

SAFETY DATA SHEET

1. IDENTIFICATION

Product name: Ranitidine base

CAS No. : 66357-35-5

Brand: Macklin

Company: Shanghai Macklin Biochemical Co.,Ltd.

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2. HAZARDS IDENTIFICATION

GHS classification

PHYSICAL HAZARDS

no data available

HEALTH HAZARDS

no data available

ENVIRONMENTAL HAZARDS

no data available

GHS label elements, including precautionary statements

Pictograms or hazard symbols

Signal word

no data available

Hazard statements

no data available

Precautionary statements

Prevention

no data available

Response

no data available

Storage

no data available

Disposal

no data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components:Ranitidine base

CAS No.:66357-35-5

Chemical Formula:C₁₃H₂₂N₄O₃S

4. FIRST AID MEASURES

4.1

Description of necessary first-aid measures

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.

Following skin contact

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

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2

Most important symptoms/effects, acute and delayed

no data available

4.3

Indication of immediate medical attention and special treatment needed, if necessary

Treatment of overdose is symptomatic. Emesis should be induced, followed by Gastric lavage and then activated charcoal. Insignificant transient liver enzyme elevation may occur which does not require discontinuation of the drug. Hypersensitivity reactions leading to severe liver dysfunction require immediate withdrawal of the drug.

5. FIRE-FIGHTING MEASURES

5.1

Suitable extinguishing media

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

5.2

Specific hazards arising from the chemical

no data available

5.3

Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1

Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2

Environmental precautions

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

6.3

Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

7. HANDLING AND STORAGE

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. Prevent fire caused by electrostatic discharge steam.

Conditions for safe storage, including any incompatibilities

Ranitidine hydrochloride tablets or soln should be stored in a dry place @ 15-30 deg C in tight, light-

resistant containers. The oral soln should be stored in a tight, light-resistant container @ 4-25 deg C. Ranitidine hydrochloride injection and the commercially available injection of the drug in 0.45% sodium chloride should be protected from light and stored @ 4-30 deg C; however, it is preferable that the latter preparation be stored @ room temp (25 deg C), although brief exposure to temp up to 40 deg C will not adversely affect stability, and that freezing be avoided. Slight darkening of the injection will not affect potency. Ranitidine hydrochloride

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure limit values

no data available

Biological limit values

no data available

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice.

Set up emergency exits and the risk-elimination area.

Personal protective equipment

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flare resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state

COA

Colour

SOLID

Odour

Characteristic

Melting point/freezing point

69-70°C

Boiling point or initial boiling point and boiling range

437.1°C at 760 mmHg

Flammability

no data available

Lower and upper explosion limit/flammability limit

no data available

Flash point

no data available

Auto-ignition temperature

no data available

Decomposition temperature

no data available

pH

no data available

Kinematic viscosity

no data available

Solubility

no data available

Partition coefficient n-octanol/water

no data available

Vapour pressure

no data available

Density and/or relative density

1.184 g/cm³

Relative vapour density

no data available

Particle characteristics

no data available

10. STABILITY AND REACTIVITY

10.1

Reactivity

no data available

10.2

Chemical stability

Ranitidine hydrochloride injection is stable for up to 48 hr @ room temp when added to or diluted with most IV soln. ... The commercially available IV infusion soln of the drug in 0.45% sodium chloride is stable through the expiration date noted on the container when stored as recommended. When the pharmacy bulk package is used, infusion soln of ranitidine hydrochloride should be prepared within 24 hr after the vial is first entered; any drug remaining in the bulk package after this period should be discarded. Ranitidine hydrochloride

10.3

Possibility of hazardous reactions

no data available

10.4

Conditions to avoid

no data available

10.5

Incompatible materials

no data available

10.6

Hazardous decomposition products

no data available

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Oral: no data available

Inhalation: no data available

Dermal: 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

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. ECOLOGICAL INFORMATION

12.1

Toxicity

Toxicity to fish: no data available
Toxicity to daphnia and other aquatic invertebrates: no data available
Toxicity to algae: no data available
Toxicity to microorganisms: no data available
12.2
Persistence and degradability
no data available
12.3
Bioaccumulative potential
no data available
12.4
Mobility in soil
no data available
12.5
Other adverse effects
no data available

13. DISPOSAL CONSIDERATIONS

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. TRANSPORT INFORMATION

14.1

UN Number

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.2

UN Proper Shipping Name

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.3

Transport hazard class(es)

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.4

Packing group, if applicable

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.5

Environmental hazards

ADR/RID: No

IMDG: No

IATA: No

14.6

Special precautions for user

no data available

14.7

Transport in bulk according to IMO instruments
no data available

15. REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product in question

EC number

266-332-5

European Inventory of Existing Commercial Chemical Substances (EINECS)

Listed.

EC Inventory

Listed.

United States Toxic Substances Control Act (TSCA) Inventory

Not Listed.

China Catalog of Hazardous chemicals 2015

Not Listed.

New Zealand Inventory of Chemicals (NZIoC)

Listed.

Philippines Inventory of Chemicals and Chemical Substances (PICCS)

Not Listed.

Vietnam National Chemical Inventory

Listed.

Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)

Not Listed.

Korea Existing Chemicals List (KECL)

Not Listed.

16. OTHER INFORMATION

This SDS was prepared sincerely on the basis of the information we could obtained, however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority. The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards. If the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling, sufficient care should be taken, in addition to the safety measures suitable for the situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility.