essedielle
ENOLOGIALIMENTAZIONE
SISTEMA DI GESTIONE PER LA SICUREZZA ALIMENTARE
CERTIQUALITY
UNI EN ISO 22000:2018
OPERATORE CONTROLLATO S 1262
CERTIFICATO ICEA BIOLOGICO
essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

SAFETY DATA SHEET

ENOBIOFERM

Revision No. 5, October 2023; Complies with Reg (EU) 2020/878

INDEX

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE MANIFACTURING COMPANY 2

2. HAZARD IDENTIFICATION 2

3. COMPOSITION/INGREDIENT INFORMATION 3

4. FIRST AID MEASURES 3

5. FIRE-FIGHTING MEASURES 3

6. MEASURES IN CASE OF ACCIDENTAL RELEASE 3

7. HANDLING AND STORAGE 4

8. EXPOSURE CONTROL/INDIVIDUAL PROTECTION 4

9. PHISICAL AND CHEMICAL PROPERTIES 5

10. STABILITY AND RESPONSIVENESS 6

11. TOXICOLOGICAL INFORMATION 6

12. ECOLOGICAL INFORMATION 8

13. DISPOSAL CONSIDERATIONS 9

14. TRANSPORTATION INFORMATION 9

15. REGULATORY INFORMATION 10

16. OTHER INFORMATION 10

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE MANIFACTURING COMPANY

1.1 Product identification
Chemical name: Sodium bentonite, PVPP, Yeast peel
Trade name: Enobioferm AF, E-Clar
Trade names and synonims: complex enological clarifier
REACH number: substance is not classified and is not subject to REACH registration

1.2 Relevant identified uses of the substance/mixture and uses not recommended
Clarifiers
Usage sectors: Industrial uses [SU3], Food industries [SU4], Professional uses [SU22].
Product categories: technological adjuvant for oenological use
Uses not recommended: do not use for uses other than those indicated.

1.3 Information about the supplier of the safety data sheet
essedielle srl
S.P. 538 km. 6,950 - CALDARI
66026 ORTONA (CH)
ITALY
Phone: +39 (0) 85 9031315
Qualified persons responsible for the safety data sheet: laboratorio@essedielle.com

1.4 Emergency telephone number: essedielle srl +39 (0) 85 9031315 – 0039 3668134126
Poison Control Center
S.S. Annunziata Hospital – Chieti +39 0871 1551219

2. HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture
Criteria EC Regulation 1272/2008 (CLP): not classified

2.2 Label elements
Labeling according to Regulation (EC) 1272/2008 [CLP]: the substance does not have to be labeled according to CLP Regulation (EC) 1272/2008
Symbols: none
Hazard statements:
H315 Causes skin irritation.
H319 Causes severe eye irritation.
Cautionary Statements:
P264 Wash hands thoroughly after use.
P280 Wear protective gloves/protective clothing/eye/face protection.
P302+P352 IF ON SKIN: Wash thoroughly with water.
P305+P351+P338 IF EYE CONTACT: rinse thoroughly for several minutes.
Remove any contact lenses if it is convenient to do so. Continue to rinse.
P337+P313 If eye irritation persists, seek medical attention.
P332+P313 If skin irritation occurs seek medical attention.
Special provisions: none
Special provisions according to Annex XVII of REACH and subsequent adaptations: none

2.3 Other hazards
The substance does not meet the criteria for PBT or vPvB classification according to REACH Regulation (EC) 1907/2006.

During handling and use, the product can potentially generate respirable dust. Dust may contain respirable crystalline silica. Prolonged or massive inhalation of respirable crystalline silica may cause pulmonary fibrosis, commonly referred to as silicosis. The main symptoms of pulmonary fibrosis are coughing and difficulty breathing. Occupational exposure of respirable dust and respirable crystalline silica should be monitored and controlled

3. COMPOSITION/INGREDIENT INFORMATION

3.1 Substances
Chemical name: (see 3.2)

3.2 Mixtures

Substance	Concentration	Classification	CAS	EINECS	REACh
Sodium bentonite	40-60%		1302-78-9	215-108-5	No
PVPP	10-30%	None	25249-54-1		No
Yeast peel	10-30%				

4. FIRST AID MEASURES

4.1 Description first aid measures
In case of inhalation: no actions to be avoided, no special instructions for rescuers.
In case of skin contact: none in particular.
In case of eye contact: immediately flush with running water with open eyelids for at least 15 minutes. Consult an ophthalmologist. Protect the uninjured eye.
In case of ingestion: none in particular.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing means
Suitable extinguishing means
All standard firefighting equipment.
Extinguishing media that should not be used for safety reasons
None in particular.

5.2 Special hazards from combustion products
In case of prolonged exposure or high level of suspended dust, wear respiratory protection in accordance with national legislation.

5.3 Recommendations for fire suppression operators
Avoid dry sweeping by spraying water or using a vacuum system to prevent dust formation. Keep in mind that wet bentonite can be slippery.

5.4 Other information
None in particular.

6. MEASURES IN CASE OF ACCIDENTAL RELEASE

6.1 Personal precautions, personal protective equipment and emergency procedures
Wear personal protective equipment. Move people to a safe place. Refer to the protective measures set out in section 7 and 8.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

6.2 Environmental precautions
Prevent penetration into the soil/subsoil. Prevent runoff into the sewer system.

6.3 Methods and materials for containment and remediation
Small quantities: wash with plenty of water.

6.4 Reference to other sections
See also paragraph 8 and 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid dust formation.
Provide adequate ventilation in rooms where dust is formed. In case of insufficient ventilation, wear suitable respiratory protective equipment.

7.2 Conditions for safe storage, including any incompatibilities
No special precautions are required. Provide proper ventilation and store by preventing accidental damage. Keep away from moisture.

7.3 Specific end uses
No special technical measures or precautions are required. Indicate mode of use before use in case of mixture with other substances.

8. EXPOSURE CONTROL/INDIVIDUAL PROTECTION

8.1 Control parameters
Related to contained substances
Activated bentonite
Depending on the treatment and use (grinding, drying, bagging), respirable dust can be generated in the air. The dust contains respirable crystalline silica. Prolonged and massive inhalation or respirable crystalline silica can cause pulmonary fibrosis, commonly referred to as silicosis. The main symptoms of silicosis are cough and shortness of breath. Occupational exposure to respirable dust should be monitored and controlled. The product should be handled with methods and techniques that minimize or eliminate dust formation. The product contains less than 1% w/w RCS (crystalline silica) as determined by the SWERF method. Respirable crystalline silica content can be measured by the "Cut-Weighted Respirable Fraction-SWERF" method. Full details of the SWERF method is available atwww.crystallinesilica.eu Data are based on our latest knowledge but do not constitute any guarantee of product characteristics and do not motivate any contractual legal relationship.
PVPP
No data available

8.2 Exposure controls
Observe safety measures when handling chemicals.

Provide appropriate ventilation and filtration in workplaces where dust may be generated.
Wash hands before intervals and at the end of the workday. Take off and wash soiled clothing.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

Eye/face protection
Not required. Operate according to good work practices anyway.

Skin protection
Not necessary

Hand protection
Wash hands before intervals and at the end of the workday. Take off and wash soiled clothing.

Respiratory protection
In case of prolonged exposure to dust wear personal respiratory protection in accordance with national legislation (refer to the appropriate CEN standard).

Thermal hazards
None

Environmental exposure controls
None

9. PHISICAL AND CHEMICAL PROPERTIES

9.1 Information on general physical and chemical properties

Appearance	Beige Powder
Shape	Powder
Color	White-beige
Odor	Odorless
Olfactory threshold	Not determined
Ph value	Not determined
CHANGE OF STATE	
Melting point/interval	Non determined
Boiling point/interval	Not determined
Flash point	Non flammable
Flammability (solids, gases)	Non flammable
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Explosive properties	Non explosive
Lower flammability limits	Higher than 150 °C
Upper flammability limits	Not determined
Vapor pressure at 20°C	Not determined
Density at 20°C	0,9 – 1,4 g/ml
Relative density	0.6 g/cm^3 a 20°C
Vapor density at 20°C	Not determined
Evaporation rate	Not determined
Solubility in/Miscibility with water	Soluble only 30 % of bentonite contained, PVPP and yeast peels are insoluble
Specific rotation	Not determined
Partition coefficient: n-octanol/water	Not determined
Dynamic Viscosity at 20 °C	Not determined
Kinematic Viscosity	Not determined

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

9.2 Other information

Molecular mass	Not determined
Conductivity	Not determined
Liposolubility	Not determined
Particular properties groups of substances	None
Other Useful Information	None

10. STABILITY AND RESPONSIVENESS

10.1 Responsiveness
Under normal conditions, it is completely stable to air and light.

10.2 Chemical stability
Under normal conditions, it is completely stable to air and light.

10.3 Possibility of dangerous reactions
Stable under normal conditions.

10.4 Conditions to be avoided
Stable under normal conditions.

10.5 Incompatible materials
None in particular.

10.6 Hazardous decomposition products
None.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects
Toxicological information regarding the main substances in the mixture:
Toxicological information regarding the substance: Sodium Activated Bentonite
Oral LD50 > 2000 mg/kg bw (OECD 420 rat).
Derma data not available. Bentonite is insoluble and has low absorption through the skin
Inhalation LC50 > 5.27 mg/l) OECD 436 rat)
Classification for acute toxicity is not warranted.
Unless otherwise specified, the data required by Regulation 453/2010/EC below are intended to be undetermined:

a) acute toxicity: bentonite does not exhibit acute toxicity.
b) skin corrosion/irritation: bentonite is not irritating to the skin (in vivo, OECD 404, rabbit)
c) severe eye injury/serious eye irritation: bentonite is not irritating to eyes (in vivo, OECD 405, rabbit). Bentonite is classified as mild eye irritant (according to Kay&Calandra criteria) classification for irritation/corrosion is not warranted
d) respiratory or skin sensitization: bentonite is not a skin sensitizer (OECD 429, mouse)
e) germ cell mutagenicity: in vivo tests (OECD 471,473 and 476) NEGATIVE
f) carcinogenicity: Sepiolite has been evaluated by IARC as Class 3 ("Cannot be classified as carcinogenic to humans"). Based on read across with sepiolite, bentonite has been evaluated as non-carcinogenic.
Therefore, the classification of bentonite for carcinogenicity is not warranted
g) Reproductive toxicity: two studies are available.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

- Abdel-Wahhab et al (1999): bentonite had no effect on maternal and fetal parameters at the dietary level of 0.5% w/w (equivalent to 250 mg/kg body weight).
- Wiles et al (2004) Calcium montmorillonite 2% or sodium montmorillonite in the diet had no effect on maternal and maternal organ weights, offspring weights, embryonic implants, or resorptions.

In both animal studies, no effects on maternal/fetal parameters were found.
Classification for reproductive toxicity under Regulation (EC) 1272/2008 is not warranted.

h) Specific target organ toxicity (STOT) - single exposure: no organ toxicity was observed in acute testing.

i) Specific target organ toxicity (STOT) - repeated exposure - Oral.
The short-term repeated dose toxicity study (28 days) and toxicity sub-study (90 days) on mice were conducted with bentonite.
Mice were fed 10%, 25%, and 50% bentonite for 61 days. Hepatoma was observed in mice treated with 50% bentonite diet. This is because bentonite being an exchange silicate goes on to remove choline from the intestinal contents after more than 200 days of feeding based on a 50% bentonite diet. Hepatomas developed in 11 out of 12 mice. The liver of the mice was severely damaged. The liver damage observed in the group that ingested bentonite is speculated to be related to prolonged choline deficiency, partially explaining the development of hepatomas in the mice in these experiments. However, studies have been conducted by exposing mice to a very high concentration of bentonite, and the observed effects are considered to be secondary to digestive dysfunction. Therefore, the classification of bentonite for toxicity upon prolonged oral exposure is not justified.

j) Specific target organ toxicity (STOT) - repeated exposure - inhalation.
Data obtained from animal and in vitro experiments indicate a difference between crystalline quartz and the quartz content of bentonite.
A quantitative assessment based on animal data is not possible because no relevant study with repeated inhalation administration is available.
Human data are limited to clinical cases suggesting a relationship with high bentonite exposure (exposures in the 20th century without state-of-the-art protective measures and dust exposure ceilings). The link between bentonite exposure and silicosis is not considered to be sufficiently demonstrated.
Regarding the classification and labeling of bentonite, the evidence is not considered to be sufficient to reach a conclusion on the specific classification of bentonite with the specific target organ toxicity on repeated exposure (STOT-RE). Lung may be applicable to repeated high-dose exposure, which has been suggested by human case studies. Although this effect happens only at concentrations beyond the lung purification capacity and is not relevant to humans, given the general exposure limits established. Therefore, classification of bentonite for toxicity during prolonged inhalation exposure is not warranted.

k) Aspiration hazard: no aspiration hazard is anticipated.

<u>Toxicological information regarding the substance: PVPP</u>

(a) Acute toxicity: based on available data, the classification criteria are not met.
(b) skin corrosion/irritation: based on available data the classification criteria are not met.
(c) severe eye injury/irritation: based on available data the classification criteria are not met.
(d) respiratory or skin sensitization: based on available data, the classification criteria are not met.
(e) germ cell mutagenicity: based on the 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.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met.
(j) aspiration hazard: based on available data the classification criteria are not met.

11.2 Health hazards
Eye contact: accidental contact of the product with the eyes may cause irritation.
Skin contact: the product is not an irritant.
Repeated and prolonged direct contact may degrease and irritate the skin, causing dermatitis in some cases.
Ingestion: ingested product may cause irritation of the mucous membranes of the throat and digestive tract resulting in abnormal digestive symptoms and intestinal disorders.
Inhalation: prolonged exposures to vapors or mists of the product may cause respiratory tract irritation.

Toxicological information regarding the main substances in the mixture
Related to contained substances: POLYVINYLPOLYPYRROLIDONE (PVPP):
Acute oral toxicity: > 5000 mg/kg (rat)
Eye irritation: non-irritant (rabbit).
Mutagenicity: non-mutagenic.
Carcinogenicity: no component of this product present at a level greater than or equal to 0.1% is identified as a carcinogen by NTP. No component of this product present at a level greater than or equal to 0.1% is identified as a probable, possible, or confirmed human carcinogen by IARC. No component of this product present at a level greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
(a) Acute aquatic toxicity: activated bentonite
12.1.1 Acute/prolonged toxicity to fish
LC50 (96h) for freshwater fish (rainbow trout): 16000 mg/l
LC50 (24h) for marine water fish (black bass, bass warmouth, bluegill and sunfish): 2800-3200 mg / l
12.1.2 Acute/prolonged toxicity to aquatic invertebrates.
EC50 (96h) for freshwater invertebrates (Dungeness crab): 81.6 mg / l
EC50 (96h) for freshwater invertebrates (dock shrimp): 24.8 mg / l
LC50 (24h) for C. dubia and H. limbata:> 500 mg / L
12.1.3 acute/prolonged toxicity on aquatic plants
EC50 (72h) for freshwater algae:> 100 mg / l
12.1.4 toxicity on microorganisms (e.g., bacteria)
EC50 (48h) for Daphnia magna (OECD 202) :> 100 mg / l
12.1.5. chronic toxicity to aquatic organisms
Data not available
12.1.6 toxicity to soil-dwelling organisms
Data not available
12.1.7 toxicity to terrestrial plants
No effect was observed on the growth of beans (Phaseolus vulgaris) or corn (Zea mays) when bentonite was added at a concentration of 135 g/1.6 kg soil
12.1.8 General effects
No specific adverse effects known

(b) Acute Aquatic Toxicity: PVPP
Use according to good working practices, avoiding dispersal in the environment.
Related to contained substances: POLIVINYLPOLYPYRROLIDONE (PVPP):
Juvenile Turbot: 96-hr. LC50 >1,000 mg/L

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

Corophium Volutator: 10-day LC50 >1,000 mg/L
Seaweed: 72-hr. EC50 >1,000 mg/L

12.2 Persistence and degradability
Not relevant for inorganic substances

12.3 Bioaccumulative potential
Not relevant for inorganic substances

12.4 Mobility in soil
Bentonite is nearly insoluble and therefore has low mobility in soils

12.5 Results of PBT and vPvB assessment vPvB substances: None **- PBT substances:** None

12.6 Other adverse effects
No adverse effects found. According to the criteria of the European classification and labeling system, the substance does not require classification as environmentally hazardous.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
PRODUCT
Inorganic product not to be disposed of through biological treatment systems. Dispose of residues in accordance with current regulations through authorized disposers.
Recover if possible. Operate in accordance with current local and national regulations.
CONTAMINATED PACKAGING
Empty as best as possible by fully opening them. Dispose of in accordance with the constituent material.

13.2 HP Phrases
None

14. TRANSPORTATION INFORMATION

14.1 UN number
Non-dangerous goods within the meaning of transport regulations.

14.2 UN shipping name
N.A.

14.3 Transport hazard class(es)
N.A.

14.4 Packing group
N.A.

14.5 Environmental hazards Marine pollutant
No

14.6 Special precautions for users
N.A.

14.7 Transport of bulk according to MARPOL Annex II and the IBC Code
N.A.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

15. REGULATORY INFORMATION

15.1 Health, safety and environmental laws and regulations specific to the substance or mixture
Legislative Decree 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances)
Legislative Decree 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations)
D.M. Labor 26/02/2004 (Occupational exposure limits)
Ministerial Decree 03/04/2007 (Implementation of Directive No. 2006/8/EC)
Regulation (EC) No. 1907/2006 (REACH)
Regulation (EC) No. 1272/2008 (CLP)
Regulation (EC) No. 790/2009 (ATP 1 CLP)
Regulation (EU)No 453/2010 (Annex I)
Regulation (EU) No 286/2011 (ATP 2 CLP)
Restrictions related to the product or the contained substances according to Annex XVII of Regulation (EC) 1907/2006 (REACH) and subsequent adaptations: none
Where applicable, please refer to the following regulations:
Ministerial Circulars 46 and 61 (Aromatic Amines)
Legislative Decree No. 238 of September 21, 2005 (Seveso Ter Directive)
EC Regulation No. 648/2004 (Detergents).
Royal Decree No. 147 of January 9, 1927 (Toxic Gases)
D.L. 3/4/2006 n. 152 Environmental regulations

15.2 Chemical safety assessment
No

16. OTHER INFORMATION

This sheet cancels and replaces any previous edition.

This document was prepared by a technician competent in SDS and who has received appropriate training.
The information contained herein is based on our knowledge as of the date above.
It relates only to the product indicated and does not constitute a guarantee of any quality. The user is responsible for ensuring the suitability and completeness of this information in relation to the specific use to be made of it.

Main bibliographic sources
ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition -Van Nostrand Reinold
CCNL - Annex 1
Istituto Superiore di Sanità - National Inventory of Chemical Substances.

LEGENDA SIGLES
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Service of the Chemical Abstract (division of the American Chemical Society).CLP: Classification, Labeling, Packaging.
DNEL: Derived no-effect level.
EINECS: European Inventory of Existing Commercial Chemical Substances.
GefStoffVO: Ordinance on hazardous substances, Germany.
GHS: General harmonized system of classification and labeling of chemicals.
IATA: International Air Transport Association.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

IATA-DGR: Regulations for the Transport of Dangerous Goods of the "International Air Transport Association"(IATA).
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions of the "International Civil Aviation Organization"(ICAO).
IMDG: International Maritime Dangerous Goods Code.
INCI: International nomenclature of cosmetic ingredients.
KSt: Coefficient of explosion.
LC50: Lethal concentration for 50 percent of the population tested.
LD50: Lethal dose for 50 percent of the population tested.
N.A.: Not Available
PNEC: Predicted no-effect concentration.
RID: Regulations concerning the international transport of dangerous goods by rail.
STE: Short-term exposure.
STEL: Short-term exposure limit.
STOT: Specific target organ toxicity.TLV: Threshold limit value.
TWATLV: Threshold limit value for an 8-hour weighted average exposure per day. (ACGIH standard).
WGK: German water hazard class.