FREEZING POINT</strong></td>
<td>(145 - 146)°C, (293-294.8)°F (decomposes)</td>
</tr>
<tr>
<td><strong>SPECIFIC GRAVITY</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>VAPOR DENSITY</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>AUTO-IGNITION TEMPERATURE</strong></td>
<td>&gt; 800 °C, &gt; 1472 °F</td>
</tr>
<tr>
<td><strong>DECOMPOSITION TEMPERATURE</strong></td>
<td>125 °C, 257 °F</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>(145 - 146)°C, (293-294.8)°F (decomposes)</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Explosive Limit</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>0.0000393 kPa (25°C)</td>
</tr>
<tr>
<td><strong>Log P (OCTANOL-WATER)</strong></td>
<td>-1.8 (20°C)</td>
</tr>
</tbody>
</table>

### SECTION 10: STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REACTIVITY</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>STABILITY</strong></td>
<td>Stable under recommended storage conditions. The substance becomes unstable if heated to 125°C. At this temperature it develops a strong exothermic reaction.</td>
</tr>
<tr>
<td><strong>MATERIALS TO AVOID</strong></td>
<td>Strong oxidants</td>
</tr>
<tr>
<td><strong>HAZARDOUS DECOMPOSITION PRODUCTS</strong></td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td><strong>HAZARDOUS POLYMERIZATION</strong></td>
<td>Will not occur</td>
</tr>
<tr>
<td><strong>POSSIBILITY OF HAZARDOUS REACTION</strong></td>
<td>Not established</td>
</tr>
<tr>
<td><strong>CONDITIONS TO AVOID</strong></td>
<td>Moisture, sunlight and extreme temperatures</td>
</tr>
</tbody>
</table>

### SECTION 11: TOXICOLOGICAL INFORMATION
ACUTE TOXICITY

Oral: Rat: LD50: (mg/kg): 5760
Dermal: Rabbit: LD50: (mg/kg): Not available
Inhalation: Rat: LD50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

Skin irritation
Result: Mild irritation.
Based on available data, the classification criteria are not met.

SERIOUS EYE DAMAGE/EYE IRRITATION

Eye irritation
Result: Mild irritation.

RESPIRATORY OR SKIN SENSITIZATION

Mouse local lymph node assay
Result: Negative.
Based on available data, the classification criteria are not met.

GERM CELL MUTAGENICITY

Suspected of causing genetic defects.
DNA repair assay (rat hepatocytes)
Result: Positive.
In vivo micronucleus assay (Mouse)
Result: Positive.
In vivo sister chromatid exchange assay (rodents)
Result: Positive.
Sperm morphology (mouse)
Result: Positive.
Yeast reverse mutation assay
Result: Positive.

CARCINOGENICITY

OSHA HYDROXYUREA is listed.
NTP HYDROXYUREA is listed.
IARC HYDROXYUREA is listed in group 3 (not classifiable as to its carcinogenicity to humans).
California Proposition 65 This product contains the following chemical known to the State of California to cause birth defects or other reproductive harm: HYDROXYUREA.

ADDITIONAL CARCINOGENICITY INFORMATION

Suspected of causing cancer. Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use. Secondary leukaemias have occurred in patients receiving hydroxycarbamide for myeloproliferative disorders, although the extent to which this is due to the treatment or the underlying disorder is unknown. Skin cancers have also been associated with its use. These are often multiple and include both squamous cell and basal cell carcinomas.

125 - 250 mg/kg 6-Month study (intraperitoneal doses 0.6 to 1.2 x maximum human dose)
Result: Increased incidence of mammary tumors.
Species: Rat

100 - 200 mg/kg/day Gestational study
Result: Birth defects included abnormal development of the eye and brain and heart defects.
Species: Rat

30 mg/kg/day Reproductive study
Result: Fetotoxic and teratogenic.
Species: Rabbit

400 - 800 mg/kg/day Gestational study
Result: Increased resorption, decreased fetal body weight, and skeletal malformations.
Species: Mouse

Breast feeding: In breast-milk samples from a woman given hydroxycarbamide 500 mg three times daily, the mean concentration of the drug was found to be about 6 mg/litre. It was estimated that, had the infant been breast-fed, it would have received about 3 to 4 mg daily. Although this amount appears to be low, women are advised not to breast feed while taking hydroxycarbamide.

REPRODUCTIVE TOXICITY

May damage fertility or the unborn child.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Due to lack of data the classification is not possible.
SAFETY DATA SHEET

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Causes damage to organs (bone marrow) through prolonged or repeated exposure.

ASPIRATION HAZARDS
Due to lack of data the classification is not possible.

SIGNS AND SYMPTOMS OF EXPOSURE
Not expected to present a significant hazard under anticipated conditions of normal use.

Hydroxyurea is readily absorbed from the gastrointestinal tract and distributed throughout the body.

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

Delayed and immediate effects of exposure:
Bone marrow depression. Cancer.

Medical conditions aggravated by exposure:

POTENTIAL HEALTH EFFECTS

<table>
<thead>
<tr>
<th>Mode of Exposure</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>May be harmful if inhaled. May cause respiratory tract irritation.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>May be harmful if swallowed.</td>
</tr>
<tr>
<td>Skin</td>
<td>May be harmful if absorbed through skin. Causes skin irritation.</td>
</tr>
<tr>
<td>Eyes</td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

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
Log Pow: -1.8 (20°C)

MOBILITY IN SOIL
Water solubility: 1.00E+06 mg/L (25°C)
Henry’s Law Constant: 5.42E-11 atm-m3/mole (25°C)

OTHER ADVERSE EFFECTS
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.

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
SAFETY DATA SHEET

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>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65</th>
<th>EPA 40 CFR Part 355 Appendix A</th>
<th>Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROXYUREA 127-07-1</td>
<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>N/L</td>
<td>X</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROXYUREA 127-07-1</td>
<td>N/L</td>
<td>Listed as Schedule 4</td>
<td>N/L</td>
</tr>
</tbody>
</table>

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
09/2016

SUPERSEDES
12/2015