

Betaine Formulation

Version 2.0 Revision Date: 03.12.2024 SDS Number: 11460924-00002 Date of last issue: 18.11.2024
Date of first issue: 18.11.2024

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betaine Formulation
Product code : Prevensa Aquador, Aquador

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**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.

Other hazards

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
DL-Methionine	59-51-8	≥ 5 -< 10
Betaine	107-43-7	≥ 5 -< 10

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 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.

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

Most important symptoms and effects, both acute and delayed	:	Get medical attention if symptoms occur. Rinse mouth thoroughly with water. Contact with dust can cause mechanical irritation or drying of the skin.
Protection of first-aiders	:	Dust contact with the eyes can lead to mechanical irritation.
Notes to physician	:	No special precautions are necessary for first aid responders.
	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 Nitrogen oxides (NO _x) Sulfur oxides Silicon 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 fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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.

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

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

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|-----------------------------|---|--|
| 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 | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not breathe dust.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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 labeled containers.
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**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
DL-Methionine	59-51-8	TWA	5000 µg/m ³ (OEB 1)	Internal

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

Betaine	107-43-7	TWA	$\geq 100 < 1000$ $\mu\text{g}/\text{m}^3$ (OEB2)	Internal
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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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection
Material : 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : brown

Odor : characteristic

Odor 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, handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower : No data available

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

flammability limit

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : 0.45

Density : 0.45 g/cm³

Solubility(ies)

Water solubility : partly soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture 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**Information on likely routes of exposure**

Inhalation

Skin contact

Ingestion

Eye contact

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

Acute toxicity

Not classified based on available information.

Components:**DL-Methionine:**

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 inhalation toxicity

Betaine:

Acute oral toxicity	: LD50 (Rat): 11,179 mg/kg Method: OECD Test Guideline 401
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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 sensitization**Skin sensitization**

Not classified based on available information.

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

Respiratory sensitization

Not classified based on available information.

Components:**DL-Methionine:**

Test Type	: Buehler Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406

Betaine:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Assessment	: Does not cause skin sensitization.
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 synthesis 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 V, B.13/14. Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo)

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

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	: $\geq 1,474$ 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.

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

SECTION 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 % Exposure time: 28 d Method: OECD Test Guideline 301A
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Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

Betaine:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 88 % Exposure time: 28 d Method: OECD Test Guideline 301B
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Bioaccumulative potential**Components:****DL-Methionine:**

Partition coefficient: n-octanol/water	:	log Pow: -2.41 Remarks: Calculation
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Betaine:

Partition coefficient: n-octanol/water	:	log Pow: -3.1
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Mobility in soil

No data available

Other adverse effects

No data available

SECTION 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.

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.

Domestic regulation**NOM-002-SCT**

Not regulated as a dangerous good

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, : Not applicable
essential chemical products and machinery for
producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 03.12.2024
Date format : dd.mm.yyyy

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; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-

Betaine Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 18.11.2024
2.0	03.12.2024	11460924-00002	Date of first issue: 18.11.2024

stances 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <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.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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