

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 19.02.2020

Version number 1

Revision: 19.02.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Product name:** Ranitidine hydrochloride Assay Standard**Part number:** Cat 471**CAS Number:**
66357-59-3**EC number:**
266-333-0**1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

Application of the substance / the mixture Reference material for laboratory use only**1.3 Details of the supplier of the safety data sheet****Manufacturer/Supplier:**British Pharmacopoeia Commission
MHRA
10 South Colonnade
Canary Wharf
London E14 4PU
United Kingdom

Tel : +44 (0)20 3080 6561

eMail: bpcrs@mhra.gov.uk

Further information obtainable from: eMail: bpcrs@mhra.gov.uk**1.4 Emergency telephone number:** +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

Lact. H362 May cause harm to breast-fed children.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

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· Hazard pictograms

GHS07 GHS08

· Signal word *Danger***· Hazard statements***H315 Causes skin irritation.**H319 Causes serious eye irritation.**H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.**H317 May cause an allergic skin reaction.**H362 May cause harm to breast-fed children.**H335 May cause respiratory irritation.***· Precautionary statements***P260 Do not breathe dusts or mists.**P263 Avoid contact during pregnancy and while nursing.**P284 [In case of inadequate ventilation] wear respiratory protection.**P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**P405 Store locked up.**P501 Dispose of contents/container in accordance with local/regional/national/international regulations.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.1 Chemical characterisation: Substances****· CAS No. Description***66357-59-3 Ranitidine hydrochloride***· Identification number(s)** *None***· EC number:** *266-333-0***· RTECS:** *KM6557000***· Additional information:** *For the wording of the listed hazard phrases refer to section 16.***SECTION 4: First aid measures****· 4.1 Description of first aid measures****· After inhalation:***Supply fresh air and call a doctor.**In case of unconsciousness place patient in recovery position for transport.***· After skin contact:***Immediately wash with water and soap and rinse thoroughly.**If skin irritation continues, consult a doctor.***· After eye contact:***Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.*

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- **After swallowing:** Rinse mouth. Do not induce vomiting.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable for surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose of contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/extraction at the workplace.
Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
Store only in the original receptacle unless other advice is given on the CoA.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.

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· **Additional information:** Lists used were valid at the time of SDS preparation.

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



Protective gloves

· **Material of gloves** Butyl rubber, BR

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Solid

Colour: Off white

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/freezing point: 133-134 °C

Initial boiling point and boiling range: Not determined.

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· Flash point:	Not applicable.
· Flammability (solid, gas):	Not determined.
· Ignition temperature:	Not determined.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Not determined.
· Explosive properties:	Not determined.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	0.72 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Soluble.
· Partition coefficient: n-octanol/water:	0.0815 Log Pow
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity

Stable under normal conditions.

No further relevant information available.

· 10.2 Chemical stability

Stable under normal conditions.

· Thermal decomposition / conditions to be avoided:

Formation of toxic gases is possible during heating or in case of fire.

· 10.3 Possibility of hazardous reactions

No dangerous reactions known.

· 10.4 Conditions to avoid

Heat.

· 10.5 Incompatible materials:

Strong oxidizing agents.

· 10.6 Hazardous decomposition products:

Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

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

· LD/LC50 values relevant for classification:

Oral	LD50	4,190 mg/kg (rat)
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LD 50 (Intraperitoneal)	441 mg/kg (rat)
LD 50 (Intravenous)	85 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Lact.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
May cause harm to breast-fed children.
- **STOT-single exposure**
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

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· Recommended cleansing agents: Water, if necessary together with cleansing agents.**SECTION 14: Transport information**

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR, IMDG, IATA | Not applicable |
| · ADR, IMDG, IATA | Not applicable |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Not applicable |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not applicable |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

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PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Lact.: Reproductive toxicity – effects on or via lactation
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

· Data compared to the previous version altered. *All sections have been updated.*

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