

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH), Annex II

Version: 1.0/EN

Revision date: 09/05/2024

Product name: Hydroxyurea Capsules, USP

Printing date: -09/05/2024

Section 1: Identification

1.1 Product identifier

Product name: Hydroxyurea Capsules, USP

1.2 Details of the supplier of the SDS

Manufacturer: Qilu Pharmaceutical Co., Ltd.

Address: 8888 Lvyou Road, High-tech Zone, Jinan, Shandong Province,
P. R. China

Postcode: 250104

Telephone: +86-531-83126666

Fax: +86-531-83126688

1.3 Emergency telephone number

+86-531-83126666

Section 2: Hazards identification

2.1 Classification of the substance or mixture

The classification is in accordance with 1272/2008

GHS Classification

Germ cell mutagenicity (Category 1B), H340

Reproductive toxicity (Category 2), H361

2.2 GHS label elements, including precautionary statements



Signal word

Danger

Hazard

H340 May cause genetic defects.

H361 Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Prevention

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response

P308+P313 IF exposed or concerned: Get medical advice/ attention.

Storage

P405 Store locked up.

Disposal

P501 Dispose of contents/ container to an approved waste disposal plant.

Precautionary Statements

none

2.3 Other hazards - none

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Section 3: Composition/information on ingredients

3.1 Product information

Substance name	Strength	Effective constituent
Hydroxyurea Capsules, USP	500mg	Hydroxyurea (CAS 127-07-1)

Section 4: First aid measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

In case of skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Section 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the product

Carbon oxides

Nitrogen oxides (NO_x)

5.3 Advice for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

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Section 7: Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures: Comply with applicable regulations.

Storage: Store at 20°C-25°C (68-77°F); excursions permitted to 15°C- 30°C (59-86°F) [see USP Controlled Room]. Preserve in tight containers.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

No data available

Biological limit values

No data available

8.2 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice, Wash hands before breaks and after handling this product.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Mask and safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and appropriate government standards such as NIOSH (US) C EN 166(EU)

Skin protection

Handle with gloves. Gloves must be wore. Please use the appropriate method to remove the gloves (without touching the outer surface of the gloves) to avoid any skin contact with this product.

After use, please dispose of the contaminated gloves in accordance with relevant laws and regulations as well as effective laboratory rules and procedures. Please wash and dry your hands.

The selected protective gloves must comply with the EU's 89/686/EEC regulation and the EN 376 standard derived from it.

Protective Clothing

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Opaque pink body and opaque powder blue cap, imprinted with "83" on the body in black ink. Free from physical defects

9.2 Other information

No data available.

Section 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

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No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidant

10.6 Hazardous decomposition products

No data available

Section 11: Toxicological information

11.1 Toxic kinetics, metabolism and distribution

No relevant information available.

11.2 Information on toxicological effects

Acute toxicity:

No data available.

Skin corrosion/irritation:

No data available.

Serious eye damage/irritation:

No data available.

Respiratory or skin sensitization:

No data available.

Germ cell mutagenicity:

No data available

Carcinogenicity:

Possible human carcinogen

Reproductive toxicity:

No data available

STOT-single exposure:

No data available

STOT-repeated exposure:

No data available

Aspiration hazard:

No data available

Section 12: Ecological information

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data is available on the degradability of this product.

12.3 Bio accumulative potential

No data available.

12.4 Mobility in soil

No data available.

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12.5 Other adverse effects

No data available.

Section 13: Disposal considerations

Product

The remaining and non-recyclable solutions should be handed over to a licensed company for disposal.

Compatible or mixed with flammable solvents, they should be incinerated in a chemical incinerator equipped with post-combustion treatment and scrubbing functions.

Contaminated containers and packaging should be disposed of as unused products.

Section 14: Transport information

Not classified as dangerous in the meaning of transport regulations.

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 Regulation(EC)No.1907/2006.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

Section 16: Other information

The information in this Safety Data Sheet (SDS) was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. According to REACH Article 31(5), the SDS shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the recipient Member State(s) concerned provide otherwise.