# SAFETY DATA SHEET

## SECTION 1: PRODUCT IDENTIFICATION

| | |
|---|---|
| **PRODUCT NAME** | **HYDROXYUREA, USP** |
| **PRODUCT CODE** | **1354** |
| **SUPPLIER** | **MEDISCA Inc.**<br>Tel.: 1.800.932.1039 \| Fax.: 1.855.850.5855<br>626 Tom Miller Road, Plattsburgh, NY, 12901<br>**MEDISCA Pharmaceutique Inc.**<br>Tel.: 1.800.665.6334 \| Fax.: 514.338.1693<br>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8<br>**MEDISCA Australia PTY LTD**<br>Tel.: 1.300.786.392 \| Fax.: 61.2.9700.9047<br>Unit 7, Heritage Business Park<br>5-9 Ricketty Street, Mascot, NSW 2020 |
| **EMERGENCY PHONE** | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300<br>NSW Poisons Information Centre: 131 126<br>National Chemical Emergency Centre 44(0)1235239670 |
| **RECOMMENDED USES** | Pharmaceutical Manufacturing |
| **RESTRICTIONS ON USE** | Not applicable |

## SECTION 2: HAZARDS IDENTIFICATION

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|---|---|
| **GHS CLASSIFICATION** | Eye Irritation (Category 2B)<br>Germ Cell Mutagenicity (Category 2)<br>Toxic to Reproduction (Category 1B)<br>Carcinogenicity (Category 2)<br>Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (Bone Marrow) |
| **PICTOGRAM** |  |
| **SIGNAL WORD** | Danger |
| **HAZARD STATEMENT(S)** | Cytotoxic! Extremely hazardous to all tissues.<br>Causes eye irritation.<br>Suspected of causing genetic defects<br>May damage fertility or the unborn child.<br>Suspected of causing cancer.<br>Causes damage to organs (bone marrow) through prolonged or repeated exposure. |
| **ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS** | Not Applicable |

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| **PRECAUTIONARY STATEMENT(S)** | **Prevention** | Obtain, read and follow all special instructions before use.<br>Do not handle until all safety precautions have been read and understood.<br>Do not breathe dust/fume/gas/mist/ vapors/spray.<br>Do not eat, drink or smoke when using this product.<br>Wear protective gloves, protective clothing, eye and face protection and hearing protection.<br>Wash hands thoroughly after handling. Do not touch eyes. |
| | **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 help.<br>IF EXPOSED OR CONCERNED: Get medical advice.<br>Get medical help if you feel unwell. |
| | **Storage** | Store locked up. |
| | **Disposal** | Dispose of contents and/or container in accordance with local regulations. |

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|---|---|---|---|---|
| **HMIS CLASSIFICATION** | **Health Hazard** | 4 | **Flammability** | 0 |
| | **Reactivity** | 0 | **Personal Protection** | K |

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| | |
|---|---|
| **CHEMICAL NAME** | 1-hydroxyurea |
| **BOTANICAL NAME** | Not applicable |
| **SYNONYM** | Hydroxycarbamide; N-Hydroxyurea |
| **CHEMICAL FORMULA** | $CH_4N_2O_2$ |
| **CHEMICAL FAMILY** | Urea |
| **CAS NUMBER** | 127-07-1 |
| **ALTERNATE CAS NUMBER** | Not applicable |
| **MOLECULAR WEIGHT** | 76.05 |

**COMPOSITION**

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|---|---|---|---|
| HYDROXYUREA | 127-07-1 | 204-821-7 | 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.

**NOTES**

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

## SECTION 4: FIRST-AID MEASURES

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| **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** | If at any time there is skin contact with any cytotoxic drug, thoroughly wash the affected area with soap and water for 15 minutes. The worker should not scrape or abrade the skin by using a scrub brush as this could increase exposure. It is always recommended to seek a medical evaluation by a physician. |
| **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 |
| **MEDICAL ATTENTION AND SPECIAL TREATMENT** | Get emergency medical help. |
| **SYMPTOMS CAUSED BY EXPOSURE** | Refer to section 11 |

## SECTION 5: FIREFIGHTING MEASURES

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| **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. |
| **SUITABLE & UNSUITABLE 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. |
| **NOTES** | Dust explosion properties:<br>Kst: 78 bar.m/s<br>St class: 1<br>Minimum ignition energy (MIE) – dust cloud > 500 mJ |

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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| **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** | The use of chemical inactivates is not recommended as they may create a hazardous by-product. All contaminated areas should be cleaned a minimum of three times, and all contaminated products and equipment should be disposed of or cleaned in an appropriate manner. |
| **CLEANUP PROCEDURE** | A clearly labelled cytotoxic spill kit should be kept wherever cytotoxic medications are being prepared, stored, administered or received (shipping). A spill needs to be cleaned by members of the staff that have received the appropriate training and have the appropriate protective equipment; others should vacate the area as soon as it is safe to do so until the spill is cleaned. All spills should be immediately marked with a warning sign to prevent exposure to others. Glass should never be handled by hand; always use a scoop. The cleanup should be done by as few people as feasible, but there should be at least two people involved. |
| **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

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| **PRECAUTIONS FOR SAFE HANDLING** | Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Cytotoxic! Extremely hazardous to all tissues. Avoid all contact. 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.<br><br>Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable. |

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

**Chemical Name: HYDROXYUREA CAS #: 127-07-1**

| | Country | Limit value-8 hours | | Limit value-Short Term | | IDLH | REL | Advisory | Notes |
|---|---|---|---|---|---|---|---|---|---|
| | | ppm | mg/m³ | ppm | mg/m³ | | | | |
| 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 | 10:00 antineoplastic agents | 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**

Cytotoxic: There are no exposure limits set for cytotoxic drugs. Exposure must be kept to a minimum.

**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**

The following engineering controls should be put in place where cytotoxic medications are being used:
A minimum of a Class II biological safety cabinet with HEPA filter exhaust systems that does not allow air to be circulated back into the room should be used while manipulating cytotoxic drugs.
The preparation area within the cabinet should be covered with a plastic backed, absorbent material to reduce dispersion and facilitate the clean-up of any spilled medication.
Medications should be isolated and locked out in such a manner that only those properly trained have access to the storage location.
Puncture proof containers for the disposal of needles, syringes and vials must be provided.
Negative pressure rooms that prevent any spilled medication from leaving the room are also recommended.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

**NOTES**

Additional controls:
Safe work procedures for handling these materials should be developed and taught to all affected staff. Proper signage informing all employees of the presence of cytotoxic drugs and their hazards must be developed and displayed in highly visible locations. Eating, drinking, smoking, applying makeup and the storage of food should be completely prohibited in the preparation area.

USP: ELV: Industrial use: TWA: 0.1 mg/m³

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**PHYSICAL STATE** Solid

**DESCRIPTION** White to off-white powder. Is somewhat hygroscopic, decomposing in the presence of moisture.

**SOLUBILITY** Freely soluble in water and in hot alcohol.

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| **ODOR** | Odorless |
| **FLAMMABILITY** | May be combustible at high temperature |

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|---|---|---|---|---|---|
| **AUTO-IGNITION TEMPERATURE** | > 800 °C, > 1472 °F | **BOILING POINT** | Not available | **DECOMPOSITION TEMPERATURE** | 125 °C, 257 °F |
| **EVAPORATION RATE** | Not available | **EXPLOSIVE LIMIT** | Not available | **FLASH POINT** | Not available |
| **log P (OCTANOL-WATER)** | -1.8 (20°C) | **LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)** | Not available | **MELTING/FREEZING POINT** | (145 - 146)°C, (293-294.8)°F (decomposes) |
| **PARTICLE CHARACTERISTICS** | Not available | **OXIDIZING PROPERTY** | Not available | **pH** | 6.1 (2%) |
| **RELATIVE DENSITY (WATER = 1)** | Not available | **SPECIFIC GRAVITY** | Not available | **UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)** | Not available |
| **VAPOR DENSITY (AIR = 1)** | Not available | **VAPOR PRESSURE** | 0.0000393 kPa (25°C) | **VISCOSITY** | Not available |

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

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| **REACTIVITY** | Not established |
| **CHEMICAL STABILITY** | Stable under recommended storage conditions. The substance becomes unstable if heated to 125°C. At this temperature it develops a strong exothermic reaction. |
| **INCOMPATIBLE MATERIALS** | Strong oxidants. Strong acids or alkalis. |
| **HAZARDOUS DECOMPOSITION PRODUCTS** | Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, urea, ammonia and other gases may occur |
| **HAZARDOUS POLYMERIZATION** | Will not occur |
| **POSSIBLITY OF HAZARDOUS REACTION** | Not established |
| **CONDITIONS TO AVOID** | Moisture, sunlight and extreme temperatures |

## SECTION 11: TOXICOLOGICAL INFORMATION

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|---|---|
| **ACUTE TOXICITY** | Oral: Rat: LD50: (mg/kg): 5760<br>Dermal: Rabbit LD50: (mg/kg): Not available<br>Inhalation: Rat: LC50: (mg/L/4hr): Not available |
| **SKIN CORROSION/IRRITATION** | Based on available data, the classification criteria are not met.<br>Skin irritation; Result: Mild irritation. |
| **SERIOUS EYE DAMAGE/EYE IRRITATION** | Causes irritation.<br>Eye irritation; Result: Mild irritation. |
| **RESPIRATORY SENSITIZATION** | Due to lack of data the classification is not possible. |

| | | |
|---|---|---|
| **SKIN SENSITIZATION** | Based on available data, the classification criteria are not met.<br>Mouse local lymphnode assay: Result: Negative. | |
| **GERM CELL MUTAGENICITY** | Suspected of causing genetic defects.<br>Exposure to cytotoxic drugs has been reported to cause increased frequency of chromosome damage in exposed workers.<br>DNA repair assay (rat hepatocytes); Result: Positive.<br>In vivo micronucleus assay (Mouse); Result: Positive.<br>In vivo sister chromatid exchange assay (rodents); Result: Positive.<br>Sperm morphology (mouse); Result: Positive.; Yeast reverse mutation assay; Result: Positive.<br><br>Suspected mutagen: In vivo micronucleus test outcome positive according to ISSMIC; mutagen according to ISSSTY | |
| **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.<br>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.<br>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.<br>Skin cancers have also been associated with its use. These are often multiple and include both squamous cell and basal cell carcinomas.<br><br>Repeated long-term occupational exposure to small amounts of cytotoxic drugs has not been identified to cause cancer. However, many cytotoxic drugs are known to be: Genotoxic, Carcinogenetic, Mutagenic.<br><br>125 - 250 mg/kg 6-Month study (intraperitoneal doses 0.6 to 1.2 x maximum human dose)<br>Result: Increased incidence of mammary tumors; Species: Rat | |
| **REPRODUCTIVE TOXICITY** | May damage fertility or the unborn child.<br>100 - 200 mg/kg/day Gestational study<br>Result: Birth defects included abnormal development of the eye and brain and heart defects.; Species: Rat<br><br>30 mg/kg/day Reproductive study; Result: Fetotoxic and teratogenic.; Species: Rabbit<br><br>400 - 800 mg/kg/day Gestational study<br>Result: Increased resorption, decreased fetal body weight, and skeletal malformations.; Species: Mouse<br><br>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.<br><br>Cytotoxic drugs have also been associated with negative health effects for developing fetuses, including higher incidences of spontaneous abortions, congenital malformations, low birth weight, and infertility.<br><br>Suspected toxic for reproduction: DART database in the Toolbox reports that this substance as Known developmental potential. | |
| **SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE** | Due to lack of data the classification is not possible. | |
| **SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE** | Causes damage to organs (bone marrow) through prolonged or repeated exposure. | |
| **ASPIRATION HAZARDS** | Based on available data, the classification criteria are not met. | |

**SIGNS AND SYMPTOMS OF EXPOSURE**

ROUTES OF EXPOSURE:
Oral, Dermal, Inhalation, Eye contact
EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:
Not available
DELAYED HEALTH EFFECT FROM EXPOSURE:
Bone marrow depression. Cancer.

Symptoms related to the physical, chemical, and toxicological characteristics:
Fever. Chills. Cough. Hoarseness. Lower back or side pain. Painful or difficult urination. Bleeding or bruising. Black or bloody stools. Pinpoint red spots on skin. Loss of appetite. Mouth sores. Diarrhea. Nausea. Vomiting. Constipation. Drowsiness. Skin rash. Itching.

Medical conditions aggravated by exposure:
Anemia. Leukopenia. Neutropenia. Bone marrow depression. Chickenpox, existing or recent. Herpes zoster. Infection. HIV or AIDS. Impaired kidney function. Recent cytotoxic drug or radiation therapy.

Pharmacologically active material. Occupational exposure may cause physiological effects.

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

**POTENTIAL HEALTH EFFECTS**

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|---|---|
| **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. Causes skin irritation. |
| **Eyes** | Causes eye irritation. |

## SECTION 12: ECOLOGICAL INFORMATION

**ECOTOXICITY**

EC50: 48 Hr: Crustacea: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND DEGRADABILITY**

Not available

**BIOACCUMULATIVE POTENTIAL**

Log Pow: -1.8 (20°C)

**MOBILITY IN SOIL**

Freely soluble in water
Water solubility: 1.00E+06 mg/L (25°C)
Henry's Law Constant: 5.42E-11 atm-m³/mole (25°C)

**OTHER ADVERSE EFFECTS**

Not available

This product is not intended to be released into the environment

## SECTION 13: DISPOSAL CONSIDERATIONS

**DISPOSAL METHODS**

Plastic bags that are at least 2mm thick (if polypropylene) or 4mm thick (if polyethylene) should be used to collect potentially contaminated materials. Bags should be color-coded and labelled with a cytotoxic warning label. All sharps should be placed in puncture proof containers before bagging. All workplaces should have a policy for segregating waste materials resulting from cytotoxic drug preparation and administration. These plans must meet or exceed the government regulations for hazardous waste disposal.
Housekeeping staff should wear protective gloves while handling waste containers. Cytotoxic waste must be handled differently than regular garbage and must be disposed according to government regulations. In cases where the waste is to be incinerated, it should be noted that completely sealed (airtight) containers that could build pressure and explode must be avoided. Temperatures of 1,000°C to 1,600°C should be used to render the cytotoxic drugs harmless.

## SECTION 14: TRANSPORT INFORMATION

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|---|---|
| **UN PROPER SHIPPING NAME** | Not dangerous good |
| **UN NUMBER** | Not applicable |
| **CLASS** | Not applicable |
| **PACKING GROUP** | Not applicable |

**AUSTRALIA**

| | |
|---|---|
| **HAZCHEM** | Not applicable |

**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 Part 372.65 | EPA 40 CFR Part 355 Appendix A | EPA 40 CFR Part 355 Appendix B | Right-to-know Pennsylvania | Right-to-know New Jersey | Right-to-know Massachusetts | California Prop 65 |
|---|---|---|---|---|---|---|---|---|
| HYDROXYUREA 127-07-1 | 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 | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|---|---|---|---|---|---|---|
| HYDROXYUREA 127-07-1 | N/L | Listed as Schedule 4 | N/L | Listed | N/L | Listed |

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 |
|---|---|---|---|---|---|---|---|
| HYDROXYUREA 127-07-1 | 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.

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| SUBJECT TO INTERNATIONAL AGREEMENT | Not applicable |

## SECTION 16: OTHER INFORMATION

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|---|---|
| **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** – Instituto 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** | 06/2025 |
| **SUPERSEDES** | 04/2024 |
| | For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com |
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| **SUPPLEMENTARY INFORMATION** | For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet. |