1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Diazoxide (<15%) Formulation

Manufacturer or supplier's details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India 412 207
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

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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

GHS label elements
Hazard pictograms : ![Hazardous Chemical]
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:
P203 Obtain, read and follow all safety instructions before use.
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: 
P318 IF exposed or concerned, get medical advice. 

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>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Diazoxide</td>
<td>364-98-7</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
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
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. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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: Material

Remarks: Consider double gloving.

Hand protection: Chemical-resistant gloves

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
SAFETY DATA SHEET

Diazoxide (<15%) 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>1.3</td>
<td>10.10.2020</td>
<td>4089867-00004</td>
<td>13.09.2019</td>
<td>20.03.2019</td>
</tr>
</tbody>
</table>

Flammability (solid, gas) : May form combustible dust concentrations in air during processing, handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies) : No data available

Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

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: > 5,000 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
SAFETY DATA SHEET

Diazoxide (<15%) Formulation

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AllC - 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; KECl - 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
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