SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A

March 1, 2011

Material Safety Data Sheet (MSDS) is a written or printed material concerning a hazardous chemical which is prepared in accordance with the Occupational Safety and Health Administration (OSHA) 29 CFR 1910.1200 (Hazard Communication Standard).

The purpose of the MSDS is to communicate information concerning hazards and appropriate protective measures to ***employees who produce the hazardous chemical.***

OSHA's Hazard Communication Standard **does not require** that an MSDS be provided for finished pharmaceutical products intended for sale to consumers in a retail establishment or for personal consumption. Therefore, an MSDS is not required for Hydroxyurea Capsules, USP. If additional assistance is required with this product or you have received this letter in error please contact me.

Regards,

Rob McCafferty, CIH
Teva Americas Manager, IH

SAFETY DATA SHEET

Issuing Date 25-Jan-2018 **Revision Date** 25-Jan-2018 **Revision Number** 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name **Hydroxyurea Capsules**
Active Ingredient Hydroxyurea

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Pharmaceutical
Uses advised against Use only as directed

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier TEVA
1090 Horsham Road
North Wales, PA 19454
BUSINESS PHONE: 215-591-3000 [08:00 AM --> 05:00 PM]

For further information, please contact
E-mail Address SDS.TevaIL@teva.co.il

1.4. Emergency Telephone Number

Emergency Telephone Number United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]
International: 01-703-527-3887 (Chemtrec) [24-hours]

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Exempt - Regulated Parmaceutical

2.2. Label Elements

Exempt - Regulated Parmaceutical

2.3. Other hazards

This product contains a material considered to be cytotoxic according to Teva's internal definition. See section 11

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Chemical Name	EC No	REACH Reg. No	CAS No	Weight-%
Hydroxyurea	-	Not available	127-07-1	Proprietary
Excipients	-	Not available	-	Remainder

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
Skin Contact	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
Inhalation	Remove person to fresh air. If signs/symptoms continue, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

See product insert.

Notes to Physician Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO2). Foam. Dry extinguishing powder. Halons.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Avoid breathing of or direct contact with material.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Ensure response by people trained and equipped to respond to incidents with the potential to become emergencies, or evacuate the area until professional emergency responders or fire department arrives

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Sweep up and shovel into suitable containers for disposal. Prevent dust cloud.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use exhaust ventilation to keep airborne concentrations below exposure limits. Follow general hygiene considerations recognized as common good workplace practices.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with: label.

7.3. Specific end use(s)

Exposure scenario	No information available.
Other Guidelines	No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits	Not Determined: Mixture
Biological occupational exposure limits	No information available.
Derived No Effect Level (DNEL)	No information available.
Predicted No Effect Concentration (PNEC)	No information available.

8.2. Exposure controls

Engineering Measures	Appropriate Engineering Controls.
Personal protective equipment	
Eye/face protection	Wear appropriate eye protection to prevent eye contact.
Skin protection:	
- Body protection	Wear appropriate personal protective clothing to prevent skin contact.
- Hand protection	Wear suitable gloves.
Respiratory Protection	In case of inadequate ventilation wear respiratory protection.
Environmental exposure controls	No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	No information available
Physical State	Capsules
Flash Point	No information available

9.2. Other information

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity
No information available.

10.2. Chemical Stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions
None known.

10.4. Conditions to avoid
Heat, flames and sparks.

10.5. Incompatible materials.
None in particular.

10.6. Hazardous decomposition products
None under normal use conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute Toxicity	No hazard expected under normal handling conditions.
Skin Corrosion/Irritation	No hazard expected under normal handling conditions.
serious eye damage/irritation	No hazard expected under normal handling conditions.
respiratory or skin sensitization	No hazard expected under normal handling conditions.
Germ Cell Mutagenicity	No hazard expected under normal handling conditions.
carcinogenicity	No hazard expected under normal handling conditions.
reproductive toxicity	No hazard expected under normal handling conditions.
STOT - single exposure	No hazard expected under normal handling conditions.
STOT - repeated exposures	No hazard expected under normal handling conditions.
aspiration hazard	No hazard expected under normal handling conditions.

Other Information

Cytotoxicity Positive: According to Teva's internal policy, a compound is considered cytotoxic if it possesses the ability to interact directly with DNA or DNA-associated macromolecules, resulting in cell death. In addition, a cytotoxic agent causes such damage in an indiscriminate manner, affecting healthy cells in addition to abnormal (e.g., tumor) cells and causing serious systemic toxicity.

SECTION 12: Ecological information

12.1. Toxicity
Ecotoxicity effects
No information available.

12.2. Persistence and degradability
No information available.

12.3. Bioaccumulative potential
No information available.

12.4. Mobility in soil
No information available.

12.5. Results of PBT and vPvB assessment
No information available.

12.6. Other adverse effects
None known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused Products	Dispose of in accordance with local regulations.
Contaminated Packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1.
UN-No -

14.2.
Proper Shipping Name -

14.3. Transport hazard class(es)
Land transport (ADR/RID) -
Sea transport (IMDG) -
Air transport (ICAO-TI / IATA-DGR) -

14.4.
Packing Group -

14.5. Environmental hazards
Marine Pollutant -

14.6. Special precautions for user
Emergency No. -
ADR/RID-Labels -

14.7.
Tecnical name -
Ship type -
Annex II -

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety data sheet complies with the requirements of: GHS

California Proposition 65: developmental toxicity

15.2. Chemical Safety Assessment
No information available

SECTION 16: Other information

CLP/GHS - Regulation
Hazard Statements
Training required. To avoid risks to human health and the environment, comply with the instructions for use.

Source of data
R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
N.T.P. - NATIONAL TOXICOLOGY PROGRAM
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
ECHA (European chemicals agency) databases
FDA (Food & Drug administration) database
EMA (European Medicines agency) documents
ChemAdvisor
Chemspider database

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Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet