

1. Identification

Product identifier	Urea C13		
Other means of identification			
Catalog number	1706701		
CAS number	58069-82-2		
Synonyms	Carbon 13 Urea		
Chemical name	Isotope 13-carbon-labeled urea		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	Not available.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Urea C13	Carbon 13 Urea	58069-82-2	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.

Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Gastrointestinal disturbances. Pharmacologically active material.. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

Exposure limit values

Industrial Use Material

	Type	Value
Urea C13 (CAS 58069-82-2)	TWA	10 mg/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Ammoniacal.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	276.8 - 280.4 °F (136 - 138 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	1.2 x 10 ⁻⁵ mm Hg
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Very soluble.
Partition coefficient (n-octanol/water)	-1.427
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Molecular formula	13-CH ₄ N ₂ O
Molecular weight	61.05
Specific gravity	1.32

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	Gastrointestinal disturbances. Confusion. Dizziness. Drowsiness. Diuretic effects. Headache.

Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Urea C13 (CAS 58069-82-2)		
Dermal		
LD50	Rat	8200 mg/kg
Inhalation		
LC50	Rat	> 4.8 mg/l
Oral		
LD50	Mouse	11 g/kg
	Rat	8471 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Local effects

Irritation test
Result: Not irritating.
Species: Human
Organ: Eye
Irritation test
Result: Not irritating.
Species: Human
Organ: Skin
Irritation test, 0.5 g
Result: Not irritating.
Species: Rabbit
Organ: Skin

Respiratory or skin sensitization

Respiratory sensitization Knowledge about sensitization hazard is incomplete.

Skin sensitization Based on available data, the classification criteria are not met.

Sensitization
Result: Non-sensitizing
Species: Guinea pig
Organ: Skin
Sensitization
Result: Non-sensitizing
Species: Human
Organ: Skin

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test (Salmonella typhimurium)
Result: Negative.
Mutagenicity, Chromosome and chromatid break test in mouse bone marrow cells
Result: Positive
Mutagenicity, In vitro chromosome aberration test in human and hamster cells
Result: Positive: The result may be caused by osmotic effects.

Carcinogenicity Based on available data, the classification criteria are not met.

0.4 g/kg Carcinogenicity, intraperitoneal injections

Result: Negative.

Species: Mouse

Test Duration: 13 weeks

2.5 g/kg Carcinogenicity, subcutaneous injections

Result: Negative.

Species: Mouse

Test Duration: 11 months

2250 mg/kg/day Carcinogenicity, dietary doses

Result: Negative.

Species: Rat

Test Duration: 1 yr

6750 mg/kg/day Carcinogenicity, dietary doses

Result: Negative.

Species: Mouse

Test Duration: 1 yr

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Based on available data, the classification criteria are not met.

Reproductivity

2000 mg/kg Reproductivity

Result: Negative: No evidence of an increase in birth defects or resorptions.

Species: Rat

25 g/kg Reproductivity

Result: Negative: No evidence of adverse effects in the offspring.

Species: Rat

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

-1.427

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	07-01-2007
Revision date	08-21-2017
Version #	03
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