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

Carbimazole Formulation

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

1.1 Product identifier
   Trade name : Carbimazole Formulation

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

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 1A : H360: May damage fertility or the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   Long-term (chronic) aquatic hazard, Category 2 : H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : 
   Signal word : Danger
   Hazard statements : H360 May damage fertility or the unborn child.
                      H373 May cause damage to organs through prolonged or repeated exposure.
                      H411 Toxic to aquatic life with long lasting effects.
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.

Hazardous components which must be listed on the label:

Carbimazole

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbimazole</td>
<td>22232-54-8</td>
<td>244-854-4</td>
<td></td>
<td>Repr.1A; H360 STOT RE2; H373 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 10 - &lt; 20</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.

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

: 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.

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
5.3 Advice for firefighters

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

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.

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

Carbimazole Formulation

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.

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

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<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>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>TWA (respirable dust)</td>
<td>2 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>6 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**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**

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

Material: Chemical-resistant gloves
Remarks: Consider double gloving.

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.

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 (P)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

- **Appearance**: powder
- **Colour**: pink
- **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**: No data available
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, handling or other means.
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
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.
CARBIMAZOLE FORMULATION

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 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:
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

Skin corrosion/irritation
Not classified based on available information.

Components:
Carbimazole:
- Remarks: No data available

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

Components:
Carbimazole:
- Remarks: No data available
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

Germ cell mutagenicity
Not classified based on available information.

Components:
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

Carcinogenicity
Not classified based on available information.

Components:
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
Reproductive toxicity

May damage fertility or the unborn child.

Components:

Carbimazole:

Reproductive toxicity - Assessment: May damage fertility or 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:

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:

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

12.1 Toxicity

Components:

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

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

M-Factor (Chronic aquatic toxicity)

- : 1

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available
SAFETY DATA SHEET
generated to Regulation (EC) No. 1907/2006

Carbimazole Formulation

Version 3.0  Revision Date: 18.04.2019  SDS Number: 4098702-00003  Date of last issue: 16.04.2019
Date of first issue: 22.03.2019

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
ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Carbimazole)
IATA : Environmentally hazardous substance, solid, n.o.s. (Carbimazole)

14.3 Transport hazard class(es)
ADN : 9
## Carbimazole Formulation

<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>18.04.2019</td>
<td>4098702-00003</td>
<td>16.04.2019</td>
<td>22.03.2019</td>
</tr>
</tbody>
</table>

14.4 Packing group

### ADN
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

### ADR
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

### RID
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

### IMDG
- Packing group: III
- EmS Code: E-A, S-F
- Labels: 9

### IATA (Cargo)
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

### IATA (Passenger)
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

### ADN
- Environmentally hazardous: yes

### ADR
- Environmentally hazardous: yes

### RID
- Environmentally hazardous: yes

### IMDG
Carbimazole Formulation

Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to IMO instruments
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 - 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 (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity 1</td>
</tr>
<tr>
<td></td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.
Take note of Directive 92/85/EEC regarding maternity protection 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Carbimazole Formulation

Version: 3.0
Revision Date: 18.04.2019
SDS Number: 4098702-00003
Date of last issue: 16.04.2019
Date of first issue: 22.03.2019

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
H360: May damage fertility or the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure in contact with skin.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358: Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA: Long term exposure limit

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; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; 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 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Carbimazole Formulation

Version 3.0
Revision Date: 18.04.2019
SDS Number: 4098702-00003
Date of last issue: 16.04.2019
Date of first issue: 22.03.2019

Substance 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

Further information

Classification of the mixture:
Classification procedure:
Repr. 1A H360 Calculation method
STOT RE 2 H373 Calculation method
Aquatic Chronic 2 H411 Calculation method

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

NO / EN