

Revision Date 09/07/2019
 Revision Number 2

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Amylex® 5T
 Product Code A05851
 Pure substance/mixture Mixture

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

Recommended Use Food industry.

1.3. Details of the supplier of the safety data sheet

Supplier

DuPont Nutrition Biosciences ApS
 Edwin Rahrs Vej 38
 DK-8220 Brabrand
 Danmark
 Tel.:+45 8943 5000 Fax.: +45 8943 1077.

E-mail address

SDS.Genencor@DuPont.com

1.4. Emergency telephone number

+32 (0) 50 44 91 73

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

2.2. Label elements

Contains: Alpha Amylase

EUH208 - May produce an allergic reaction

2.3. Other hazards

None known.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Description

Preparation.

Chemical Name	CAS No.	Weight-%	EINECS	IUB-ECCode	REACH Reg. No.	CLP Classification
Glycerol	56-81-5	30-35	200-289-5	-	No data available	Not classified
Alpha Amylase	9000-90-2	<1	232-565-6	3.2.1.1	01-2119938627-26	Resp. Sens. 1 (H334)

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Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin Contact:

IF ON SKIN: Wash with plenty of water and soap. If skin irritation occurs: Get medical advice/ attention.

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.

Ingestion

Rinse mouth thoroughly with water. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

Treat symptomatically.

Section 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguish with alcohol-resistant foam, fire extinguishing powder or water spray.

5.2. Special hazards arising from the substance or mixture

None known

5.3. Advice for firefighters

Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid generation of dust and aerosols. Avoid breathing dust or spray mist.

Advice for Emergency Responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Contain spill.

6.3. Methods and material for containment and cleaning up

Methods for Containment

Cover with absorbent or contain. Collect and dispose.

Methods for Cleaning Up

Use appropriate personal protective equipment (PPE). Contain and/or absorb spill with inert material, then place in suitable container. Prevent runoff from entering drains, sewers or waterways.

6.4. Reference to other sections

Use personal protection recommended in Section 8.

Section 7: HANDLING AND STORAGE

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7.1. Precautions for safe handling

Avoid generation of dust and aerosols. Avoid contact with eyes, skin and clothing. Avoid breathing dust or spray mist. Ensure adequate ventilation.

Hygiene Measures

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

7.2. Conditions for safe storage, including any incompatibilities

Store at temperatures not exceeding 25 °C/ 77 °F. Protect from light. Keep/store only in original container. Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

See section 1 for more information.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Based on data available for ingredients.

Chemical Name	EU	UK WEL	France	Spain	German MAK:
Glycerol	None known	30 mg/m ³ STEL (calculated, mist) 10 mg/m ³ mist	VME: 10 mg/m ³	TWA: 10 mg/m ³	Peak: 400 mg/m ³
Alpha Amylase	None known	None known	None known	None known	None known

Chemical Name	Italy	Portugal	Netherlands	Finland	Denmark
Glycerol	None known	TWA: 10 mg/m ³	None known	TWA: 20 mg/m ³	None known
Alpha Amylase	None known	None known	None known	None known	None known

Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Glycerol	None known	STEL: 100 mg/m ³ TWA: 50 mg/m ³	TWA: 10 mg/m ³	None known	TWA: 10 mg/m ³ STEL: 30 mg/m ³
Alpha Amylase	None known	None known	None known	None known	None known

Chemical Name	Belgium	Russia	Sweden	Turkey
Glycerol	TWA: 10 mg/m ³	None known	None known	None known
Alpha Amylase	None known	None known	None known	None known

DNEL/DMEL - Workers

Derived minimal effect level (DMEL) of 60 ng/m³ for workers and 15 ng/m³ for consumers has been derived for enzyme proteins.

DNEL/DMEL - General population

Derived minimal effect level (DMEL) of 60 ng/m³ for workers and 15 ng/m³ for consumers has been derived for enzyme proteins

Predicted No Effect Concentration (PNEC)

No data available

8.2. Exposure controls

Engineering Measures

Transfer via enclosed lines. Formulate in enclosed or ventilated mixing vessels. Carefully handle the substance to minimise releases. Avoid generation of dust and aerosols.

Personal protective equipment

Eye/Face Protection

Wear safety glasses with side shields (or goggles).

Hand Protection

Use any protective gloves that meet the minimum requirements of EN420 when handling

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Skin and Body Protection Respiratory Protection

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.

Wear protective gloves and protective clothing.

Ensure adequate ventilation. If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. Respirators with a particle filter (EN143) or P3 filters are recommended.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	
Physical State	Liquid
Colour	Light brown
Odour	Typical odor of fermented product
Odour Threshold	No data available
pH	5.5-6.5
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper Flammability Limit	No data available
Upper explosive limits	No data available
Lower Flammability Limit	No data available
Lower explosive limits	No data available
Vapour Pressure	No data available
Vapour Density	No data available
Bulk Density	No data available
Specific Gravity	1.15-1.19
Water Solubility	Soluble
Partition Coefficient (n-octanol/water)	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Dynamic viscosity	No data available
Oxidising Properties	No data available

9.2. Other information No data available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Not expected.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Avoid dust formation.

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10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Product Information

Acute Toxicity

Inhalation	No data available.
Eye Contact	If applicable: Classification is shown in section 2 of this SDS
Skin Contact	If applicable: Classification is shown in section 2 of this SDS
Ingestion	Toxicity: Not expected

Sensitisation

May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol (dust or mist) can cause a respiratory allergy in some individuals.

Germ cell mutagenicity

No data available.

Carcinogenic effects

No data available.

Reproductive effects

No data available.

STOT - single exposure

No data available.

STOT - repeated exposure

No data available.

Aspiration hazard

Not expected.

Component Information

Classification based on data available for ingredients.

Glycerol

Oral	12600 mg/kg Oral LD50 (rat)
Skin irritation	Not classified
Respiratory irritation	May cause irritation of respiratory tract
Sensitisation	Not a skin sensitiser.
Reproductive effects	Not a developmental toxicant in the rat. Not a reproductive toxicant in the rat.
Mutagenic effects	Negative in Ames assay with and without metabolic activation up to 5000 µg/plate Negative in unscheduled DNA synthesis with rat liver hepatocytes. Negative in SCE assay using CHO cells with and without metabolic activation up to 1.0 mg/ml. Negative in in-vitro cytogenetic assay using CHO cells with and without metabolic activation up to 1.0 mg/ml. In a 13-week inhalation study with rats, no adverse effects were seen. A NOAEL was established at 0.167 mg/l . A two-year feeding study on rats did not reveal adverse health effects A NOAEL was established at 5000 mg/kg/d.
Systemic Toxicity	

Alpha Amylase

Oral	Oral LD50 (rat) > 2000 mg/kg
Dermal	No information available
Inhalation	Rat LC50 = >3.9 mg/L.
Eye irritation	Non-irritant
Skin irritation	Non-irritant
Sensitisation	May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol (dust or mist) can cause a respiratory allergy in some individuals.
Reproductive effects	Not expected
Mutagenic effects	Not mutagenic in bacterial assays in the presence and absence of metabolic activation up to 5,000 µg/plate. Negative in chromosome aberration using human lymphocytes with and without metabolic activation up to 5000 µg/ml
Systemic Toxicity	In a 90-day study with rats, the NOEL was found to be 1000 ppm.

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

Not applicable

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Classification based on data available for ingredients.

Contains 0 % of components with unknown hazards to the aquatic environment

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to daphnia and other aquatic invertebrates
Glycerol 56-81-5	No data	Leuciscus idus LC50 = >250 mg/l.	LC50/24h/daphnia = > 500 mg/l.
Alpha Amylase 9000-90-2	EC50/72h/algae = >100 mg/l. (Desmodesmus subspicatus).	LC50/96h/Fathead minnows = >100 mg/l.	48 hr daphnia EC50 >100 mg/L

12.2. Persistence and degradability

Based on data available for ingredients.

Chemical Name	Biodegradation
Glycerol 56-81-5	Readily biodegradable (93 % after 30 days).
Alpha Amylase 9000-90-2	Readily biodegradable (96 % after 14 days).

12.3. Bioaccumulative potential

No bioaccumulation potential.

12.4. Mobility in soil

Soluble in water.

12.5. Results of PBT and vPvB assessment

The substance does not require registration according to REACH.

12.6. Other adverse effects

None known.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Disposal Methods

Dispose of wastes in an approved waste disposal facility. Dispose of contents/containers in accordance with local regulations.

Contaminated Packaging

Dispose of empty containers and wastes safely. Dispose of waste product or used containers according to local regulations.

Section 14: TRANSPORT INFORMATION

IMDG/IMO

14.1 UN-No. Not regulated

14.2 Proper Shipping Name Not regulated

14.3. Hazard Class Not regulated

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14.4. Packing Group	Not regulated
14.5. Marine Pollutant	None
14.6. Special Provisions	None
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	None

RID

14.1 UN-No.	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3. Hazard Class	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	None
14.6. Special Provisions	None

ADR:

14.1 UN-No.	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3. Hazard Class	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	None
14.6. Special Provisions	None

ICAO

14.1 UN-No.	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3. Hazard Class	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	None
14.6. Special Provisions	None

IATA

14.1 UN-No.	Not regulated
14.2 Proper Shipping Name	Not regulated
14.3. Hazard Class	Not regulated
14.4. Packing Group	Not regulated
14.5. Environmental hazard	None
14.6. Special Provisions	None

Section 15: REGULATORY INFORMATION

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

Chemical Name	Water hazard class (WGK)
Glycerol	1
Alpha Amylase	1

Chemical Name	TA Luft (German Air Pollution Control Regulation)	Occupational Illnesses (R-463-3, France)
Glycerol	Not regulated	Not regulated
Alpha Amylase	Not regulated	RG 63

15.2. Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

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Section 16: OTHER INFORMATION

Prepared By SDS.Genencor@DuPont.com

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SDS sections updated 8, 16.

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No 1272/2008.

Disclaimer

The information provided in this Material 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