

**Betaine Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 13.12.2024
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**SECTION 1: Identification of the hazardous chemical and of the supplier****Product identifier**

Product name : Betaine Formulation

Chemical name :

CAS-No. : Not Assigned

Product code : Prevensa Aquador, Aquador

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

**Manufacturer or supplier's details**

Company : Merck & Co., Inc

Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

**SECTION 2: Hazards identification****Classification of the hazardous chemical**

Not a hazardous substance or mixture.

**Label elements**

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

**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.

**SECTION 3: Composition and information of the ingredients of the hazardous chemical**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
DL-Methionine	59-51-8	>= 5 -< 10

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Betaine	107-43-7	>= 5 -< 10
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**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.  
Get medical attention if symptoms occur.  
Rinse mouth thoroughly with water.
- Most important symptoms 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.

**SECTION 5: Firefighting measures****Extinguishing media**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

- Unsuitable extinguishing media : None known.

**Physicochemical hazards arising from the chemical**

- 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<sub>x</sub>)  
Sulphur oxides  
Silicon oxides

**Special protective equipment and precautions for fire-fighters**

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

**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.  
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****Handling****Precautions for safe 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.
- 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.

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**Storage****Conditions for safe storage, including any incompatibilities**

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

**SECTION 8: Exposure controls and personal protection****Control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
DL-Methionine	59-51-8	TWA	5000 µg/m <sup>3</sup> (OEB 1)	Internal
Betaine	107-43-7	TWA	≥ 100 < 1000 µg/m <sup>3</sup> (OEB2)	Internal

**Appropriate engineering controls** : 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.

**Individual protection measures, such as personal protective equipment (PPE)**

Eye/face 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 protection : Work uniform or laboratory coat.

Hand protection : Chemical-resistant gloves

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

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.

**SECTION 9: Physical and chemical properties**

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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, 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	:	0.45
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.

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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

**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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****DL-Methionine:**

Species : Rabbit  
Method : OECD Test Guideline 404

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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.

**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

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	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, B.13/14
	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.



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**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.

**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

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Toxicity to daphnia and other	: EC50 (Daphnia magna (Water flea)): 4,335 mg/l
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aquatic invertebrates	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:**

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 information****Disposal methods**

Waste from residues	: Disposal of waste to be in accordance with the Environmental Quality (Scheduled Wastes) Regulations and other guidelines issuance by DOE and/or local authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste han-

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

**SECTION 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	:	no

**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
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

**SECTION 15: Regulatory information****Safety, health, and environmental regulations specific for the hazardous chemical**

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013.

Occupational Safety and Health (Use and Standards of Exposure of Chemicals Hazardous to Health) Regulations 2000.

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

AICS	:	not determined
DSL	:	not determined

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IECSC : not determined

**SECTION 16: Other information**

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**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 : 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; 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

# SAFETY DATA SHEET



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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.

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