SAFETY DATA SHEET

Diazoxide (<15%) Formulation

Version: 1.3  Revision Date: 2020/10/10  SDS Number: 4089866-00004  Date of last issue: 2019/09/13  Date of first issue: 2019/03/20

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Diazoxide (<15%) Formulation

Manufacturer or supplier's details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 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: Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pancreas, Kidney, Heart)

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
H372 Causes damage to organs (Pancreas, Kidney, Heart) through prolonged or repeated exposure.

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 11.36 %

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 combustible dust concentrations in air during processing, handling or other means.

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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazoxide</td>
<td>364-98-7</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled:
If inhaled, remove to fresh air. Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact:
If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
## 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  
|                             | Chlorine compounds  
|                             | Nitrogen oxides (NOx)  
|                             | Sulphur 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).  
| 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.  

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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.
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: If sufficient ventilation is unavailable, 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.
- Wash skin thoroughly after handling.
- 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.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazoxide</td>
<td>364-98-7</td>
<td>TWA</td>
<td>50 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>500 µg/100 cm²</td>
<td>Internal</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: 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: 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.

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.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: white

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 combustible dust concentrations in air during pro-
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: May form combustible dust concentrations in air 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**
Not classified based on available information.

**Product:**
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

**Components:**
**Diazoxide:**
Acute oral toxicity: LD50 (Rat): 980 mg/kg
LD50 (Mouse): 444 mg/kg
LD50 (Guinea pig): 191 mg/kg

Acute toxicity (other routes of administration):
LD50 (Mouse): 228 mg/kg
Application Route: Intravenous

LD50 (Mouse): 326 mg/kg
Application Route: Intraperitoneal

LD50 (Rat): 510 mg/kg
Application Route: Intraperitoneal

**Skin corrosion/irritation**
Not classified based on available information.

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

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

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

**Carcinogenicity**
Not classified based on available information.

**Reproductive toxicity**
May damage the unborn child.

**Components:**
Diazoxide:
Effects on foetal development:

- **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** NOAEL: 30 mg/kg body weight
  - **Result:** Effects on foetal development, foetal abnormalities

- **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Oral
  - **Developmental Toxicity:** LOAEL: 100 mg/kg body weight
  - **Result:** Effects on foetal development, foetal abnormalities

- **Test Type:** Development
  - **Species:** Rat
  - **Application Route:** Intravenous
  - **Developmental Toxicity:** LOAEL: 10 mg/kg body weight
  - **Result:** Fetotoxicity

- **Test Type:** Development
  - **Species:** Mouse
  - **Application Route:** Intraperitoneal
  - **Developmental Toxicity:** NOAEL: 30 mg/kg body weight
  - **Result:** Foetal mortality

- **Test Type:** Development
  - **Species:** Mouse
  - **Application Route:** Intraperitoneal
  - **Developmental Toxicity:** LOAEL: 60 mg/kg body weight
  - **Result:** Foetal mortality

- **Test Type:** Development
  - **Species:** Rabbit
  - **Application Route:** Intravenous
  - **Developmental Toxicity:** NOAEL: 7 mg/kg body weight
  - **Result:** Foetal abnormalities

- **Test Type:** Development
  - **Species:** Rabbit
  - **Application Route:** Intravenous
  - **Developmental Toxicity:** LOAEL: 21 mg/kg body weight
  - **Result:** Foetal abnormalities

- **Test Type:** Development
  - **Species:** Dog
  - **Application Route:** Intravenous
  - **Developmental Toxicity:** NOAEL: 5 mg/kg body weight
  - **Result:** Foetal mortality

- **Test Type:** Development
  - **Species:** Dog
  - **Application Route:** Intravenous
  - **Developmental Toxicity:** LOAEL: 10 mg/kg body weight
  - **Result:** Foetal mortality

- **Test Type:** Development
Species: Monkey  
Application Route: Intravenous  
Developmental Toxicity: LOAEL: 5 mg/kg body weight  
Result: No teratogenic effects  

Reproductive toxicity - Assessment: May damage the unborn child.

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

**STOT - repeated exposure**
Causes damage to organs (Pancreas, Kidney, Heart) through prolonged or repeated exposure.

**Components:**

**Diazoxide:**
Target Organs: Pancreas, Kidney, Heart  
Assessment: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Diazoxide:**
Species: Rat  
LOAEL: 400 mg/kg  
Application Route: Oral  
Exposure time: 2 Weeks  
Target Organs: Adrenal gland

Species: Rat  
LOAEL: 1,080 mg/kg  
Application Route: Oral  
Exposure time: 3 Months  
Target Organs: Pancreas  
Symptoms: hyperglycemia

Species: Rat  
LOAEL: 200 mg/kg  
Application Route: Oral  
Exposure time: 52 Weeks  
Target Organs: Heart, Liver, Adrenal gland, Thyroid

Species: Dog  
NOAEL: 200 mg/kg  
Application Route: Oral  
Exposure time: 82 Weeks  
Target Organs: Pancreas  
Symptoms: hyperglycemia

**Aspiration toxicity**
Not classified based on available information.
Experience with human exposure

**Components:**

**Diazoxide:**

- **General Information:** Symptoms: hyperglycemia, hypotension, Nausea, Vomiting, Dizziness, Weakness
- **Ingestion:** Symptoms: sodium retention, water retention, anorexia, Abdominal pain, Diarrhoea, tachycardia, Palpitation

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Diazoxide:**

**Ecotoxicology Assessment**

- **Acute aquatic toxicity:** Toxic effects cannot be excluded
- **Chronic aquatic toxicity:** Toxic effects cannot be excluded

**Persistence and degradability**

No data available

**Bioaccumulative potential**

**Components:**

**Diazoxide:**

- **Partition coefficient: n-octanol/water:** log Pow: 1.2
- **Mobility in soil:** No data available
- **Other adverse effects:** No data available

**13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

- **Waste from residues:** Dispose of in accordance with local regulations.
- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

**14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

Not regulated as a dangerous good
11. IATA-DGR
Not regulated as a dangerous good

12. IMDG-Code
Not regulated as a dangerous good

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

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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
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.