SAFETY DATA SHEET
Carbimazole Formulation

Version 3.0  Revision Date: 18.04.2019  SDS Number: 4098647-00003  Date of last issue: 16.04.2019  Date of first issue: 22.03.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Carbimazole Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Rua Coronel Bento Soares, 530  Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity: Category 1A
Specific target organ systemic toxicity - repeated exposure (Dermal): Category 2 (Thyroid, Adrenal gland, Testis)
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H360 May damage fertility or the unborn child.
H373 May cause damage to organs (Thyroid, Adrenal gland, Testis) through prolonged or repeated exposure in contact with skin.
H411 Toxic to aquatic life with long lasting effects.
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Precautionary Statements

**Prevention:**
- P201 Obtain special instructions before use.
- 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.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Carbimazole</td>
<td>22232-54-8</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
</tbody>
</table>

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 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 in contact with skin.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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. 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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 spills 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.
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:
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:
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.

Conditions for safe storage:
Keep in properly labeled 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:
Strong oxidizing agents
Organic peroxides
Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>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>Talc</td>
<td>14807-96-6</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

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: pink
Odor: No data available
Odor 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: No data available

Evaporation rate: Not applicable

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): Not applicable
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Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor 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
Autoignition 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.
Molecular weight: No data available
Particle size: No data available

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.

SECTION 11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
   Inhalation
   Skin contact
   Ingestion
   Eye contact
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**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 toxicity
  - LD50 (Mouse): 860 mg/kg
  - Remarks: Based on data from similar materials
- **Acute inhalation toxicity**: Remarks: No data available
- **Acute dermal toxicity**: Remarks: No data available

**Talc:**
- **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - Remarks: Based on data from similar materials

**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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Carbimazole:
Remarks: No data available

Talc:
Routes of exposure: 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

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

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

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

Reproductive toxicity
May damage fertility or the unborn child.

Components:
Effects on fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
May cause damage to organs (Thyroid, Adrenal gland, Testis) through prolonged or repeated exposure in contact with skin.

Components:

Carbimazole:
Routes of exposure: 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: >= 9.000 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

SECTION 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
Exposure time: 24 h

**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

**SECTION 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.

**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

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

**IATA-DGR**
- UN/ID No. : UN 3077
- Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Carbimazole)

**Class**
- : 9
- : III
- : 9
SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

International Regulations

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

AICS : not determined
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SECTION 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.

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA: 8-hour, time-weighted average

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.

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