

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

Product name : CLAROUGE AF

This substance/mixture contains nanoforms (Reg. EC 1907/2006 REACH)

Product code: refer to sales department

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

Specific Treatment

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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1.4. Emergency telephone number

Centralino/Switchboard +39.030.2307.1 - (h 8.30-12.00 13.30-18.00 GMT+1; Lingua/Language: Italiano, English)

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

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

This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

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):
not applicable

Precautionary statements:
None in particular.

Ingredients:
activated bentonite, pea protein, fish gelatine(a), polyvinylpolypyrrolidone (PVPP), silica gel, swine food gelatin, yeast cell wall .
Food use, oenological use. Not intended for the final consumer. In accordance with current regulations on the specific matter.

(a) = gelatine and isinglass (from fish) are exempt from labelling requirements when used for the clarification of wine and beer. (<Fish and fishery products except: b) gelatine or isinglass used as a clarifying agent in beer and wine.> in accordance with EU Regulation No. 1169 of 25 October 2011 – Annex II and subsequent additions and amendments)

2.3. Other hazards

Based on available data, there are no PBT or vPvB substances according to Regulation (EC) 1907/2006, Annex XIII, in concentration >0.1% w/w.

Based on available data, there are no substances that disrupt the endocrine system according to Regulations (EU) 2017/2100 and 2018/605 in concentration >0.1% w/w.

Use according to good working practices, avoiding dispersal of the product into the environment.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Amorphous silica, colloidal aqueous solution CAS No. 112926-00-8
Silicon dioxide, amorphous:
Substance containing nanoforms (Regulation (EC) No 1907/2006)
Particle information: Section 9 (experimental data)

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
ACTIVED BENTONITE substance for which there are Community workplace exposure limits	>= 25 < 50%			1302-78-9	215-108-5	
Synthetic amorphous silica	>= 1 < 5%				231-545-4	

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
hydrated (Silica gel) substance for which there are Community workplace exposure limits						

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation: Ventilate the area. Immediately remove the patient from the contaminated area and keep him or her at rest in a well-ventilated area.

If you feel unwell, consult a doctor. Direct skin contact: Remove shoes and clothing and wash thoroughly with soap and water. If you feel unwell, consult a doctor.

Direct eye contact: Remove any contact lenses, protect the uninjured eye, and immediately flush with plenty of water for at least 10 minutes. If you feel unwell, consult a doctor.

Ingestion: Rinse mouth immediately. Do not give anything to an unconscious person. If you feel unwell, consult a doctor.

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

If you feel unwell, go to a doctor or emergency room with this document. Symptomatic treatment.

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:

Move away from 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**

=====
Related to contained substances:
ACTIVED BENTONITE:
INHALABLE, DUST

TLV - TWA (Threshold Limit Value - Time Weighted Average) - Eight hours (ppm)/(mg/m³)

Austria: x/10

Belgium: x/10

Denmark: x/10

France: x/4 (1) General remarks: Bold type: Restrictive statutory limit values - Remarks: (1) Inhalable fraction

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

Germany (DFG): x/4

Hungary: x/10

Ireland: x/10

Poland: x/10

Singapore: x/10

Spain: x/10

Sweden: x/10

Switzerland: x/10

TLV-STEL Threshold limit value – short-term exposure limit (ppm)/(mg/m³)

Austria: x/20

Denmark: x/20

Germany (AGS): x/20(1)(2)(3) Remarks: (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

RESPIRABLE DUST

TLV - TWA (Threshold Limit Value - Time Weighted Average) - Eight hours (ppm)/(mg/m³)

Austria: x/5

Belgium: x/3

France: x/0,9 Remarks: (1) type: Restrictive statutory limit values

Germany (AGS): x/1,25 (1)(2)(3)(4)(5) Remarks: (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/m³ (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): x/0,3 (1) Remarks: (1) For granular, bio-resistant dusts, except ultra-fine particles (2) 15 minutes average value

Hungary: x/6

Ireland: x/4

Spain: x/3

Switzerland: x/3

USA – OSHA: x/5

TLV-STEL Threshold limit value – short-term exposure limit (ppm)/(mg/m³)

Austria: x/10

Germany (DFG): x/2,4 (1)(2) Remarks: (1) For granular, bio-resistant dusts, except ultra-fine particles (2) 15 minutes average value

Synthetic amorphous silica hydrated (Silica gel):
Silica, amorphous

Limit value - Eight hours TWA
(ppm)/(mg/m³)

Australia: -/2 (1)
Austria: -/4 (1) inhalable aerosol
Belgium: -/10
Canada – Ontario: -/10
Canada - Québec: -/6(1)(2)
Denmark: 0-/ 2 inhalable aerosol
Finland: -/5
Germany (AGS): -/1 (1)
Germany (DFG): -/0,02 (1)
Ireland: (1) -/6 (1)
Latvia: -/1
New Zealand: -/1
People's Republic of China: -/2(1)
Poland: -/10(1)
Singapore: -/10
South Africa mining: -/6 (1)
South Korea: -/10
Switzerland: -/4 (1)
USA - NIOSH: -/6
USA - OSHA: 20 (1)(2)
United Kingdom: -/6 (1)

Limit value - Short term STEL
(ppm)/(mg/m³)

Australia: -/-
Austria: -/-
Belgium: -/-
Canada – Ontario: -/-
Canada - Québec: -/-
Denmark: 0-/-
Finland: -/-
Germany (AGS): -/8 (1)(2)
Germany (DFG): -/0.16 (1)
Ireland: (1) -/-
Latvia: -/-
New Zealand: -/-
People's Republic of China: -/-
Poland: -/-
Singapore: -/-
South Africa mining: -/-
South Korea: -/-
Switzerland: -/-
USA - NIOSH: -/-
USA - OSHA: -/-
United Kingdom: -/-

Remarks:

Australia (1) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.
Austria (1) Inhalable fraction
Canada - Québec (1) Respirable fraction (2) The standard corresponds to dust containing no asbestos and the

percentage in crystalline silica is less than 1%.

Germany (AGS): Colloidal amorphous silica including fumed silica and wet-process silica (precipitated silica, silica gel)

(1) Inhalable fraction (2) 15 minutes average value

Ireland: (1) Inhalable fraction

New Zealand: (1) Inhalable fraction

Norway: (1) Respirable fraction

People's Republic of China: (1) Inhalable fraction

Poland: (1) Inhalable fraction

South Africa Mining: (1) Inhalable fraction

Switzerland: (1) inhalable aerosol

USA (OSHA) : (1) mppcf (2) mppcf × 35.3 = million particles per cubic meter = particles per c.c.

UK: (1) Inhalable fraction

- Substance: Synthetic amorphous silica hydrated (Silica gel)

DNEL

Local effects Long term Workers inhalation = 4 (mg/m³)

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 required for normal use, unless otherwise specified by the Health and Safety Manager and/or following the results of environmental hygiene surveys.

(b) Skin protection

(i) Hand protection

Not required for normal use, unless otherwise specified by the employer and/or following the findings of an occupational health and safety assessment. Rubber and PVC gloves are recommended

(ii) Other

Wear normal work clothing.

(c) Respiratory protection

Not required for normal use, unless otherwise specified by the employer and/or following the findings of an environmental health assessment.

(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	White cream	
Odour	not determined as it is considered not relevant for the characterization of the product	
Odour threshold	not determined as it is 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 it is considered not relevant for the characterization of the product	
Flammability	not determined as it is considered not relevant for the characterization of the product	
Lower and upper explosion limit	not determined as it is considered not relevant for the characterization of the product	
Flash point	not determined as it is considered not relevant for the characterization of the product	
Auto-ignition temperature	not determined as it is considered not relevant for the characterization of the product	
Decomposition temperature	not determined as it is considered not relevant for the characterization of the product	
pH	7,5 ± 0,5 (20°C; sol. 5%)	
Kinematic viscosity	not determined as it is considered not relevant for the characterization of the product	
Solubility	not determined as it is considered not relevant for the characterization of the product	
Water solubility	dispersible	
Partition coefficient n-octanol/water (log value)	not determined as it is considered not relevant for the characterization of the product	
Vapour pressure	not determined as it is considered not relevant for the characterization of the product	
Density and/or relative density	0,45 ± 0,05 (20°C)	
Relative vapour density	not determined as it is considered not relevant for the characterization of the product	
Particle characteristics	This substance-mixture contains nanoforms (under Reach reg.)	

9.2. Other information

Particle characteristics: micron-sized aggregates and agglomerates with an internal structure in the range of 1–100 nm

9.2.1 Information with regard to physical hazard classes

Irrilevant

9.2.2 Other safety characteristics

Irrilevant

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

=====
Related to contained substances:
ACTIVED BENTONITE:
Inert - Non-reactive

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

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

10.4. Conditions to avoid

Heat: Keep away from heat sources. Exposure to light and heating. Container opened.

10.5. Incompatible materials

No one 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 hazard classes as defined in Regulation (EC) No 1272/2008**

(a) acute toxicity: based on the available data, the classification criteria are not met
ATE(mix) oral = Not classified (no relevant components)
ATE(mix) dermal = Not classified (no relevant components)
ATE(mix) inhal = Not classified (no relevant component)

- (b) skin corrosion/skin irritation: based on available data, the classification criteria are not met
(c) serious eye damage/eye irritation: based on available data, the classification criteria are not met
(d) respiratory or skin sensitisation: based on available data, the classification criteria are not met
(e) germ cell mutagenicity: based on available data, the classification criteria are not met.
(f) carcinogenicity: based on available data, the classification criteria are not met.
(g) reproductive toxicity: based on available data, the classification criteria are not met.
(h) specific target organ toxicity (STOT) – single exposure: based on available data, the classification criteria are not met.
(i) specific target organ toxicity (STOT) – repeated exposure: based on available data, the classification criteria are not met.
(j) Aspiration hazard: based on the available data, the classification criteria are not met.

With regard to the substances contained:

- (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

Synthetic amorphous silica hydrated (Silica gel): Ingestion - LD50 rat (mg/kg/24h bw): >5000

Skin contact - LC50 rat/rabbit (mg/kg/24h bw): >2000

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

- (b) skin corrosion/irritation: ACTIVED BENTONITE: Non-corrosive
Synthetic amorphous silica hydrated (Silica gel): Non-corrosive
ACTIVED BENTONITE: Non-irritating
Synthetic amorphous silica hydrated (Silica gel): Non-irritating
(c) serious eye damage/irritation: ACTIVED BENTONITE: Non-corrosive
Synthetic amorphous silica hydrated (Silica gel): Non-corrosive
ACTIVED BENTONITE: Slightly irritating
Synthetic amorphous silica hydrated (Silica gel): Non-irritating
(d) respiratory or skin sensitisation: ACTIVED BENTONITE: Non-sensitizing
Synthetic amorphous silica hydrated (Silica gel): Non-sensitizing
(e) germ cell mutagenicity: ACTIVED BENTONITE: Non-mutagenic
Synthetic amorphous silica hydrated (Silica gel): Non-mutagenic
(f) carcinogenicity: ACTIVED BENTONITE: Non-carcinogenic
Synthetic amorphous silica hydrated (Silica gel): Not cacerogeno
(g) reproductive toxicity: ACTIVED BENTONITE: Non-toxic for reproduction
Synthetic amorphous silica hydrated (Silica gel): Non-toxic for reproduction
(h) specific target organ toxicity (STOT) single exposure: ACTIVED BENTONITE: Non-toxic
Synthetic amorphous silica hydrated (Silica gel): Not classified. Oral NOAEL (rat): > 1000 mg/kg body weight/day
(i) specific target organ toxicity (STOT) repeated exposure: ACTIVED BENTONITE: Non-toxic
Synthetic amorphous silica hydrated (Silica gel): Not available
(j) aspiration hazard: ACTIVED BENTONITE: There are no dangers for aspiration
Synthetic amorphous silica hydrated (Silica gel): Not available

11.2. Information on other hazards

No data available.

11.2.1. Endocrine disrupting properties

The product does not contain substances identified as endocrine disruptors for human health according to the criteria established by Regulation (EC) No. 1272/2008, as amended by Regulation (EU) 2023/707.

12.1. Toxicity

=====
Related to contained substances:
ACTIVED 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

Synthetic amorphous silica hydrated (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

=====
Related to contained substances:
ACTIVED BENTONITE:
Not persistent

Synthetic amorphous silica hydrated (Silica gel):
not applicable to inorganic substances

12.3. Bioaccumulative potential

=====
Related to contained substances:
ACTIVED BENTONITE:
Not bioaccumulative

Synthetic amorphous silica hydrated (Silica gel):
Not bioaccumulative

12.4. Mobility in soil

=====
Related to contained substances:
ACTIVED BENTONITE:
Not available

Synthetic amorphous silica hydrated (Silica gel):
Minimally soluble. Migration into soil is not expected.

12.5. Results of PBT and vPvB assessment

The product does not contain substances identified as PBT according to the criteria established by Regulation (EC) No. 1272/2008, as amended by Regulation (EU) 2023/707.

The product does not contain substances identified as vPvB according to the criteria established by Regulation (EC) No.



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In conformity to Regulation (EU) 2020/878

1272/2008, as amended by Regulation (EU) 2023/707.

12.6. Endocrine disrupting properties

The product does not contain substances identified as endocrine disruptors for human health according to the criteria established by Regulation (EC) No. 1272/2008, as amended by Regulation (EU) 2023/707.

The product does not contain substances identified as endocrine disruptors for the environment according to the criteria established by Regulation (EC) No. 1272/2008, as amended by Regulation (EU) 2023/707.

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 \geq a 0.1 %.

Regulation (EU) 1169/2011: see point 2.2

Regulation (EU) 1308/2013; see point 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**

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

No hazard to report. 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: Enviroment Release Classes

EU/UE: European Union

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization



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In conformity to Regulation (EU) 2020/878

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://chem.echa.europa.eu/>

- 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)
