# Carbimazole Formulation

## 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>2019/04/18</td>
<td>4098650-00003</td>
<td>2019/04/16</td>
<td>2019/03/22</td>
</tr>
</tbody>
</table>

**Product name**: Carbimazole Formulation

**Manufacturer or supplier’s details**

<table>
<thead>
<tr>
<th>Company</th>
<th>Address</th>
<th>Telephone</th>
<th>Emergency telephone number</th>
<th>E-mail address</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSD</td>
<td>No. 485 Jing Tai Road, Pu Tuo District - Shanghai - China 200331</td>
<td>908-740-4000</td>
<td>86-571-87268110</td>
<td><a href="mailto:EHSDATASTEWARD@msd.com">EHSDATASTEWARD@msd.com</a></td>
</tr>
</tbody>
</table>

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

- Recommended use: Veterinary product

## 2. HAZARDS IDENTIFICATION

**Emergency Overview**

<table>
<thead>
<tr>
<th>Appearance</th>
<th>powder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>pink</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.

**GHS Classification**

- Reproductive toxicity: Category 1A
- Specific target organ toxicity - repeated exposure: Category 2
- Short-term (acute) aquatic hazard: Category 2
- Long-term (chronic) aquatic hazard: Category 2

**GHS label elements**

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="image" alt="Pictogram" /></td>
<td></td>
</tr>
</tbody>
</table>

- Signal word: Danger

- Hazard statements:
  - H360 May damage fertility or the unborn child.
  - H373 May cause damage to organs through prolonged or repeated exposure.
peated exposure.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

**Storage:**
P405 Store locked up.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Carbimazole</td>
</tr>
<tr>
<td></td>
<td>Talc</td>
</tr>
</tbody>
</table>

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 and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure.

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.

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

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

Specific extinguishing methods : 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.

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

6. ACCIDENTAL RELEASE MEASURES
Carbimazole Formulation

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

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.

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.

7. HANDLING AND STORAGE

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:
- 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.

Avoidance of contact:
- Oxidizing agents

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

Materials to avoid: Do not store with the following product types:
- Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Carbimazole</td>
<td>22232-54-8</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>PC-TWA (Total dust)</td>
<td>3 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-TWA (Respirable dust)</td>
<td>1 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures:
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection:
- Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
- Filter type: Particulates type
- 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.
- Additional body garments should be used based upon the task being performed (e.g., sleevelts, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.
Carbimazole Formulation

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : Ensure that eye flushing systems and safety showers are located 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>pink</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility : No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Carbimazole Formulation

<table>
<thead>
<tr>
<th>octanol/water</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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.
Incompatible materials: Avoid dust formation.
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity: Not classified based on available information.

Components:

Cellulose:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Carbimazole:
Acute oral toxicity: LD50 (Rat): 2,250 mg/kg
Assessment: The substance or mixture has no acute oral tox-
# Carbimazole Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbimazole</td>
<td>LD50 (Mouse): 860 mg/kg</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Talc</td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**

- Not classified based on available information.

## Components:

### Carbimazole:
- Remarks: No data available

### Talc:
- Species: Rabbit
- Result: No skin irritation

## Serious eye damage/eye irritation

- Not classified based on available information.

## Components:

### Carbimazole:
- Remarks: No data available

### Talc:
- Species: Rabbit
- Result: No eye irritation

**Respiratory or skin sensitisation**

### Skin sensitisation

- Not classified based on available information.

### Respiratory sensitisation

- Not classified based on available information.

## Components:

### Carbimazole:
- Remarks: No data available
Carbimazole Formulation

**Talc:**
- **Exposure routes**: Skin contact
- **Species**: Humans
- **Result**: negative

**Germ cell mutagenicity**
- Not classified based on available information.

**Components:**

**Cellulose:**
- **Genotoxicity in vitro**:
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

**Carbimazole:**
- **Genotoxicity in vitro**:
  - Test Type: Chromosome aberration test in vitro
  - Result: positive
  - Remarks: Based on data from similar materials

**Genotoxicity in vivo**:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
- Species: Mouse
- Application Route: Subcutaneous
- Result: equivocal
- Remarks: Based on data from similar materials

**Talc:**
- **Genotoxicity in vitro**:
  - Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  - Result: negative

**Genotoxicity in vivo**:
- Test Type: Chromosome aberration test in vitro
- Species: Rat
- Application Route: Ingestion
- Result: negative
### Carcinogenicity

Not classified based on available information.

### Components:

#### Cellulose:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 72 weeks
- **Result**: negative

#### Carbimazole:
- **Species**: Mouse
- **Application Route**: Oral
- **Result**: positive
- **Remarks**: Based on data from similar materials

- **Species**: Rat
- **Application Route**: Oral
- **Result**: positive
- **Remarks**: Based on data from similar materials

#### Talc:
- **Species**: Mouse
- **Application Route**: Inhalation (dust/mist/fume)
- **Exposure time**: 2 Years
- **Result**: negative

### Reproductive toxicity

May damage fertility or the unborn child.

### Components:

#### Cellulose:
- **Effects on fertility**: Test Type: One-generation reproduction toxicity study
  - **Species**: Rat
  - **Application Route**: Ingestion
  - **Result**: negative

- **Effects on foetal development**: Test Type: Fertility/early embryonic development
  - **Species**: Rat
  - **Application Route**: Ingestion
  - **Result**: negative

#### Carbimazole:
- **Reproductive toxicity - Assessment**: May damage fertility or the unborn child.

#### Talc:
- **Effects on foetal development**: Test Type: Embryo-foetal development
  - **Species**: Rat
  - **Application Route**: Ingestion
Carbimazole Formulation

Result: negative

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

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

**Components:**

**Carbimazole:**
- Exposure routes: Skin contact
- Target Organs: Thyroid, Adrenal gland, Testis
- Assessment: May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Cellulose:**
- Species: Rat
- NOAEL: \( \geq 9,000 \text{ mg/kg} \)
- Application Route: Ingestion
- Exposure time: 90 Days

**Carbimazole:**
- Species: Rat
- LOAEL: 0.5 mg/kg
- Application Route: Intraperitoneal
- Exposure time: 15 Days
- Target Organs: Thyroid
- Species: Rat
- LOAEL: 1.35 mg/kg
- Application Route: Oral
- Exposure time: 8 Weeks
- Target Organs: Thyroid, Testis

**Aspiration toxicity**
- Not classified based on available information.

**Experience with human exposure**

**Components:**

**Carbimazole:**
- Ingestion: Symptoms: Rash, hearing loss, Headache, Nausea, hair loss
Carbimazole Formulation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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

Carbimazole:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 120 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.43 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

LC50 (Americamysis): 2.1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 1
M-Factor (Chronic aquatic toxicity): 1

Toxicity to microorganisms: EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

NOEC: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Remarks: Based on data from similar materials

Talc:
Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
Persistence and degradability

Components:

Cellulose:
Biodegradability: Result: Readily biodegradable.

Bioaccumulative potential
No data available

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Carbimazole)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)

Class : 9
Packing group : III
Labels : 9

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

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

according to GB/T 16483 and GB/T 17519

### Carbimazole Formulation

<table>
<thead>
<tr>
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<th>Date of last issue: 2019/04/16</th>
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- **Full text of other abbreviations**
  - ACGIH: USA. ACGIH Threshold Limit Values (TLV)
  - ACGIH / TWA: 8-hour, time-weighted average
  - GBZ 2.1-2007 / PC-TWA: Permissible concentration - time weighted average

**Disclaimer**

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.

CN / EN