

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 4242356-00012      Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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### Section 1: Identification

Product name : Cimetidine Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Reproductive toxicity : Category 1

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Kidney, Testis)

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.  
H373 May cause damage to organs (Liver, Kidney, Testis) through prolonged or repeated exposure if swallowed.

Precautionary statements :

P201 Obtain special instructions before use.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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### **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.

### **Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 40 %

### **Other hazards which do not result in classification**

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

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## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### **Components**

| Chemical name      | CAS-No.    | Concentration (% w/w) |
|--------------------|------------|-----------------------|
| cimetidine         | 51481-61-9 | >= 30 -< 50           |
| Cellulose          | 9004-34-6  | >= 10 -< 20           |
| Starch             | 9005-25-8  | >= 1 -< 10            |
| Magnesium stearate | 557-04-0   | >= 1 -< 10            |

## Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms : Contact with dust can cause mechanical irritation or drying of

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|                                     |   |
|-------------------------------------|---|
| and effects, both acute and delayed | the skin.<br>Dust contact with the eyes can lead to mechanical irritation.<br>May damage the unborn child.<br>May cause damage to organs through prolonged or repeated exposure if swallowed. |
| Protection of first-aiders          | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).                 |
| Notes to physician                  | : Treat symptomatically and supportively.   |

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### Section 5: Fire-fighting measures

|   |   |
|---|---|
| Suitable extinguishing media                  | : Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                | : None known.   |
| Specific hazards during fire-fighting         | : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                   |
| Hazardous combustion products                 | : Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )<br>Sulphur oxides<br>Metal oxides   |
| Specific extinguishing methods                | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### Section 6: Accidental release measures

|   |   |
|---|---|
| Personal precautions, protective equipment and emergency procedures | : Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).  |
| Environmental precautions   | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |

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Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**Section 7: Handling and storage**

Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe dust. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

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Strong oxidizing agents

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

| Components         | CAS-No.    | Value type<br>(Form of<br>exposure)                | Control parame-<br>ters / Permissible<br>concentration | Basis  |
|--------------------|------------|--|--|--------|
| cimetidine         | 51481-61-9 | TWA  | 1000 µg/m <sup>3</sup> (OEB<br>1)                      |        |
| Cellulose          | 9004-34-6  | WES-TWA  | 10 mg/m <sup>3</sup>                                   | NZ OEL |
|                    |            | TWA  | 10 mg/m <sup>3</sup>                                   | ACGIH  |
| Starch             | 9005-25-8  | WES-TWA  | 10 mg/m <sup>3</sup>                                   | NZ OEL |
|                    |            | TWA  | 10 mg/m <sup>3</sup>                                   | ACGIH  |
| Magnesium stearate | 557-04-0   | WES-TWA  | 10 mg/m <sup>3</sup>                                   | NZ OEL |
|                    |            | TWA (Inhal-<br>able particu-<br>late matter)       | 10 mg/m <sup>3</sup>                                   | ACGIH  |
|                    |            | TWA (Res-<br>pirable par-<br>ticulate mat-<br>ter) | 3 mg/m <sup>3</sup>                                    | ACGIH  |

**Engineering measures** : Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

### Section 9: Physical and chemical properties

Appearance : powder

Colour : No data available

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|  |   |   |
|--|---|---|
| Odour  | : | No data available   |
| Odour Threshold                                  | : | No data available   |
| pH   | : | No data available   |
| Melting point/freezing point                     | : | No data available   |
| Initial boiling point and boiling range          | : | No data available   |
| Flash point                                      | : | Not applicable  |
| Evaporation rate                                 | : | Not applicable  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | No data available   |
| Upper explosion limit / Upper flammability limit | : | No data available   |
| Lower explosion limit / Lower flammability limit | : | No data available   |
| Vapour pressure                                  | : | Not applicable  |
| Relative vapour density                          | : | Not applicable  |
| Relative density                                 | : | No data available   |
| Density  | : | No data available   |
| Solubility(ies)                                  |   |   |
| Water solubility                                 | : | No data available   |
| Partition coefficient: n-octanol/water           | : | Not applicable  |
| Auto-ignition temperature                        | : | No data available   |
| Decomposition temperature                        | : | No data available   |
| Viscosity  |   |   |
| Viscosity, kinematic                             | : | Not applicable  |
| Explosive properties                             | : | Not explosive   |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.                        |

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Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.  
  
Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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### Section 11: Toxicological information

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **cimetidine:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): 2,550 mg/kg  
LD50 (Hamster): > 4,000 mg/kg  
  
Acute toxicity (other routes of administration) : LD50 (Rat): 106 mg/kg  
Application Route: Intravenous  
LD50 (Rabbit): 164 mg/kg  
Application Route: Intravenous  
LD50 (Rat): 860 mg/kg  
Application Route: Subcutaneous  
LD50 (Mouse): 437 mg/kg  
Application Route: Subcutaneous  
Symptoms: Convulsions

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### **Cellulose:**

|                           |  |
|---------------------------|--|
| Acute oral toxicity       | : LD50 (Rat): > 5,000 mg/kg  |
| Acute inhalation toxicity | : LC50 (Rat): > 5.8 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity     | : LD50 (Rabbit): > 2,000 mg/kg   |

### **Starch:**

|                       |                                |
|-----------------------|--------------------------------|
| Acute oral toxicity   | : LD50 (Rat): > 5,000 mg/kg    |
| Acute dermal toxicity | : LD50 (Rabbit): > 2,000 mg/kg |

### **Magnesium stearate:**

|                       |  |
|-----------------------|--|
| Acute oral toxicity   | : LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 423<br>Assessment: The substance or mixture has no acute oral toxicity<br>Remarks: Based on data from similar materials |
| Acute dermal toxicity | : LD50 (Rabbit): > 2,000 mg/kg<br>Remarks: Based on data from similar materials  |

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Magnesium stearate:**

|         |  |
|---------|--|
| Species | : Rabbit                               |
| Result  | : No skin irritation                   |
| Remarks | : Based on data from similar materials |

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Starch:**

|         |                     |
|---------|---------------------|
| Species | : Rabbit            |
| Result  | : No eye irritation |

#### **Magnesium stearate:**

|         |  |
|---------|--|
| Species | : Rabbit                               |
| Result  | : No eye irritation                    |
| Remarks | : Based on data from similar materials |

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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Starch:

|                 |   |                   |
|-----------------|---|-------------------|
| Test Type       | : | Maximisation Test |
| Exposure routes | : | Skin contact      |
| Species         | : | Guinea pig        |
| Result          | : | negative          |

##### Magnesium stearate:

|                 |   |                                      |
|-----------------|---|--------------------------------------|
| Test Type       | : | Maximisation Test                    |
| Exposure routes | : | Skin contact                         |
| Species         | : | Guinea pig                           |
| Method          | : | OECD Test Guideline 406              |
| Result          | : | negative                             |
| Remarks         | : | Based on data from similar materials |

### Chronic toxicity

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### cimetidine:

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                         |
|                       |   | Test Type: Chromosomal aberration<br>Result: negative  |
|                       |   | Test Type: unscheduled DNA synthesis assay<br>Test system: rat hepatocytes<br>Result: negative |
|                       |   | Test Type: unscheduled DNA synthesis assay<br>Result: negative                                 |

##### Cellulose:

|                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative    |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |

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**Genotoxicity in vivo:**

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Starch:**

**Genotoxicity in vitro:**

: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

**Magnesium stearate:**

**Genotoxicity in vitro:**

: Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:**

**cimetidine:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Target Organs : Testis  
Remarks : Benign tumor(s)

**Carcinogenicity - Assessment:**

: No evidence of carcinogenicity in animal studies.

**Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

**Reproductive toxicity**

May damage the unborn child.

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### Components:

#### **cimetidine:**

|                                    |  |
|------------------------------------|--|
| Effects on fertility               | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 950 mg/kg body weight<br>Result: No effect on reproduction capacity                                     |
| Effects on foetal development      | : Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 17 mg/kg body weight<br>Symptoms: male reproductive effects<br>Remarks: Adverse effects were observed in males only. |
| Reproductive toxicity - Assessment | : May damage the unborn child.   |

#### **Cellulose:**

|                               |   |
|-------------------------------|---|
| Effects on fertility          | : Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative      |

#### **Magnesium stearate:**

|                               |  |
|-------------------------------|--|
| Effects on fertility          | : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 422<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative<br>Remarks: Based on data from similar materials  |

#### **STOT - single exposure**

Not classified based on available information.

#### **STOT - repeated exposure**

May cause damage to organs (Liver, Kidney, Testis) through prolonged or repeated exposure if swallowed.

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**Components:****cimetidine:**

Exposure routes  
Target Organs  
Assessment

: Oral  
: Liver, Kidney, Testis  
: May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****cimetidine:**

Species  
LOAEL  
Application Route  
Exposure time  
Target Organs  
Remarks

: Rat  
: 160 mg/kg  
: Oral  
: 2 Months  
: Gastrointestinal tract  
: May cause damage to organs.

Species  
NOAEL  
Application Route  
Exposure time  
Symptoms

: Rat  
: 200 mg/kg  
: Oral  
: 12 Months  
: No adverse effects

Species  
LOAEL  
Application Route  
Exposure time  
Target Organs  
Remarks

: Rat  
: 950 mg/kg  
: Oral  
: 2 yr  
: Liver, Testis, Prostate  
: May cause damage to organs.

Species  
NOAEL  
Application Route  
Exposure time  
Target Organs  
Remarks

: Dog  
: 366 mg/kg  
: Oral  
: 12 Months  
: Liver, Kidney, Prostate  
: May cause damage to organs.

Species  
NOAEL  
Application Route  
Exposure time  
Symptoms

: Dog  
: 144 mg/kg  
: Oral  
: 4 yr  
: No adverse effects

**Cellulose:**

Species  
NOAEL  
Application Route  
Exposure time

: Rat  
: >= 9,000 mg/kg  
: Ingestion  
: 90 Days

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### **Starch:**

|                   |   |                         |
|-------------------|---|-------------------------|
| Species           | : | Rat                     |
| NOAEL             | : | >= 2,000 mg/kg          |
| Application Route | : | Skin contact            |
| Exposure time     | : | 28 Days                 |
| Method            | : | OECD Test Guideline 410 |

### **Magnesium stearate:**

|                   |   |                                      |
|-------------------|---|--------------------------------------|
| Species           | : | Rat                                  |
| NOAEL             | : | > 100 mg/kg                          |
| Application Route | : | Ingestion                            |
| Exposure time     | : | 90 Days                              |
| Remarks           | : | Based on data from similar materials |

### **Aspiration toxicity**

Not classified based on available information.

### **Experience with human exposure**

#### **Components:**

##### **cimetidine:**

|           |   |  |
|-----------|---|--|
| Ingestion | : | Symptoms: The most common side effects are:, Headache, Dizziness, Nausea, skin rash, Itching, May cause, central nervous system effects, gynecomastia, impotence, kidney effects |
|           |   | Remarks: May cause harm to breast-fed children.  |

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## Section 12: Ecological information

### **Ecotoxicity**

#### **Components:**

##### **cimetidine:**

#### **Ecotoxicology Assessment**

|                          |   |                                  |
|--------------------------|---|----------------------------------|
| Acute aquatic toxicity   | : | Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : | Toxic effects cannot be excluded |

##### **Cellulose:**

|                  |   |  |
|------------------|---|--|
| Toxicity to fish | : | LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |
|------------------|---|--|

##### **Magnesium stearate:**

|                  |   |   |
|------------------|---|---|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l |
|------------------|---|---|

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|   |   |  |
|---|---|--|
|   |   | Exposure time: 48 h<br>Method: DIN 38412<br>Remarks: Based on data from similar materials  |
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 1 mg/l<br>Exposure time: 47 h<br>Test substance: Water Accommodated Fraction<br>Method: Directive 67/548/EEC, Annex V, C.2.<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility        |
| Toxicity to algae/aquatic plants                    | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br>No toxicity at the limit of solubility |
|   |   | NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Test substance: Water Accommodated Fraction<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials  |
| Toxicity to microorganisms                          | : | EC10 (Pseudomonas putida): > 100 mg/l<br>Exposure time: 16 h<br>Test substance: Water Accommodated Fraction<br>Remarks: Based on data from similar materials   |

### Persistence and degradability

#### Components:

##### **Cellulose:**

|                  |   |                                |
|------------------|---|--------------------------------|
| Biodegradability | : | Result: Readily biodegradable. |
|------------------|---|--------------------------------|

##### **Magnesium stearate:**

|                  |   |  |
|------------------|---|--|
| Biodegradability | : | Result: Not biodegradable<br>Remarks: Based on data from similar materials |
|------------------|---|--|

### Bioaccumulative potential

#### Components:

##### **cimetidine:**

|  |   |               |
|--|---|---------------|
| Partition coefficient: n-octanol/water | : | log Pow: 0.40 |
|--|---|---------------|

##### **Magnesium stearate:**

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Partition coefficient: n-octanol/water : log Pow: > 4

### **Mobility in soil**

No data available

### **Other adverse effects**

No data available

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## Section 13: Disposal considerations

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## Section 14: Transport information

### **International Regulations**

#### **UNRTDG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### **IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

#### **IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

# SAFETY DATA SHEET



## Cimetidine Formulation

Version 4.0      Revision Date: 14.04.2025      SDS Number: 4242356-00012      Date of last issue: 30.09.2023  
Date of first issue: 03.05.2019

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### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### NZS 5433

|                      |   |                |
|----------------------|---|----------------|
| UN number            | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class                | : | Not applicable |
| Subsidiary risk      | : | Not applicable |
| Packing group        | : | Not applicable |
| Labels               | : | Not applicable |
| Hazchem Code         | : | Not applicable |

### Special precautions for user

Not applicable

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## Section 15: Regulatory information

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

#### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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## Section 16: Other information

Revision Date : 14.04.2025

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

**Cimetidine Formulation**

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

# SAFETY DATA SHEET



## Cimetidine Formulation

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