SAFETY DATA SHEET
given to Regulation (EC) No. 1907/2006

Cimetidine Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Cimetidine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 1B
Specific target organ toxicity - repeated exposure, Category 2
H360D: May damage the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P260  Do not breathe dust.
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.

Hazardous components which must be listed on the label:  
cimetidine

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

2.3 Other hazards  
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.

SECTION 3: Composition/information on ingredients  

3.2 Mixtures  

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cimetidine</td>
<td>51481-61-9</td>
<td>257-232-2</td>
<td></td>
<td></td>
<td>Repr. 1B; H360D STOT RE 2; H373</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures  

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : 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.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides
Metal oxides

5.3 Advice for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.
for firefighters

Specific extinguishing methods:
Use personal protective equipment.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions:
Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>cimetidine</td>
<td>51481-61-9</td>
<td>TWA</td>
<td>1000 µg/m³ (OEB 1)</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respira-</td>
<td>4 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.
8.2 Exposure controls

**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**

- **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.

- **Hand protection**: Chemical-resistant gloves

- **Skin and body protection**: Work uniform or laboratory coat.

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143

  - **Filter type**: Particulates type (P)

**SECTION 9: Physical and chemical properties**

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

- **Appearance**: powder
- **Colour**: No data available
- **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
Cimetidine Formulation

**SECTION 10: Stability and reactivity**

**10.1 Reactivity**
Not classified as a reactivity hazard.

**10.2 Chemical stability**
Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

<table>
<thead>
<tr>
<th>Hazardous reactions</th>
<th>May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.</th>
</tr>
</thead>
</table>

**10.4 Conditions to avoid**
Cimetidine Formulation

Conditions to avoid:
- Heat, flames and sparks.
- Avoid dust formation.

Incompatible materials:
- Materials to avoid: Oxidizing agents

Hazardous decomposition products:
- No hazardous decomposition products are known.

SECTION 11: Toxicological information

Information on toxicological effects:
- Information on likely routes of exposure:
  - 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

Skin corrosion/irritation:
- Not classified based on available information.

Serious eye damage/eye irritation:
- Not classified based on available information.

Respiratory or skin sensitisation:
- Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:
cimetidine:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Result: negative

Test Type: unscheduled DNA synthesis assay
Test system: rat hepatocytes
Result: negative

Test Type: unscheduled DNA synthesis assay
Result: negative

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.

Reproductive toxicity
May damage the unborn child.

Components:
cimetidine:
Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 950 mg/kg body weight
Result: No effect on reproduction capacity

Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 17 mg/kg body weight
Symptoms: male reproductive effects
Remarks: Adverse effects were observed in males only.
Reproductive toxicity - Assessment
May damage the unborn child.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.

**Components:**

**cimetidine:**
- **Exposure routes:** Oral
- **Target Organs:** Liver, Kidney, Testis
- **Assessment:** May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**cimetidine:**
- **Species:** Rat
- **LOAEL:** 160 mg/kg
- **Application Route:** Oral
- **Exposure time:** 2 Months
- **Target Organs:** Gastrointestinal tract
- **Remarks:** May cause damage to organs.

- **Species:** Rat
  - **NOAEL:** 200 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 12 Months
  - **Symptoms:** No adverse effects
  - **Target Organs:** Liver, Testis, Prostate
  - **Remarks:** May cause damage to organs.

- **Species:** Rat
  - **LOAEL:** 950 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 2 yr
  - **Target Organs:** Liver, Testis, Prostate
  - **Remarks:** May cause damage to organs.

- **Species:** Dog
  - **NOAEL:** 366 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 12 Months
  - **Target Organs:** Liver, Kidney, Prostate
  - **Remarks:** May cause damage to organs.

- **Species:** Dog
  - **NOAEL:** 144 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 4 yr
  - **Symptoms:** No adverse effects
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.

SECTION 12: Ecological information

12.1 Toxicity

**Components:**
cimetidine:

Ecotoxicology Assessment
Acute aquatic toxicity : Toxic effects cannot be excluded
Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

**Components:**
cimetidine:
Partition coefficient: n-octanol/water : log Pow: 0.40

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

### Full text of H-Statements

- **H360D**: May damage the unborn child.
- **H373**: May cause damage to organs through prolonged or repeated exposure if swallowed.

### Full text of other abbreviations

- **Repr.**: Reproductive toxicity
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **IE OEL**: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- **IE OEL / OELV - 8 hrs (TWA)**: Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; 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; KECI - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Cimetidine Formulation

Version 1.3
Revision Date: 23.03.2020
SDS Number: 4244041-00004
Date of last issue: 13.09.2019
Date of first issue: 03.05.2019

Further information

Classification of the mixture:
Repr. 1B H360D Calculation method
STOT RE 2 H373 Calculation method

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.

IE / EN