

SECTION 1. Identification of the substance/mixture and of the company/enterprise**1.1. Product identifier**

Product name : CATALASI

Product code: refer to sales department

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

Clarifying Agents

Sectors of use:

Manufacture of food products[SU4]

Product category:

Process aid for enological use

Not recommended uses

Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

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SECTION 2. Hazards identification**2.1. Classification of the substance or mixture**

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Pictograms:

GHS05, GHS07

Hazard Class and Category Code(s):

Skin Irrit. 2, Eye Dam. 1

Hazard statement Code(s):

H315 - Causes skin irritation.

H318 - Causes serious eye damage.

If brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.

If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2. Label elements

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

Pictogram, Signal Word Code(s):

GHS05 - Danger

Hazard statement Code(s):

H315 - Causes skin irritation.

H318 - Causes serious eye damage.



Supplemental Hazard statement Code(s):

EUH031 - Contact with acids liberates toxic gas (SO₂)

Precautionary statements:

Prevention

P280 - Wear protective gloves and eye/face protection.

Response

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a POISON CENTER or a doctor.

Contains:

Potassium metabisulfite

Ingredients: activated bentonite, potassium caseinate(a), potassium metabisulfite(b) 10,84% (10 g/hL increase the total SO₂ by 6,24 mg/L), swine soluble gelatin, ascorbic acid 3,5%.

Food use, oenological use. Not intended for the final consumer. In accordance with current regulations on the specific matter. Only for industrial use.

(a)= milk and products thereof

(<Milk and products thereof>in compliance with Regulation (EU) No 1169/2011 - Annex II and subsequent additions and modifications)

(b)=sulfites

(<Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂>in compliance with Regulation (EU) No 1169/2011 - Annex II and subsequent additions and modifications)

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent implies the obligation of the "risk assessment" by the employer according to the provisions of Legislative Decree April 9, 2008 no. 81 and subsequent amendments. If the results of the risk assessment demonstrate that, in relation to the type, quantity, methods and frequency of exposure, there is only a low risk for the safety and irrelevant for the health of the workers and that the measures referred to in paragraph 1 of Legislative Decree April 9, 2008 no. 81 are sufficient to reduce the risk, the provisions of articles 225, 226, 229, 230 of the same Legislative Decree do not apply

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrelevant

3.2 Mixtures

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
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Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Bentonite substance for which there are Community workplace exposure limits	>= 25 < 50%			1302-78-9	215-108-5	
Potassium metabisulfite	>= 10 < 25%	EUH031; Skin Irrit. 2, H315; Eye Dam. 1, H318		16731-55-8	240-795-3	exempt, art 2 par. 5

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation:

Ventilate the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

Direct contact with skin (of the pure product):

Take off immediately contaminated clothing.

Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product):

Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately

Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion:

Not dangerous. In case of malaise consult a doctor.

4.2. Most important symptoms and effects, both acute and delayed

Contact with eyes causes very severe irritation, including redness and tear.

4.3. Indication of any immediate medical attention and special treatment needed

If skin irritation occurs: Get medical advice/attention.

Immediately call a POISON CENTER or a doctor.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Suggested extinguishing media:

Water spray, CO₂, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing media to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective clothing.

The water spray can be used to protect the people involved in the extinction.

You may also use self-contained breathing apparatus, especially when working in confined and poorly ventilated areas.

Keep containers cool with water spray

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Leave the area surrounding the spill or release. Do not smoke

Wear mask, gloves and protective clothing.

6.1.2 For emergency responders:

Eliminate all unguarded flames and possible sources of ignition. No smoking.

Provide a sufficient ventilation.

Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spills

Inform the competent authorities.

Dispose of the waste material in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 Containment:

Rapidly recover the product, wear a mask and protective clothing (for specifications refer to section 8.2. SDS)

Recover the product for reuse, if possible, or for elimination.

6.3.2 Cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Wear protective gloves and eye/face protection.

At work do not eat or drink.

See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabelled containers.
Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in a cool and dry place, away from heat sources and direct exposure to sunlight.

7.3. Specific end use(s)

Manufacture of food products:
Handle with care.
Store in a clean, dry, ventilated area away from heat and direct sunlight.
Keep container tightly closed.

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

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Related to contained substances:

Bentonite:

INHALABLE, DUST

Limit value – Eight hours

(ppm)/(mg/m³)

Austria: x/10

Belgium: x/10

Denmark: x/10

France: x/10

Germany (AGS): x/10(1)(2)(3)

Germany (DFG): x/4

Hungary: x/10

Ireland: x/10

Singapore: x/10

Spain: x/10

Sweden: x/10

Switzerland: x/10

USA – OSHA: x/15

RESPIRABLE DUST

Limit value – Eight hours

Austria: x/5

Belgium: x/3

France: x/5 respirable aerosol

Germany (AGS): x/1,25 (1)(2)(3)(4)(5)

Germany (DFG): x/1,5

Hungary: x/6

Ireland: x/4

Spain: x/3

Sweden: x/5

Switzerland: x/3

USA – OSHA: x/5

Remarks

INHALABLE DUST

Germany (AGS): (1) Insoluble particulates (2) not applicable for ultra – fine dusts and dusts with specific toxicity (3) the limit value is a general upper limit for technical measures, as long as no specific regulations for toxic or carcinogenic substance are available

RESPIRABLE DUST

France: Bold type: Restrictive statutory limit values

Germany (AGS): (1) Insoluble particulates (2) not applicable for ultra – fine dusts and dusts with specific toxicity (3) the limit value is a general upper limit for technical measures, as long as no specific regulations for toxic or carcinogenic substances are available (4) the limit value was derived for dusts with an average density of 2.5 mg/mg₃ (5) at work areas where all technical and further measures are state of the art but the LV is still not adhered, the old LV can be applied for a transitional period until 31st December 2018 (8 h – LV: 3.0 mg/m₃, 15 minutes average value: 6.0 mg/m₃)
Germany (DFG): Insoluble particulate

The ACGIH believes that even biologically inert, insoluble or poorly soluble particles can have adverse effects and, therefore, recommends that the concentration of such dust in the air be kept below: 3mg/m₃, for respirable particles; 10mg/m₃, for inhalable particles, at which time a TLV will be established for the particular substance.

Potassium metabisulfite:

Sulphur dioxide (7446-09-5) EU

8h*TWA= 1.3 mg/m₃ - 0.5 ppm

Short term**= 2.7 mg/m₃ - 1 ppm

* Measured or calculated in relation to a reference period of eight hours, as a time weighted average

** Short-term exposure level. Limit value above which exposure should not occur and which refers to a 15-minute period unless otherwise stated.

ACGIH - STEL: 0.25 ppm - Notes: (SO₂)

- Substance: Potassium metabisulfite

DNEL

Systemic effects Long term Workers inhalation = 263 (mg/m₃)

Systemic effects Long term Consumers inhalation = 78 (mg/m₃)

Systemic effects Long term Consumers oral = 10 (mg/kg bw/day)

PNEC

Sweet water = 1,17 (mg/l)

Sea water = 0,12 (mg/l)

STP = 88,1 (mg/l)

8.2. Exposure controls



Appropriate engineering controls:

Manufacture of food products:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)

8.2.2 Individual protection measures:

(a) Eye / face protection

When handling the pure product use safety glasses (EN 166).

(b) Skin protection

(i) Hand protection

When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

(ii) Other

Wear normal work clothing.

(c) Respiratory protection

During manual operations in case of insufficient ventilation, use a mask (UNI EN 149) with FFP dust filter

commensurate with the environmental hygiene conditions, unless otherwise specified by the employer.

(d) Thermal hazards

No hazard to report

Environmental exposure controls:

Use according to good working practices and avoid to disperse the product into the environment.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Physical state	Fine powder	
Colour	beige	
Odour	not determined as it is considered not relevant for the characterization of the product	
Odour threshold	not determined as considered not relevant for the characterization of the product	
Melting point/freezing point	not determined as it is considered not relevant for the characterization of the product	
Boiling point or initial boiling point and boiling range	not determined as considered not relevant for the characterization of the product	
Flammability	not determined as considered not relevant for the characterization of the product	
Lower and upper explosion limit	not determined as considered not relevant for the characterization of the product	
Flash point	not determined as considered not relevant for the characterization of the product	ASTM D92
Auto-ignition temperature	not determined as considered not relevant for the characterization of the product	
Decomposition temperature	not determined as considered not relevant for the characterization of the product	
pH	5.0 ± 0.5 (20 ° C; sol. 5%)	
Kinematic viscosity	not determined as considered not relevant for the characterization of the product	
Solubility	in water	
Water solubility	miscible in all proportions	
Partition coefficient n-octanol/water (log value)	not determined as considered not relevant for the characterization of the product	
Vapour pressure	not determined as considered not relevant for the characterization of the product	
Density and/or relative density	0,65 ± 0,05 (20°C)	
Relative vapour density	not determined as considered not relevant for the characterization of the product	
Particle characteristics	not determined as considered not relevant for the characterization of the product	

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Irrelevant

9.2.2 Other safety characteristics

Irrelevant

SECTION 10. Stability and reactivity**10.1. Reactivity**

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Related to contained substances:
Bentonite:
None under normal conditions.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions

10.4. Conditions to avoid

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Related to contained substances:
Bentonite:
None under normal conditions.

10.5. Incompatible materials

Acids and oxidizing agents

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11. Toxicological information

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

(a) acute toxicity: Bentonite: Ingestion - LD50 rat (mg / kg / 24h bw): na

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw): na

Inhalation - LD50 rat (mg / l / 4h): na

Potassium metabisulfite: Based on available data, the classification criteria are not met

Ingestion - LD50 rat (mg/kg/24h bw): >1540 - OECD 401

Skin contact - LC50 rat / rabbit (mg/kg/24h bw): >2000 The product has not been tested. The declaration was derived from substances/products of similar structure or composition. - OECD 402

Inhalation - LD50 rat (mg/l/4h): >5.5 The product has not been tested. The declaration was derived from substances/products of similar structure or composition. - OECD 403

(b) skin corrosion/irritation: If brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.

Potassium metabisulfite: Based on available data, the classification criteria are not met.

Corrosive to skin: Negative - In vitro - OECD 435

Potassium metabisulfite: The product is classified: Skin Irrit. 2

Skin Irritant rabbit: Positive - OECD 404 Skin Irritant: Positive - In vitro - OECD 439

(c) serious eye damage/irritation: If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.

Potassium metabisulfite: The product is classified: Eye Dam. 1

Corrosive to eyes rabbit: Positive - OECD 405

Potassium metabisulfite: The product is classified: Eye Dam. 1

Corrosive to eyes rabbit: Positive - OECD 405

(d) respiratory or skin sensitisation: Potassium metabisulfite: Based on available data, the classification criteria are not met.

Skin sensitisation: Negative - OECD 429

(e) germ cell mutagenicity: Potassium metabisulfite: Based on available data, the classification criteria are not met.

(f) carcinogenicity: Potassium metabisulfite: Based on available data, the classification criteria are not met.

(g) reproductive toxicity: Potassium metabisulfite: Based on available data, the classification criteria are not met.

(h) specific target organ toxicity (STOT) single exposure: Potassium metabisulfite: Based on available data, the classification criteria are not met.

(i) specific target organ toxicity (STOT) repeated exposure: Potassium metabisulfite: Based on available data, the classification criteria are not met.

(j) aspiration hazard: Potassium metabisulfite: Based on available data, the classification criteria are not met.

11.2. Information on other hazards

No data available.

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

SECTION 12. Ecological information**12.1. Toxicity**

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Related to contained substances:

Bentonite:

Acute toxicity - fish LC50 (mg / l / 96h): na
Acute toxicity - crustaceans EC50 (mg / l / 48h): na
Acute algae toxicity ErC50 (mg / l / 72-96h): na
Chronic toxicity - fish NOEC (mg / l): nd
Chronic toxicity - NOEC crustaceans (mg / l): nd
Chronic toxicity NOEC algae (mg / l): nd

Potassium metabisulfite:

Acute toxicity - fish LC50 (mg/l/96h): 149.5 - *O. mykiss*
Acute toxicity - crustaceans EC50 (mg/l/48h): 74.9 - *Daphnia cladocera* *Daphnia magna* Acute toxicity algae ErC50 (mg/l/72-96h): 36.8 - *Algae Scenedesmus subspicatus*
Chronic toxicity - fish NOEC (mg/l): 50 - *Danio rerio*
Chronic toxicity - crustaceans NOEC (mg/l): 8.41 - *Daphnia cladocera* *Daphnia magna* Chronic toxicity algae NOEC (mg/l): 28 - *Scenedesmus subspicatus*

Acute toxicity M-factor = 1
Chronic toxicity M-factor = 1

Use according to good working practices and avoid to disperse the product into the environment.

12.2. Persistence and degradability

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Related to contained substances:
Bentonite:
Not available

Potassium metabisulfite:

The substance is an inorganic compound, and therefore cannot be subject to biodegradation

12.3. Bioaccumulative potential

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Related to contained substances:
Bentonite:
Not available

Potassium metabisulfite:

No bioaccumulation is expected

12.4. Mobility in soil

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Related to contained substances:
Bentonite:
Not available

Potassium metabisulfite:

No adsorption into the solid phase of the soil is expected.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects

SECTION 13. Disposal considerations**13.1. Waste treatment methods**

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.
Recover if possible. Operate according to local or national regulations

SECTION 14. Transport information**14.1. UN number or ID number**

Not included in the field of application of regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Maritime transport in bulk according to IMO instruments

Transport in bulk is not foreseen

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Restrictions relating to the product or the substances contained (Annex XVII EC Reg. 1907/2006): not applicable
Substances in Candidate list (art. 59 EC Reg. 1907/2006): the product does not contain SVHC in percentage = a 0.1 %.

Regulation (EU) 1169/2011: see point 2.2

Regulation (EU) 1308/2013: see point 2.2

Regulation (EC) 1333/2008: see point 2.2

REGULATION (EU) No 1357/2014 - waste:
HP4 - Irritant — skin irritation and eye damage

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION 16. Other information**16.1. Other information**

Points modified compared to previous release: 2.1. Classification of the substance or mixture, 2.2. Label elements, 3.2 Mixtures, 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Description of hazard statements set out in paragraph 3

H315 = Causes skin irritation.

H318 = Causes serious eye damage.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008

H315 - Causes skin irritation. Classification procedure: Calculation method

H318 - Causes serious eye damage. Classification procedure: Calculation method

Main normative references:

Reg. (CE) n. 1907 del 18/12/06 REACH (Registration, Evaluation and Authorisation of CHemicals) et seq.

Reg. (CE) 1272/2008 CLP (Classification Labelling and Packaging) et seq.

Directive 2012/18/EU (on the control of major-accident hazards involving dangerous substances) et seq.

Training required: This document must be submitted to the employer to determine the possible need for appropriate training for workers to ensure protection of human health and the environment.

n.a.: not applicable

n.d.: not available

ADR: Accord européen relative au transport International des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute Toxicity Estimati

BFC: BioconCentration Factor

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstract Service number
CAP: Centre AntiPoison
CE/EC number EINECS (European Inventory of existing Commercial Substances) e ELINCS (European List of notified Chemical Substances)
CL50/LC50: Lethal Concentration 50
DL50/LD50: Lethal Dose 50
COD: Chemical Oxygen Demand
DNEL: Derived No Effect Level
EC50: half maximal Effective Concentration
ERC: Environment Release Classes
EU/UE: European Union
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
IMDG: International Maritime Dangerous Goods code
Kow: Octanol water partition coefficient
NOEC: No Observed Effect Concentration
OEL: Occupational Exposure Limit
PBT: Persistent Bioaccumulative and Toxic
PC: Product Categories
PNEC: Predicted No Effect Concentration
PROC: Process Categories
RID: Règlement concernant le transport International ferroviaire des marchandises dangereuses (Regulations concerning International rail transport of dangerous goods)
STOT: Target Organ Systemic Toxicity
STOT (RE): Repeated Exposure
STOT (SE): Single Exposure
STP: Sewage Treatment Plants
SU: Sector of Use
SVCH: Substance of Very High Concern
TLV: Threshold Limit Value
vPvB: Very Persistent Very Bioaccumulative

References and Sources:

- ECHA Registered Substances:
<https://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>
- SDS raw material supplier
- GESTIS International Limit Value: <http://limitvalue.ifa.dguv.de>

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*** this tab annuls and replaces any previous edition. (IIXX)

Changes to the previous edition: variation on classification.
