

SECTION 1. Identification of the substance/mixture and of the company/enterprise

1.1. Product identifier

Product name : CLAROUGE
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:

None

Hazard Class and Category Code(s):

Non hazardous

Hazard statement Code(s):

Non hazardous

2.2. Label elements

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

Pictogram, Signal Word Code(s):

None

Hazard statement Code(s):

Non hazardous

Supplemental Hazard statement Code(s):

EUH210 - Safety data sheet available on request.

Precautionary statements:

None in particular.

Contains:

Information concerning the components: egg albumin - (<Eggs and products thereof>in compliance with Regulation (EU) No 1169/2011 - Annex II and subsequent additions and modifications), activated bentonite, silica gel, atomized soluble gelatin (swine).

Only for professional use. Food use, oenological use. In accordance with current regulations on the specific matter.

2.3. Other hazards

The substance / mixture does NOT contain substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

No dangerous substance to report.

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
ACTIVED BENTONITE substance for which there are Community workplace exposure limits	$\geq 30 < 50\%$			1302-78-9	215-108-5	
SILICA GEL substance for which there are Community workplace exposure limits	$\geq 1 < 5\%$			112926-00-8	231-545-4	01-2119379 499-16-XXX X

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).:

Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product).:

Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion:

Not hazardous. It's possible to give activated charcoal in water or medicinal mineral vaseline oil.

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

No data available.

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

No data available.

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 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:

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

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:
ACTIVED 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 particulates

SILICA GEL:

UK EH40: Amorphous silica completely inhalable powder: WEL 6 mg / m³ 8h TWA. Respirable: WEL 2.4 mg / m³ 8h TWA.

Particles (insoluble) not otherwise classified (PNOC), inhalable fraction: 10 mg / m³ 8h TWA

Particles (insoluble) not differently classified (PNOC), respirable fraction: 3 mg / m³ 8h TWA

- Substance: SILICA GEL

DNEL

Local effects Long term Workers inhalation = 4

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

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(b) Skin protection

(i) Hand protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(ii) Other

Wear normal work clothing.

(c) Respiratory protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations

(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
Appearance	Fine cream-white powder	
Odour	not determined as it is considered not relevant for the product characterization	
Odour threshold	not determined as it is considered not relevant for the product characterization	
pH	7,5 ± 0,5 (20°C; sol.5%)	
Melting point/freezing point	not determined as it is considered not relevant for the product characterization	
Initial boiling point and boiling range	not determined as it is considered not relevant for the product characterization	
Flash point	not determined as it is considered not relevant for the product characterization	ASTM D92
Evaporation rate	not determined as it is considered not relevant for the product characterization	
Flammability (solid, gas)	not determined as it is considered not relevant for the product characterization	
Upper/lower flammability or explosive limits	not determined as it is considered not relevant for the product characterization	
Vapour pressure	not determined as it is considered not relevant for the product characterization	
Vapour density	not determined as it is considered not relevant for the product characterization	
Relative density	0,50 ± 0,10 (20°C)	
Solubility	not determined as it is considered not relevant for the product characterization	
Water solubility	not determined as it is considered not relevant for the product characterization	
Partition coefficient: n-octanol/water	not determined as it is considered not relevant for the product characterization	
Auto-ignition temperature	not determined as it is considered not relevant for the product characterization	
Decomposition temperature	not determined as it is considered not relevant for the product characterization	
Viscosity	not determined as it is considered not relevant for the product characterization	
Explosive properties	not determined as it is considered not relevant for the product characterization	
Oxidising properties	not determined as it is considered not relevant for the product characterization	

Physical and chemical properties	Value	Determination method
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9.2. Other information

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

No risk of reactivity

10.2. Chemical stability

No dangerous reaction if manipulated and stored according to regulations.

10.3. Possibility of hazardous reactions

High humidity (it should not cause dangerous reactions, but it could cause microbiological changes in the product).
Hygroscopic product, store in dry conditions.

10.4. Conditions to avoid

Avoid exposure to heat

10.5. Incompatible materials

None in particular

10.6. Hazardous decomposition products

None under normal storage conditions. Decomposition temperature: stable under normal storage conditions.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: ACTIVED BENTONITE: Ingestion-rat LD50 (mg/kg/bw 24h): > 2000

Skin contact-LC50 rat/coniglio (mg/kg/bw 24h): n.a.

Inhalation-rat LD50 (mg/l/4h): > 5.27
SILICA GEL: Ingestion-rat LD50 (mg/kg/bw24h): > 3100

Skin contact-LC50 rat/coniglio (mg/kg/bw 24h): > 5000

Inhalation-rat LD50 (mg/l/4h): n.a.

(b) skin corrosion/irritation: ACTIVATED BENTONITE: Non-corrosive

SILICA GEL: Non-corrosive

ACTIVATED BENTONITE: Non-irritating

SILICA GEL: Non-irritating

(c) serious eye damage/irritation: ACTIVATED BENTONITE: Non-corrosive

SILICA GEL: Non-corrosive

ACTIVATED BENTONITE: Slightly irritating

SILICA GEL: Non-irritating

(d) respiratory or skin sensitization: ACTIVATED BENTONITE: Non-sensitizing

SILICA GEL: Non-sensitizing

(e) germ cell mutagenicity: ACTIVATED BENTONITE: Non-mutagenic

SILICA GEL: Non-mutagenic

(f) carcinogenicity: ACTIVATED BENTONITE: Non-carcinogenic

SILICA GEL: Not carcinogenic

(g) reproductive toxicity: ACTIVATED BENTONITE: Non-toxic for reproduction

SILICA GEL: Non-toxic for reproduction

(h) specific target organ toxicity (STOT) single exposure: ACTIVATED BENTONITE: Non-toxic

SILICA GEL: Not available

(i) specific target organ toxicity (STOT) repeated exposure: ACTIVATED BENTONITE: Non-toxic

SILICA GEL: Not available

(j) aspiration hazard: ACTIVATED BENTONITE: There are no dangers for aspiration

SILICA GEL: Not available

Health Hazards:

Eye contact: Accidental contact of product with eyes may cause irritation.

Skin Contact: Product is not an irritant. Prolonged or repeated contact may defeat and irritate the skin and cause dermatitis in some cases.

Ingestion: The ingested product may cause irritation of the mucous membranes of the throat and digestive system leading to digestive symptoms and abnormal bowel disorders.

Inhalation: Prolonged exposure to vapours or mists of product may cause respiratory irritation.

SECTION 12. Ecological information

12.1. Toxicity

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Related to contained substances:

ACTIVATED BENTONITE:

Acute toxicity - fish LC50 (mg / l / 96h): 16000

Acute toxicity - crustaceans EC50 (mg / l / 48h): nd

Acute algae toxicity ErC50 (mg / l / 72-96h): > 100

SILICA GEL:

Acute toxicity-fish LL50 (mg/l/96H): > 10000

Acute toxicity-crustaceans EL50 (mg/l/24H): > 10000

Acute algae toxicity ErC50 (mg/l/72-96H): n.a.

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:

ACTIVATED BENTONITE:

Not persistent

SILICA GEL:

Not biodegradable

12.3. Bioaccumulative potential

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Related to contained substances:

ACTIVED BENTONITE:

Not bioaccumulative

SILICA GEL:

Not bioaccumulative

12.4. Mobility in soil

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Related to contained substances:

ACTIVED BENTONITE:

Not available

SILICA GEL:

Not applicable

12.5. Results of PBT and vPvB assessment

No PBT/vPvB ingredient is present

12.6. 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

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. Transport in bulk according to Annex II of MARPOL73/78 and IBC Code

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 contained substances (All. XVII Reg. EC 1907/2006): not applicable
Substances in Candidate List (art. 59 Reg. EC 1907/2006): the product does not contain SVHC
Substances subject to authorisation (Ann. XIV Reg. CEC 1907/2006): the product does not contain SVHC
Reg. EC 648/04: see 2.2
Reg. (EU) n. 1169/2011: see 2.2
Reg (UE) 528/2012: see.to 2.2

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: 1.2. Relevant identified uses of the substance or mixture and uses advised against, 8.2. Exposure controls, 9.1. Information on basic physical and chemical properties.

Classification based on data of all mixture components

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.
Regulation (EC) n. 648 of 31/03/04 (on detergents) et seq.
Regulation (UE) n. 1169/2011 (on the provision of food information to consumers)
Directive 2012/18/EU (on the control of major-accident hazards involving dangerous substances) et seq.
Regulation (UE) 528/2012 (Biocides) et seq.

Procedure used to classify under CLP mixture (Reg. EC 1272/2008): irrelevant

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 Estimat

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: Enviroment 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 supplier
- GESTIS DNEL Database: <http://www.dguv.de/ifa/gestis/gestis-dnel-datenbank/index-2.jsp>
- 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: error correction in section 9.
