Urea 40% Cream

SECTION 1: IDENTIFICATION

Product Identifier

Product Name: Urea 40% Cream

Other Means of Identification: N/A

Recommended use of the chemical and restriction on use

Recommended Use: Topical Application

Restrictions on Use: Do not swallow.

Name, address, telephone number of the supplier/distributor:

Company Address: BIOCOMP PHARMA, INC.
San Antonio, TX 78230-1355
USA

Information Telephone Number: 1-866-762-2365

Emergency Telephone Number: Call a Doctor or Poison Control Center immediately, (800)-222-1222.

SECTION 2: HAZARD(S) IDENTIFICATION

GHS Classification

- Eye Irritation Category 2.

GHS Label Elements, including Precautionary Statements

Signal Word: Warning

Hazard Statements:

Causes eye irritation.

May be harmful if swallowed.

Pictograms:



Precautionary Statements:

40% Urea Cream is for external use only.

Keep out of reach of children.

Not for Ophthalmic Use.

Keep container tightly closed.

Wash hands thoroughly after handling.

See packaging insert for full details on Precautions.

Hazards not otherwise classified: None

Unknown Acute Toxicity: No ingredients with unknown toxicity.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No./ EINECS No.	Percent
Urea	57-13-6	40.0%
Propylene Glycol	57-55-6	3.0%
Dimethyl Isosorbide	5306-85-4	1.0%

SECTION 4: FIRST AID MEASURES

Eye Contact: Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation develops or persists.

Ingestion: Do not induce vomiting. Rinse out mouth with water and give copious amounts of water. If symptoms persist, get immediate medical attention.

Inhalation: Move victim to fresh air. Get medical attention if irritation persists.

Most Important symptoms/effects, acute and delayed: Itching, rashes and hives.

Indication of immediate medical attention and special treatment needed.

Notes to Physician: Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Use media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Use of water spray may be inefficient.

Specific hazards arising from the chemical: May cause sensitization by skin contact.

Special Protective equipment and precautions for firefighters: Firefighters should wear full emergency equipment and positive pressure self-contained breathing apparatus.

Unusual Fire/Explosion Hazards: None known.

Known or Anticipated Hazardous Products of Combustion: Carbon oxides, Hydrogen fluoride.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Avoid contact with eyes, skin and clothing. Use appropriate protective equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Environmental Precautions: Prevent spill from entering waterways.

Methods and materials for containment and cleaning up: Prevent further leakage or spillage if safe to do so. Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers tightly closed when not in use.

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all safety precautions when handling empty containers.

Conditions for safe storage including any incompatibilities: Store at controlled room temperature 68-77°F (20-25°C) with excursions permitted to 15 ° - 30 °C (59 ° to 86 °F). Keep out of reach of children. Protect from freezing and excessive heat.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Exposure Control Parameters: The parameters are not provided for the product itself. They are provided for the ingredients listed below:

This product, as supplied, does not contain hazardous substances with occupational exposure limit values.

Occupational Exposure Limits: No limits are established for the product. The limits indicated are for the ingredients listed below:

Urea	ACGIH Threshold Limit Value: 10 mg/ m3, 8-hour TWA. OSHA Permissible Exposure Limit is not available.
Propylene Glycol	10 mg/ m3 TWA
Dimethyl Isosorbide	Not available

Appropriate Engineering Controls: No special ventilation normally required. For bulk handling, use ventilation that is adequate to maintain exposure levels below the occupational exposure limits.

Personal Protective Equipment: See below for details.

Eye Protection: Safety glasses recommended, if splash is likely to occur. None required for consumer use.

Skin Protection: Wear impervious gloves for bulk handling. None required for normal use.

Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded an approved respirator with particulate cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

Other Protective Clothing or Equipment: None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White to off-white cream

Odor: None

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Odor Threshold: Not available
pH: Not available
Melting point: Not available
Freezing Point: Not available
Boiling Point/Range: Not available
Flashpoint: Not available
Evaporation Rate: Not available
Flammability (solid, gas): Not available
Upper/lower flammability or explosive limits:
LEL: Not available
UEL: Not available
Vapor Pressure: Not available
Vapor Density: Not available
Relative Density: Not available
Solubility in water: No data available
Partition coefficient(n-octanol/water): Not available
Autoignition Temperature: Not available
Decomposition Temperature: Not available

SECTION 10: STABILITY AND REACTIVITY

Reactivity: May react with strong oxidizing agents.
Chemical Stability: Stable under recommended storage conditions.
Possibility of Hazardous Reactions: None under normal conditions of processing.
Conditions to Avoid: Excessive heat above 86 °F for prolonged periods, conditions that might generate heat, and sources of ignition.
Incompatible Materials: Strong oxidizing agents.
Hazardous Decomposition Products: Carbon dioxide and Carbon monoxide may be produced during pyrolysis.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
Toxicological data is not available for the product itself. The data provided are for the ingredients listed below.
Urea:

- Acute Oral Toxicity (LD 50): 8471 mg/kg [Rat].

Propylene Glycol:

- Oral LD50: Acute: 2200 mg/kg [Rat]
- Dermal LD50: Acute: 20800 mg/kg [Rabbit].

Dimethyl Isosorbide:

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- The information on toxicity is not available.

Likely Routes of Exposure and the Symptoms related to the Physical, Chemical and Toxicological Characteristics:

Eyes: Direct contact causes eye irritation. Prolonged exposure can cause severe damage.

Skin: May cause sensitization for a susceptible person. Urea 40% Cream is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

Inhalation: Can irritate the respiratory system.

Ingestion: May produce numbness of the tongue and anesthetic effects on the stomach.

Chronic Health Effects: Not expected under normal conditions of use. May cause sensitization for a susceptible person.

Mutagenicity: Not known.

Teratogenicity: Not known.

Carcinogenicity: Not known to be as carcinogen or potential carcinogen by NTP (National Toxicological Program), IARC (International Agency for the Research of Cancer) or OSHA (Occupational Safety and Health Administration).

Medical Conditions Aggravated by Exposure: Not known.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

Ecological data is not available for the product itself. The data provided are for the ingredients listed below:

Urea:

Component	Freshwater Algae	Freshwater Fish	Microtox	Water Flea
Urea	Not listed	LC50: 16200 - 18300 mg/L, 96h (Poecilia reticulata)	= 23914 mg/L EC50 Photobacterium phosphoreum 5 min	EC50: > 10000 mg/L, 24h (Daphnia magna Straus) EC50: = 3910 mg/L, 48h Static (Daphnia magna)

Propylene Glycol:

- 48 hrs. EC50 Daphnia magna: 1000 mg/L

Dimethyl Isosorbide:

- No data is available.

Persistence and degradability: Not readily biodegradable.

Bioaccumulative Potential: Low potential for bioaccumulation.

Mobility in soil: No data available.

Other adverse effects: No information available.

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SECTION 13: DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated
DOT Hazard Class: N/A
UN Number: N/A
IATA Shipping Name: Not Regulated
IATA Hazard Class: N/A
UN Number: N/A
IMDG Shipping Name: Not Regulated
IMDG Class: N/A
UN Number: N/A

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

SARA TITLE III: None regulated.

Hazard Category for Section 311/312: None regulated.

Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements under SARA Title III, Section 313 (40 CFR 372): None at or above reportable quantity.

Section 302 extremely hazardous Substances (TPQ): None at or above reportable quantity.

EPA Toxic Substances Control Act (TSCA) Status: This product complies with TSCA inventory requirements.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

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SECTION 16: OTHER INFORMATION

Risk phrases used in Sections 2: Not applicable

Date of preparation of SDS: March 22, 2018

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.