

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

1.1. Product identifier

Product name : PROTECT-F
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:
Additive 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:
GHS07

Hazard Class and Category Code(s):
Eye Irrit. 2

Hazard statement Code(s):
H319 - Causes serious eye irritation.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.

2.2. Label elements

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

Pictogram, Signal Word Code(s):
GHS07 - Warning

Hazard statement Code(s):
H319 - Causes serious eye irritation.

Supplemental Hazard statement Code(s):
not applicable

Precautionary statements:

Prevention

P280 - Wear 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.

P337+P313 - If eye irritation persists: Get medical advice/attention.

Contains:



Ingredients: Fumaric acid, Gallic and proantocianidinic tannins.
Food use, oenological use. Not intended for the final consumer. In accordance with current regulations on the specific matter. Only for industrial use.

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

Refer to paragraph 16 for full text of hazard statements

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Fumaric acid	>= 50 < 100%	Eye Irrit. 2, H319	607-146-00-x	110-17-8	203-743-0	01-2119485 492-31-xxxx

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

No data available.

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

If eye irritation persists: Get medical advice/attention.

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 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

- Substance: Fumaric acid

DNEL

Systemic effects Long term Workers inhalation = 75 (mg/m³)

Systemic effects Long term Workers dermal = 50 (mg/kg bw/day)

Systemic effects Long term Consumers inhalation = 53 (mg/m³)

Systemic effects Long term Consumers dermal = 30 (mg/kg bw/day)

Systemic effects Long term Consumers oral = 30 (mg/kg bw/day)

Systemic effects Short term Workers inhalation = 175 (mg/m³)

Systemic effects Short term Workers dermal = 50 (mg/kg bw/day)

Systemic effects Short term Consumers inhalation = 53 (mg/m³)

Systemic effects Short term Consumers dermal = 30 (mg/kg bw/day)

Systemic effects Short term Consumers oral = 30 (mg/kg bw/day)

PNEC

Sweet water = 0,1 (mg/l)

Sea water = 0,01 (mg/l)

intermittent emissions = 1 (mg/l)

STP = 3 (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

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	Dust	
Colour	light brown	
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	
pH	2.5 ± 0.5 (20°C, sol 5%)	
Melting point/freezing point	not determined as it is considered not relevant for the characterization of the product	
Initial boiling point and boiling range	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	
Evaporation rate	not determined as it is considered not relevant for the characterization of the product	

Physical and chemical properties	Value	Determination method
Flammability (solid, gas)	not determined as it is considered not relevant for the characterization of the product	
Upper/lower flammability or explosive limits	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	
Vapour density	not determined as it is considered not relevant for the characterization of the product	
Relative density	0.7 ± 0.05 (20 ° C)	
Solubility	not determined as it is considered not relevant for the characterization of the product	
Water solubility	not determined as it is considered not relevant for the characterization of the product	
Partition coefficient: n-octanol/water	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	
Viscosity	not determined as it is considered not relevant for the characterization of the product	
Explosive properties	not determined as it is considered not relevant for the characterization of the product	
Oxidising properties	not determined as it is considered not relevant for the characterization of the product	

9.2. Other information

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

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 Related to contained substances:
 Fumaric acid:
 Stable 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:

Fumaric acid:

Avoid the formation of electrostatic charges. Avoid exposure to heat sources. Avoid the formation of dust.

10.5. Incompatible materials

No one in particular

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

ATE(mix) oral = ∞

ATE(mix) dermal = ∞

ATE(mix) inhal = ∞

(a) acute toxicity: Fumaric acid: Ingestion - LD50 rat (mg / kg / 24h bw): 9300 (equivalent or similar to OECD Guideline 401)

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw): 2000 (equivalent or similar to OECD Guideline 402)

Inhalation - LD50 rat (mg / l / 4h): not available

(b) skin corrosion/irritation: Fumaric acid: Non corrosive (OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Fumaric acid: Slightly irritating (OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

(c) serious eye damage/irritation: If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.

Fumaric acid: Non corrosive (OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Fumaric acid: Moderately irritating (OECD Guideline 405 (Acute Eye Irritation / Corrosion)

(d) respiratory or skin sensitisation: Fumaric acid: Respiratory sensitization: not available Skin sensitization: not sensitizing (OECD Guideline 406 (Skin Sensitization)

(e) germ cell mutagenicity: Fumaric acid: Mammalian cell gene mutation assay (gene mutation): negative (Equivalent and similar to OECD Guideline 476)

Mammalian chromosome aberration test (chromosome aberration): negative (equivalent or similar to OECD Guideline 473)

(f) carcinogenicity: Fumaric acid: unavailable

(g) reproductive toxicity: Fumaric acid: Effects on sexual function and fertility:

NOAEL (P): > 400 mg / kg bw / day (nominal) (male / female) (no effect observed)

NOAEL (F1): > 400 mg / kg bw / day (nominal) (no effect observed)

(h) specific target organ toxicity (STOT) single exposure: Fumaric acid: unavailable

(i) specific target organ toxicity (STOT) repeated exposure: Fumaric acid: NOAEL: 600 mg / kg bw / day (nominal) (male) (equivalent or similar to OECD Guideline 452)

(j) aspiration hazard: Fumaric acid: Unavailable

11.2. Information on other hazards

No data available.

SECTION 12. Ecological information

12.1. Toxicity

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Related to contained substances:

Fumaric acid:

Acute toxicity - fish LC50 (mg / l / 96h):> 100 Brachydanio rerio (new name: Danio rerio), freshwater, semi-static. (OECD Guideline 203)

Acute toxicity - crustaceans EC50 (mg / l / 48h):> 100 (Daphnia magna, freshwater, semi-static); 212 Daphnia magna, freshwater, static) (OECD Guideline 202)

Acute toxicity algae ErC50 (mg / l / 72-96h):> 100 Pseudokirchnerella subcapitata (algae), freshwater, static. Based on: biomass and growth rate. (OECD Guideline 201)

Acute toxicity of aquatic microorganisms EC50 (mg / L / 3h):> 300 activated sludge of a predominantly domestic sewage; fresh water, static. Based on: respiration rate. (OECD Guideline 209)

Chronic toxicity - fish NOEC (mg / l): not available

Chronic toxicity - crustaceans NOEC (mg / l): not available

Chronic toxicity algae NOEC (mg / l): 100 Pseudokirchnerella subcapitata (algae), fresh water , static. Based on: biomass and growth rate. (OECD Guideline 201)

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:

Fumaric acid:

Degradability:

Abiotic degradation:

Hydrolysis: According to REACH regulation 1907/2006, annex VIII, column 2, this assessment is not required if the substance is readily biodegradable.

Phototransformation in air: Not required

Biotic Degradation:

Aquatic Environment:

Method: OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test)

Test type: ready biodegradability activated sludge, domestic, non-adapted

Results:% degradation of the test substance: Degr %. 60.3 after 11 d (CO2 Evolution) Degr%. 67.5 after 28 d (CO2 Evolution) Value used for CSA: Biodegradation in water: readily biodegradable

12.3. Bioaccumulative potential

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Related to contained substances:

Fumaric acid:

According to REACH regulation 1907/2006 (Annex IX - 9.3.2, column 2) the bioaccumulation test is not necessary if the substance has a low bioaccumulation potential calculated on the basis of a log Kow value <3. The value experimentally determined by the Log Kow is 0.46, this implies a low potential for bioaccumulation.

12.4. Mobility in soil

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Related to contained substances:

Fumaric acid:

Adsorption / desorption: According to REACH regulation 1907/2006, Annex VIII - 9.3.1 column 2, screening tests for adsorption / desorption do not need to be conducted when the substance has a low adsorption potential calculated on the basis of a log Kow of 0.46

12.5. Results of PBT and vPvB assessment

No PBT/vPvB ingredient is present

12.6. Endocrine disrupting properties

No data available.

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 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 in a proportion $\geq 0.1\%$.
Substances subject to authorisation (Ann. XIV Reg. CEC 1907/2006): the product does not contain SVHC in a proportion $\geq 0.1\%$.

Reg. EC 648/04: see 2.2

Reg. (EU) n. 1169/2011: see 2.2

Reg (UE) 528/2012: see.to 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

Description of hazard statements set out in paragraph 3
H319 = Causes serious eye irritation.

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): calculation method

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 Oxigen 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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Changes to the previous edition: first issue.