

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Issue date 08/10/2015

Reviewed on 08/10/2015

1. Identification

• **Product identifier**

• **Trade name: Urea 20% Cream**

• **Relevant identified uses of the substance or mixture and uses advised against:**

No further relevant information available.

• **Application of the substance / the mixture:**

For debridement and promotion of normal healing of hyperkeratotic surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris or eschar. Urea is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.

• **Details of the supplier of the safety data sheet:**

• **Manufacturer/Supplier:**

Sonar Products, Inc.
609 Industrial Road
Carlstadt, NJ 07072
Phone: (201) 729-1116
Fax: (201) 729-1066

• **Emergency telephone number:**

Chemtrec (US): (800) 424-9300
Chemtrec (Outside US): (703) 527-3887 (Collect calls accepted)

2. Hazard(s) identification

• **Classification of the substance or mixture:**



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2B H320 Causes eye irritation.

• **Label elements:**

• **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

• **Hazard pictograms:**



GHS07

• **Signal word:** Warning

• **Hazard statements:**

Causes skin and eye irritation.

• **Precautionary statements:**

Wear protective gloves.

Wash thoroughly after handling.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

If on skin: Wash with plenty of water.

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Take off contaminated clothing and wash it before reuse.

- **Unknown acute toxicity:**
2.5 percent of the mixture consists of ingredient(s) of unknown toxicity.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**

HEALTH 1 Health = 1
FIRE 0 Fire = 0
REACTIVITY 0 Reactivity = 0

- **Hazard(s) not otherwise classified (HNOC):** None known

Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture: consisting of the following components.
- **Dangerous Components:**

CAS: 57-13-6	Urea	15-35%
RTECS: YR 6250000		
CAS: 57-11-4	Stearic Acid, pure	5-10%
RTECS: WI 2800000	⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	
CAS: 142-91-6	Isopropyl palmitate	≤ 2.5%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
CAS: 102-71-6	Triethanolamine, TEA	≤ 2.5%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2B, H320	
CAS: 9004-82-4	Sodium Laureth Sulfate	≤ 2.5%
	⚠ Flam. Liq. 3, H226; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	
CAS: 57-55-6	Propylene Glycol	≤ 2.5%
RTECS: TY 2000000		

First aid measures

- **Description of first aid measures:**
- **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation occurs, consult a doctor.
- **After eye contact:**
Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If swallowed and symptoms occur, consult a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

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6 Fire-fighting measures

- **Extinguishing media:**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:**
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

8 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Dispose of the collected material according to regulations.
- **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.

7 Handling and Storage

- **Handling**
- **Precautions for safe handling:**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities:**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s):** No further relevant information available.

8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**

• **Components with occupational exposure limits:**

57-13-6 Urea	WEEL	Long-term value: 10 mg/m ³
102-71-6 Triethanolamine, TEA	TLV	Long-term value: 5 mg/m ³
57-55-6 Propylene Glycol	WEEL	Long-term value: 10 mg/m ³

- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
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- **Exposure controls:**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - The usual precautionary measures for handling chemicals should be followed.
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing and wash before reuse.
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Select glove material based on penetration times, rates of diffusion and degradation.

- **Material of gloves:**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material:**

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.
- **Eye protection:**



Tightly sealed goggles

Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
 - Form: Cream
 - Color: White
- **Odor:** Lemon
- **Odor threshold:** Not determined.
- **Change in condition**
 - Melting point/Melting range: Not determined.
 - Boiling point/Boiling range: 100 °C (212 °F)
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **Ignition temperature:** 395 °C (743 °F)
- **Decomposition temperature:** Not determined.

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- **Auto igniting:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower: 0.0 Vol %
 - Upper: 0.0 Vol %
- **Vapor pressure @ 20 °C (68 °F):** 23 hPa (17 mm Hg)
- **Density:**
 - Relative density: Not determined.
 - Vapor density: Not determined.
 - Evaporation rate: Not determined.
- **Solubility in / Miscibility with:**
 - Water: Not miscible or difficult to mix.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic: Not determined.
 - Kinematic: Not determined.
- **Solvent content:**
 - Organic solvents: 2.0 %
 - Water: 64.0 %
 - VOC content: 4.5 %
 - Solids content: 27.2 %
- **Other information:** No further relevant information available.

10 Stability and reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects:**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**

57-13-6 Urea		
Oral	LD50	8471 mg/kg (rat)
57-11-4 Stearic Acid, pure		
Dermal	LD50	>5000 mg/kg (rabbit)
102-71-6 Triethanolamine, TEA		
Oral	LD50	5530 mg/kg (rat)
		2200 mg/kg (rabbit)
	LD50 Oral	2200 ml/kg (Guinea Pig)

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		5846 ml/kg (mouse)
Dermal	LD50	>22500 mg/kg (rabbit)
57-55-6 Propylene Glycol		
Oral	LD50	20000 mg/kg (rat)
Dermal	LD50	20800 mg/kg (rabbit)
Inhalative	LC50/96 hours	52930 mg/l (Pimephales)
	Intravenous	6630 mg/kg (mouse)
		6423 mg/kg (rat)
		6500 mg/kg (rabbit)

• **Primary irritant effect:**

- **On the skin:** Irritant to skin and mucous membranes.
- **On the eye:** Irritating effect.

• **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

• **Carcinogenic categories:**

• IARC (International Agency for Research on Cancer):	
102-71-6 Triethanolamine, TEA	3
9003-01-4 Carbomer	3

• **NTP (National Toxicology Program):**

None of the ingredients are listed.

• **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

Ecological Information

• **Toxicity:**

• **Aquatic toxicity:**

57-13-6 Urea
EC50 >10000 mg/l (daphnia)
102-71-6 Triethanolamine, TEA
EC50 609.98 mg/l (daphnia)
57-55-6 Propylene Glycol
EC50 >10000 mg/l (daphnia)

• **Persistence and degradability:** No further relevant information available.

• **Behavior in environmental systems:**

• **Bioaccumulative potential:** No further relevant information available.

• **Mobility in soil:** No further relevant information available.

• **Additional ecological information:**

• **General notes:**

Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

• **Results of PBT and vPvB assessment:**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.



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- **Other adverse effects:** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods:**
- **Recommendation:** Recycle or dispose with household trash.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number:** Non-Regulated Material
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:** Non-Regulated Material
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Class:** Non-Regulated Material
- **Packing group:** Non-Regulated Material
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

• **Section 355 (extremely hazardous substances):**
None of the ingredients are listed.

• **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.

• **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

• **California Proposition 65:**

• **Chemicals known to cause cancer:**
None of the ingredients are listed.

• **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed.

• **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients are listed.

• **Chemicals known to cause developmental toxicity:**
None of the ingredients are listed.

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• **Carcinogenic categories:**

• **EPA (Environmental Protection Agency):**

57-13-6 Urea

• **TLV (Threshold Limit Value established by ACGIH):**

None of the ingredients are listed.

• **NIOSH-Ca (National Institute for Occupational Safety and Health):**

None of the ingredients are listed.

• **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

• **Hazard pictograms:**



GHS07

• **Signal word:** Warning

• **Hazard statements:**

Causes skin and eye irritation.

• **Precautionary statements:**

Wear protective gloves.

Wash thoroughly after handling.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

If on skin: Wash with plenty of water.

Take off contaminated clothing and wash it before reuse.

• **National regulations:**

The product is subject to be classified according with the latest version of the regulations on hazardous substances.

• **State Right to Know:**

CAS: 57-13-6	Urea	15-35%
RTECS: YR 6250000		
CAS: 57-11-4	Stearic Acid, pure	5-10%
RTECS: WI 2800000	⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	
CAS: 142-91-6	Isopropyl palmitate	≤ 2.5%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
CAS: 110-27-0	Isopropyl myristate	≤ 2.5%
RTECS: XB 8600000		
CAS: 9004-82-4	Sodium Laureth Sulfate	≤ 2.5%
	⚠ Flam. Liq. 3, H226; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	

All ingredients are listed.

• **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

• **Date of preparation / last revision:** 08/10/2015 / -

• **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids, Hazard Category 3

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

Eye Irrit. 2B: Serious eye damage/eye irritation, Hazard Category 2B

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

• *** Data compared to the previous version altered.**

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