

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

Supersedes date 05-May-2020

Revision date 29-Oct-2025

Revision Number 2

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

1.1. Product identifier

Product Code(s) 60264
Safety data sheet number 60264
Product Name NOVOZYM 37071

Pure substance/mixture Mixture

Contains SUBTILISIN

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

Recommended use Biocatalyst
Industrial use
Food industry

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 1 - (H318)
Respiratory sensitisation	Category 1 - (H334)
Chronic aquatic toxicity	Category 3 - (H412)

2.2. Label elements

Contains SUBTILISIN

**Signal word**

Danger

Hazard statements

H318 - Causes serious eye damage

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

H412 - Harmful to aquatic life with long lasting effects

Precautionary statements

P280 - Wear protective gloves and eye/face protection

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

P284 - In case of inadequate ventilation wear respiratory protection

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

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

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

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 - < 10%	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	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air. May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration. Get medical attention immediately. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Eye contact	Get immediate medical attention. 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.
Skin contact	Take off contaminated clothing and wash it before reuse. Wash off immediately with soap and plenty of water for at least 15 minutes. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a doctor.
Ingestion	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. May produce an allergic reaction. Get immediate medical attention.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. 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 damage.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Eyes	Causes serious eye damage.
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 .
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. Use personal protective equipment as required. Ensure adequate ventilation. 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. Avoid generation of dust. 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.

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. Do not eat, drink or smoke when using this product. Ensure adequate ventilation. Avoid handling which leads to dust formation.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice. Remove contaminated clothing and protective equipment before entering eating areas. 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 10 °C.

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 No information available

Derived No Effect Level (DNEL) - General Public No information available.

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 166.

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 Handle in accordance with good industrial hygiene and safety practice. Remove contaminated clothing and protective equipment before entering eating areas. 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	brown
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	> 100 °C	No information available.
Flammability Limit in Air		No information available.
Upper flammability or explosive limits		
Lower flammability or explosive limits		
Flash point		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	1.17 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.
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10.2. Chemical stability

Stability	Stable under normal conditions.
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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.
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10.4. Conditions to avoid

Conditions to avoid	Keep at temperatures between 0 and 10 °C.
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10.5. Incompatible materials

Incompatible materials	None known based on information supplied.
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10.6. Hazardous decomposition products

Hazardous decomposition products	None known based on information supplied.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Specific test data for the substance or mixture is not available. May cause sensitisation in susceptible persons. (based on components).
Eye contact	Causes serious eye damage. May cause irreversible damage to eyes. 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).
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 Causes serious eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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.

SUBTILISIN (9014-01-1)

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

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

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.

SUBTILISIN (9014-01-1)

Method	Species	Exposure route	Results
	Human evidence	Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Germ cell mutagenicity No information available.

Component Information
SUBTILISIN (9014-01-1)

Method	Species	Results
OECD 471 OECD 473 OECD 476		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

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

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 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

Other Regulations

The product complies with the recommended purity specifications for food-grade enzymes given by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemical Codex (FCC).

International Inventories

TSCA

Contact supplier for inventory compliance status

DSL/NDL

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/NDL - 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

Prepared By N Bajaj
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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