

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identification

Product Name	Avizyme® 1502
Material number	15CM
Synonyms	Not applicable.
Formula	Not applicable.
Pure substance/preparation	Preparation

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

Recommended Use	Animal feed.
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1.3 Details of the supplier of the safety data sheet

Company/Undertaking Identification:

Danisco Animal Nutrition
PO Box 777
Marlborough
Wiltshire SN81XN
United Kingdom
Tel: +441672 517777.

E-mail address	SDS.Genencor@Danisco.com.
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1.4 Emergency Telephone Number

Emergency telephone:	+32 (0) 50 44 91 73
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

This product is a mixture and according to transitional provisions in Article 61(1) of Regulation (EC) No 1272/2008 classification is not applicable until 1 June 2015.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

R42 - May cause sensitization by inhalation

2.2 Label Elements

Contains:	Alpha-amylase, Xylanase, Subtilisin. May produce an allergic reaction
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Hazardous classification :	Xn - Harmful
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Xn



R-phrase(s)

R42 - May cause sensitization by inhalation

S-phrase(s)

S22 - Do not breathe dust

2.3 OTHER INFORMATION

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Properties Affecting Health	Inappropriate handling may cause formation of aerosols or dust. Inhalation of aerosols or dust may induce sensitization and may cause allergic type reactions in sensitized individuals.
Environmental properties	See Section 12 for additional Ecological Information.
PBT and vPvB assessment	This substance is exempted from registration according to the provisions of REACH Article 2 (5) b food and feed.
Physical and chemical hazards	The data available do not support any physical or chemical hazard.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Description This product is a powder enzyme preparation.

Chemical name	%	CAS-No	EINECS-No	IUB Code	REACH No	Hazardous classification	CLP Classification
Wheat flour	85-90	130498-22-5	-		-	Not classified	Not classified
Subtilisin	<1	9014-01-1	232-752-2	3.4.21.62	01-2119480434-38	Xn;R42, R22 Xi;R37/38-41 N;R50	Acute Oral 4 (H302) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Resp. Sens. 1 (H334) STOT SE 3 (H335) Acute Aquatic 1 (H400)
Xylanase	<1	9025-57-4	232-800-2	3.2.1.8	-	Xn;R42	Resp. Sens. 1 (H334)
Alpha Amylase	<1	9000-90-2	232-565-6	3.2.1.1	-	Xn;R42	Resp. Sens. 1 (H334)
Calcium propionate	<1	4075-81-4	223-795-8		-	Not classified	Not classified

For the full text of the R-phrases and H-statements mentioned in this section, see section 16.

4. FIRST AID MEASURES
4.1 Description of first aid measures

Eye Contact:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention.
Skin contact:	IF ON SKIN: Wash with plenty of soap and water If skin irritation occurs, seek medical advice/attention.
Ingestion	Rinse mouth. If swallowed: Call a POISON CENTRE or doctor/physician if exposed or you feel unwell.
Inhalation	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

4.2 Most important symptoms and effects, both acute and delayed

May cause allergy or asthma symptoms or breathing difficulties if inhaled

4.3 Indication of any immediate medical attention and special treatment needed

May cause allergic respiratory reaction

5. FIRE-FIGHTING MEASURES

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5.1 Extinguishing media

Suitable Extinguishing Media: Standard procedure for chemical fires. Foam Water

5.2 Special hazards arising from the substance or mixture

Dust can form an explosive mixture in air. May cause sensitization by inhalation.

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use only with adequate ventilation/personal protection. Avoid breathing dust or spray mist. Avoid formation of dust and aerosols. For personal protection see section 8.

6.2 Environmental Precautions

Prevent further leakage or spillage if safe to do so.

6.3 Methods and materials for containment and cleaning up

Use appropriate personal protection (see Section 8). Contain spilled product. Take up spilled substance by mechanical means or with a vacuum cleaner equipped with a high efficiency filter. After spillage avoid raising aerosols or dust from dried preparation. Avoid splashing and high pressure washing (formation of aerosols). Provide for sufficient ventilation. Wash with plenty of water.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid formation of dust and aerosols. Avoid breathing dust or spray mist. Avoid prolonged contact with eyes, skin and clothing.

Handle in accordance with good industrial hygiene and safety practice

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place

7.3 Specific end use(s)

See Section 1: Use of the substance/preparation.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION
8.1 Control parameters
Exposure limits

Component information below is as complete as possible. Any fields not shown indicate no data is presently available.

Chemical name	UK WEL	UK MEL	Ireland	Germany	France
Subtilisin	TWA= 0.00004 mg/m ³	0.00012 mg/m ³	TWA= 0.00006 mg/m ³ = 0.00006 mg/m ³		

Chemical name	Denmark	Finland	Norway	Sweden	The Netherlands
Subtilisin	Ceiling= 0.00006 mg/m ³			LLV= 3 glycineunit/m ³ LLV= 1 glycineunit/m ³	
Organic dust	TWA = 3 mg/m ³	TWA= 5 mg/m ³ STEL= 10 mg/m ³		LLV= 10 mg/m ³ LLV= 5 mg/m ³	

Chemical name	Italy	Portugal	Spain	Austria	Switzerland
Subtilisin		Ceiling= 0.00006 mg/m ³	VLA-EC= 0.00006 mg/m ³		STEL= 0.00006 mg/m ³

Chemical name	Russia	Estonia	Latvia	Lithuania	Poland
Organic dust		TWA= 5 mg/m ³		IPRV= 5 mg/m ³	

DNEL/DMEL - Workers

This substance has not been registered according to Regulation (EC) No. 1907/2006 (REACH). No information available

Chemical name	Acute (local)	Acute (systemic)	Chronic (local)	Chronic (systemic)
Subtilisin	-	-	60ng/m ³	60ng/m ³
Chemical name	Acute (local)	Acute (systemic)	Chronic (local)	Chronic (systemic)
Subtilisin	0.2% w/w	-	0.2% w/w	-

DNEL/DMEL - General population

This substance has not been registered according to Regulation (EC) No. 1907/2006 (REACH). No information available

Chemical name	Acute (local)	Acute (systemic)	Chronic (local)	Chronic (systemic)
Subtilisin	-	-	-	-
Chemical name	Acute (local)	Acute (systemic)	Chronic (local)	Chronic (systemic)
Subtilisin	-	-	15ng/m ³	15ng/m ³
Chemical name	Acute (local)	Acute (systemic)	Chronic (local)	Chronic (systemic)
Subtilisin	0.2% w/w	-	0.2% w/w	-

Predicted No Effect Concentration (PNEC)

This substance has not been registered according to Regulation (EU) No. 1907/2006 (REACH). This information is not available

Chemical name	Marine water	Fresh Water	Intermittent release (water)	Sewage Treatment Plant (STP)	Fresh water sediment	Marine water sediment	oral	Soil
Subtilisin	0.006 ug/L	0.06 ug/L	0.9 ug/L	65000 ug/L	-	-	-	568 ug/kg soil dw

8.2 Exposure controls
Hygiene measures

Handle in accordance with good industrial hygiene and safety practice Regular cleaning of equipment, work area and clothing is recommended Prevent contact with skin, eyes, and clothing. Wear suitable gloves and eye/face protection

Engineering measures

Process enclosure and/or ventilation systems. Ensure adequate ventilation. Any equipment used to handle this product, should be designed to minimize the escape of aerosols and dust.

Personal protective equipment

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Respiratory protection	Maintain adequate ventilation. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Respirator with a particle filter (EN 143). P3 filters are recommended.
Eye Protection	Safety glasses with side-shields. Avoid contact with eyes
Skin and body protection	Wear protective gloves/clothing.
Hand Protection	Use any protective gloves that meet the minimum requirements of EN420 when handling solid product. Gloves meeting the additional requirements of EN374-2 should be worn when handling liquid products. Practical experience has shown that gloves of nitrile rubber, butyl rubber, latex, and polyvinyl chloride (PVC) offer sufficient protection. There are no additional material, thickness and breakthrough time requirements. Chemical resistant gloves, as defined by EN374-3 are not required.

Environmental exposure controls Avoid dispersion to the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical State:	Fine granular
Appearance	Light brown
Odor	Odourless
pH	Not applicable
Flash Point	Not applicable
Boiling Point/Range	Not applicable
Autoignition temperature	Not applicable.
Vapor pressure	Not applicable
Vapor density	Not determined
Viscosity	Not applicable
Water solubility	Soluble.
Specific gravity	0.75
Evaporation Rate	Not applicable
Bulk density	650 kg/m ³
Flammability Limits in Air	Not applicable.

9.2 OTHER INFORMATION

Explosive properties	Dust can form an explosive mixture in air.
Minimum ignition energy (mJ)	50-300
Layer (5mm) Ignition Temp (C)	310-360
Min. (dust cloud) Ignition Temp (°C)	380-440
Min. explosive concentration (g/m³)	50-100
Kst (bar*m/s)	107-139
Dust explosion class:	St1
Max. explosion pressure (bar)	6.55-7.1
Max. rate of pressure rise (bar/s)	260-396

10. STABILITY AND REACTIVITY

10.1 Reactivity

Not expected.

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

Hazardous polymerisation does not occur

10.4 Conditions to avoid

Avoid dust formation. Dust can form an explosive mixture in air.

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10.5 Incompatible materials

None in particular

10.6 Hazardous decomposition products

None known

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11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Product Information

Acute toxicity

Oral	No data available.
Dermal	No data available.
Inhalation	No data available.

Irritation

Skin irritation	May cause slight irritation
Eye irritation	May cause slight irritation
Respiratory irritation	May cause slight irritation

Other effects

Systemic toxicity	There is no data available for this product.
Mutagenic effects	Not expected to cause mutagenic effects.
Carcinogenicity	There are no known carcinogenic chemicals in this product.
Reproductive effects	This product does not contain any known or suspected reproductive hazards
Sensitization	Inhalation of enzyme mist/dust may cause allergic respiratory reactions, including asthma, in susceptible individuals on repeated exposure.

Component Information

Component information below is as complete as possible. Any fields not shown indicate no data is presently available.

Xylanase

Inhalation	LC50/inhalation/4h/rat > 5.1 mg/l.
Sensitization	May cause sensitization by inhalation
Mutagenic effects	Negative in Ames assay up to 5000 µg/plate. Negative in chromosome aberration studies using Chinese hamster ovary cells.
Systemic toxicity	In a 91-day feeding study in rats, the NOAEL can be established at > 37,500 U/kg/day.

Alpha Amylase

Oral	LD50/oral/rat 2000 mg/kg.
Inhalation	Single dose rat LC50 3.9 mg/l.
Eye irritation	Not an irritant.
Skin irritation	Not an irritant.
Sensitization	Inhalation of enzyme mist/dust may cause allergic respiratory reactions, including asthma, in susceptible individuals on repeated exposure.
Reproductive effects	Not expected to produce reproductive or developmental toxicity.
Mutagenic effects	Negative in Ames assay with and without metabolic activation up to 5000 µg/plate. Negative in chromosome aberration using human lymphocytes with and without metabolic activation up to 5000 µg/ml. Data from similar enzyme.
Systemic toxicity	In a 90-day study with rats, the NOEL was found to be 1000 ppm. In a 14-day feeding study with rats, a NOAEL was established at 5,000 ppm. Data from similar enzyme.

Subtilisin

Oral	LD50/oral/rat =1800 mg/kg.
Dermal	LD50/dermal/rabbit > 2 ml/kg.
Inhalation	LC50/inhalation/4h/rat =0.8 mg/l.
Eye irritation	May cause severe irritation.
Skin irritation	May cause skin irritation
Respiratory irritation	May cause irritation of respiratory tract
Sensitization	Patch test on human volunteers did not demonstrate sensitisation properties
Reproductive effects	Not expected to produce reproductive or developmental toxicity.
Mutagenic effects	Negative in chromosomal aberration using human lymphocytes. Negative in Ames assay with and without metabolic activation up to 5000 µg/plate.
Systemic toxicity	In a 90-day feeding study with rats, no evidence of toxicity attributed to treatment was seen at levels up to 50000 ppm/d. A NOAEL was established at > 50000 ppm/d.

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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Contains a substance which is: Harmful to aquatic organisms However, at the concentration present, this preparation is not expected to present significant adverse environmental effects.

12.2 Persistence and degradability

Enzymes are considered readily biodegradable.

12.3 Bioaccumulative potential

Bioaccumulation is unlikely.

12.4 Mobility in soil

Soluble in water.

12.5 Results of PBT and vPvB assessment

This substance is exempted from registration according to the provisions of REACH Article 2 (5) b food and feed.

12.6 Other adverse effects

None known

Component Information

Component information below is as complete as possible. Any fields not shown indicate no data is presently available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia	biodegradation
Subtilisin	NOEC = 0.041 mg protein/l (72 h). (Pseudokirchneriella subcapitata).	LC50: 8.2 mg/L (96 h) Rainbow trout.	EC0/48hr/daphnia 0.17 mg/L.	Readily biodegradable (102 % after 29 days).
Alpha Amylase	EC50/72h/algae >100 mg/l. (Desmodesmus subspicatus).	96 hr LC50 >100 mg/L. Fathead minnow.	EC50/48hr/daphnia >100 mg/L.	Readily biodegradable (96% after 14 days).

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste from residues / unused products

Dispose of in accordance with the European Directives on waste and hazardous waste.
Dispose of in accordance with local regulations.

Empty packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Dispose of in accordance with local regulations.

14. TRANSPORT INFORMATION

14.1 UN-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 regulated

14.6 Special precautions for users

Not regulated.

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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not regulated

Dangerous goods

Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR.

15. REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Germany**

Water Endangering Classes (WGK) WGK: 1

Chemical name	TA Luft List (Germany)	Occupational Illnesses (R-463-3, France)
Xylanase		RG63
Alpha Amylase		RG63
Subtilisin		RG63

15.2 Chemical safety assessment

A Chemical Safety Assessment has been carried out for a substance in this mixture.

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16. OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3

R42 - May cause sensitization by inhalation
R22 - Harmful if swallowed
R41 - Risk of serious damage to eyes
R50 - Very toxic to aquatic organisms
R37/38 - Irritating to respiratory system and skin

Full text of Hazard statements referred to under section 3

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H302 - Harmful if swallowed
H315 - Causes skin irritation
H318 - Causes serious eye damage
H335 - May cause respiratory irritation
H400 - Very toxic to aquatic life

Prepared By	SDS.Genencor@Danisco.com.
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The following has been revised since the last issue of this MSDS:

(M)SDS sections updated: 1 2. 3 4 8. 12. 16.

Training Advice Details on the safe handling of enzymes can be found in the 'AMFEP Guide to the Safe Handling of Enzymes' (www.amfep.org).

Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet