SAFETY DATA SHEET

Guanidine Hydrochloride Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Guanidine Hydrochloride Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Acute toxicity (Oral) : Category 4
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2A
Specific target organ toxicity - repeated exposure : Category 1 (Nervous system, Bone marrow, Kidney)
Short-term (acute) aquatic hazard : Category 3

GHS label elements
Hazard pictograms
Signal word : Danger
Hazard statements : H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H372 Causes damage to organs (Nervous system, Bone marrow, Kidney) through prolonged or repeated exposure.
H402 Harmful to aquatic life.
Precautionary statements : Prevention:
P260 Do not breathe dust.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ eye protection/ face protection.

Response:  
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
P302 + P352 IF ON SKIN: Wash with plenty of water.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P314 Get medical advice/ attention if you feel unwell.  
P332 + P313 If skin irritation occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:  
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 50 - &lt; 60</td>
<td></td>
</tr>
<tr>
<td>Guanidinium chloride</td>
<td>50-01-1</td>
<td>&gt;= 30 - &lt; 40</td>
<td>2-1773 / 1-215</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</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 if symptoms occur.

In case of skin contact:  
In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing.
and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

**In case of eye contact**: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

**If swallowed**: If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

**Most important symptoms and effects, both acute and delayed**: Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. Causes 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 (see section 8).

**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  
Nitrogen oxides (NOx)  
Chlorine compounds  
Metal 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

| Personal precautions, protective equipment and emergency procedures | Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
SAFETY DATA SHEET

Guanidine Hydrochloride Formulation

Environmental precautions : Avoid release to the environment.
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 only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

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.

Storage
Conditions for safe storage : Keep in properly labelled containers.
Store in accordance with the particular national regulations.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>Guanidinium chloride</td>
<td>50-01-1</td>
<td>TWA</td>
<td>0,1 mg/m³ (OEB2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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: Chemical-resistant gloves

Remarks: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection: Wear the following personal protective equipment:
Safety goggles

Skin and body protection: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc.).
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</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>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</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>No data available</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</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>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density and / or relative density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics
Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity : Acute toxicity estimate: 1,330 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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
**Guanidine Hydrochloride Formulation**

<table>
<thead>
<tr>
<th>Component</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Guanidinium chloride</strong></td>
<td>LD50 (Rat): 474.6 mg/kg</td>
<td>LC50 (Rat): 3.181 mg/l</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 571 mg/kg</td>
<td>Exposure time: 4 h</td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td><strong>Magnesium stearate</strong></td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 423</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**
Causes skin irritation.

**Components:**

**Guanidinium chloride**

- Species: Rabbit
- Result: Skin irritation

**Magnesium stearate**

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

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Guanidinium chloride**

- Result: Irritation to eyes, reversing within 21 days
- Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

**Magnesium stearate**

- Species: Rabbit
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<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>6.0</td>
<td>2021/04/09</td>
<td>438986-00014</td>
<td>2020/10/10</td>
<td>2016/01/06</td>
</tr>
</tbody>
</table>

Result: No eye irritation
Remarks: Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Guanidinium chloride:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
</tbody>
</table>

Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
<td>Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

Guanidinium chloride:

| Genotoxicity in vitro | Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 | Result: negative |
|                       | Test Type: Chromosome aberration test in vitro | 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:

Cellulose:

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

Reproductive toxicity

Not classified based on available information.

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

Guanidinium chloride:

- **Effects on foetal development**
  - **Test Type:** Embryo-foetal development
    - **Species:** Rat
    - **Application Route:** Ingestion
    - **Method:** OECD Test Guideline 414
    - **Result:** negative

Magnesium stearate:

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

Effects on foetal development  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

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

**STOT - repeated exposure**  
Causes damage to organs (Nervous system, Bone marrow, Kidney) through prolonged or repeated exposure.

**Components:**

**Guanidinium chloride:**  
Exposure routes: Ingestion  
Target Organs: Nervous system, Kidney, Bone marrow  
Assessment: Causes 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

**Guanidinium chloride:**  
Species: Rat  
NOAEL: 100 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  
Method: OECD Test Guideline 408

**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:**

**Guanidinium chloride:**

| Ingestion | Symptoms: tingling, numbness, anorexia, Diarrhoea |

### 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 |

**Guanidinium chloride:**

| Toxicity to fish | LC50 (Leuciscus idus (Golden orfe)): 1,758 mg/l |
| Exposure time: 48 h |
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 70.2 mg/l |
| Exposure time: 48 h |
| Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | ErC50 (Pseudokirchneriella subcapitata (green algae)): 11.8 mg/l |
| Exposure time: 72 h |
| NOEC (Pseudokirchneriella subcapitata (green algae)): 6.3 mg/l |
| Exposure time: 72 h |

**Toxicity to fish (Chronic toxicity):**

| NOEC (Pimephales promelas (fathead minnow)): 181 mg/l |
| Exposure time: 35 d |
| Remarks: Based on data from similar materials |

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):**

| NOEC (Daphnia magna (Water flea)): 2.9 mg/l |
| Exposure time: 21 d |
| Remarks: Based on data from similar materials |

**Toxicity to microorganisms:**

| EC10 (Pseudomonas putida): 7,125 mg/l |
| Exposure time: 18 h |

**Magnesium stearate:**

| Toxicity to fish | LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l |
| Exposure time: 48 h |
| Method: DIN 38412 |
| Remarks: Based on data from similar materials |
Toxicity to daphnia and other aquatic invertebrates:
- **EL50** (Daphnia magna (Water flea)): > 1 mg/l
- Exposure time: 47 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials
- No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials
- No toxicity at the limit of solubility

Toxicity to microorganisms:
- **EC10** (Pseudomonas putida): > 100 mg/l
- Exposure time: 16 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

Persistence and degradability

Components:

**Cellulose:**
- Biodegradability: Result: Readily biodegradable.

**Guanidinium chloride:**
- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 0 %
- Exposure time: 56 d
- Method: OECD Test Guideline 301C

**Magnesium stearate:**
- Biodegradability: Result: Not biodegradable
- Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

**Guanidinium chloride:**
- Partition coefficient: n-octanol/water
  - log Pow: < -1.7

**Magnesium stearate:**
Partition coefficient: n-octanol/water

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

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
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

National Regulations
Refer to section 15 for specific national regulation.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable
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Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
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</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law
 Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

**Waste Disposal and Public Cleansing Law**
Industrial waste

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**
Sources of key data used to compile the Safety Data Sheet :

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**
- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA : 8-hour, 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; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect
SAFETY DATA SHEET

Guanidine Hydrochloride Formulation

Version 6.0  Revision Date: 2021/04/09  SDS Number: 438986-00014  Date of last issue: 2020/10/10

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; 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.

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