

SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006

Product name: Betaine

Creation date: 08.02.2026, Revision: 08.02.2026, Version: 1.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name

Betaine

Product code

[AL00367]

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Raw material for cosmetic products.

Uses advised against

No information.

1.3 Details of the supplier of the safety data sheet

Supplier

Farmadria DOO
Heroja Pinkija 44
26300 Vršac, Serbia
+381695565029
info@avenalab.com

1.4 Emergency Telephone Number

Emergency

112

Supplier

+381695565029

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

According to the regulation, the chemical is not classified as hazardous.

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2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Hazard statements:

Not applicable.

Supplemental hazard information (EU):

Not applicable.

Precautionary statements:

Not applicable.

2.3 Other hazards

PBT/vPvB

No information.

Endocrine disrupting properties

The product does not contain substances with the potential for endocrine disorders.

Additional information

No information.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

For mixtures see 3.2.

3.2 Mixtures

Name	CAS EC Index REACH	%	Classification according to Regulation (EC) No 1272/2008 (CLP)	Specific Concentration Limits	Notes for substances
Betaine	107-43-7 203-490-6 -	100	/	/	/

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Following inhalation

Remove patient to fresh air - move out of dangerous area. If symptoms develop and persist, seek medical attention.

Following skin contact

Wash affected skin areas immediately with plenty of water and soap. If symptoms develop and persist, seek medical attention.

Following eye contact

Immediately flush eyes with running water, keeping eyelids apart. If irritation persists, seek professional medical attention.

Following ingestion

Do not induce vomiting! Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. In case of doubt or if feeling unwell seek medical help. Show the physician the safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

Following inhalation

No information.

Following skin contact

Contact with skin may cause irritation (redness, itching).

Following eye contact

Contact with eyes can cause irritation (redness, tearing, pain).

Following ingestion

May cause nausea/vomiting and diarrhea. May cause abdominal discomfort.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

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5.1 Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media

Full water jet.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

In case of a fire toxic gases can be generated; do not inhale gases/smoke.

5.3 Advice for firefighters

Protective actions

In case of fire or heating do not breathe fumes/vapours. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters

Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (BS EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (BS EN 137).

Additional information

No information.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment

No information.

Precautionary measures

Ensure adequate ventilation.

Emergency procedures

No action shall be taken involving any personal risk or without suitable training. Avoid breathing dust. Avoid contact with skin, eyes and clothing.

For emergency responders

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Use personal protective equipment.

6.2 Environmental precautions

Do not allow product to reach water/drains/sewage systems or permeable soil. In case of release into the environment, inform the relevant authorities.

6.3 Methods and material for containment and cleaning up

For containment

No information.

For cleaning up

Clean contaminated area with plenty of water.

Other information

No information.

6.4 Reference to other sections

See also sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Protective measures

Measures to prevent fire

Ensure adequate ventilation.

Measures to prevent aerosol and dust generation

Prevent dust formation.

Measures to protect the environment

Avoid release to the environment.

Other measures

No information.

Advice on general occupational hygiene

Use good personal hygiene practices – wash hands at breaks and when done working with material. Do not eat, drink or smoke while working. Avoid contact with skin, eyes and clothes.

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7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep in a cool, dry and well ventilated place. Keep away from food, drink and animal feeding stuffs.

Packaging materials

No information.

Requirements for storage rooms and vessels

Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers.

Storage temperature

No information.

Storage class

No information.

Further information on storage conditions

No information.

7.3 Specific end use(s)

Recommendations

No information.

Industrial sector specific solutions

No information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure limit values

No information.

Information on monitoring procedures

BS EN 14042:2003 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. BS EN 689:2018 Workplace exposure. Measurement of exposure by inhalation to chemical agents. Strategy for testing compliance with occupational exposure limit values. BS EN 482:2021 Workplace exposure. Procedures for the determination of the concentration of chemical agents. Basic performance requirements.

DNEL/DMEL values

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For product

No information.

For components

Name	Type	Exposure route	exp. frequency	Remark	Value
Betaine	Consumer	oral	long term systemic effects	/	25 mg/kg bw/day

PNEC values

For product

No information.

For components

Name	Exposure route	Remark	Value
Betaine	fresh water	/	0.85 mg/L
Betaine	marine water	/	0.085 mg/L
Betaine	water, intermittent release	/	2 mg/L
Betaine	water treatment plant	/	10 mg/L
Betaine	fresh water sediment	/	1.78 mg/kg
Betaine	marine water sediment	/	0.178 mg/L
Betaine	soil	/	0.13 mg/kg

8.2 Exposure controls

Appropriate engineering control

Substance/mixture related measures to prevent exposure during identified uses

Use good personal hygiene practices – wash hands at breaks and when done working with material. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe dust.

Structural measures to prevent exposure

No information.

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Organisational measures to prevent exposure

No information.

Technical measures to prevent exposure

Provide good ventilation and local exhaust in areas with increased concentration. Keep away from food, drink and animal feeding stuffs.

Personal protective equipment

Eye and face protection

No requirements under normal use conditions. If there is a risk of eye contact use safety glasses.

Hand protection

No requirements under normal use conditions. In case of prolonged exposure, wear protective gloves (BS EN ISO 374).

Appropriate materials

No information.

Skin protection

No requirements under normal use conditions. With excessive exposure wear protective working clothing (overalls and boots). Cotton protective clothing and shoes that cover the entire foot (BS EN ISO 20345:2022).

Respiratory protection

Not needed under normal use and adequate ventilation.

Thermal hazards

No information.

Environmental exposure controls

Substance/mixture related measures to prevent exposure

No information.

Instruction measures to prevent exposure

No information.

Organisational measures to prevent exposure

No information.

Technical measures to prevent exposure

Do not allow product to reach drains, sewage systems or ground water.

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9.1 Information on basic physical and chemical properties
Important health, safety and environmental information

Physical state	solid
Shape	powder
Colour	white
Odour	No information.
Odour threshold	No information.
Melting/freezing point	301 °C
Boiling point or initial boiling point and boiling range	No information.
Flammability	No information.
Lower and upper explosion limit	No information.
Flash point	No information.
Auto-ignition temperature	No information.
Decomposition temperature	No information.
pH	5 — 7
Viscosity	No information.
Solubility (Water)	soluble
Partition coefficient n-octanol/water (log value)	No information.
Vapour pressure	No information.
Density / weight	No information.
Relative vapour/gas density	No information.
Particle characteristics	No information.

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9.2 Other information

Information with regard to physical hazard classes

No information.

Other safety characteristics

No information.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No information.

10.2 Chemical stability

Hygroscopic.

10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4 Conditions to avoid

Incompatible products. Exposure to moist air or water

10.5 Incompatible materials

Incompatible products. Exposure to moist air or water

10.6 Hazardous decomposition products

Under normal use conditions no hazardous decomposition products are expected. In case of fire/explosion vapours/gases that pose a health hazard are released.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

(a) Acute toxicity

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For components

Name	Exposure route	Type	Species	Time	Value	Method	Remark
Betaine	oral	LD ₅₀	rat (male)	/	22800 mg/kg	/	/
Betaine	inhalation	LC ₀	rat (male)	4 h	290 mg/m ³	OECD 403	/

Additional information

The product is not classified as acutely toxic.

(b) Skin corrosion/irritation

For components

Name	Species	Time	Result	Method	Remark
Betaine	rabbit	/	Non-irritant.	/	/

Additional information

The product is not classified as irritating to skin.

(c) Serious eye damage/irritation

For components

Name	Exposure route	Species	Time	Result	Method	Remark
Betaine	/	rabbit	/	Mild irritating.	/	/

(d) Respiratory or skin sensitisation

For components

Name	Exposure route	Species	Time	Result	Method	Remark
Betaine	dermal	human	/	Non sensitising.	repeated patch test	/

Additional information

The product is not classified as sensitising.

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(e) (Germ cell) mutagenicity

For components

Name	Type	Species	Time	Result	Method	Remark
Betaine	in-vivo mutagenicity	rat (male/female)	/	Negative.	/	/

(f) Carcinogenicity

For components

Name	Exposure route	Type	Species	Time	Value	Result	Method	Remark
Betaine	oral	NOAEL	rat (male/female)	/	5000 mg/kg bw	/	/	/

(g) Reproductive toxicity

For components

Name	Reproductive toxicity type	Type	Species	Time	Value	Result	Method	Remark
Betaine	Reproductive toxicity	LOAEL	rat	/	12000 mg/kg/day	/	/	oral
Betaine	Reproductive toxicity	NOAEL	rat	/	5000 mg/kg/day	/	/	oral
Betaine	Maternal toxicity	NOAEL	rat	/	2500 mg/kg/day	/	/	oral
Betaine	Teratogenicity	NOAEL	rat	/	12000 mg/kg/day	/	/	oral
Betaine	Developmental toxicity	LOAEL	rat	/	5000 mg/kg/day	/	/	oral

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Name	Reproductive toxicity type	Type	Species	Time	Value	Result	Method	Remark
Betaine	Developmental toxicity	NOAEL	rat	/	2500 mg/kg/day	/	/	oral

Summary of evaluation of the CMR properties

The product is not classified as carcinogenic, mutagenic or toxic for reproduction.

(h) STOT-single exposure

No information.

Additional information

STOT SE (single exposure): Not classified.

(i) STOT-repeated exposure

For components

Name	Exposure route	Type	Species	Time	Exposure	Organ	Value	Result	Method	Remark
Betaine	oral	NOAEL	rat (male/female)	2 years	chronic	/	5000 mg/kg/day	/	/	/

Additional information

STOT RE (repeated exposure): Not classified.

(j) Aspiration hazard

No information.

Symptoms related to the physical, chemical and toxicological characteristics

No information.

Interactive effects

No information.

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Endocrine disrupting properties

The product does not contain substances with the potential for endocrine disorders.

Other information

No information.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute (short-term) toxicity

For components

Name	Type	Value	Exposure time	Species	Organism	Method	Remark
Betaine	EC ₅₀	> 1000 mg/L	48 h	daphnia	<i>Daphnia magna</i>	OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	/
Betaine	EC ₅₀	> 1070 mg/L	72 h	algae	<i>Desmodesmus subspicatus</i>	OECD Guideline 201 (Alga, Growth Inhibition Test)	/
Betaine	LC ₅₀	> 100 mg/L	96 h	fish	<i>Oryzias latipes</i>	OECD Guideline 203 (Fish, Acute Toxicity Test)	/
Betaine	EC ₂₀	> 100 mg/L	3 h	activated sludge	Activated sludge	OECD 209 Activated Sludge, Respiration Inhibition Test	/

Chronic (long-term) toxicity

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For components

Name	Type	Value	Exposure time	Species	Organism	Method	Remark
Betaine	EC ₅₀	> 85 mg/L	21 days	Magna Daphnia	<i>Daphnia magna</i>	OECD 202	/

12.2 Persistence and degradability

Abiotic degradation, physical- and photo-chemical elimination

No information.

Biodegradation

For components

Name	Type	Rate	Time	Evaluation	Method	Remark
Betaine	aerobic	81 %	29 days	/	OECD 301 B	activated sludge

12.3 Bioaccumulative potential

Partition coefficient n-octanol/water (log value)

For components

Name	Value	Temperature °C	pH	Concentration	Method
Betaine	-0.9	/	/	/	OECD 117

Bioconcentration factor (BCF)

No information.

12.4 Mobility in soil

Known or predicted distribution to environmental compartments

No information.

Surface tension

No information.

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Adsorption/Desorption

No information.

12.5 Results of PBT and vPvB assessment

No evaluation.

12.6 Endocrine disrupting properties

The product does not contain substances with the potential for endocrine disorders.

12.7 Other adverse effects

No information.

12.8 Additional information

For product

Product is not classified as hazardous for environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / Packaging disposal

Waste chemical

Dispose the product to an authorised collector/remover of waste/company performing waste recovery.

Waste codes / waste designations according to LoW

No information.

Packaging

Deliver completely emptied containers to approved waste disposal authorities.

Waste codes / waste designations according to LoW

No information.

Waste treatment-relevant information

No information.

Sewage disposal-relevant information

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No information.

Other disposal recommendations

No information.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number or ID number

ADR/RID	IMDG	IATA	ADN
Not dangerous according to transport regulations.	Not dangerous according to transport regulations.	Not dangerous according to transport regulations.	Not dangerous according to transport regulations.

14.2 UN proper shipping name

ADR/RID	IMDG	IATA	ADN
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable

14.3 Transport hazard class(es)

ADR/RID	IMDG	IATA	ADN
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable

14.4 Packing group

ADR/RID	IMDG	IATA	ADN
Not given/not applicable	Not given/not applicable	Not given/not applicable	Not given/not applicable

14.5 Environmental hazards

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ADR/RID	IMDG	IATA	ADN
NO	NO	NO	NO

14.6 Special precautions for user

ADR/RID	IMDG	IATA	ADN
Limited quantities: Not given/not applicable	Limited quantities: Not given/not applicable		Limited quantities: Not given/not applicable

14.7 Maritime transport in bulk according to IMO instruments

ADR/RID	IMDG	IATA	ADN
/	Not given/not applicable	/	/

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (including last amendment Commission Regulation (EU) 2020/878)
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
- EH40/2005 Workplace exposure limits (Fourth Edition 2020)

Information according 2004/42/EC about limitation of emissions of volatile organic compounds (VOC-guideline)

not applicable

Ingredients according to Regulation (EC) No 648/2004 on detergents

No information.

Special instructions

No information.

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15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION

Indication of changes

No information.

Key literature references and sources for data

No information.

Abbreviations and acronyms

ATE - Acute Toxicity Estimate
ADR - Agreement concerning the International Carriage of Dangerous Goods by Road
ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CEN - European Committee for Standardisation
C&L - Classification and Labelling
CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
CAS# - Chemical Abstracts Service number
CMR - Carcinogen, Mutagen, or Reproductive Toxicant
CSA - Chemical Safety Assessment
CSR - Chemical Safety Report
DMEL - Derived Minimal Effect Level
DNEL - Derived No Effect Level
DPD - Dangerous Preparations Directive 1999/45/EC
DSD - Dangerous Substances Directive 67/548/EEC
DU - Downstream User
EC - European Community
ECHA - European Chemicals Agency
EC-Number - EINECS and ELINCS Number (see also EINECS and ELINCS)
EEA - European Economic Area (EU + Iceland, Liechtenstein and Norway)
EEC - European Economic Community
EINECS - European Inventory of Existing Commercial Substances
ELINCS - European List of notified Chemical Substances
EN - European Standard
EQS - Environmental Quality Standard
EU - European Union
Euphrac - European Phrase Catalogue
EWC - European Waste Catalogue (replaced by LoW – see below)
GES - Generic Exposure Scenario
GHS - Globally Harmonized System
IATA - International Air Transport Association
ICAO-TI - Technical Instructions for the Safe Transport of Dangerous Goods by Air
IMDG - International Maritime Dangerous Goods

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IMSBC - International Maritime Solid Bulk Cargoes
IT - Information Technology
IUCLID - International Uniform Chemical Information Database
IUPAC - International Union for Pure Applied Chemistry
JRC - Joint Research Centre
Kow - octanol-water partition coefficient
LC50 - Lethal Concentration to 50 % of a test population
LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)
LE - Legal Entity
LoW - List of Wastes (see <http://ec.europa.eu/environment/waste/framework/list.htm>)
LR - Lead Registrant
M/I - Manufacturer / Importer
MS - Member States
MSDS - Material Safety Data Sheet
OC - Operational Conditions
OECD - Organization for Economic Co-operation and Development
OEL - Occupational Exposure Limit
OJ - Official Journal
OR - Only Representative
OSHA - European Agency for Safety and Health at work
PBT - Persistent, Bioaccumulative and Toxic substance
PEC - Predicted Effect Concentration
PNEC(s) - Predicted No Effect Concentration(s)
PPE - Personal Protection Equipment
(Q)SAR - Qualitative Structure Activity Relationship
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
RID - Regulations concerning the International Carriage of Dangerous Goods by Rail
RIP - REACH Implementation Project
RMM - Risk Management Measure
SCBA - Self-Contained Breathing Apparatus
SDS - Safety data sheet
SIEF - Substance Information Exchange Forum
SME - Small and Medium sized Enterprises
STOT - Specific Target Organ Toxicity
(STOT) RE - Repeated Exposure
(STOT) SE - Single Exposure
SVHC - Substances of Very High Concern
UN - United Nations
vPvB - Very Persistent and Very Bioaccumulative

List of relevant H phrases

No information.