



SAFETY DATA SHEET SAVINASE 12 T

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

1.1. Product identifier

Product name SAVINASE 12 T

Product number 57914

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

Identified uses Biocatalyst
For further information, see attached Exposure Scenario.

1.3. Details of the supplier of the safety data sheet

Supplier Univar Solutions UK Ltd
Aquarius House
6 Mid Point Business Park
Bradford
BD3 7AY
+44 1274 267300
+44 1274 267306
SDS.EMEA@univarsolutions.com

1.4. Emergency telephone number

Emergency telephone SGS - +32 (0)3 575 55 55 (24h)

Sds No. 57914

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Resp. Sens. 1 - H334

Environmental hazards Aquatic Chronic 3 - H412

2.2. Label elements

Hazard pictograms



Signal word Danger

Hazard statements H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H412 Harmful to aquatic life with long lasting effects.

SAVINASE 12 T

Precautionary statements	P261 Avoid breathing dust. P273 Avoid release to the environment. P284 [In case of inadequate ventilation] wear respiratory protection. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor. P501 Dispose of contents/ container in accordance with national regulations.
Supplemental label information	EUH212: Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.
Contains	SUBTILISIN

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

SUBTILISIN 2.5 - < 5%		
CAS number: 9014-01-1	EC number: 232-752-2	REACH registration number: 01-2119480434-38-XXXX
M factor (Acute) = 1		
Classification Acute Tox. 4 - 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		
TITANIUM DIOXIDE (> 10 µm) 2.5 – <5%		
CAS number: 13463-67-7	EC number: 236-675-5	REACH registration number: 01-2119489379-17-XXXX
Classification Not Classified		

The full text for all hazard statements is displayed in Section 16.

Composition comments The data shown are in accordance with the latest EC Directives.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	First aid personnel should wear appropriate protective equipment during any rescue. Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be taken without appropriate training or involving any personal risk. Show this Safety Data Sheet to the medical personnel.
Inhalation	Move affected person to fresh air at once. Rinse nose and mouth with water. Get medical attention if symptoms are severe or persist.

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Ingestion	Never give anything by mouth to an unconscious person. Do not induce vomiting. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if any discomfort continues.
Skin contact	Remove contaminated clothing. Remove affected person from source of contamination. Rinse immediately with plenty of water. Get medical attention if any discomfort continues.
Eye contact	Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

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

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause coughing and difficulties in breathing. Effects may be delayed.
Ingestion	May cause irritation. May cause discomfort if swallowed.
Skin contact	May be slightly irritating to skin.
Eye contact	May be slightly irritating to eyes.

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

Notes for the doctor	Treat symptomatically. Effects may be delayed.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards	May cause respiratory allergy. Harmful to aquatic life with long lasting effects.
Hazardous combustion products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

5.3. Advice for firefighters

Protective actions during firefighting	No action shall be taken without appropriate training or involving any personal risk. Control run-off water by containing and keeping it out of sewers and watercourses. Contain and collect extinguishing water.
Special protective equipment for firefighters	Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Provide adequate ventilation. Wear protective clothing as described in Section 8 of this safety data sheet. Do not allow to dry out. Avoid generation and spreading of dust. Avoid inhalation of dust and vapours.
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6.2. Environmental precautions

Environmental precautions	Do not discharge into drains or watercourses or onto the ground. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.
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6.3. Methods and material for containment and cleaning up

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Methods for cleaning up Provide adequate ventilation. Remove spillage with vacuum cleaner or collect with a shovel and broom, or similar. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. For waste disposal, see Section 13. Flush contaminated area with plenty of water. Confirm disposal procedures with environmental engineer and local regulations.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Avoid contact with skin and eyes. Avoid the formation of mists. Avoid generation and spreading of dust. Provide adequate ventilation.

Advice on general occupational hygiene Take off immediately all contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash at the end of each work shift and before eating, smoking and using the toilet. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Store at temperatures between 0°C and 25°C. Avoid exposure to high temperatures or direct sunlight.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

Occupational exposure limits

SUBTILISIN

Long-term exposure limit (8-hour TWA): WEL 0.00004 mg/m³

Sen

TITANIUM DIOXIDE (> 10 µm)

Long-term exposure limit (8-hour TWA): WEL 4 mg/m³ respirable dust

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³ inhalable dust

WEL = Workplace Exposure Limit.

Sen = Capable of causing occupational asthma.

SUBTILISIN (CAS: 9014-01-1)

DNEL	Workers - Dermal; Short term local effects: 0.2 %
DMEL	Workers - Inhalation; Long term local effects: 60 ng/m ³ Professional, Consumer - Inhalation; Long term local effects: 15 ng/m ³
PNEC	- Fresh water; 0.06 µg/l - marine water; 0.006 µg/l - STP; 65000 µg/l

8.2. Exposure controls

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Protective equipment



Appropriate engineering controls

Provide adequate ventilation.

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses. Personal protective equipment for eye and face protection should comply with European Standard EN166.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. Nitrile rubber. Neoprene. Thickness: > 0.3 mm The selected gloves should have a breakthrough time of at least > 4 hours. To protect hands from chemicals, gloves should comply with European Standard EN374.

Other skin and body protection

Wear suitable protective clothing as protection against splashing or contamination.

Hygiene measures

Wash at the end of each work shift and before eating, smoking and using the toilet. Wash promptly if skin becomes contaminated. Do not eat, drink or smoke when using this product. Take off immediately all contaminated clothing and wash it before reuse. Remove contaminated clothing and protective equipment before entering eating areas.

Respiratory protection

If ventilation is inadequate, suitable respiratory protection must be worn. Particulate filter, type P3. Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Granules.
Colour	Off-white.
Odour	Characteristic.
Odour threshold	No information available.
pH	No information available.
Melting point	No information available.
Initial boiling point and range	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Evaporation factor	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Other flammability	No information available.

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Vapour pressure	No information available.
Vapour density	No information available.
Relative density	1.13
Bulk density	No information available.
Solubility(ies)	No information available.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.
Viscosity	No information available.

9.2. Other information

Other information	Not determined.
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	There are no known reactivity hazards associated with this product.
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10.2. Chemical stability

Stability	Stable under the prescribed storage conditions.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Not determined.
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10.4. Conditions to avoid

Conditions to avoid	Avoid excessive heat for prolonged periods of time. Avoid generation and spreading of dust.
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10.5. Incompatible materials

Materials to avoid	Not determined.
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10.6. Hazardous decomposition products

Hazardous decomposition products	Does not decompose when used and stored as recommended. Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological effects	No information available.
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Acute toxicity - oral

ATE oral (mg/kg)	36,734.69
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Skin corrosion/irritation

Skin corrosion/irritation	May be slightly irritating to skin.
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Serious eye damage/irritation

Serious eye damage/irritation	Slightly irritating. Read-across data.
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Respiratory sensitisation

Respiratory sensitisation	Sensitising.
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Skin sensitisation

Skin sensitisation No information available.

Germ cell mutagenicity

Genotoxicity - in vitro No information available.

Carcinogenicity

Carcinogenicity No information available.

Reproductive toxicity

Reproductive toxicity - fertility No information available.

Reproductive toxicity - development No information available.

Specific target organ toxicity - single exposure

STOT - single exposure No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available.

Aspiration hazard

Aspiration hazard Not anticipated to present an aspiration hazard, based on chemical structure.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Wheezing/breathing difficulties. Effects may be delayed.

Ingestion May cause irritation. Gastro-intestinal tract

Skin contact May be slightly irritating to skin.

Eye contact May be slightly irritating to eyes.

Toxicological information on ingredients.

SUBTILISIN

Acute toxicity - oral

Acute toxicity oral (LD₅₀ mg/kg) 1,800.0

Species Rat

Notes (oral LD₅₀) Harmful if swallowed. LD₅₀ 1800 mg/kg, Oral, Rat OECD 401

ATE oral (mg/kg) 1,800.0

Skin corrosion/irritation

Skin corrosion/irritation Slightly irritating.

Serious eye damage/irritation

Serious eye damage/irritation Slightly irritating.

Respiratory sensitisation

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Germ cell mutagenicity

Genotoxicity - in vitro This substance has no evidence of mutagenic properties.

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Specific target organ toxicity - single exposure

STOT - single exposure May cause respiratory irritation.

TITANIUM DIOXIDE (> 10 µm)

Acute toxicity - oral

Notes (oral LD₅₀) LD₅₀ >5000 mg/kg, Oral, Rat OECD 425

Acute toxicity - dermal

Notes (dermal LD₅₀) LD₅₀ >10000 mg/kg, Dermal, Rabbit

Acute toxicity - inhalation

Notes (inhalation LC₅₀) LD₅₀ 3.43-5.09 mg/l, Inhalation, Rat OECD 403

Skin corrosion/irritation

Animal data Not irritating. Rabbit OECD 404

Serious eye damage/irritation

Serious eye damage/irritation Not irritating. Rabbit OECD 405

Respiratory sensitisation

Respiratory sensitisation Not sensitising. Based on available data the classification criteria are not met.

Skin sensitisation

Skin sensitisation Not sensitising. Local Lymph Node Assay (LLNA) OECD 429

Germ cell mutagenicity

Genotoxicity - in vitro Ames test Negative. OECD 471

Carcinogenicity

IARC carcinogenicity IARC Group 2B Possibly carcinogenic to humans.

Reproductive toxicity

Reproductive toxicity - fertility No information available.

Specific target organ toxicity - single exposure

STOT - single exposure No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available.

Aspiration hazard

Aspiration hazard No information available.

Inhalation Dust may irritate the respiratory system. Coughing, chest tightness, feeling of chest pressure.

Ingestion May cause discomfort if swallowed.

Skin contact Prolonged contact may cause dryness of the skin.

Eye contact May cause temporary eye irritation.

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SECTION 12: Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Ecological information on ingredients.

SUBTILISIN

Ecotoxicity Very toxic to aquatic life with long lasting effects.

TITANIUM DIOXIDE (> 10 µm)

Ecotoxicity The product is not expected to be hazardous to the environment. However, large or frequent spills may have hazardous effects on the environment.

12.1. Toxicity

Toxicity Harmful to aquatic life with long lasting effects.

Ecological information on ingredients.

SUBTILISIN

Toxicity Very toxic to aquatic life with long lasting effects.

Acute aquatic toxicity

LE(C)₅₀ 0.1 < L(E)C₅₀ ≤ 1

M factor (Acute) 1

Acute toxicity - fish LC₅₀, 96 hours: 8.2 mg/l, Fish
OECD 203

Acute toxicity - aquatic invertebrates EC₅₀, 48 hours: 0.586 mg/l, Daphnia magna
OECD 202

Acute toxicity - aquatic plants EC₅₀, 72 hours: 0.83 mg/l, Algae
OECD 201

TITANIUM DIOXIDE (> 10 µm)

Acute aquatic toxicity

Acute toxicity - fish LC₅₀, 96 hours: >10000 mg/l, Cyprinodon variegatus (Sheepshead minnow)

Acute toxicity - aquatic plants NOEC, 480 hours: 100000 mg/l, Algae

12.2. Persistence and degradability

Persistence and degradability No information available.

Ecological information on ingredients.

SUBTILISIN

Persistence and degradability The substance is readily biodegradable.

TITANIUM DIOXIDE (> 10 µm)

Persistence and degradability The product contains inorganic substances which are not biodegradable.

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12.3. Bioaccumulative potential

Bioaccumulative potential No information available.

Partition coefficient No information available.

Ecological information on ingredients.

SUBTILISIN

Bioaccumulative potential The product is not bioaccumulating.

Partition coefficient log Pow: < 0

TITANIUM DIOXIDE (> 10 µm)

Bioaccumulative potential The product is not bioaccumulating. BCF: 19-352, Oncorhynchus mykiss (Rainbow trout)

Partition coefficient No information available.

12.4. Mobility in soil

Mobility No information available.

Ecological information on ingredients.

TITANIUM DIOXIDE (> 10 µm)

Mobility The product is insoluble in water.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This product does not contain any substances classified as PBT or vPvB.

Ecological information on ingredients.

SUBTILISIN

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

TITANIUM DIOXIDE (> 10 µm)

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

12.6. Other adverse effects

Other adverse effects None known.

Ecological information on ingredients.

TITANIUM DIOXIDE (> 10 µm)

Other adverse effects Not determined.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General information Waste is classified as hazardous waste. Do not puncture or incinerate, even when empty. Harmful to aquatic life with long lasting effects. Do not discharge into drains or watercourses or onto the ground.

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Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

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

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78
and the IBC Code

SECTION 15: Regulatory information

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

EU legislation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

15.2. Chemical safety assessment

Not applicable.

SECTION 16: Other information

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Abbreviations and acronyms used in the safety data sheet

ATE: Acute Toxicity Estimate.
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
 CAS: Chemical Abstracts Service.
 DNEL: Derived No Effect Level.
 IATA: International Air Transport Association.
 IMDG: International Maritime Dangerous Goods.
 Kow: Octanol-water partition coefficient.
 LC₅₀: Lethal Concentration to 50 % of a test population.
 LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).
 PBT: Persistent, Bioaccumulative and Toxic substance.
 PNEC: Predicted No Effect Concentration.
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
 RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
 vPvB: Very Persistent and Very Bioaccumulative.
 IARC: International Agency for Research on Cancer.
 MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978.
 cATpE: Converted Acute Toxicity Point Estimate.
 BCF: Bioconcentration Factor.
 BOD: Biochemical Oxygen Demand.
 EC₅₀: 50% of maximal Effective Concentration.
 LOAEC: Lowest Observed Adverse Effect Concentration.
 LOAEL: Lowest Observed Adverse Effect Level.
 NOAEC: No Observed Adverse Effect Concentration.
 NOAEL: No Observed Adverse Effect Level.
 NOEC: No Observed Effect Concentration.
 LOEC: Lowest Observed Effect Concentration.
 DMEL: Derived Minimal Effect Level.
 EL50: Exposure Limit 50
 hPa: Hectopascal
 LL50: Lethal Loading fifty
 OECD: Organisation for Economic Co-operation and Development
 POW: Octanol-water partition coefficient
 SCBA: self-contained breathing apparatus
 STP: Sewage Treatment Plant
 VOC: Volatile Organic Compounds

Classification abbreviations and acronyms

Acute Tox. = Acute toxicity
 Aquatic Acute = Hazardous to the aquatic environment (acute)
 Aquatic Chronic = Hazardous to the aquatic environment (chronic)

Key literature references and sources for data

Supplier's information.

Revision comments

NOTE: Lines within the margin indicate significant changes from the previous revision.

Revision date

08/12/2021

Version number

3.000

Supersedes date

11/05/2020

SDS number

57914

SAVINASE 12 T

SDS status

Approved.

Hazard statements in full

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.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.



Exposure scenario
Subtilisin: Formulation or re-packing

Identification

Product name	Protease (Subtilisin)
REACH registration number	01-2119480434-38-XXXX
CAS number	9014-01-1
EC number	232-752-2
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Subtilisin: Formulation or re-packing
Process scope	Formulation of the substance and its mixtures in batch or continuous operations within closed or contained systems, including incidental exposures during storage, materials transfers, mixing, maintenance, sampling and associated laboratory activities.
Product category	PC21 Laboratory chemicals. PC35 Washing and cleaning products PC37 Water treatment chemicals. PC39 Cosmetics, personal care.
Main sector	SU3 Industrial uses
Sector of use	SU10 Formulation [mixing] of preparations and/or re-packaging
<u>Environment</u>	
Environmental release category	ERC2 Formulation into mixture
<u>Worker</u>	

Subtilisin: Formulation or re-packing

Process category	PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
	PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
	PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
	PROC4 Chemical production where opportunity for exposure arises
	PROC5 Mixing or blending in batch processes
	PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
	PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
	PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
	PROC14 Tableting, compression, extrusion, pelletisation, granulation
	PROC15 Use as laboratory reagent.

2. Conditions of use affecting exposure (Industrial - Environment 1)

Control of environmental exposure

Environmental release category	ERC2 Formulation into mixture
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Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %.

Amounts used

Daily amount per site: 10 tonnes
Annual amount per site: 2500 tonnes

Frequency and duration of use

Emission days: 365 days/year
Continuous release.

Environmental factors not influenced by risk management measures

Dilution	Receiving surface water flow: 18000 m ³ /day
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Risk management measures

STP type	Municipal STP.
STP details	Assumed domestic sewage treatment plant flow: 2000 m ³ /day Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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2. Conditions of use affecting exposure (Workers - Health 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %. Concentration of substance in product: 0.5%

Frequency and duration of use

Covers daily exposure up to 12hours

Subtilisin: Formulation or re-packing

Other given operational conditions affecting workers exposure

Setting	Indoor.
Ventilation rate	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Technical conditions and measures at process level (source) to prevent release

Technical protective measures	High efficiency particulate air filter (HEPA filter) Provide extract ventilation to points where emissions occur. PROC15 Use as laboratory reagent. Handle in a fume cupboard or under extract ventilation.
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Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented. Ensure operatives are trained to minimise exposures. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.
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Risk management measures

Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent/minimise exposures and to report any skin problems that may develop. Wear suitable coveralls to prevent exposure to the skin. Use suitable eye protection. In case of insufficient ventilation, wear suitable respiratory equipment. with filter for particulates: P3.

Additional advice	Avoid splashing.
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3. Exposure estimation (Environment 1)

Environmental release category	ERC2 Formulation into mixture
Assessment method	Used ECETOC TRA model.
Environmental release	Water: 100 kg/day Air: 0 kg/day Soil: 0 kg/day
Environmental exposure	Fresh water: Exposure 0.0009 mg/l, PNEC 0.0017 mg/l, RCR 0.53 Marine water: Exposure 0.00009 mg/l, PNEC 0.00017 mg/l, RCR 0.53 STP: Exposure 0.005 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method	Used ECETOC TRA model.
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Subtilisin: Formulation or re-packing

Exposure

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition

PROC4 Chemical production where opportunity for exposure arises

PROC5 Mixing or blending in batch processes

Worker - inhalation, long-term - local: Exposure 20 ng/m³, DNEL 60 ng/m³, RCR 0.33

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities

Worker - inhalation, long-term - local: Exposure 10 ng/m³, DNEL 60 ng/m³, RCR 0.17

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

PROC15 Use as laboratory reagent.

Worker - inhalation, long-term - local: Exposure 6 ng/m³, DNEL 60 ng/m³, RCR 0.1

PROC14 Tableting, compression, extrusion, pelletisation, granulation

Worker - inhalation, long-term - local: Exposure 30 ng/m³, DNEL 60 ng/m³, RCR 0.5

Worker - dermal Qualitative approach used to conclude safe use.

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.



Exposure scenario
Subtilisin: Industrial processing aid (including Cleaning in Place)

Identification

Product name	Protease (Subtilisin)
REACH registration number	01-2119480434-38-XXXX
CAS number	9014-01-1
EC number	232-752-2
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Subtilisin: Industrial processing aid (including Cleaning in Place)
Main sector	SU3 Industrial uses
Sector of use	SU2b Offshore industries SU5 Manufacture of textiles, leather, fur SU6b Manufacture of pulp, paper and paper products SU8 Manufacture of bulk, large-scale chemicals (including petroleum products) SU9 Manufacture of fine chemicals SU23 Electricity, steam, gas, water supply and sewage treatment SU24 Scientific research and development

Environment

Environmental release category	ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
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Worker

Subtilisin: Industrial processing aid (including Cleaning in Place)

Process category	PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
	PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
	PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
	PROC4 Chemical production where opportunity for exposure arises
	PROC5 Mixing or blending in batch processes
	PROC7 Industrial spraying
	PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
	PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
	PROC13 Treatment of articles by dipping and pouring.
	PROC15 Use as laboratory reagent.

2. Conditions of use affecting exposure (Industrial - Environment 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %.

Amounts used

Daily amount per site: 0.8 tonnes
Annual amount per site: 200 tonnes

Frequency and duration of use

Emission days: 365 days/year
Continuous release.

Environmental factors not influenced by risk management measures

Dilution	Receiving surface water flow: 18000 m ³ /day
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Risk management measures

STP type	Municipal STP.
STP details	Assumed domestic sewage treatment plant flow: 2000 m ³ /day Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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2. Conditions of use affecting exposure (Workers - Health 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %. Concentration of substance in product: 0.5% PROC7 Industrial spraying Maximum concentration after dilution for use: 0.0065 %

Frequency and duration of use

Covers daily exposure up to 12hours

Other given operational conditions affecting workers exposure

Setting	Indoor.
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Subtilisin: Industrial processing aid (including Cleaning in Place)

Ventilation rate Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Technical conditions and measures at process level (source) to prevent release

Technical protective measures High efficiency particulate air filter (HEPA filter) Provide extract ventilation to points where emissions occur.
PROC15 Use as laboratory reagent. Handle in a fume cupboard or under extract ventilation.

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures Assumes a good basic standard of occupational hygiene is implemented. Ensure operatives are trained to minimise exposures. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.

Risk management measures

Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent/minimise exposures and to report any skin problems that may develop. Wear suitable coveralls to prevent exposure to the skin. Use suitable eye protection. In case of insufficient ventilation, wear suitable respiratory equipment. with filter for particulates: P3.

Additional advice Avoid splashing.

3. Exposure estimation (Environment 1)

Assessment method Used ECETOC TRA model.

Environmental release Water: 80 kg/day
Air: 0 kg/day
Soil: 0 kg/day

Environmental exposure Fresh water: Exposure 0.0009 mg/l, PNEC 0.0017 mg/l, RCR 0.53
Marine water: Exposure 0.00009 mg/l, PNEC 0.00017 mg/l, RCR 0.53
STP: Exposure 0.005 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method Used ECETOC TRA model.

Subtilisin: Industrial processing aid (including Cleaning in Place)

Exposure

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition

PROC4 Chemical production where opportunity for exposure arises

PROC5 Mixing or blending in batch processes

PROC13 Treatment of articles by dipping and pouring.

Worker - inhalation, long-term - local: Exposure 20 ng/m³, DNEL 60 ng/m³, RCR 0.33

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities

Worker - inhalation, long-term - local: Exposure 10 ng/m³, DNEL 60 ng/m³, RCR 0.17

PROC15 Use as laboratory reagent.

Worker - inhalation, long-term - local: Exposure 6 ng/m³, DNEL 60 ng/m³, RCR 0.1

PROC7 Industrial spraying

Worker - inhalation, long-term - local: Exposure 40 ng/m³, DNEL 60 ng/m³, RCR 0.67

Worker - dermal Qualitative approach used to conclude safe use.

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.



Exposure scenario

Subtilisin: Professional use of laundry products

Identification

Product name	Protease (Subtilisin)
REACH registration number	01-2119480434-38-XXXX
CAS number	9014-01-1
EC number	232-752-2
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Subtilisin: Professional use of laundry products
Product category	PC35 Washing and cleaning products
Main sector	SU22 Professional uses
<u>Environment</u>	
Environmental release category	ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
<u>Worker</u>	
Process category	PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

2. Conditions of use affecting exposure (Industrial - Environment 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
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Amounts used

Daily amount for wide dispersive uses: 0.00011 tonnes

Frequency and duration of use

Emission days: 365 days/year
Continuous release.

Subtilisin: Professional use of laundry products

Environmental factors not influenced by risk management measures

Dilution Receiving surface water flow: 18000 m³/day

Risk management measures

STP type Municipal STP.

STP details Assumed domestic sewage treatment plant flow: 2000 m³/day
Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment External treatment and disposal of waste should comply with applicable local and/or national regulations.

2. Conditions of use affecting exposure (Workers - Health 1)

Product characteristics

Physical state Solid, low dustiness , or: Liquid

Concentration details Concentration of substance in product: 0.2%

Frequency and duration of use

Covers daily exposure up to 12hours

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

Application duration: 0.1 hours/day

Other given operational conditions affecting workers exposure

Setting Indoor.

Technical conditions and measures at process level (source) to prevent release

Technical protective measures No specific risk management measure identified beyond those operational conditions stated.

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures Assumes a good basic standard of occupational hygiene is implemented.

Risk management measures

Additional advice Avoid contact with skin and eyes. Wash off any skin contamination immediately.

3. Exposure estimation (Environment 1)

Assessment method Used ECETOC TRA model.

Environmental release Water: 0.00275 kg/day
Air: 0 kg/day
Soil: 0 kg/day

Environmental exposure Fresh water: Exposure 0.0005 mg/l, PNEC 0.0017 mg/l, RCR 0.3
Marine water: Exposure 0.00005 mg/l, PNEC 0.00017 mg/l, RCR 0.3
STP: Exposure 0.000001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method Used ECETOC TRA model.

Subtilisin: Professional use of laundry products

Exposure

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

Worker - inhalation, long-term - local: Exposure 1 ng/m³, DNEL 15 ng/m³, RCR 0.07

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

Worker - inhalation, long-term - local: Exposure 3 ng/m³, DNEL 15 ng/m³, RCR 0.2

Worker - dermal Qualitative approach used to conclude safe use.

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.



Exposure scenario

Subtilisin: Consumer use of laundry products

Identification

Product name	Protease (Subtilisin)
REACH registration number	01-2119480434-38-XXXX
CAS number	9014-01-1
EC number	232-752-2
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Subtilisin: Consumer use of laundry products
Product category	PC35 Washing and cleaning products
Main sector	SU21 Consumer uses

Environment

Environmental release category	ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
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2. Conditions of use affecting exposure (Workers - Health 1)

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented.
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2. Conditions of use affecting exposure (Non-industrial - Environment 1)

Amounts used

Daily amount for wide dispersive uses: 0.0011 tonnes
Amount refers to local.

Risk management measures

STP type	Municipal STP.
STP details	Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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Subtilisin: Consumer use of laundry products

Conditions and measures related to external recovery of waste

Recovery method External recovery and recycling of waste should comply with applicable local and/or national regulations.

2. Conditions of use affecting exposure (Non-industrial - Health 1)

Product characteristics

Physical state Solid, low dustiness , or: Liquid

Concentration details Concentration of substance in product: 0.2%

Amounts used

Laundry regular
Powder products
Amount per use: 290 g
Laundry compact
Powder products
Amount per use: 200 g
Laundry compact
Tablet.
Amount per use: 135 g
Laundry regular
Liquid
Amount per use: 230 g
Laundry compact
Liquid
Amount per use: 140 g

Frequency and duration of use

Application duration: 0.1 hours

Other given operational conditions affecting Non-industrial exposure

Setting Indoor.

3. Exposure estimation (Environment 1)

Assessment method Used ECETOC TRA model.

Environmental release Water: 0.11 kg/day
Air: 0 kg/day
Soil: 0 kg/day

Environmental exposure Fresh water: Exposure 0.0004 mg/l, PNEC 0.0017 mg/l, RCR 0.25
Marine water: Exposure 0.00004 mg/l, PNEC 0.00017 mg/l, RCR 0.25
STP: Exposure 0.00001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method Used ECETOC TRA model.

Exposure Consumer - inhalation, long-term - local and systemic: Exposure 3 ng/m³, DNEL 15 ng/m³, RCR 0.2
Consumer - combined, long-term - systemic: Exposure 0 mg/kg/day, DNEL 1.8 mg/kg/day, RCR <0.01

4. Guidance to check compliance with the exposure scenario (Health 1)

Subtilisin: Consumer use of laundry products

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.



Exposure scenario

Subtilisin: Consumer hand dishwashing

Identification

Product name	Protease (Subtilisin)
REACH registration number	01-2119480434-38-XXXX
CAS number	9014-01-1
EC number	232-752-2
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Subtilisin: Consumer hand dishwashing
Product category	PC35 Washing and cleaning products
Main sector	SU21 Consumer uses

Environment

Environmental release category	ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
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2. Conditions of use affecting exposure (Workers - Health 1)

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented.
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2. Conditions of use affecting exposure (Non-industrial - Environment 1)

Amounts used

Daily amount for wide dispersive uses: 0.0000027 tonnes
Amount refers to local.

Risk management measures

STP type	Municipal STP.
STP details	Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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Subtilisin: Consumer hand dishwashing

Conditions and measures related to external recovery of waste

Recovery method External recovery and recycling of waste should comply with applicable local and/or national regulations.

2. Conditions of use affecting exposure (Non-industrial - Health 1)

Product characteristics

Physical state Liquid

Concentration details Concentration of substance in product: 0.015%

Amounts used

Amount per use: 10 g

Frequency and duration of use

Application duration: <60 minutes

Other given operational conditions affecting Non-industrial exposure

Setting Indoor.

3. Exposure estimation (Environment 1)

Assessment method Used ECETOC TRA model.

Environmental release Water: 0.000275 kg/day
Air: 0 kg/day
Soil: 0 kg/day

Environmental exposure Fresh water: Exposure 0.0004 mg/l, PNEC 0.0017 mg/l, RCR 0.25
Marine water: Exposure 0.00004 mg/l, PNEC 0.00017 mg/l, RCR 0.25
STP: Exposure 0.00001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method Used ECETOC TRA model.

Exposure Consumer - inhalation, long-term - local and systemic: Exposure 3 ng/m³, DNEL 15 ng/m³, RCR 0.2
Consumer - combined, long-term - systemic: Exposure 0 mg/kg/day, DNEL 1.8 mg/kg/day, RCR <0.01

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.



Exposure scenario

Subtilisin: Consumer use of machine dishwashing products

Identification

Product name	Protease (Subtilisin)
REACH registration number	01-2119480434-38-XXXX
CAS number	9014-01-1
EC number	232-752-2
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Subtilisin: Consumer use of machine dishwashing products
Product category	PC35 Washing and cleaning products
Main sector	SU21 Consumer uses

Environment

Environmental release category	ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
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2. Conditions of use affecting exposure (Workers - Health 1)

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented.
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2. Conditions of use affecting exposure (Non-industrial - Environment 1)

Amounts used

Daily amount for wide dispersive uses: 0.0011 tonnes
Amount refers to local.

Risk management measures

STP type	Municipal STP.
STP details	Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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Subtilisin: Consumer use of machine dishwashing products

Conditions and measures related to external recovery of waste

Recovery method External recovery and recycling of waste should comply with applicable local and/or national regulations.

2. Conditions of use affecting exposure (Non-industrial - Health 1)

Product characteristics

Physical state Solid, low dustiness , or: Liquid

Concentration details Concentration of substance in product: 0.2%

Amounts used

Amount per use: 50 g

Frequency and duration of use

Application duration: 0.1 hours

Other given operational conditions affecting Non-industrial exposure

Setting Indoor.

3. Exposure estimation (Environment 1)

Assessment method Used ECETOC TRA model.

Environmental release Water: 0.11 kg/day
Air: 0 kg/day
Soil: 0 kg/day

Environmental exposure Fresh water: Exposure 0.0004 mg/l, PNEC 0.0017 mg/l, RCR 0.25
Marine water: Exposure 0.00004 mg/l, PNEC 0.00017 mg/l, RCR 0.25
STP: Exposure 0.00001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method Used ECETOC TRA model.

Exposure Consumer - inhalation, long-term - local and systemic: Exposure 3 ng/m³, DNEL 15 ng/m³, RCR 0.2
Consumer - combined, long-term - systemic: Exposure 0 mg/kg/day, DNEL 1.8 mg/kg/day, RCR <0.01

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.