according to GB/T 16483 and GB/T 17519



# **Betaine Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/11/18 2.0 2024/12/03 11460915-00002 Date of first issue: 2024/11/18

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betaine Formulation

Product code : Prevensa Aquador, Aquador

Manufacturer or supplier's details

Company : MSD

Address : No. 485 Jing Tai Road

Pu Tuo District - Shanghai - China 200331

Telephone : +1-908-740-4000

Emergency telephone number : 86-571-87268110

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

Appearance : powder Colour : brown

Odour : characteristic

Not a hazardous substance or mixture.

#### **GHS Classification**

Not a hazardous substance or mixture.

#### **GHS** label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

### Physical and chemical hazards

Not classified based on available information.

### **Health hazards**

Not classified based on available information.

#### **Environmental hazards**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### 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 explosive dust-air mixture during processing, handling or other means.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
DL-Methionine	59-51-8	>= 1 -< 10	
Betaine	107-43-7	>= 1 -< 10	

### 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 if symptoms occur.

In case of skin contact : Wash with water and soap.

Get medical attention if symptoms occur.

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 if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms : Conf

and effects, both acute and

delayed

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 : No special precautions are necessary for first aid responders.

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- : Carbon oxides

according to GB/T 16483 and GB/T 17519



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ucts Nitrogen oxides (NOx)

Sulphur oxides Silicon 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

Wear self-contained breathing apparatus for firefighting if nec-

essary

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

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.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

### Handling

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.

according to GB/T 16483 and GB/T 17519



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Local/Total ventilation Use only with adequate ventilation.

Do not breathe dust. Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

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.

Oxidizing agents Avoidance of contact

Storage

Conditions for safe storage Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid Do not store with the following product types:

Strong oxidizing agents

Unsuitable material: None known. Packaging material

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	
DL-Methionine	59-51-8	TWA	5000 μg/m3 (OEB	Internal
Betaine	107-43-7	TWA	>= 100 < 1000 µg/m3 (OEB2)	Internal

**Engineering measures** Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

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.

Particulates type Filter type

Wear safety glasses with side shields or goggles. Eye/face protection

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.

according to GB/T 16483 and GB/T 17519



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Hand protection

Material : Chemical-resistant gloves

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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 : brown

Odour : characteristic

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 : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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 : 0.45

according to GB/T 16483 and GB/T 17519



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Density 0.45 g/cm<sup>3</sup>

Solubility(ies)

Water solubility partly soluble

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

Not classified as a reactivity hazard. Reactivity Chemical stability

Possibility of hazardous reac-

Stable under normal conditions.

May form explosive dust-air mixture during processing, han-

dling 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

tions

No hazardous decomposition products are known.

## 11. TOXICOLOGICAL INFORMATION

Exposure routes Inhalation

Skin contact Inaestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

**DL-Methionine:** 

according to GB/T 16483 and GB/T 17519



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Acute oral toxicity : LD50 (Rat): > 5,610 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.25 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

**Betaine:** 

Acute oral toxicity : LD50 (Rat): 11,179 mg/kg

Method: OECD Test Guideline 401

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

### **DL-Methionine:**

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Betaine:

Species : human skin
Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

# **Components:**

## **DL-Methionine:**

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Betaine:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



### **Betaine Formulation**

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### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

### **DL-Methionine:**

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

#### Betaine:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Method : OECD Test Guideline 406

### Germ cell mutagenicity

Not classified based on available information.

## Components:

### **DL-Methionine:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Betaine:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: Directive 67/548/EEC, Annex V, B.10.

Result: negative

Test Type: Bacterial reverse mutation assay (AMES) Method: Directive 67/548/EEC, Annex, B.13/14

according to GB/T 16483 and GB/T 17519



# **Betaine Formulation**

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Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral

Method: OECD Test Guideline 474

Result: negative

### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Betaine:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

### Reproductive toxicity

Not classified based on available information.

## STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

## Repeated dose toxicity

## **Components:**

### **DL-Methionine:**

Species : Rat, male

NOAEL : >= 1,474 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Method : OECD Test Guideline 408

#### Betaine:

Species : Rat, female

NOAEL : > 5,771 mg/kg

Application Route : Ingestion

Exposure time : 28 Days

Method : OECD Test Guideline 407

### **Aspiration toxicity**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

## **Components:**

**DL-Methionine:** 

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 3,200 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 324 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 1,000

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

EC10 (Desmodesmus subspicatus (green algae)): > 1,000

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Pseudomonas putida): 10,000 mg/l

Exposure time: 18 h

Betaine:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 4,335 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

NOEC (Desmodesmus subspicatus (green algae)): 312.5 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

ErC50 (Desmodesmus subspicatus (green algae)): 1,199 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Persistence and degradability

Components:

**DL-Methionine:** 

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 %

according to GB/T 16483 and GB/T 17519



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Exposure time: 28 d

Method: OECD Test Guideline 301A

Betaine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 88 % Exposure time: 28 d

Method: OECD Test Guideline 301B

**Bioaccumulative potential** 

Components:

DL-Methionine:

Partition coefficient: n- : log Pow: -2.41

octanol/water Remarks: Calculation

Betaine:

Partition coefficient: n- : log Pow: -3.1

octanol/water

Mobility in soil
No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

no

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** 

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

Environmentally hazardous :

IATA-DGR

11 / 14

according to GB/T 16483 and GB/T 17519



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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 : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

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

Marine pollutant : no

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

Not applicable for product as supplied.

#### **National Regulations**

GB 6944/12268

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

Marine pollutant : no

Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

#### **National regulatory information**

Law on the Prevention and Control of Occupational Diseases

### **Regulations on Safety Management of Hazardous Chemicals**

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals and it does not meet the definition of hazardous chemicals and its principles

of determination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

according to GB/T 16483 and GB/T 17519



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Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

**Regulation on the Administration of Precursor Chemicals** 

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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 : 2024/12/03

**Further information** 

Sources of key data used to : compile the Safety Data

Sheet cy, http://e

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 : yyyy/mm/dd

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

according to GB/T 16483 and GB/T 17519



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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

### **Disclaimer**

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.

CN / EN