SAFETY DATA SHEET

Guanidine Hydrochloride Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Guanidine Hydrochloride Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 4
Acute toxicity (Inhalation): Category 5
Skin irritation: Category 2
Eye irritation: Category 2A
Specific target organ toxicity - repeated exposure: Category 1 (Nervous system, Bone marrow, Kidney)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H333 May be harmful if inhaled.
H372 Causes damage to organs (Nervous system, Bone marrow, Kidney) through prolonged or repeated exposure.

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.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON
Other hazards
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Guanidinium chloride</td>
<td>50-01-1</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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 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.
- May be harmful if inhaled.
- 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.

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
- 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 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 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.

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 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.
- 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.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.

Conditions for safe storage: Keep in properly labeled containers.
- 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
  - Gases

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>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</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:
- Material: Chemical-resistant gloves
- Remarks: Choose gloves to protect hands against chemicals depending on the concentration 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.).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: No data available
Odor: No data available
Odor Threshold: No data available
**SAFETY DATA SHEET**

**Guanidine Hydrochloride Formulation**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</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>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>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Explosive properties</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
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</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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**

**Acute toxicity**

Harmful if swallowed. May be harmful if inhaled.

**Product:**

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

Acute inhalation toxicity: Acute toxicity estimate: 8.91 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

**Guanidinium chloride:**

Acute oral toxicity: LD50 (Rat): 474.6 mg/kg
LD50 (Mouse): 571 mg/kg

Acute inhalation toxicity: LC50 (Rat): 3.181 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
**Guanidine Hydrochloride 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>
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<tbody>
<tr>
<td>3.3</td>
<td>23.03.2020</td>
<td>438988-00012</td>
<td>13.09.2019</td>
<td>06.01.2016</td>
</tr>
</tbody>
</table>

Assessment: The substance or mixture has no acute dermal toxicity

**Magnesium stearate:**

- **Acute oral toxicity**
  - LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 423
  - Assessment: The substance or mixture has no acute oral toxicity
  - Remarks: Based on data from similar materials

- **Acute dermal toxicity**
  - LD50 (Rabbit): > 2,000 mg/kg
  - Remarks: Based on data from similar materials

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

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.
Components:

Guanidinium chloride:
- Test Type: Buehler Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative

Magnesium stearate:
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative
- Remarks: Based on data from similar materials

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

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

#### Guanidinium chloride:
- **Effects on fetal development:** Test Type: Embryo-fetal development
  - **Species:** Rat
  - **Application Route:** Ingestion
  - **Method:** OECD Test Guideline 414
  - **Result:** negative
  - **Remarks:** Based on data from similar materials

#### 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 fetal development:** Test Type: Embryo-fetal 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:
Routes of exposure : 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, Diarrhea
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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELC (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>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.</td>
</tr>
<tr>
<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l</td>
<td>Exposure time: 72 h; Test substance: Water Accommodated Fraction; Method: OECD Test Guideline 201; Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC10 (Pseudomonas putida)</td>
<td>&gt; 100 mg/l</td>
<td>Exposure time: 16 h; Test substance: Water Accommodated Fraction; Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 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: \( \log \text{Pow} < -1.7 \)

**Magnesium stearate:**
- Partition coefficient: n-octanol/water: \( \log \text{Pow} > 4 \)

### 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
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.

Domestic regulation

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.
Not applicable

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting

Revision Date: 23.03.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8