

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Creapure® pH 10

Version 3.3 / REG_EU
Revision Date: 05.03.2020

Specification: 164329
Material no.:

Date of first issue: 01.07.2008
Print Date: 06.03.2020

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

1.1 Product identifier

Trade name : Creapure® pH 10
Registration number : if available listed in Chapter. 3

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

Use of the Sub-
stance/Mixture : dietary supplement

1.3 Details of the supplier of the safety data sheet

Company : AlzChem Trostberg GmbH
Dr.-Albert-Frank-Str. 32
83308 Trostberg, Germany
Telephone : +49 8621 86-3351
E-mail address of person
responsible for the SDS : alz-pst@alzchem.com

1.4 Emergency telephone number

Emergency telephone num-
ber : +49 8621 86-2776
AlzChem Trostberg GmbH, Fire Brigade

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
No labelling required

2.3 Other hazards

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out
Dusts can form explosive mixtures with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---------------|---|----------------|--------------------------|
| | | | |

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| | | | |
|--------------------------|---|--------------------|------|
| Creatine Monohydrate | 6020-87-7 200-306-6 01-2119931462-43-0000 | not classified | > 94 |
| Sodium hydrogencarbonate | 144-55-8 205-633-8 01-2119457606-32-XXXX | not classified | <= 3 |
| sodium carbonate | 497-19-8 207-838-8 01-2119485498-19-XXXX | Eye Irrit. 2; H319 | <= 3 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Seek medical advice in case of symptoms caused by eye or skin contact, inhalation or swallowing.
- If inhaled : Move to fresh air.
- In case of skin contact : Wash off with plenty of water and soap.
- In case of eye contact : Rinse thoroughly with plenty of water, also under the eyelids.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray, foam, CO₂, dry powder.
- Unsuitable extinguishing media : high volume water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon oxides
Ammonia

5.3 Advice for firefighters

Special protective equipment for firefighters : In the case of fire, wear respiratory protective equipment independent of surrounding air and chemical protective suit.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Wear personal protective equipment; see section 8.
Ensure adequate ventilation.

6.2 Environmental precautions

Environmental precautions : Product or extinguishing water with product must not be allowed to enter soil, sewers or natural bodies of water.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up and shovel into suitable containers for disposal.
Avoid dust formation.

6.4 Reference to other sections

|| For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice.
Avoid dust formation.

Advice on protection against fire and explosion : Avoid formation of air-dust mixtures and keep away from ignition sources (sparks, flames, open flame) to prevent dust explosions.

Hygiene measures : Do not breathe dust. Take off clothing and shoes contaminated with product. Clean before reuse. Do not eat, drink or smoke while working. Wash hands, and/or face before breaks and when workday is finished. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed. Store in a cool and dry place.

Storage class (TRGS 510) : 13, Non Combustible Solids

Storage period : 36 Months

Packaging material : Suitable material: polyethylene, Polypropylene

7.3 Specific end use(s)

|| Specific use(s) : We are unaware of any specific end uses which go beyond the data reported in Section 1.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

None known

8.2 Exposure controls

Personal protective equipment

Eye protection : Safety glasses

Hand protection

Material : Nitrile rubber, Recommendation: Camatril 730
Break through time : > 480 min
Glove thickness : 0,4 mm
Directive : DIN EN 374
Manufacturer : Kächele-Cama Latex GmbH (KCL), Germany

Material : Nitrile rubber, Recommendation: Dermatril 740
Break through time : > 480 min
Glove thickness : 0,11 mm
Directive : DIN EN 374
Manufacturer : Kächele-Cama Latex GmbH (KCL), Germany

Skin and body protection : Long sleeved clothing

Respiratory protection : Use suitable respiratory protection in the presence of dust.
Dust protection mask in accordance with EN 149 FFP2

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid

Colour : colourless

Odour : odourless

pH : 10,0 (20 °C)
(saturated solution)

Melting point/range : 285 °C
Decomposition: yes

Flash point : Not applicable

Burning number : BZ 1 - does not ignite.

Upper explosion limit / upper flammability limit : no data available

Lower explosion limit / Lower : no data available

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flammability limit

Solubility(ies)

Water solubility : 15,2 g/l saturated solution (20 °C)

Partition coefficient: n-
octanol/water

: log Pow: < -2 (20 °C)
Method: EEC method 92/69/EEC, A 8

Auto-ignition temperature : no data available

Decomposition temperature : no data available

9.2 Other information

no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : No hazardous reactions are known if properly handled and stored.

10.4 Conditions to avoid

Conditions to avoid : Avoid dust formation.
temperatures > 250 °C

10.5 Incompatible materials

Materials to avoid : Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.
see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Components:

Creatine Monohydrate:

Acute oral toxicity : LD50 (Rat): > 2000 mg/kg
Method: OECD TG 423
Assessment: Based on available data, the classification crite-

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ria are not met.
Remarks: Own test result.

Acute dermal toxicity : LD50 (rat, male/female): > 2000 mg/kg
Method: OECD Test Guideline 402
Assessment: Based on available data, the classification criteria are not met.
Remarks: Own test result.

Sodium hydrogencarbonate:

Acute oral toxicity : (rat): > 4000 mg/kg
Remarks: literature

Acute inhalation toxicity : (rat): > 4,74 mg/l

sodium carbonate:

Acute oral toxicity : LD50 (rat): 2800 mg/kg
Remarks: literature

Acute inhalation toxicity : (rat): 2,3 mg/l
Exposure time: 2 h
Remarks: literature

Acute dermal toxicity : LD50 (Rabbit): > 2000 mg/kg
Remarks: literature

Skin corrosion/irritation

Components:

Creatine Monohydrate:

Species : Rabbit
Method : Directive 67/548/EEC, Annex V, B.4.
Result : No skin irritation
Remarks : Own test result.

Sodium hydrogencarbonate:

Species : Rabbit
Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

sodium carbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

Serious eye damage/eye irritation

Components:

Creatine Monohydrate:

Species : Rabbit

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Method : Guideline 92/69/EEC B.5
Result : No eye irritation
Remarks : Own test result.

Sodium hydrogencarbonate:

Species : Rabbit
Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

sodium carbonate:

Species : Rabbit
Assessment : Causes serious eye irritation.
Remarks : literature

Respiratory or skin sensitisation

Components:

Creatine Monohydrate:

Test Type : Magnusson & Kligman
Species : guinea pig
Method : Directive 96/54/EC, B.6
Result : not sensitizing
Remarks : Own test result.

Sodium hydrogencarbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

sodium carbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

Germ cell mutagenicity

Components:

Creatine Monohydrate:

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test, Own study

Sodium hydrogencarbonate:

Germ cell mutagenicity- Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

sodium carbonate:

Germ cell mutagenicity- Assessment : In vitro tests did not show mutagenic effects
Remarks: Literature, IUCLID

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Carcinogenicity

Components:

Creatine Monohydrate:

Carcinogenicity - Assessment : No evidence that cancer may be caused.

Sodium hydrogencarbonate:

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

sodium carbonate:

Carcinogenicity - Assessment : no data available
Remarks: Literature, IUCLID

Reproductive toxicity

Components:

Creatine Monohydrate:

Reproductive toxicity - Assessment : No indications of effects of reproductive / developmental toxicity.

Sodium hydrogencarbonate:

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

sodium carbonate:

Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.
Remarks: Literature, IUCLID

STOT - single exposure

Components:

Creatine Monohydrate:

Remarks : no data available

Sodium hydrogencarbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

sodium carbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

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STOT - repeated exposure

Components:

Creatine Monohydrate:

Remarks : no data available

Sodium hydrogencarbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

sodium carbonate:

Assessment : Based on available data, the classification criteria are not met.
Remarks : literature

Repeated dose toxicity

Components:

Creatine Monohydrate:

Species : Rat
NOAEL : 2000 mg/kg
Exposure time : 28-day
Assessment : Based on available data, the classification criteria are not met.

Aspiration toxicity

Components:

Creatine Monohydrate:

No data available

Experience with human exposure

Components:

Creatine Monohydrate:

General Information : Creatine is found in muscular tissue and is produced by the liver and kidneys. No health effects have been reported in humans.

Further information

Product:

Remarks : No tests were performed with this mixture.
No additional toxicological data are available.

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SECTION 12: Ecological information

12.1 Toxicity

Components:

Creatine Monohydrate:

Toxicity to fish : LC50 (Brachydanio rerio): > 100 mg/l
Exposure time: 96 h
Method: Directive 92/69/EEC, C.2
Remarks: Own test result.

NOEC : > 100 mg/l
Method: Directive 92/69/EEC, C.2
Remarks: Own test result.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna): > 1000 mg/l
Exposure time: 48 h
Method: Directive 92/69/EEC C.2
Remarks: Own test result.

Sodium hydrogencarbonate:

Toxicity to fish : NOEC (Oncorhynchus mykiss): 2300 mg/l
Exposure time: 96 h
Remarks: literature

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 4100 mg/l
Exposure time: 48 h
Remarks: literature

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 576 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: literature

sodium carbonate:

Toxicity to fish : (Lepomis macrochirus): 300 mg/l
Exposure time: 96 h
Remarks: literature

Toxicity to daphnia and other aquatic invertebrates : (Daphnia magna (Water flea)): 200 - 227 mg/l
Exposure time: 48 h
Remarks: literature

12.2 Persistence and degradability

Product:

Biodegradability : Remarks: Readily biodegradable.

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Components:

Creatine Monohydrate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 96,6 %
Exposure time: 28 d
Remarks: Own study

Sodium hydrogencarbonate:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

sodium carbonate:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

12.3 Bioaccumulative potential

Components:

Creatine Monohydrate:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: < -2 (20 °C)

Sodium hydrogencarbonate:

Bioaccumulation : Remarks: Not expected due to rapid hydrolysis.

sodium carbonate:

Bioaccumulation : Remarks: Not expected due to rapid hydrolysis.

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

12.6 Other adverse effects

Product:

Additional ecological information : No further ecotoxicological data are available.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Product : Must be brought to an adequate waste treatment facility, in conformity with applicable waste disposal regulations.
- Contaminated packaging : Packaging, that can not be reused after cleaning must be disposed or recycled in accordance with all federal, national and local regulations.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Remarks : Not classified as dangerous in the meaning of transport regulations.

ADR
Remarks : Not regulated as a dangerous good
: Not classified as dangerous in the meaning of transport regulations.

RID
Remarks : Not regulated as a dangerous good
: Not classified as dangerous in the meaning of transport regulations.

IMDG
Remarks : Not regulated as a dangerous good
: Not classified as dangerous in the meaning of transport regulations.

IATA (Cargo)
Remarks : Not regulated as a dangerous good
: Not classified as dangerous in the meaning of transport regulations.

IATA_P (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

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

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

15.2 Chemical safety assessment

No substance safety assessment is required for this product.

SECTION 16: Other information

Full text of H-Statements

H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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Further information

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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