

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

Supersedes date 07-Jan-2021

Revision date 16-Sep-2024

Revision Number 7

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

1.1. Product identifier

Product Code(s) 53461
Safety data sheet number 53461
Product Name ALCALASE 2.5 L
Pure substance/mixture Mixture

Contains SUBTILISIN

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

Recommended use Biocatalyst
Industrial application
Consumer use

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



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	2.5 - < 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	-

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.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing.
Eyes	Causes serious eye irritation.
Dermal	May cause slight skin irritation.
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.

5.2. Special hazards arising from the substance or mixture**Specific hazards arising from the chemical**

Product is or contains a sensitiser. May cause sensitisation by inhalation.

Hazardous combustion products

No information available.

5.3. Advice for firefighters**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 generation of dust. 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.

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.

6.3. Methods and material for containment and cleaning up**Methods for containment**

Avoid handling which leads to dust formation. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Take up mechanically, placing in appropriate containers for disposal. 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.

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 handling which leads to dust formation.

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 STEL: 0.00012 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

Chemical name	Oral	Dermal	Inhalation
SUBTILISIN 9014-01-1		0.2 % [5] [7]	

[5] Local health effects.
[7] Short term.

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
SUBTILISIN 9014-01-1	1.8 mg/kg bw/day [4] [6] 3.6 mg/kg bw/day [4] [7]		

[4] Systemic health effects.
[6] Long term.
[7] Short term.

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			65000 µg/L	568 µg/kg soil dw	65000 µg/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 Use eye protection according to EN 166. Wear safety glasses with side shields (or goggles).

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.
Odour threshold	No information available

Property	Values	Remarks • Method
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	1.08 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.

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	May cause slight skin irritation. 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.
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	Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes serious eye irritation.
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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)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
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SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Effective dose	Exposure time	Results
OECD 404		Dermal			Irritant

Serious eye damage/eye irritation	Causes serious eye irritation. On basis of test data.
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SUBTILISIN (9014-01-1)

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

Respiratory or skin sensitisation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Results
	Human evidence	Inhalation	Sensitising

Germ cell mutagenicity No information available.

Component Information
SUBTILISIN (9014-01-1)

Method	Species	Results
OECD 471 OECD 473 OECD 476		Not mutagenic

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	Daphnia magna	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

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: CO ₂ Evolution Test (TG 301 B)			Readily biodegradable

12.3. Bioaccumulative potential

Bioaccumulation No information available.

Component Information

Chemical name	Partition coefficient
SUBTILISIN	< 0

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

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

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

14.3 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 No information available

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
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

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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