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Diazoxide (<15%) Formulation

Section 1: Identification

Product name: Diazoxide (<15%) Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908 Upper Hutt - New Zealand
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

Section 2: Hazard identification

GHS Classification

Reproductive toxicity: Repr.1B
Specific target organ toxicity - repeated exposure: STOT RE1 (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.
P281 Use personal protective equipment as required.

Response:
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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.

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.

Section 3: Composition/information on ingredients

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

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.

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.

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.

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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
</tbody>
</table>

**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, 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.

## 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: 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. 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: 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.

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

Section 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.

**Section 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 processing, handling or other means.
- **Flammability (liquids)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower**: No data available
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flammability limit
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity
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

Section 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.

Section 11: Toxicological information
Exposure routes : Inhalation
              Skin contact
              Ingestion
              Eye contact

Acute toxicity
Not classified based on available information.
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.

Chronic toxicity

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 abnormalities

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

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 abnormalities

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

**Symptoms**: hyperglycemia

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:**
- **Symptoms**: hyperglycemia, hypotension, Nausea, Vomiting,
Ingestion: Symptoms: sodium retention, water retention, anorexia, abdominal pain, diarrhoea, tachycardia, palpitation

Section 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

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.

National Regulations

NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

| AICS | not determined |
| DSL  | not determined |
| IECSC| not determined |

Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 Chemi-
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