

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Prozyme One
Product code : FE

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

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Freedom Hygiene
46 Main Street Buckminster
NG33 5SA Grantham – Lincolnshire
England
T 07774 898904
paul@freedomhygiene.co.uk

1.4. Emergency telephone number

Emergency number : 07774 898904

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Serious eye damage/eye irritation, Category 1 H318
Respiratory sensitisation, Category 1 H334
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Contains

: Subtilisin

Hazard statements (CLP)

: H318 - Causes serious eye damage.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 - Harmful to aquatic life with long lasting effects.
P261 - Avoid breathing mist, spray.
P280 - Wear protective gloves, eye protection.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Precautionary statements (CLP)

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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 doctor.

P501 - Dispose of contents and container to a hazardous or special waste collection point.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Subtilisin	CAS-No.: 9014-01-1 EC-No.: 232-752-2 EC Index-No.: 647-012-00-8 REACH-no: 01-2119480434-38	$\geq 5 - < 10$	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 2, H411

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/effects after eye contact	: Serious damage to eyes.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment. Avoid breathing dust/fume/gas/mist/vapours/spray.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Yellow-ish.
Odour	: slight.
Odour threshold	: -
pH	: 5 – 7
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: -
Boiling point	: No data available
Flash point	: Not flammable
Auto-ignition temperature	: -
Decomposition temperature	: 150 °C -
Flammability (solid, gas)	: Not applicable
Vapour pressure	: ≈ 20 hPa (20°C)
Vapour pressure at 50 °C	: 100 hPa
Relative vapour density at 20 °C	: -
Relative density	: -
Density	: 1 – 1.1 g/cm ³
Solubility	: Miscible.
Partition coefficient n-octanol/water (Log Pow)	: -
Viscosity, kinematic	: -
Viscosity, dynamic	: -
Explosive properties	: Not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: -

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Subtilisin (9014-01-1)	
LD50 oral rat	1800 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 1200 - 2300

Skin corrosion/irritation : Not classified
pH: 5 – 7
Serious eye damage/irritation : Causes serious eye damage.
pH: 5 – 7
Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified

Subtilisin (9014-01-1)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified

Subtilisin (9014-01-1)	
NOAEL (oral, rat, 90 days)	360 – 891 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)

Aspiration hazard : Not classified

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Viscosity, kinematic	-

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term : Not classified
(acute)
Hazardous to the aquatic environment, long-term : Harmful to aquatic life with long lasting effects.
(chronic)

Subtilisin (9014-01-1)

LC50 - Fish [1]	14.6 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
LC50 - Fish [2]	8.2 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	0.306 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	170 µg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	0.513 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
EC50 72h - Algae [2]	1.48 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

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Partition coefficient n-octanol/water (Log Pow)	-
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

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ADR	IMDG	IATA	ADN	RID
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 16: Other information

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
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Full text of H- and EUH-statements:

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.