according to regulation (EC) 1907/2006 - REACH



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Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Betaine Powder

Chemical name Betaine

CAS- No. 107-43-7

EC- No. 203-490-6

Registration-No. 01-2119520508-42-XXXX

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

Identified uses Personal care

1.3 Supplier Naturally Balmy Ltd

8 Benson Road, Nuffield Industrial

Estate Poole, BH17 0GB T: 01202 567046

Email: sales@naturallybalmy.co.uk

1.4 Emergency telephone

number

01202 567046

Available during office hours: Mo – Fr: 8 a.m. – 5 p.m.

Please contact the regional poison center or emergency call.

Section 2: Hazards identification

2.1 Classification of the substance or mixture

According to regulation (EC) No. 1272/2008

The substance is not classified as hazardous in sense of the regulation (EC) No. 1272/2008.

2.2 Label elements

According to regulation (EC) No. 1272/2008

Not applicable.

The substance is not classified as hazardous and does not require labelling in sense of the regulation (EC) No. 1272/2008.

Hazard components for labelling

Not applicable.

according to regulation (EC) 1907/2006 - REACH



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2.3 Other hazards

Dust can combine with air to form an explosive mixture.

Results of PBT and vPvB assessment:

PBT: Betaine does not meet the criteria for classification as PBT in sense of REACH. **vPvB:** Betaine does not meet the criteria for classification as vPvB in sense of REACH.

Section 3: Composition/information on ingredients

3.1 Substances

Betaine – Purity > 99% (w/w)

CAS: 107-43-7 EC: 203-490-6

Section 4: First aid measures

4.1 Description of first aid measures

Seek medical advice.

Never give anything by mouth to an unconscious person or a person with cramps. Change contaminated, saturated clothing.

In case of inhalation of dust

Provide fresh air. Consult a doctor in case of any complaints. If unconscious, place and transport in recovery position.

In case of skin contact

After contact with skin, wash with plenty of water. Change contaminated, saturated clothing. Consult a physician if symptoms occur.

In case of eye contact

In case of contact with eyes, flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Consult a physician.

In case of ingestion

Rinse mouth with cold water and then drink plenty of water. Avoid vomiting. Consult a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

No further information available.

4.3 Indication of any immediate medical attention and special treatment needed

Depending on the condition of the patients, the doctor must assess the symptoms and the overall general condition.

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Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Use firefighting measures that suit the environment. CO_2 , foam, dry chemicals, water spray

Extinguishing media which must not be used for safety reasons

Water jet

5.2 Special hazards arising from the substance or mixture

Fire may cause evolution of CO_x, NO_x, trimethylamine Dust can combine with air to form an explosive mixture.

5.3 Advice for firefighters

Special protective equipment:

Wear a self-contained breathing apparatus and chemical protective clothing.

Collect contaminated fire extinguishing water separately. Do not allow to enter into drains or surface water.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Restricted access to contaminated areas, until cleaning work is finished.

Wear personal protection equipment.

Avoid contact with skin and eyes. Provide adequate ventilation.

Avoid formation of dust. Avoid breathing dust.

Keep ignition sources away.

Dust can combine with air to form an explosive mixture.

6.2 Environmental precautions

Do not allow to enter into surface water, groundwater or drains.

6.3 Methods and material for containment and cleaning up

Pick up mechanically.

Avoid formation of dust.

Treat the recovered material as prescribed in the section on waste disposal (section 13)

6.4 Reference to other sections

See protective measures under section 8 and disposal under section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Provide adequate ventilation. Avoid contact with skin and eyes.

Avoid generation of dust – do not breathe dust. Keep containers tightly closed.

Observe protective measures and safety instructions.

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7.2 Conditions for safe storage, including any incompatibilities

Precautions against fire and explosion

Keep ignition sources away – Do not smoke.

Requirements on storage and packaging/containers

Keep dry.

Provide adequate ventilation.

Keep containers tightly closed.

Product is hygroscopic. Protect from light.

Incompatibility with materials

No data available.

Conditions of storage

Room temperature

7.3 Specific end use(s)

Personal care.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Customers are advised to check their local regulations.

Valid for Austria & Germany: The product does not contain any relevant quantities of substances with critical values that have to be monitored at the workplace.

DNEL-value (Derived no effect level)

betaine (CAS 107-43-7)

Workers:

No hazards identified.

Consumers:

DNEL long-term, systemic, oral: 4413 mg/kg BW/d DNEL short-term, systemic, oral: 11178 mg/kg BW/d

PNEC-Werte (Predicted no effect concentration)

betaine (CAS 107-43-7)

Fresh water: 1,2 mg/l

8.2 Exposure control

General protection and hygiene measures

When handling with chemical substances observe usual precautionary measures. Keep away from foods and drinks.

When using do not eat, drink, smoke.

Wash hands after working with product.

according to regulation (EC) 1907/2006 - REACH



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Avoid contact with skin and eyes.

Avoid formation of dust.

Avoid breathing dust.

Change contaminated clothing before reuse.

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Hand protection

Suitable protective gloves are recommended. EN 374.

Nitrile rubber, butyl rubber, latex, PVC

The selection of suitable gloves depends not only on the material, but also on other quality characteristics. Breakthrough times and swelling properties of the material must be taken into consideration.

Eye protection

Protective goggles. EN 166.

Body protection

Protective clothes.

Environment exposure control measures

Do not allow to enter into surface water, groundwater or drains.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state / Appearance crystalline Colour white

Odour Faint molasses odour
Odour threshold No information available.

pH value n. a.

Melting point/freezing point No information available.

Initial boiling point/range No information available.

Flash point n. a.

Flammability (solid, gas)

Evaporation rate

Upper explosive limits

No information available.

No information available.

No information available.

No information available.

according to regulation (EC) 1907/2006 - REACH



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Vapour pressure (50 °C) n. a.

Density No information available.

Solubility in water (20 °C) soluble

Partition coefficient: n-

ocanol/water

No information available.

Ignition temperature No information available.

Decomposition temperature No information available.

Viscosity n. a.

Not explosive.

Explosive properties Fine dust can combine with air to form an explosive

mixtures.

Oxidising properties No information available.

9.2 Other information

None.

Section 10: Stability and reactivity

10.1 Reactivity

No hazardous reactions known if stored and used as prescribed.

10.2 Chemical stability

Product is hygroscopic.

10.3 Possibility of hazardous reactions

Dust explosions hazard.

10.4 Conditions to avoid

Heat, ignition sources Humidity

10.5 Incompatible materials

Oxidizing agetns, alkalis, concentrated

10.6 Hazardous decomposition products

Risk of development of trimethylamine in hot, strongly alkaline solution.

Section 11: Toxicological information

11.1 Information on toxicological effects

■ LD₅₀ values of single components relevant for classification

Betaine:

LD₅₀ oral (rat): 11179 mg/kg (Source: European Chemicals Agency <u>www.echa.eu</u>)

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Acute toxicity

Based on available data classification criteria are not fulfilled.

Skin corrosion/irritation

Based on available data classification criteria are not fulfilled.

Serious eye damage/irritation

Based on available data classification criteria are not fulfilled.

Skin/Respiratory sensitization

Based on available data classification criteria are not fulfilled.

Germ cell mutagenicity

Based on available data classification criteria are not fulfilled.

Cancerogenicity

Based on available data classification criteria are not fulfilled.

Reproductive toxicity

Based on available data classification criteria are not fulfilled.

Specific target organ toxicity – single exposure

Based on available data classification criteria are not fulfilled.

Specific target organ toxicity – repeated exposure

Based on available data classification criteria are not fulfilled.

Aspiration hazard

Based on available data classification criteria are not fulfilled.

Section 12: Ecological information

12.1 Toxicity

Aquatic Toxicity of ingredients

Betaine:

Daphnia: EC50 (48 h): 4335 mg/l - Daphnia magna

Algae: EC50 (72 h): 1199 mg/l - Desmodesmus subspicatus (Source: European Chemicals Agency www.echa.eu)

12.2 Persistence and degradability

Readily biodegradable (88% (28 d))

12.3 Bioaccumulative potential

No bioaccumulation potential

12.4 Mobility in soil

No data available.

according to regulation (EC) 1907/2006 - REACH



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12.5 Results of PBT and vPvB assessment

Betaine does not meet the criteria for classification as PBT or vPvB in sense of REACH.

12.6 Other adverse effects

Do not allow to enter into surface water, groundwater or drains.

Section 13: Disposal considerations

13.1 Waste treatment methods

Any disposal practice must be in compliance with all local and national laws and regulations. Customers are advised to check their local legislation governing the disposal of waste materials.

If this preparation becomes a waste, the final user must define and assign the appropriate European Waste Catalogue code. Use only authorized contractors.

Do not allow to enter into surface water or drains.

• European waste catalogue (complies with UVEK valid for CH)

16 03 06 – organic wastes other than those mentioned in 16 03 05

Notes: The European Waste Catalogue (EWC) classifies waste materials and categorises them according to what they are and how they were produced. This may cause other classifications. The final decision belongs to the last user.

Uncleaned packaging

Recommendation: after complete emptying and cleaning, send to an authorized contractor to be reconditioned or recycled.

Section 14: Transport information

No dangerous good in sense of the transport regulation for land, air and sea.

14.1 UN number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

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14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

Section 15: Regulatory information

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

Safety Data Sheet according to REACH – Regulation (EC) No. 1907/2006. The mixture was classified on the basis of the calculation procedure of the CLP- Regulation (EC) 1272/2008 (Annex 1)

National Regulations:

Austria:

VbF – Regulation on combustible liquids (BGBI 1991/240)
 Not applicable

Germany:

Water hazard class acc. to AwSV of 18.04.2017 WGK 1 (slightly water-endangering)

15.2 Chemical safety assessment

Not available.

Section 16: Other information

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. All materials may present unknown hazards and should be used with caution and only for identified uses as prescribed in section 1.

The classification is based on manufacturer's data and additional information of hazardous substances database and the European Chemicals Agency.

• **Version** Version 1.0

Translation of German version 1.0

Abbreviations n. a. not applicable

PBT persistent, bioaccumulative, toxic vPvB very persistent, very bioaccumulative