

This safety data sheet was created pursuant to the requirements of:
UK REACH Regulations (SI 2019/758 as amended)

Supersedes date 03-Dec-2020

Revision date 08-Dec-2025

Revision Number 2

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

1.1. Product identifier

Product Code(s) 61308
Safety data sheet number 61308
Product Name EVERIS PRECISE

Pure substance/mixture Mixture

Contains SUBTILISIN; DISUBSTITUTED ALANINAMIDE

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

Recommended use Biocatalyst
Industrial application
Consumer use
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
GBR

For further information, please contact

E-mail address SDS.EMEA@univarsolutions.com
Non-Emergency Telephone Number +44 1274 267300 / +44 1274 267306

1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Serious eye damage/eye irritation	Category 2 - (H319)
Respiratory sensitisation	Category 1 - (H334)
Chronic aquatic toxicity	Category 3 - (H412)

2.2. Label elements

Contains SUBTILISIN; DISUBSTITUTED ALANINAMIDE

**Signal word**

Danger

Hazard statements

H319 - Causes serious eye irritation

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P280 - Wear protective gloves/protective clothing/eye protection/face protection

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 or doctor/physician

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Additional information

This product requires tactile warnings if supplied to the general public.

2.3. Other hazards

May cause slight skin irritation.

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable

3.2 Mixtures

Chemical name	Weight-%	EC No (EU Index No)	UK REACH registration number	Classification according to GB CLP (SI 2020/1567 as amended)	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
SUBTILISIN 9014-01-1	5 - < 7.5%	232-752-2 (647-012-00-8)	-	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)	-	1	-
DISUBSTITUTED ALANINAMIDE 2940997-67-9	0.1 - < 1%	938-640-6	-	Skin Sens. 1B (H317)	-	-	-

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

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (UK REACH Article 59)

SECTION 4: First aid measures**4.1. Description of first aid measures**

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Take off contaminated clothing and wash it before reuse. Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	May produce an allergic reaction. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical attention.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information.

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

Symptoms	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes serious eye irritation. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Eyes	Causes serious eye irritation.
Dermal	May cause slight skin irritation. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.
Ingestion	May cause irritation

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

Note to doctors	May cause sensitisation in susceptible persons. Treat symptomatically.
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SECTION 5: Firefighting measures**5.1. Extinguishing media**

Suitable Extinguishing Media	Water spray. Alcohol resistant foam. Dry chemical or CO ₂ .
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
<u>5.2. Special hazards arising from the substance or mixture</u>	
Specific hazards arising from the chemical	Product is or contains a sensitiser. May cause sensitisation by inhalation.
Hazardous combustion products	No information available.
<u>5.3. Advice for firefighters</u>	
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid formation of dust and aerosols.
Other information	Refer to protective measures listed in Sections 7 and 8.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Collect spillage. Prevent further leakage or spillage if safe to do so.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Avoid formation of dust and aerosols. Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Avoid generation of dust. Take up mechanically, placing in appropriate containers for disposal. Flush remainder carefully with plenty of water. Avoid splashing and high pressure washing (avoid formation of aerosols). Ensure adequate ventilation. Remove and wash contaminated clothing and gloves, including the inside, before re-use.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections	See section 8 for more information. See section 13 for more information.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Do not eat, drink or smoke when using this product. Avoid generation of dust and aerosols.
General hygiene considerations	Remove contaminated clothing and protective equipment before entering eating areas. Handle in accordance with good industrial hygiene and safety practice. Ensure that eyewash stations and safety showers are close to the workstation location. Avoid contact

with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep at temperatures between 0 and 25 °C. Protect from direct sunlight.

7.3. Specific end use(s)

Specific use(s)

See section 1 for more information.

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	United Kingdom
SUBTILISIN 9014-01-1	TWA: 0.00004 mg/m ³ Sen+

Biological occupational exposure limits This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

Derived No Effect Level (DNEL) - General Public

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
SUBTILISIN 9014-01-1	0.06 µg/L	0.9 µg/L	0.006 µg/L		

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
SUBTILISIN 9014-01-1			65 mg/L	568 µg/kg	65 mg/L

8.2. Exposure controls

Engineering controls

Ensure adequate ventilation. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles). Use eye protection according to EN ISO 16321-1.

Hand protection Wear suitable gloves. Gloves must conform to standard EN 374.

Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
Long term (repeated)	Nitrile rubber	> 0.3 mm	> 4 hours
Long term (repeated)	Neoprene gloves	> 0.3 mm	> 4 hours

Skin and body protection Wear suitable protective clothing.

Respiratory protection In case of inadequate ventilation wear respiratory protection. Use respiratory equipment with particle filter, type P3.

General hygiene considerations Remove contaminated clothing and protective equipment before entering eating areas. Handle in accordance with good industrial hygiene and safety practice. Ensure that eyewash stations and safety showers are close to the workstation location. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

Environmental exposure controls Local authorities should be advised if significant spillages cannot be contained. Ensure all waste water is collected and treated via a waste water treatment plant.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	Liquid
Appearance	Liquid
Colour	Amber
Odour	Slight fermentation odour.
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point		No information available.
Initial boiling point and boiling range		No information available.
Flammability		No information available.
Flammability Limit in Air		No information available.
Upper flammability or explosive limits		
Lower flammability or explosive limits		
Flash point	> 100 °C	No information available.
Autoignition temperature		No information available.
Decomposition temperature		No information available.
pH	4 - 9	No information available.
pH (as aqueous solution)		No information available.
Kinematic viscosity		No information available.
Dynamic viscosity		No information available.
Water solubility	Soluble in water	No information available.
Solubility(ies)		No information available.
Partition coefficient		No information available.
Vapour pressure		No information available.
Relative density		No information available.
Bulk density		No information available.

Liquid Density	1.1 g/mL	No information available
Relative vapour density		No information available.
Particle characteristics		No information available.
Particle Size	No information available	
Particle Size Distribution	No information available	
Explosive properties	No data available	
Oxidising properties	No data available	

9.2. Other information**SECTION 10: Stability and reactivity****10.1. Reactivity**

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Keep at temperatures between 0 and 25 °C. Protect from direct sunlight.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Information on likely routes of exposure****Product Information**

Inhalation Specific test data for the substance or mixture is not available. May cause sensitisation in susceptible persons. (based on components). May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Eye contact Causes serious eye irritation. On basis of test data.

Skin contact Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Prolonged contact may cause redness and irritation. May cause slight skin irritation. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.

Ingestion

Specific test data for the substance or mixture is not available. May cause additional affects as listed under "Inhalation". May cause irritation.

Symptoms related to the physical, chemical and toxicological characteristics**Symptoms**

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes serious eye irritation. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.

Acute toxicity**Numerical measures of toxicity**

The following values are calculated based on chapter 3.1 of the GHS document

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
SUBTILISIN	504 mg/kg (Rat)	-	-
DISUBSTITUTED ALANINAMIDE	> 2000 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Skin corrosion/irritation**

No information available.

SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD 404		Dermal			Causes skin irritation

DISUBSTITUTED ALANINAMIDE (2940997-67-9)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD 439		Dermal			Not classified

Serious eye damage/eye irritation Causes serious eye irritation. On basis of test data.

Method	Species	Exposure route	Effective dose	Exposure time	Results
Isolated Chicken Eye Test	Chicken eye.	eye			Causes serious eye irritation

SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD 405		eye			Causes serious eye damage

DISUBSTITUTED ALANINAMIDE (2940997-67-9)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD 437		eye			Not classified

Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled. The product contains a small amount of sensitising substance which may provoke an allergic reaction among sensitive individuals in contact with skin.

SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Results
	Human evidence	Inhalation	May cause allergy or asthma

			symptoms or breathing difficulties if inhaled
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DISUBSTITUTED ALANINAMIDE (2940997-67-9)

Method	Species	Exposure route	Results
OECD 429		Dermal	May cause an allergic skin reaction

Germ cell mutagenicity No information available.

Component Information

SUBTILISIN (9014-01-1)

Method	Species	Results
OECD 471 OECD 473 OECD 476		Not classified

DISUBSTITUTED ALANINAMIDE (2940997-67-9)

Method	Species	Results
OECD 471		Not classified

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Effective dose	Exposure time	Results
		Inhalation			May cause respiratory irritation

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Other adverse effects No information available.

SECTION 12: Ecological information**12.1. Toxicity**

Ecotoxicity Harmful to aquatic life with long lasting effects.

SUBTILISIN (9014-01-1)

Method	Species	Endpoint type	Effective dose	Exposure time	Results
OECD Test No. 202: Daphnia sp., Acute Immobilisation Test	Crustacea	EC50	0.586 mg/L	48 hours	Very toxic to aquatic life
OECD Test No. 203: Fish, Acute Toxicity Test	Fish	LC50	8.2 mg/L	96 hours	Toxic to aquatic life

OECD Test No. 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test	Algae	ErC50	0.83 mg/L	72 hours	Very toxic to aquatic life
OECD Test No. 211: Daphnia magna Reproduction Test	Crustacea	EC10	0.145 mg/L	21 days	Harmful to aquatic life with long lasting effects
OECD Test No. 210: Fish, Early-Life Stage Toxicity Test	Fish	EC10	0.017 mg/L	32 days	Toxic to aquatic life with long lasting effects
OECD Test No. 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test	Algae	NOEC	0.317 mg/L	72 hours	Harmful to aquatic life with long lasting effects

DISUBSTITUTED ALANINAMIDE (2940997-67-9)

Method	Species	Endpoint type	Effective dose	Exposure time	Results
OECD Test No. 202: Daphnia sp., Acute Immobilisation Test	Daphnia magna	EC0	> 88.4 mg/L	48 hours	
OECD Test No. 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test	Algae	ErC50	> 100 mg/L	72 hours	Not classified
OECD Test No. 201: Freshwater Algae and Cyanobacteria, Growth Inhibition Test	Algae	NOEC	> 1 mg/L	72 hours	Not classified

12.2. Persistence and degradability

Persistence and degradability No information available.

SUBTILISIN (9014-01-1)

Method	Exposure time	Value	Results
OECD Test No. 301B: Ready Biodegradability: CO2 Evolution Test (TG 301 B)			Readily biodegradable

DISUBSTITUTED ALANINAMIDE (2940997-67-9)

Method	Exposure time	Value	Results
OECD Test No. 301F: Ready Biodegradability: Manometric Respirometry Test (TG 301 F)			Readily biodegradable

12.3. Bioaccumulative potential

Bioaccumulation No information available.

Component Information

Chemical name	Partition coefficient
SUBTILISIN	< 0
DISUBSTITUTED ALANINAMIDE	1.8

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

Chemical name	PBT and vPvB assessment
SUBTILISIN	The substance is not PBT / vPvB
DISUBSTITUTED ALANINAMIDE	The substance is not PBT / vPvB

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste from residues/unused products Waste is classified as hazardous waste. Disposal to licensed waste disposal site in accordance with the local Waste Disposal Authority.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information**IATA**

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None
14.7 Maritime transport in bulk according to IMO instruments	No information available

RID

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special precautions for user	
Special Provisions	None

ADR

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions None

SECTION 15: Regulatory information

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

National regulations

Authorisations and/or restrictions on use:

This product contains one or more substances subject to restriction (UK REACH - Annex XVII).

This product does not contain substances subject to authorisation (UK REACH - Annex XIV).

Product restricted per REACH Annex XVII: 3

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
SUBTILISIN - 9014-01-1	75	-

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH Regulations 2015 (as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Not applicable

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons Act 1972 (Explosive Precursors) Regulations (as Amended)

Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECI	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status
NZIoC	Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AIIC - Australian Inventory of Industrial Chemicals
NZIoC - New Zealand Inventory of Chemicals

15.2. Chemical safety assessment

Chemical Safety Report

A Chemical Safety Assessment has been carried out for one or more substances present in the material

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
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

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation
+	Sensitisers		

Revision Note **SDS sections updated 1 2 3 4 5 6 7 8 9 10 11 12 13 15 16**

Classification procedure

Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	On basis of test data
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)
European Chemicals Agency (ECHA) (ECHA_API)
Environmental Protection Agency
Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
National Institute of Technology and Evaluation (NITE)
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Prepared By N Bajaj
Supersedes date 03-Dec-2020
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**This material safety data sheet complies with the requirements of UK REACH Regulations (SI 2019/758 as amended)
Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The 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, unless specified in the text.

End of Safety Data Sheet

Annex to the Safety Data Sheet according to Regulation (EC) No 1907/2006 [REACH]

Chemical name SUBTILISIN
REACH registration number 01-2119480434-38-XXXX
CAS No 9014-01-1
EC No (EU Index No) 232-752-2
Supplier Univar Solutions UK Ltd
 Aquarius House
 6 Mid Point Business Park
 Bradford
 GBR

Non-Emergency Telephone Number +44 1274 267300 / +44 1274 267306

E-mail address SDS.EMEA@univarsolutions.com

Section 1 - Title

Title Formulation & (re)packing of substances and mixtures
Type Worker
Main user group Industrial uses: Uses of substances as such or in preparations at industrial sites
Environmental release category(ies) ERC2 - Formulation of preparations (mixtures)
Process category(ies) PROC1 - Use in closed process, no likelihood of exposure
 PROC2 - Use in closed, continuous process with occasional controlled exposure
 PROC3 - Use in closed batch process (synthesis or formulation)
 PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
 PROC5 - Mixing or blending in batch processes for formulation of preparations and articles (multi-stage and/or significant contact)
 PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities
 PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
 PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
 PROC14 - Production of preparations or articles by tableting, compression, extrusion, pelettising
 PROC15 - Use as laboratory reagent
Product category(ies) PC0 - Other Products PC21 - Laboratory chemicals PC35 - Washing and cleaning products (including solvent based products) PC37 - Water treatment chemicals PC39 - Cosmetics, personal care products
Sector(s) of use SU3 - Industrial uses: Uses of substances as such or in preparations at industrial sites

Section 2 - Operational conditions and risk management measures

Section 2.1 - Control of environmental exposure

Environmental release category(ies) - ERC2 - Formulation of preparations (mixtures)

Amounts used

Type	Daily amount per site
Value	10,000
Units	kg/d

Type	Annual amount per site
Value	2500
Units	t(ons)/year

Conditions and measures related to municipal sewage treatment plant

Type	Municipal STP
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Assumed domestic sewage treatment plant flow	2000 m3/d
Removal efficiency fraction (offsite; STP)	99.99 %
Sludge treatment	Controlled application to agricultural soil

Environmental factors not influenced by risk management

Receiving water dilution (fresh or marine)	18,000 m3/d
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Conditions and measures related to external treatment of waste for disposal

Disposal	External treatment and disposal of waste should comply with applicable local and/or national regulations
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Control of worker exposure

Process category(ies)	PROC5 - Mixing or blending in batch processes for formulation of preparations and articles (multi-stage and/or significant contact) PROC1 - Use in closed process, no likelihood of exposure PROC2 - Use in closed, continuous process with occasional controlled exposure PROC3 - Use in closed batch process (synthesis or formulation) PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
Title	Mixing operations (open systems) Mixing operations (closed systems)
Covers concentrations up to	15 %
Physical form of product	Liquid or granules
Exposure duration	Covers use up to 12 h/d
Technical conditions and measures to control dispersion from source towards the worker	HEPA Filtration Provide extract ventilation to points where emissions occur Avoid splashing
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN 374) 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
Organisational measures to prevent /limit releases, dispersion and exposure	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

Process category(ies)	PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities
Title	Material transfers
Covers concentrations up to	15 %
Physical form of product	Liquid or granules
Exposure duration	Covers use up to 12 h/d
Technical conditions and measures to control dispersion from source towards the worker	HEPA Filtration Provide extract ventilation to points where emissions occur Avoid splashing
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN 374) 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
Organisational measures to prevent /limit releases, dispersion and exposure	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

Process category(ies)	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
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Title	Material transfers
Covers concentrations up to	30 %
Physical form of product	Liquid or granules
Exposure duration	Covers use up to 12 h/d
Technical conditions and measures to control dispersion from source towards the worker	HEPA Filtration Provide extract ventilation to points where emissions occur Use in semi-automated and predominantly enclosed filling lines Avoid splashing
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN 374) 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
Organisational measures to prevent /limit releases, dispersion and exposure	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

Process category(ies)	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Title	Drum and small package filling
Covers concentrations up to	0.5 %
Physical form of product	Liquid or granules
Exposure duration	Covers use up to 12 h/d
Technical conditions and measures to control dispersion from source towards the worker	HEPA Filtration Provide extract ventilation to points where emissions occur Avoid splashing
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN 374) 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
Organisational measures to prevent /limit releases, dispersion and exposure	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

Process category(ies)	PROC14 - Production of preparations or articles by tableting, compression, extrusion, pelettising
Title	Tabletting, compression, extrusion or pelletisation
Covers concentrations up to	0.5 %
Physical form of product	granules
Exposure duration	Covers use up to 12 h/d
Technical conditions and measures to control dispersion from source towards the worker	HEPA Filtration Provide extract ventilation to points where emissions occur Avoid splashing
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN 374) 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
Organisational measures to prevent /limit releases, dispersion and exposure	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

Process category(ies)	PROC15 - Use as laboratory reagent
Title	Laboratory activities
Covers concentrations up to	15 %
Physical form of product	Liquid or granules
Exposure duration	Covers use up to 12 h/d

Technical conditions and measures to control dispersion from source towards the worker	HEPA Filtration Handle in a fume cupboard or under extract ventilation Avoid splashing
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN 374) 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
Organisational measures to prevent /limit releases, dispersion and exposure	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

Section 3 - Exposure estimation

Environmental release category(ies) - ERC2 - Formulation of preparations (mixtures)

Predicted No Effect Concentration (PNEC)

Freshwater	1.7 ug/l
Marine water	0.17 ug/l
Soil	586 ug/l
Impact on Sewage Treatment	65000 ug/l

Environment	predicted exposure level	Risk characterisation ratio (RCR)
Freshwater	<0.0009 mg/l	<0.53
Marine water	<0.00009 mg/l	<0.53
STP: Sewage Treatment Plant	0.005 mg/l	<0.01
Soil	<1.0E-11 mg/kg	<0.01

Derived No Effect Level (DNEL):

Worker - inhalative, long-term - local 60 ng/m³

Calculation method

Workplace measurements

Remarks

Dermal exposure : Qualitative approach used to conclude safe use

Process category(ies)	Exposure route	predicted exposure level	Risk characterisation ratio (RCR)
PROC5 - Mixing or blending in batch processes for formulation of preparations and articles (multi-stage and/or significant contact) PROC1 - Use in closed process, no likelihood of exposure PROC2 - Use in closed, continuous process with occasional controlled exposure PROC3 - Use in closed batch process (synthesis or formulation) PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises	Worker - inhalative, long-term - local	<20 ng/m ³	<0.33
PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities PROC8b - Transfer of substance or preparation	Worker - inhalative, long-term - local	<10 ng/m ³	<0.17

(charging/discharging) from/to vessels/large containers at dedicated facilities			
PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Worker - inhalative, long-term - local	<6 ng/m ³	<0.1
PROC14 - Production of preparations or articles by tableting, compression, extrusion, pelettising	Worker - inhalative, long-term - local	<30 ng/m ³	<0.5
PROC15 - Use as laboratory reagent	Worker - inhalative, long-term - local	<6 ng/m ³	<0.1

Section 4 - Guidance to check compliance with the exposure scenario

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Where other risk management measures/operational conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.

Annex to the Safety Data Sheet according to Regulation (EC) No 1907/2006 [REACH]

Chemical name SUBTILISIN
REACH registration number 01-2119480434-36-XXXX
CAS No 9014-01-1
EC No (EU Index No) 232-752-2
Supplier Univar Solutions UK Ltd
 Aquarius House
 6 Mid Point Business Park
 Bradford
 GBR

Non-Emergency Telephone Number +44 1274 267300 / +44 1274 267306

E-mail address SDS.EMEA@univarsolutions.com

Section 1 - Title

Title Equipment cleaning and maintenance (Medical Devices)
Type Worker
Main user group Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
Environmental release category(ies) ERC8a - Wide dispersive indoor use of processing aids in open systems
Process category(ies) PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities
 PROC10 - Roller application or brushing
 PROC13 - Treatment of articles by dipping and pouring
Product category(ies) PC35 - Washing and cleaning products (including solvent based products)
Sector(s) of use SU22 - Professional uses SU20 - Health services

Section 2 - Operational conditions and risk management measures

Section 2.1 - Control of environmental exposure

Environmental release category(ies) - ERC8a - Wide dispersive indoor use of processing aids in open systems

Amounts used

Type	Daily amount for wide dispersive uses (Daily amount per site)
Value	0.00000055
Units	tonnes

Conditions and measures related to municipal sewage treatment plant

Type	Municipal STP
Assumed domestic sewage treatment plant flow	2000 m3/d
Removal efficiency fraction (offsite; STP)	99.99 %

Conditions and measures related to external treatment of waste for disposal

Disposal	External treatment and disposal of waste should comply with applicable local and/or national regulations
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Control of worker exposure

Process category(ies)	PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities
Covers concentrations up to	0.2 %

Physical form of product	Liquid
Exposure duration	Covers use up to 1 h/d
Technical conditions and measures to control dispersion from source towards the worker	Ensure adequate ventilation Avoid splashing Clear spills immediately
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid contact with eyes and skin Wash skin thoroughly after handling In case of eye contact Rinse with water. Contact physician if discomfort continues.
Organisational measures to prevent /limit releases, dispersion and exposure	Assumes a good basic standard of occupational hygiene is implemented Regular cleaning of equipment Ensure operatives are trained to minimise exposures Supervision in place to check that the RMMs in place are being used correctly and OCs followed Pre-employment screening and appropriate health surveillance

Process category(ies)	PROC10 - Roller application or brushing
Covers concentrations up to	0.2 %
Physical form of product	Liquid
Exposure duration	Covers use up to 1 h/d
Technical conditions and measures to control dispersion from source towards the worker	Ensure adequate ventilation Avoid splashing Clear spills immediately
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid contact with eyes and skin Wash skin thoroughly after handling In case of eye contact Rinse with water. Contact physician if discomfort continues. Pre-employment screening and appropriate health surveillance
Organisational measures to prevent /limit releases, dispersion and exposure	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

Process category(ies)	PROC13 - Treatment of articles by dipping and pouring
Covers concentrations up to	0.2 %
Physical form of product	Liquid
Exposure duration	Covers use up to 1 h/d
Technical conditions and measures to control dispersion from source towards the worker	Ensure adequate ventilation Avoid splashing Clear spills immediately
Conditions and measures related to personal protection, hygiene and health evaluation	Avoid contact with eyes and skin Wash skin thoroughly after handling In case of eye contact Rinse with water. Contact physician if discomfort continues. Pre-employment screening and appropriate health surveillance
Organisational measures to prevent /limit releases, dispersion and exposure	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

Section 3 - Exposure estimation

Environmental release category(ies) - ERC8a - Wide dispersive indoor use of processing aids in open systems

Predicted No Effect Concentration (PNEC)

Freshwater	27.3 ug/l
Marine water	2.73 ug/l
Soil	3.26 ug/l
Impact on Sewage Treatment	65000 ug/l

Environment	predicted exposure level	Risk characterisation ratio (RCR)
Freshwater	<0.0005 mg/l	<0.3

Marine water	<0.00005 mg/l	<0.3
STP: Sewage Treatment Plant	0.000001 mg/l	<0.01
Soil	<1.0E-11 mg/kg	<0.01

Derived No Effect Level (DNEL):

Worker - inhalative, long-term - local

60 ng/m³

Calculation method

Workplace measurements

Remarks

Dermal exposure : Qualitative approach used to conclude safe use

Process category(ies)	Exposure route	predicted exposure level	Risk characterisation ratio (RCR)
PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities	Worker - inhalative, long-term - local	<3 ng/m ³	<0.2
PROC10 - Roller application or brushing	Worker - inhalative, long-term - local	<8 ng/m ³	<0.54
PROC13 - Treatment of articles by dipping and pouring	Worker - inhalative, long-term - local	<9 ng/m ³	<0.6

Section 4 - Guidance to check compliance with the exposure scenario

Guidance is based on assumed operating conditions which may not be applicable to all sites; thus, scaling may be necessary to define appropriate site-specific risk management measures. Where other risk management measures/operational conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.