

**Diazoxide (<15%) Formulation**

Version 2.1      Revision Date: 2023/09/30      SDS Number: 4089866-00009      Date of last issue: 2023/04/04  
Date of first issue: 2019/03/20

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**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

**Recommended use of the chemical and restrictions on use**


Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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**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.

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## Diazoxide (<15%) Formulation

Version 2.1	Revision Date: 2023/09/30	SDS Number: 4089866-00009	Date of last issue: 2023/04/04 Date of first issue: 2019/03/20
----------------	------------------------------	------------------------------	---

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

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Diazoxide	364-98-7	>= 10 -< 30

## 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.

## Diazoxide (<15%) Formulation

Version 2.1	Revision Date: 2023/09/30	SDS Number: 4089866-00009	Date of last issue: 2023/04/04 Date of first issue: 2019/03/20
----------------	------------------------------	------------------------------	---

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.
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 (CO <sub>2</sub> ) 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 Chlorine compounds Nitrogen oxides (NO <sub>x</sub> ) 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

## Diazoxide (<15%) Formulation

Version 2.1	Revision Date: 2023/09/30	SDS Number: 4089866-00009	Date of last issue: 2023/04/04 Date of first issue: 2019/03/20
----------------	------------------------------	------------------------------	---

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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labelled containers.<br>Store locked up.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations.   |
| Materials to avoid          | : | Do not store with the following product types:<br>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/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	500 µg/100 cm <sup>2</sup>	Internal

## Diazoxide (<15%) Formulation

Version 2.1	Revision Date: 2023/09/30	SDS Number: 4089866-00009	Date of last issue: 2023/04/04 Date of first issue: 2019/03/20
----------------	------------------------------	------------------------------	---

**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 : 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

**Diazoxide (<15%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

---

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 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 size	:	No data available

**Diazoxide (<15%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

---

**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.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Not classified based on available information.

**Product:**

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

**Diazoxide (<15%) Formulation**

Version 2.1      Revision Date: 2023/09/30      SDS Number: 4089866-00009      Date of last issue: 2023/04/04  
Date of first issue: 2019/03/20

---

**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



## Diazoxide (<15%) Formulation

Version 2.1	Revision Date: 2023/09/30	SDS Number: 4089866-00009	Date of last issue: 2023/04/04 Date of first issue: 2019/03/20
----------------	------------------------------	------------------------------	---

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

## Diazoxide (<15%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

---

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

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## 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

## Diazoxide (<15%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

---

### 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

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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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable

#### IATA-DGR

UN/ID No. : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Packing instruction (cargo aircraft) : Not applicable  
 Packing instruction (passenger aircraft) : Not applicable

#### IMDG-Code

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable

**Diazoxide (<15%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

---

Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**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 Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION**

**Diazoxide (<15%) Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

---

Revision Date : 2023/09/30

**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 Agency, <http://echa.europa.eu/>

Date format : yyyy/mm/dd

**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; 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.

# SAFETY DATA SHEET



## Diazoxide (<15%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	4089866-00009	Date of first issue: 2019/03/20

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