According to Regulation (EC) No. 1907/2006 (REACH)



Protease SA - A01910

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

1.1	Product identifier					
	Product name:	Protease SA				
	Product No.: SDS No.: Material No.	A01910 906013 025288				
	CAS No.: EC No.: Index No.:	Not applicable. Not applicable. Not applicable.				
1.2	Relevant identified uses of the substa	nce or mixture and uses advised against				
	Identified use(s):	Enzymatic mixture for use in educational science experiments. Professional use only.				
	Uses advised against:	Follow supplier's recommendations on correct use of the product				
1.3	Details of the supplier of the safety data sheet					
	Supplier:	Philip Harris Manufacturing Ltd. Unit 72, Gazelle Road Weston Industrial Estate Weston-super-Mare BS24 9BJ				
	Telephone:	+44 (0)1934 413 606				
	Fax:	+44 (0)1934 626 421				
	E-mail:	sdsinfo@philipharrismanufacturing.co.uk				
1.4	Emergency telephone number					
	In case of emergency, call:	+44 (0)1934 413 606 Monday – Thursday: 08:30 – 17:00 UK time Friday: 08:30 – 13:00 UK time				

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SECTION 2: Hazard Identification

2.1 Classification of the substance or mixture

2.1.1. Classification according to Regulation (EC) No. 1272/2008 (CLP)

Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Resp. Sens. 1 ; H334 STOT SE 3; H335 Aquatic Acute 1; H400

2.1.2. Classification according to Directive 67/548/EEC & Directive 1999/45/EC

Harmful; Xn; R22 Irritant; Xi; R37/38 Irritant; Xi; R41 Harmful; Xn; R42 Dangerous for the environment; N; R50

2.2 Label elements

2.2.1. Label according to Regulation (EC) No. 1272/2008 (CLP)

Hazard pictogram(s):



Signal Word:	Danger.
Hazard Statement(s):	 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.
Precautionary Statement(s):	 P261: Avoid breathing vapour. P280: Wear protective gloves/protective clothing/eye protection/face protection. P284: 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.

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P342 + P311: If experiencing respiratory symptoms: Call a
POISON CENTER or doctor.
P501: Dispose of contents/container to hazardous waste collection point for disposal in accordance with local, regional, national or international regulations.

Supplemental Hazard information (EU):

None.

2.3 Other hazards

The product does not meet the criteria for PBT or vPvB substances.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical name	% w/w	CAS No.	EC No.	Index No.	Classification (Regulation (EC) No. 1272/2008 (CLP))	Classification (Directive 67/548/EEC)
Subtilisin	30-50	9014-01-1	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	Xn; R22 Xi; R37/38 Xi; R41 Xn; R42 N; R50

See Section 16 for full description of R phrases and H statements.

SECTION 4: First Aid Measures

4.1 Description of first aid measures

INHALATION:	Remove person to fresh air and keep in a position comfortable for breathing. Keep warm and at rest. If experiencing respiratory symptoms, obtain immediate medical attention.
SKIN CONTACT:	Take off immediately all contaminated clothing. Rinse skin with plenty of water. If irritation develops and persists, get medical attention. Contaminated clothing should be washed before reuse.
EYE CONTACT:	Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing, making sure to rinse under eyelids. Obtain immediate medical attention.
INGESTION:	Do not induce vomiting. Provided the patient is conscious, rinse mouth out with water and give 200-300 mL of water to drink. Never give anything by mouth to an unconscious person. If symptoms develop, get medical attention.

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

Inhalation may cause allergy or asthma symptoms or breathing difficulties if inhaled. Shortness of breath, wheezing and coughing. The effect of inhalation may be delayed. May cause respiratory irritation. Skin contact

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causes irritation, redness and pain. Eye contact causes serious damage, burning, redness and watering. Ingestion may cause nausea. Ingestion may cause irritation to the mouth and gastrointestinal system.

4.3 Indication of any immediate medical attention and special treatments needed:

In case of accident or if you feel unwell, seek medical advice immediately. Show this Safety Data Sheet to the doctor in attendance. If breathing is laboured, oxygen should be administered by qualified personnel.

SECTION 5: Fire-fighting Measures

5.1 Extinguishing Media

Suitable extinguishing media:	Use extinguishant suitable for surrounding fire. Water spray, alcohol-resistant foam, CO_2 or dry powder.
Unsuitable extinguishing media:	None identified.

5.2 Special hazards arising from the substance or mixture

Containers exposed to fire may burst due to a build-up of pressure.

May cause allergy or asthma symptoms or breathing difficulties if inhaled. Combustion may liberate toxic fumes: Carbon monoxide, carbon dioxide, nitrogen oxides, sulphur oxides.

5.3 Advice for fire-fighters

A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Keep fire exposed containers cool by spraying with water. Do not allow to enter drains, sewers or watercourses.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Provide adequate ventilation to minimise exposure to vapour. Do not breathe vapour. Avoid contact with skin, eyes or clothing. Wear suitable personal protective equipment. Wear appropriate respirator when ventilation is inadequate (See Section 8).

6.1.2 For emergency responders

Keep unnecessary personnel away. Wear suitable protective clothing (See Section 8). Take off contaminated clothing and wash it before reuse.

6.2 Environmental precautions

Do not allow to enter watercourses or surface water drainage (storm drains). Spillages or uncontrolled discharges into watercourses must be alerted to the Environment Agency or other appropriate regulatory body.

6.3 Methods and materials for containment and clearing up

6.3.1 For containment

Stop the leak if it is safe to do so. Contain the spillage with sand, earth or any suitable adsorbent material.



6.3.2 For cleaning up

Use sand, earth or any suitable non-combustible adsorbent material to adsorb spillages. Transfer the contaminated absorbent material into a sealable container for disposal. Dispose of contaminated material as waste according to Section 13. Wash spill area with large amounts of water (discharge to foul sewer only).

6.3.3 Other advice

None.

6.4 Reference to other sections

See Section 8 for personal protective equipment. See Section 13 for waste disposal.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Provide adequate ventilation to minimise exposure to vapour. Do not breathe vapour. Avoid contact with skin, eyes or clothing. Wear suitable personal protective equipment (See Section 8).

Do not eat, drink or smoke when using this product. Wash thoroughly after handling. Take off contaminated clothing and wash it before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store in a well-ventilated place. Keep cool. Storage in a refrigerator will prolong useful life. Recommended storage temperature: 0 – 25°C. Protect from direct sunlight.

Keep away from: strong oxidising agents.

7.3 Specific end use(s)

Enzymatic mixture for use in educational science experiments. Professional use only.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control parameters

Workplace exposure limits

Source: EH40/2005, 2nd Ed., 2011.

Substance	CAS No.	LTEL (8 hr TWA)		STEL (15 min)		Comments
Substance	CAS NO.	ppm	mg/m³	ppm	mg/m³	Comments
Subtilisins (<i>Bacillus subtilis</i> Carlsberg)	9014-01-1	-	0.00004		-	Sen

Sen: Capable of causing occupational asthma.

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DNELs (Workers)

Substance	Route	Acute/short-te	erm exposure	Long-term exposure		
		Systemic effects	Local effects	Systemic effects	Local effects	
Subtilisin	Inhalation	-	-	0.00006 mg/m ^{3*}	0.00006 mg/m ^{3*}	
	Dermal	-	0.2% w/w in mixture	-	0.2% w/w in mixture	

*DMEL

PNECs

Substance	Aqua (fresh water)	Aqua (marine water)	Aqua (intermittent releases)	Sewage Treatment Plants	Sediment (fresh water)	Sediment (marine water)	Soil	Oral
Subtilisin	0.00006 mg/L	0.000006 mg/L	0.0009 mg/L	65 mg/L	Exposure not expected	Exposure not expected	0.568 mg/kg soil dw	No bioaccum- ulation potential.

dw: dry weight

8.2 **Exposure controls**

8.2.1 Appropriate engineering controls

Provide adequate ventilation to minimise exposure to vapour.

8.2.2 **Personal protection**

Eye protection:

If eye-protection is not integral to the respirator being worn, wear goggles or safety glasses with side shields giving complete protection to eyes (EN 166).

Skin protection:

Hand protection:	Chemical-resistant gloves conforming (EN 374). Butyl rubber, natural rubber or neoprene gloves are recommended. Contact glove supplier to confirm suitable glove material, thickness and breakthrough times.	
Other:	Long sleeve protective clothing.	

P3 particle filter or better (EN 143).

Other:

Thermal hazards:

If case of insufficient ventilation, wear a respirator (EN 140) with a

Respiratory protection:

Not applicable.

8.2.3 **Environmental exposure controls**

Inform environmental manager of all incidents involving this product.

SECTION 9: Physical and Chemical Properties

Information on basic physical and chemical properties 9.1

Appearance:

Liquid.

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Odour:	Characteristic.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	Not available.
Initial boiling point and boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid; gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility(ies):	Soluble in water. Subtilisin: > 100 g/L (25°C)
Partition coefficient: n-octanol/water:	Not available. Subtilisin: Log Kow = -3.1
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not applicable.
Explosive properties:	Not explosive.
Oxidising properties:	Not oxidising.
9.2 Other information	

SECTION 10: Stability and Reactivity				
10.1	Reactivity	Reacts with oxidising agents.		
10.2	Chemical stability	Stable under normal conditions.		
10.3	Possibility of hazardous reactions	No hazardous reactions expected during normal use.		
10.4	Conditions to avoid	Avoid extreme temperatures. Storage in a refrigerator will prolong useful life. Recommended storage temperature: $0 - 25^{\circ}$ C. Protect from direct sunlight.		
10.5	Incompatible materials	Strong oxidising agents.		
10.6	Hazardous decomposition products	Combustion may liberate toxic fumes: Carbon monoxide, carbon dioxide, nitrogen oxides, sulphur oxides.		

None known.

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SECTION 11: Toxicological Information

11.1 Information on toxicological effects

	Acute toxicity	Harmful if swallowed. May cause nausea.
		No data are available for the mixture. The following data are for the ingredients:
		Subtilisin: LD ₅₀ (oral/rat): 1,800 mg/kg LC ₅₀ (inhalation/rat/4 h): > 4.96 mg/L air (analytical)
	Skin corrosion/irritation	Causes skin irritation.
	Serious eye damage/irritation	Causes serious eye damage.
	Skin sensitisation	Not classified. The product does not contain substances classified as skin sensitisers above the classification thresholds.
	Respiratory sensitisation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	Germ cell mutagenicity	Not classified. The product does not contain substances classified as mutagenic above the classification thresholds.
	Carcinogenicity	Not classified. The product does not contain substances classified as carcinogenic above the classification thresholds.
	Reproductive toxicity	Not classified. The product does not contain substances classified as toxic to reproduction above the classification thresholds.
	Specific Target Organ Toxicity – single exposure	May cause respiratory irritation.
	Specific Target Organ Toxicity – repeated exposure	Not classified. The product does not contain substances classified for specific target organ toxicity following repeated exposure above the classification thresholds.
	Aspiration hazard	Not classified. Based on available data, the classification criteria are not met.
Informa	tion on likely routes of exposure	
	Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.
	Skin contact	Causes skin irritation.
	Eye contact	Causes serious eye damage.
	Ingestion	Harmful if swallowed. May cause nausea. May cause irritation to the mouth and gastrointestinal system.

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	ms related to the physical, chemical icological characteristics	Inhalation may cause allergy or asthma symptoms or breathing difficulties if inhaled. Shortness of breath, wheezing and coughing. The effect of inhalation may be delayed. May cause respiratory irritation. Skin contact causes irritation, redness and pain. Eye contact causes serious damage, burning, redness and watering. Ingestion may cause nausea. Ingestion may cause irritation to the mouth and gastrointestinal system.
Mixture	versus substance Information	No data available.
Other information		None.
SECT	TION 12: Ecological Information	
12.1	Toxicity	Very toxic to aquatic life.
		No data are available for the mixture. The following data are for the ingredients:
		 Subtilisin: LC₅₀ (<i>Oncorhynchus mykiss</i>): 8.2 mg/L active enzyme protein, 96 h NOEC (<i>Oncorhynchus mykiss</i>): 4.6 mg/L active enzyme protein, 96 h NOEC (<i>Danio rerio</i>): 0.006 mg/L active enzyme protein, 33 days EC₅₀ (<i>Daphnia magna</i>): 0.17 mg/L active enzyme protein, 48 h NOEC (<i>Daphnia magna</i>): 0.0367 mg/L active enzyme protein, 48 h NOEC (<i>Daphnia magna</i>): 0.0008 mg/L active enzyme protein, 21 days EbC₅₀ (<i>Pseudokirchnerella subcapitata</i>): 0.29 mg/L active enzyme protein, 72 h NOEC (<i>Pseudokirchnerella subcapitata</i>): 0.29 mg/L active enzyme protein, 72 h (biomass) ErC₅₀ (<i>Pseudokirchnerella subcapitata</i>): 0.83 mg/L active enzyme protein, 72 h NOEC (<i>Pseudokirchnerella subcapitata</i>): 0.317 mg/L active enzyme
12.2	Persistence and degradability	Readily biodegradable.
12.3	Bioaccumulative potential	No potential to bioaccumulate.
12.4	Mobility in soil	No data available.
12.5	Results of PBT and vPvB assessment	The product does not contain substances assessed to be PBT or $\nu P\nu B.$
12.6	Other adverse effects	None known.

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SECTION 13: Disposal Considerations

13.1 Waste treatment methods

To be disposed of as hazardous waste. Disposal should be in accordance with local, state or national legislation.

SECTION 14: Transport Information

ADR

14.1	UN Number	3077
14.2	UN Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
		N.O.S. (contains Subtilisin)
14.3	Transport hazard class(es)	9
14.4	Packing group	
14.5	Environmental hazards	Yes
14.6	Special precautions for the user	Read SDS and supplier instructions on correct use of the product.
ADN		
14.1	UN Number	3077
14.2	UN Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Subtilisin)
14.3	Transport hazard class(es)	9
14.4	Packing group	
14.5	Environmental hazards	Yes
14.6	Special precautions for the user	Read SDS and supplier instructions on correct use of the product.
RID		
14.1	UN Number	3077
14.2	UN Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
		N.O.S. (contains Subtilisin)
14.3	Transport hazard class(es)	9
14.4	Packing group	
14.5	Environmental hazards	Yes
14.6	Special precautions for the user	Read SDS and supplier instructions on correct use of the product.
IATA/I	CAO	
14.1	UN Number	3077
14.2	UN Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Subtilisin)
14.3	Transport hazard class(es)	9
14.4	Packing group	III
14.5	Environmental hazards	Yes
14.6	Special precautions for the user	Read SDS and supplier instructions on correct use of the product.

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IMDG

14.1	UN Number	3077
14.2	UN Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Subtilisin)
14.3	Transport hazard class(es)	9
14.4	Packing group	III III III III III III III III III II
14.5	Environmental hazards	Yes
14.6	Special precautions for the user	Read SDS and supplier instructions on correct use of the product.
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code	The product is not intended to be transported in bulk.

SECTION 15: Regulatory Information

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

This Safety Data Sheet was prepared in accordance with EC Regulation (EC) No. 1907/2006 as amended. The product has been classified in accordance with Regulation (EC) No. 1272/2008 (CLP), Directive 67/548/EEC & Directive 1999/45/EC.

15.2 Chemical Safety Assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other Information

Full text of relevant R-phrases and/or H-statements:

Hazard Statement(s):	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.
Supplemental Hazard information (EU):	None.
Risk phrase(s):	R22: Harmful if swallowed.
	R37/38: Irritating to respiratory system and skin.
	R41: Risk of serious damage to eyes.
	R42: May cause sensitisation by inhalation.

R50: Very toxic to aquatic organisms.

Abbreviations:

CAS:	Chemical Abstracts Service;
DMEL:	Derived Minimal Effect Level
DNEL:	Derived No Effect Level
EINECS:	European Inventory of Existing Commercial Chemical Substances
EC ₅₀ :	Effective Concentration 50%

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EL ₅₀ :	Effective Loading rate 50%
EbC ₅₀ :	Concentration at which 50% reduction in biomass is observed
ErC ₅₀ :	Concentration at which 50% reduction in growth rate is observed
IC ₅₀ :	Inhibitory Concentration 50%
LC ₅₀ :	Lethal Concentration 50%
LD ₅₀ :	Lethal Dose 50%
LL ₅₀ :	Lethal Loading rate 50%
LCLo:	Lowest lethal concentration
LOEL:	Lowest Observed Effect Level
NOEC:	No Observed Effect Concentration
NOEL:	No Observed Effect Level
PBT:	Persistent, Bioaccumulative and Toxic
PNEC:	Predicted No Effect Concentration
vPvB:	Very Persistent and Very Bioaccumulative

References:

Supplier's Safety Data Sheets for ingredients ECHA disseminated REACH dossiers ECHA Classification & Labelling Inventory Approved Classification and Labelling Guide (Sixth edition) The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)

Disclaimer:

THE INFORMATION PRESENTED HEREIN IS BELIEVED TO BE ACCURATE, BUT IS NOT WARRANTED TO BE, WHETHER ORIGINATING WITH THE COMPANY OR NOT. RECIPIENTS ARE ADVISED TO CONFIRM, IN ADVANCE OF NEED, THAT THE INFORMATION IS CURRENT, APPLICABLE, AND SUITABLE TO THEIR CIRCUMSTANCES.

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