

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

1.1. Product identifier

Product name : REMOVIL Zyme
Product code: refer to sales department

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

Enzymatic Cleaner

Sectors of use:

Industrial Manufacturing[SU3]

Product category:

Washing and Cleaning Products (including solvent based products)

Process categories:

Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions[PROC2], Transfer of substance or mixture (charging and discharging) at dedicated facilities[PROC8B], Treatment of articles by dipping and pouring [PROC13]

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

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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):
EUH208 - Contains Subtilisin, alpha-amylase. May produce an allergic reaction.

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 (Reg. EC 648/2004):

< 5% enzymes, phosphonates, non-ionic surfactants

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

Do not ingest. Keep out of reach of children.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements

Note V - If the substance is to be placed on the market as fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.

Note W - It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung. This note aims to describe the particular toxicity of the substance; it does not constitute a criterion for classification according to this Regulation.

| Substance | Concentration[w/w] | Classification | Index | CAS | EINECS | REACH |
|--|---------------------|--|--------------|------------|-----------|-------------------------------|
| Sodium carbonate | >= 50 < 100% | Eye Irrit. 2, H319 | 011-005-00-2 | 497-19-8 | 207-838-8 | 01-2119485 498-19-XXX X |
| (1-hydroxyethylidene)bisphosphonic acid, sodium salt | >= 1 < 2,5% | Acute Tox. 4, H302 ATE oral = 500,0 mg/kg | | | 701-238-4 | 01-2119510 382-52-XXX X |
| Alcohols, C12-14, Ethoxylated propoxylated | >= 1 < 2,5% | Aquatic Chronic 3, H412 Chronic toxicity M-factor = 1 | | 68439-51-0 | | |
| Titanium dioxide V W 1 | >= 0,1 < 1% | Carc. 2, H351 | 022-006-002 | 13463-67-7 | 236-675-5 | 01-2119489 379-17-XXX X |
| Subtilisin | >= 0,1 < 1% | Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Dam. 1, H318; Resp. Sens. 1, H334; | | 9014-01-1 | 232-752-2 | 01-2119480 434-38-XXX X |

| Substance | Concentration[w/w] | Classification | Index | CAS | EINECS | REACH |
|---------------|---------------------|---|-------|-----------|-----------|-------------------------------|
| | | STOT SE 3, H335; Aquatic Acute 1, H400; Aquatic Chronic 2, H411 Acute toxicity M-factor = 1 Chronic toxicity M-factor = 1 ATE oral = 1.800,0 mg/kg | | | | |
| alpha-amylase | >= 0,1 < 1% | Resp. Sens. 1, H334 | | 9000-90-2 | 232-565-6 | 01-2119938 627-26-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):

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

Contact with eyes causes very severe irritation, including redness and tear. In contact with skin it causes irritation and redness. Inhalation may cause allergic reaction, anaphylactic shock

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)

Industrial Manufacturing:
Handle with extreme caution.
Store in a well ventilated place away from heat sources. (7-30°C)

See the annex exposure scenario.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

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Related to contained substances:
Sodium carbonate:
Tipo OEL: OEL TWA: 10mg/m³

Titanium dioxide:
Limit value – Eight hours
(ppm)/(mg/m³)
Australia: x/5 (1)
Austria: x/5
Belgium: x/10
Canada – Ontario: x/10
Canada – Québec: x/10
Croatia: x/10
 x/4
Denmark: x/6
Finland: x/x
France: x/10
Hungary: x/x
Ireland: x/10 (1)
 x/4 (2)

Latvia: x/10
New Zealand: x/10 (1)
Norway: x/5
People's Republic of China: x/8 (1)
Poland: x/10
Portugal: x/10
Singapore: x/10
Slovakia: x/5
South Korea: x/10
Spain: x/10
Sweden: x/5 inhalable aerosol
Switzerland: x/3 inhalable aerosol
USA – NIOSH: x/x
USA – OSHA: x/15 total dust
United Kingdom: x/10 inhalable aerosol
x/4 respirable aerosol

Limit Value – Short Term
(ppm)/(mg/m³)

Australia: x/x
Austria: x/10
Belgium: x/x
Canada - Ontario: x/x
Canada – Québec: x/x
Denmark: x/12 total dust
Finland: x/x
France: x/x
Hungary: x/x
Ireland: x/12
x/30
Latvia: x/x
New Zealand: x/x
Norway: x/x
People's Republic of China: x/x
Poland: x/x
Romania: x/15 (1)
Singapore: x/x
Slovakia: x/x
South Korea: x/x
Spain: x/x
Sweden: x/x
Switzerland: x/x
USA – NIOSH: x/x
USA – OSHA: x/x
United Kingdom: x/30 (total inhalable)

Australia

(1) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.

Ireland

(1) Inhalable fraction (2) Respirable fraction

Japan - JSOH

(1) nanoparticle, as Ti

New Zealand

(1) The value for inhalable dust containing no asbestos and less than 1% free silica.

People's Republic of China

(1) Inhalable fraction

Romania

(1) 15 minutes average value

Subtilisin:

Limit value – Eight hours

(ppm)/(mg/m³)

Argentina: x/x

Australia: x/x

Austria: x/x

Belgium: x/0,00006

Canada – Ontario: x/x

Canada – Québec: x/x

Croatia: x/0.00004

Denmark: x/0,00006

Finland: x/x

France: x/x

Hungary: x/x

Ireland: x/0,00006

Latvia: x/x

New Zealand: x/x

People's Republic of China: x/0,000015

Poland: x/x

Singapore: x/x

South Korea: x/x

Spain: x/x

Sweden: x/1 glycine unit/m³

Switzerland: x/x

USA – NIOSH: x/x

USA – OSHA: x/x

United Kingdom: x/0,00004

Limit Value – Short Term

(ppm)/(mg/m³)

Argentina: x/0.00006 (1)

Australia: x/0,00006 (1)

Austria: x/x

Belgium: x/x

Canada - Ontario: x/0,00006 (1)

Canada – Québec: x/0,00006 (1)

Croatia: x/x

Denmark: x/0,00006

Finland: x/x

France: x/x

Hungary: x/x

Ireland: x/0,00006 (1)

Latvia: x/x

New Zealand: x/0,00006 (1)

People's Republic of China: x/0,00003 (1)

Poland: x/x

Singapore: x/0,00006

South Korea: x/x

Spain: x/0,00006

Sweden: x/3 glycine unit/m³ (1)

Switzerland: x/0,00006

USA – NIOSH: x/0,00006 (1)

USA – OSHA: x/x

United Kingdom: x/x

Australia

(1) Ceiling limit value

Canada - Ontario

(1) Ceiling limit value

Canada - Québec

(1) Ceiling limit value

Ireland

(1) 15 minutes reference period

New Zealand

(1) Ceiling limit value

People's Republic of China

(1) 15 minutes average value

Spain

sen

Sweden

(1) 15 minutes average value

USA - NIOSH

(1) 60 minutes average value

- Substance: Sodium carbonate

DNEL

Local effects Long term Workers inhalation = 10 (mg/m³)

Local effects Long term Consumers inhalation = 10 (mg/m³)

- Substance: (1-hydroxyethylidene)bisphosphonic acid, sodium salt

DNEL

Systemic effects Long term Workers inhalation = 2,95 (mg/m³)

Systemic effects Long term Workers dermal = 17 (mg/kg bw/day)

PNEC

Sweet water = 0,068 (mg/l)

sediment Sweet water = 136 (mg/kg/sediment)

Sea water = 0,007 (mg/l)

- Substance: Subtilisin

DNEL

Systemic effects Long term Workers inhalation = 0,06 (mg/m³)

Systemic effects Long term Consumers oral = 1,8 (mg/kg bw/day)

Systemic effects Short term Consumers oral = 3,6 (mg/kg bw/day)

Local effects Long term Consumers inhalation = 0,015 (mg/m³)

PNEC

Sweet water = 0,0017 (mg/l)

Sea water = 0,00017 (mg/l)

intermittent emissions = 0,0009 (mg/l)

STP = 65 (mg/l)

ground = 0,568 (mg/kg ground)

- Substance: alpha-amylase

DNEL

Local effects Long term Workers inhalation = 0,06 (mg/m³)

Local effects Long term Consumers inhalation = 0,015 (mg/m³)

PNEC

Sweet water = 0,0052 (mg/l)

Sea water = 0,00052 (mg/l)

intermittent emissions = 0,052 (mg/l)

STP = 65 (mg/l)

ground = 0,001 (mg/kg ground)

8.2. Exposure controls

Appropriate engineering controls:

Industrial Manufacturing:

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

Wear protective goggles (EN 166).

(b) Skin protection

(i) Hand protection

Not needed for normal use.

In the case of individuals who are already sensitised to the substance or mixture in the product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3) unless otherwise provided by the employer and / or assessments of environmental investigations hygienistic

(ii) Other

During working operation wear protective clothing (generic workwear / antacid, safety shoes or other protective equipment) according to the instructions of the employer

(c) Respiratory protection

Not needed for normal use.

None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 245/2016 UE), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization

(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 | Granular powder | |
| Colour | white and gray | |
| Odour | Not determined as it is considered not relevant to the characterization of the product | |
| Odour threshold | Not determined as it is considered not relevant to the characterization of the product | |
| Melting point/freezing point | Not determined as it is considered not relevant to the characterization of the product | |

| Physical and chemical properties | Value | Determination method |
|--|--|----------------------|
| Boiling point or initial boiling point and boiling range | Not determined as it is considered not relevant to the characterization of the product | |
| Flammability | Not determined as it is considered not relevant to the characterization of the product | |
| Lower and upper explosion limit | Not determined as it is considered not relevant to the characterization of the product | |
| Flash point | Not determined as it is considered not relevant to the characterization of the product | |
| Auto-ignition temperature | Not determined as it is considered not relevant to the characterization of the product | |
| Decomposition temperature | Not determined as it is considered not relevant to the characterization of the product | |
| pH | 11,5 ± 0,5 (20°C; sol.1%) | |
| Kinematic viscosity | Not determined as it is considered not relevant to the characterization of the product | |
| Solubility | in water | |
| Water solubility | In all proportions | |
| Partition coefficient n-octanol/water (log value) | Not determined as it is considered not relevant to the characterization of the product | |
| Vapour pressure | Not determined as it is considered not relevant to the characterization of the product | |
| Density and/or relative density | 1,01 ± 0,05 (20°C) | |
| Relative vapour density | Not determined as it is considered not relevant to the characterization of the product | |
| Particle characteristics | not determined as considered not relevant for the characterization of the product | |

9.2. Other information

9.2.1 Information with regard to physical hazard classes

No data available.

9.2.2 Other safety characteristics

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

base

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

Nothing to report

10.5. Incompatible materials

Strong acids.

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 = 18.840,3 mg/kg

(a) acute toxicity: Sodium carbonate: Ingestion - LD50 rat (mg / kg / 24h bw): 2800
Skin contact - LC50 rat / rabbit (mg / kg / 24h bw):> 2000
Inhalation - LD50 rat (mg / l / 4h): 2.3
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Ingestion-rat LD50 (mg/kg/bw 24h): 300-2000

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

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

Alcohols, C12-14, Ethoxylated propoxylated: Ingestion - LD50 rat (mg / kg / 24h bw):> 2000

Inhalation - LC50 rat: nd

Skin - LD50 rat (mg / kg):> 2000

Titanium dioxide: Ingestion: LD50 (rat)> 10000 mg / kg

Contact with skin - LD50 rabbit (mg / kg / 24h bw): nd

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

Subtilisin: Ingestion - LD50 rat (mg / kg / 24h bw): 1800

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

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

alpha-amylase: Ingestion - LD50 rat (mg / kg / 24h bw):> 2000

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

Inhalation - LD50 rat (mg / l / 4h):> 5

(b) skin corrosion/irritation: Sodium carbonate: Non-corrosive

(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-corrosive

Alcohols, C12-14, Ethoxylated propoxylated: Non-corrosive

Titanium dioxide: Non-corrosive

Subtilisin: Non-corrosive

alpha-amylase: Not corrosive

Sodium carbonate: Irritating

(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-irritating
Alcohols, C12-14, Ethoxylated propoxylated: Non-irritating to the skin
Titanium dioxide: May cause slight irritation
Subtilisin: May cause skin irritation
alpha-amylase: Not irritating
(c) serious eye damage/irritation: If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.
Sodium carbonate: Non-corrosive
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-corrosive
Alcohols, C12-14, Ethoxylated propoxylated: Non-corrosive
Titanium dioxide: Non-corrosive
Subtilisin: Non-corrosive
alpha-amylase: Not corrosive
Sodium carbonate: Irritating
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-irritating
Alcohols, C12-14, Ethoxylated propoxylated: Not irritating to the eyes
Titanium dioxide: May cause slight irritation
Subtilisin: Causes serious eye irritation
alpha-amylase: Not irritating
(d) respiratory or skin sensitization: Sodium carbonate: Non-sensitizing
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-sensitizing
Alcohols, C12-14, Ethoxylated propoxylated: Does not exert sensitising action.
The product has not been tested. The directions are derived from substances/products or composition similar structure.
Titanium dioxide: Not sensitizing
Subtilisin: Epicutaneous tests on human volunteers have not detected sensitization properties. May cause sensitization in susceptible individuals. Repeated inhalation of aerosol (dust or mist) containing enzyme may cause respiratory allergy in some individuals.
alpha-amylase: Respiratory sensitizer
(e) germ cell mutagenicity: Sodium carbonate: Non-mutagenic
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-mutagenic
Alcohols, C12-14, Ethoxylated propoxylated: Experimental/calculated data: negative (OECD guideline 471)
Titanium dioxide: Negative in Ames studies with and without metabolic activation up to 10,000 µg / plate. Negative in the lymphoma assay on mice with and without metabolic activation. Negative in the brother chromatid exchange assay using Chinese hamster ovary cells with and without metabolic activation. Negative in chromosome aberration studies using Chinese hamster ovary cells.
Subtilisin: Negative in chromosomal aberration using human lymphocytes. Negative in Ames test with and without metabolic activation up to 5000 µg / plate.
alpha-amylase: Not mutagenic
(f) carcinogenicity: Sodium carbonate: Non-carcinogenic
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-carcinogenic
Alcohols, C12-14, Ethoxylated propoxylated: Not available
Titanium dioxide: The rats exposed by inhalation to TiO₂ particles (one component of this product) at 0, 10, 50 or 250 mg / m³, 6 hours / day for 2 years showed a statistically significant increase in the incidence of lung tumors. However, administration of 2.5 or 5% of TiO₂ in the diet to rats for 2 years showed no evidence of carcinogenicity. IARC has classified TiO₂ as "possibly carcinogenic to humans" based on sufficient animal data and insufficient evidence in humans.
Subtilisin: Scientifically not necessary study
alpha-amylase: Unavailable
(g) reproductive toxicity: Sodium carbonate: Non-toxic for reproduction
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Non-toxic for reproduction
Alcohols, C12-14, Ethoxylated propoxylated: Not available
Titanium dioxide: Non-toxic
Subtilisin: This product does not contain any known or presumed reproductive hazard
alpha-amylase: Unavailable
(h) specific target organ toxicity (STOT) single exposure: Sodium carbonate: Not available
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Not available
Alcohols, C12-14, Ethoxylated propoxylated: Not available

Titanium dioxide: Non-toxic
Subtilisin: No data
alpha-amylase: Unavailable
(i) specific target organ toxicity (STOT) repeated exposure Sodium carbonate: Not available
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Not available
Alcohols, C12-14, Ethoxylated propoxylated: Not available
Titanium dioxide: Non-toxic
Subtilisin: OECD Test No. 408: 90-Day Repeated Dose Oral Toxicity Study in Rodents: Negative. NOAEL (highest concentration of a substance to which no harmful effects are observed) = 360 *** mg / kg bw / day ***
alpha-amylase: Unavailable
(j) aspiration hazard: Sodium carbonate: Not available
(1-hydroxyethylidene)bisphosphonic acid, sodium salt: Not disponible
Alcohols, C12-14, Ethoxylated propoxylated: Not available
Titanium dioxide: May cause irritation of the respiratory tract
Subtilisin: May cause irritation of the respiratory system

11.2. Information on other hazards

No data available.

SECTION 12. Ecological information

12.1. Toxicity

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Related to contained substances:

Sodium carbonate:

Acute toxicity - LC50 fish (mg / l / 96h): > 300

Acute toxicity - crustaceans EC50 (mg / l / 48h): 210

Acute toxicity algae ErC50 (mg / l / 72-96h): 740

(1-hydroxyethylidene)bisphosphonic acid, sodium salt:

Acute toxicity-fish LC50 (mg/l/96h): 2670-3400

Acute toxicity-crustacea EC50 (mg/l/48 h): 466-610

Acute algae toxicity ErC50 (mg/l/72-96h): > 960

Chronic toxicity-crustaceans NOEC (mg/l): 0.1

Alcohols, C12-14, Ethoxylated propoxylated:

The product has not been tested. The indications are derived from substances / products of similar composition or structure.

Acute toxicity - LC50 fish (mg / l / 96h): 1 - 10

Acute toxicity - invertebrates EC50 (mg / l / 24h): 10 - 100

Acute toxicity algae ErC50 (mg / l / 72-96h): 0.1- 1

Microorganisms / Effects on activated sludge: CE0 > 100 mg / l

Titanium dioxide:

Acute toxicity - fish LC50, *Leuciscus idus* (mg / l / 96h): > 1000mg / l

Acute toxicity - crustaceans, *Daphnia* EC50 (mg / l / 48h): > 1000mg / l

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

Chronic toxicity - NOEC fish (mg / l): nd

Chronic toxicity - crustaceans NOEC (mg / l): nd

Chronic toxicity NOEC algal (mg / l): nd

Subtilisin:

Acute toxicity - fish LC50 (mg / l / 96h): 17.7
Acute toxicity - crustaceans EC50 (mg / l / 48h): 1.29
Acute toxicity - Daphnia EC50 (mg / l / 48h): 0.17
Acute toxicity algae ErC50 (mg / l / 72-96h): 0.513
Chronic toxicity - fish NOEC (mg / l): 10.2
Chronic toxicity - shellfish NOEC (mg / l): 0.066
Chronic toxicity algae NOEC (mg / l) 72h: 0.073

alpha-amylase:

Acute toxicity - fish LC50 (mg / l / 96h): > 100
Acute toxicity - crustaceans EC50 (mg / l / 48h): 212
Acute toxicity algae ErC50 (mg / l / 72-96h): 5.2
Chronic toxicity - fish NOEC (mg / l): 45.5
Chronic toxicity - crustaceans NOEC (mg / l): 106
Chronic toxicity algae NOEC (mg / l): 1.3

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:

Sodium carbonate:

Not available

(1-hydroxyethylidene)bisphosphonic acid, sodium salt:

~ 50% OECD 302 B

* COD (Std. Method 5220 D): 330 mg / g

* BOD-5 (Std. Method 5210 B): 20 mg / g

* MBAS: 0 mg / g * BiAS: 0 mg / g

Alcohols, C12-14, Ethoxylated propoxylated:

Evaluation of biodegradability and elimination (H₂O): Readily biodegradable (according to OECD criteria). Disposal considerations: > 60% (28 d) (OECD 301F; ISO 9408; 92/69 / EEC, C.4-D) Readily biodegradable (according to OECD criteria).

Titanium dioxide:

Not available

Subtilisin:

Rapidly biodegradable (102% after 29 days)

alpha-amylase:

Easily biodegradable (99% 28d)

12.3. Bioaccumulative potential

=====

Related to contained substances:

Sodium carbonate:

Not available

(1-hydroxyethylidene)bisphosphonic acid, sodium salt:

No other information available

Alcohols, C12-14, Ethoxylated propoxylated:

Assessment of bioaccumulation potential: No accumulation in organisms should be expected.

Titanium dioxide:

No data

Subtilisin:

Not bioaccumulative

alpha-amylase:

No bioaccumulation potential

12.4. Mobility in soil

=====
Related to contained substances:

Sodium carbonate:

Not available

(1-hydroxyethylidene)bisphosphonic acid, sodium salt:

Not available

Alcohols, C12-14, Ethoxylated propoxylated:

The substance does not evaporate in the atmosphere from the surface of the water. An absorption to the solid phase of the soil is possible.

Titanium dioxide:

No data

Subtilisin:

LogPow: -1.3

alpha-amylase:

Log: -1.3

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No adverse effects

Regulation (EC) No 2006/907 - 2004/648

The (l) surfactant (s) content (s) in this preparation complies (comply) with (i) the biodegradability criteria as laid down in Regulation CE/648/2004 on detergents. All data are held at the disposal of the competent authorities of Member States and will be provided, at their direct request or at the request of a detergent manufacturer, to those authorities.

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

Substances in the Candidate List (REACH Article 59)
Based on available data, no SVHC substances are present

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: 2.2. Label elements

Description of hazard statements set out in paragraph 3

H319 = Causes serious eye irritation.

H302 = Harmful if swallowed.

H412 = Harmful to aquatic life with long lasting effects.

H351 = Suspected of causing cancer .

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.

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

Classification according to Regulation (EC) Nr. 1272/2008

H319 - Causes serious eye irritation. 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.

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 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: Environment 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>

This msds was made in good faith by technical Office on the basis of the information available at the date of the last revision. The person in charge must regularly inform the employees about the specific risks they encounter when using this substance/product. The information contained here relate only to the substance/the preparation indicated and may not apply if the product is used improperly or in combination with others. Nothing contained herein shall be construed as a guarantee, either express or implied. It is the responsibility of the user to ensure the opportunities and completeness of the information contained herein for their own particular use.

*** this tab annuls and replaces any previous edition. (IIXX)

Changes to the previous edition: label elements variation

SUMI**Safe Use of Mixtures Information****AISE_SUMI_IS_2_1***Version 1.1, August 2018****Industrial uses; use in closed process***

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.

General description of the process covered

The SUMI applies to industrial uses where products are used in closed process with occasional controlled exposure. This Safe Use Information is based on the **AISE_SWED_IS_2_1**.

Operational Conditions

| | |
|--|---|
| Maximum duration | 480 minutes per day. |
| Range of application / Process conditions | Indoor Use. Process carried out at room temperature. In case of dilution, tap water at a maximum temperature of 45°C is used. |
| Air exchange rate | Provide a basic standard of general ventilation (1 to 3 air changes per hour). No LEV required. |

Risk Management Measures

| | |
|---|---|
| Measures related to personal protective equipment (PPE), hygiene and health evaluation | See section 8 of the SDS of this product for specifications. |
| | Training of workers in relation to proper use and maintenance of PPEs must be ensured. |
| Environmental measures | Prevent that undiluted product reaches surface waters. |
| | If appropriate AISE SPERC 8a.1.a.v2 may apply: wide dispersive use resulting in release to municipal sewage treatment plant. |

Additional good practice advice

| | |
|--|--|
| <p>Don't eat or drink. Don't smoke. Don't use in proximity of open flame.</p> |  |
| <p>Wash hands after use. Avoid contact with damaged skin. Do not mix with other products.</p> |  |
| <p>Spillage instructions</p> | <p>Dilute with fresh water and mop up.</p> |
| <p>Hygiene practices</p> | <p>Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the product SDS.</p> |

Additional information depending on product composition

The label and (when required) the Safety Data Sheet contain additional, product specific information crucial for working safely with mixtures. Please refer to the product label and SDS for information including, but not limited to: product hazard classification, potentially allergenic fragrances, notable ingredients and threshold limit values (when available).

Disclaimer

This is a document for communicating generic conditions of safe use of a product. It is the responsibility of the formulator to link this SUMI to the SDS of a specific product that he is selling.

If a SUMI (or associated SWED) code is mentioned in the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the SUMI is safe. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.

Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following SUMI conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, SUMI Sheets should always be considered in combination with the SDS and the label of the product.

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SUMI**Safe Use of Mixtures Information****AISE_SUMI_IS_8b_2***Version 1.1, August 2018****Transfer and dilution of concentrated product by using dedicated dosing system***

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.

General description of the process covered

This SUMI applies to industrial uses where products are transferred to or diluted in a dedicated dosing system. This Safe Use Information is based on the **AISE_SWED_IS_8b_2_L** and **AISE_SWED_IS_8b_2_S**

Operational Conditions

| | |
|--|---|
| Maximum duration | 60 minutes per day. |
| Range of application / Process conditions | Indoor Use. |
| | Process carried out at room temperature. |
| | In case of dilution, tap water at a maximum temperature of 45°C is used. |
| Air exchange rate | Provide a basic standard of general ventilation (1 to 3 air changes per hour). No LEV required. |

Risk Management Measures

| | |
|---|---|
| Measures related to personal protective equipment (PPE), hygiene and health evaluation | See section 8 of the SDS of this product for specifications. |
| | Training of workers in relation to proper use and maintenance of PPEs must be ensured. |
| Environmental measures | Prevent that undiluted product reaches surface waters. |
| | If appropriate AISE SPERC 8a.1.a.v2 may apply: wide dispersive use resulting in release to municipal sewage treatment plant. |

Additional good practice advice

| | |
|---|--|
| <p>Don't eat or drink. Don't smoke. Don't use in proximity of open flame.</p> |  |
| <p>Wash hands after use. Avoid contact with damaged skin. Do not mix with other products.</p> |  |
| <p>Spillage instructions</p> | <p>Dilute with fresh water and mop up.</p> |
| <p>Hygiene practices</p> | <p>Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the product SDS.</p> |

Additional information depending on product composition

The label and (when required) the Safety Data Sheet contain additional, product specific information crucial for working safely with mixtures. Please refer to the product label and SDS for information including, but not limited to: product hazard classification, potentially allergenic fragrances, notable ingredients and threshold limit values (when available).

Disclaimer

This is a document for communicating generic conditions of safe use of a product. It is the responsibility of the formulator to link this SUMI to the SDS of a specific product that he is selling.

If a SUMI (or associated SWED) code is mentioned in the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the SUMI is safe. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.

Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following SUMI conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, SUMI Sheets should always be considered in combination with the SDS and the label of the product.

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SUMI**Safe Use of Mixtures Information****AISE_SUMI_IS_13_4***Version 1.1, August 2018****Industrial uses; Treatment of articles by dipping or pouring***

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.

General description of the process covered

This SUMI applies to industrial uses where articles are treated by dipping or pouring. This Safe Use Information is based on the **AISE_SWED_IS_13_4**.

Operational Conditions

| | |
|--|---|
| Maximum duration | 480 minutes per day. |
| Range of application / Process conditions | Indoor Use. Process carried out at room temperature. In case of dilution, tap water at a maximum temperature of 45°C is used. |
| Air exchange rate | Provide a basic standard of general ventilation (1 to 3 air changes per hour). No LEV required. |

Risk Management Measures

| | |
|---|---|
| Measures related to personal protective equipment (PPE), hygiene and health evaluation | See section 8 of the SDS of this product for specifications. |
| | Training of workers in relation to proper use and maintenance of PPEs must be ensured. |
| Environmental measures | Prevent that undiluted product reaches surface waters. |
| | If appropriate AISE SPERC 8a.1.a.v2 may apply: wide dispersive use resulting in release to municipal sewage treatment plant. |

Additional good practice advice

| | |
|--|--|
| <p>Don't eat or drink. Don't smoke. Don't use in proximity of open flame.</p> |  |
| <p>Wash hands after use. Avoid contact with damaged skin. Do not mix with other products.</p> |  |
| <p>Spillage instructions</p> | <p>Dilute with fresh water and mop up.</p> |
| <p>Hygiene practices</p> | <p>Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the product SDS.</p> |

Additional information depending on product composition

The label and (when required) the Safety Data Sheet contain additional, product specific information crucial for working safely with mixtures. Please refer to the product label and SDS for information including, but not limited to: product hazard classification, potentially allergenic fragrances, notable ingredients and threshold limit values (when available).

Disclaimer

This is a document for communicating generic conditions of safe use of a product. It is the responsibility of the formulator to link this SUMI to the SDS of a specific product that he is selling.

If a SUMI (or associated SWED) code is mentioned in the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the SUMI is safe. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.

Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following SUMI conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, SUMI Sheets should always be considered in combination with the SDS and the label of the product.

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WORKING ISTRUCTION TABLE



This tab provides instructions for appropriate and safe use of products and proper management of emergency situations for cleaning staff/users.

Attached to MSDS rel#6 06/13/2022

| | |
|--|--|
| Use description | Use in closed, continuous process with occasional controlled exposure [PROC2]; Transfer of substance or mixture (charging and discharging) at dedicated facilities [PROC8b]; Treatment of articles by dipping and pouring [PROC13] |
| Product name | REMOVIL Zyme |
| Classification of the product (100%) | H319 - Causes serious eye irritation. EUH208 - Contains: Subtilisina, alfa-amilasi. May produce an allergic reaction |
| Classification of the diluted product (maximum use concentration) | At maximux concentration of use (1%) the product is classified: Non hazardous according to Regulation (EC) No 1272/2008 |
| Handling of the product (100%) | Avoid contact and inhalation of vapors Wear eye protection/face protection. At work do not eat or drink. |
| Handling of the diluted product | Avoid contact and inhalation of vapors At work do not eat or drink. |
| DPI required concentrated product (racking, concentrated use, spillage...) | No DPI required for the intended use |
| Diluted product | No DPI required for the intended use |

| | |
|--|---|
| In case of emergency (accidents involving exposure to the product) | Immediately inform the customer. Immediately inform the employer. Contact Poisons Centres tel. number in 1.4 section of the MSDS |
| Accidental release large quantities measures: concentrated product | Wear gloves, glasses and protective clothing (for specifications refer to section 8.2. SDS) Possibly absorb it with inert materia or sucked it. After wiping up, wash with water the area and materials involved |
| Diluted product | Possibly absorb it with inert materia. Wash with water the area and materials involved . |
| Storage of the product | 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. |
| In case of accidents, emergency or fire | Immediately inform the customer. Follow company emergency instruction. |