according to the Globally Harmonized System



Diazoxide (<15%) Formulation

Revision Date: Date of last issue: 30.09.2023 Version SDS Number: 28.09.2024 4089867-00010 Date of first issue: 20.03.2019 3.0

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 +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Pharmaceutical Recommended use Restrictions on use Not applicable

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

repeated exposure

Specific target organ toxicity - : Category 1 (Pancreas, Kidney, Heart)

GHS label elements

Hazard pictograms

Signal word

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.

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P260 Do not breathe dust.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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

Substance / Mixture Mixture

Components

•		
Chemical name	CAS-No. Concentration	
		w/w)
Diazoxide	364-98-7	>= 10 - < 20

4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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

May damage the unborn child.

and effects, both acute and Causes damage to organs through prolonged or repeated

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delayed 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.

5. FIREFIGHTING 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 prod-

ucts

Carbon oxides

Chlorine compounds Nitrogen oxides (NOx)

Sulphur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer for disposal.

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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 as-

sessment

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Diazoxide	364-98-7	TWA	50 μg/m3 (OEB 3)	Internal
		Wipe limit	500 µg/100 cm ²	Internal

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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 contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Particulates type

Material : 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

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

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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-

cessing, 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)

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 characteristics

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

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Possibility of hazardous reac-

tions

May form combustible dust concentrations in air during pro-

cessing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

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 toxicity estimate: > 5,000 mg/kg Acute oral toxicity

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.

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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 develop-

ment

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

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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 - As-

sessment

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

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LOAEL : 200 mg/kg
Application Route : Oral
Exposure time : 52 Weeks

Target Organs : Heart, Liver, Adrenal gland, Thyroid

Species: DogNOAEL: 200 mg/kgApplication Route: OralExposure time: 82 WeeksTarget Organs: PancreasSymptoms: 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, Ab-

dominal 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-

: log Pow: 1.2

octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

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13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling 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

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.

Special precautions for user

Not applicable

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

Revision Date 28.09.2024

Further information

Sources of key data used to

compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

Date format dd.mm.yyyy

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Full text of other abbreviations

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 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; TECI - Thailand Existing Chemicals Inventory; 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.

IN / EN