

**Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1. Product identifier**

Product Name Syncra® AVI 101  
Product Code A67001  
Pure substance/mixture Mixture

**1.2. Relevant identified uses of the substance or mixture and uses advised against**  
Recommended Use Animal feed

**1.3. Details of the supplier of the safety data sheet**

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

**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 not hazardous according to regulation (EC) 1272/2008 [GHS]

**2.2. Label elements**

**Contains:** Subtilisin, Xylanase, Alpha Amylase

**Signal word**

None

EUH208 - May produce an allergic reaction

**2.3. Other hazards**

None known

**Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Description

Preparation.

Chemical Name	CAS No	%	EC No	REACH Reg. No	CLP Classification
Calcium carbonate	471-34-1	45-50	-	No data available	-
Talc	14807-96-6	1-5	238-877-9	No data available	-
Starch	9005-25-8	1-5	232-679-6	No data available	-
Subtilisin	9014-01-1	<1	232-752-2	01-2119480434-38	Acute Oral 4 (H302) Skin Irrit. 2 (H315) Eye Dam. 1 (H318)

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					Resp. Sens. 1 (H334) STOT SE 3 (H335) Acute Aquatic 1 (H400) Chronic Aquatic 2 (H411)
Xylanase	9025-57-4	<1	232-800-2	No data available	Resp. Sens. 1 (H334)
Alpha Amylase	9000-90-2	<1	232-565-6	01-2119938627-26	Resp. Sens. 1 (H334)
Bacillus subtilis	NA	<1	Na	No data available	-

## 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: FIRE FIGHTING 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 contact with eyes, skin and clothing. Avoid breathing dust or spray mist.

### 6.2. Environmental precautions

Contain spill. Keep out of waterways.

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

#### Methods for Containment

Cover with absorbent or contain. Collect and dispose.

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**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**

**7.1. Precautions for safe handling**

**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**

Keep container tightly closed in a dry and well-ventilated place. Protect from light. Keep/store only in original container.

**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:
Calcium carbonate	None known	None known	TWA: 10 mg/m <sup>3</sup>	None known	None known
Talc	None known	3 mg/m <sup>3</sup> STEL (calculated, respirable dust) 1 mg/m <sup>3</sup> respirable dust	None known	TWA: 2 mg/m <sup>3</sup>	Category 3B
Starch	None known	30 mg/m <sup>3</sup> STEL (calculated, total inhalable); 12 mg/m <sup>3</sup> STEL (calculated, respirable) 10 mg/m <sup>3</sup> total inhalable 4 mg/m <sup>3</sup> respirable	None known	TWA: 10 mg/m <sup>3</sup>	None known
Subtilisin	None known	TWA= 0.00004 mg/m <sup>3</sup>	None known	STEL: 0.00006 mg/m <sup>3</sup>	None known

Chemical Name	Italy	Portugal	The Netherlands	Finland	Denmark
Calcium carbonate	None known	TWA: 10 mg/m <sup>3</sup>	None known	None known	None known
Talc	None known	TWA: 2 mg/m <sup>3</sup>	TWA: 0.25 mg/m <sup>3</sup>	TWA: 0.5 fiber/cm <sup>3</sup> STEL: 2 ppm STEL: 1 ppm	TWA: 0.3 fiber/cm <sup>3</sup>
Starch	None known	TWA: 10 mg/m <sup>3</sup>	None known	None known	None known
Subtilisin	None known	Ceiling= 0.00006 mg/m <sup>3</sup>	None known	None known	Ceiling= 0.00006 mg/m <sup>3</sup>

Chemical Name	Austria	Switzerland	Poland	Norway	Ireland
Calcium carbonate	None known	TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	None known	None known
Talc	TWA: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup>	TWA: 4.0 mg/m <sup>3</sup> TWA: 1.0 mg/m <sup>3</sup>	TWA: 6 mg/m <sup>3</sup> TWA: 2 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 0.8 mg/m <sup>3</sup> STEL: 30 mg/m <sup>3</sup> STEL: 2.4 mg/m <sup>3</sup>



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Starch	None known	TWA: 3 mg/m <sup>3</sup>	None known	None known	TWA: 10 mg/m <sup>3</sup> TWA: 4 mg/m <sup>3</sup> STEL: 30 mg/m <sup>3</sup> STEL: 12 mg/m <sup>3</sup>
Subtilisin	None known	STEL= 0.00006 mg/m <sup>3</sup>	None known	None known	TWA= 0.00006 mg/m <sup>3</sup> = 0.00006 mg/m <sup>3</sup>

### DNEL/DMEL - Workers

Derived minimal effect level (DMEL) of 60 ng/m<sup>3</sup> for workers and 15 ng/m<sup>3</sup> for consumers has been derived for enzyme proteins.

#### Inhalation

Chemical Name	Acute effects, local	Acute effects, systemic	Chronic (local)	Chronic effects, systemic
Subtilisin	None known	None known	None known	60ng/m <sup>3</sup>
Alpha Amylase	None known	None known	60ng/m <sup>3</sup>	60ng/m <sup>3</sup>

#### Dermal

Chemical Name	Acute effects, local	Acute effects, systemic	Chronic (local)	Chronic effects, systemic
Subtilisin	0.2% w/w	None known	0.2% w/w	None known
Alpha Amylase	None known	None known	None known	None known

### DNEL/DMEL - General population

Derived minimal effect level (DMEL) of 60 ng/m<sup>3</sup> for workers and 15 ng/m<sup>3</sup> for consumers has been derived for enzyme proteins

#### Oral

Chemical Name	Acute effects, local	Acute effects, systemic	Chronic (local)	Chronic effects, systemic
Subtilisin	None known	None known	None known	None known
Alpha Amylase	None known	None known	None known	None known

#### Inhalation

Chemical Name	Acute effects, local	Acute effects, systemic	Chronic (local)	Chronic effects, systemic
Subtilisin	None known	None known	15ng/m <sup>3</sup>	15ng/m <sup>3</sup>
Alpha Amylase	None known	None known	15ng/m <sup>3</sup>	15ng/m <sup>3</sup>

#### Dermal

Chemical Name	Acute effects, local	Acute effects, systemic	Chronic (local)	Chronic effects, systemic
Subtilisin	0.2% w/w	None known	0.2% w/w	None known
Alpha Amylase	None known	None known	None known	None known

### Predicted No Effect Concentration (PNEC)

Chemical Name	Marine water	Freshwater	Intermittent release	Sewage treatment plant	Freshwater sediment	Marine sediment	Oral	Soil
Subtilisin	0.006 ug/L	0.06 ug/L	0.9 ug/L	65000 ug/L	None known	None known	None known	568 ug/kg soil dw
Alpha Amylase	0.52 ug/L	5.2 ug/L	52 ug/L	65000 ug/L	None known	None known	None known	0.76 ug/kg d.w.

## 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

#### Hand Protection

Wear safety glasses with side shields (or goggles).

Use any protective gloves that meet the minimum requirements of EN420 when handling solid product. Practical experience has shown that gloves of nitrile rubber, butyl rubber, latex, and polyvinyl chloride (PVC) offer sufficient protection. solid. There are no additional material, thickness and breakthrough time requirements. Chemical resistant gloves, as defined by EN374-3 are not required.

#### Skin and Body Protection

#### Respiratory Protection

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

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Appearance	
Physical State	Granular,
Colour	Light Tan
Odour	Typical odor of fermented product
Odour Threshold	No data available
pH	No data available
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
Relative density	No data available
Specific Gravity	No data available
Water Solubility	Soluble
Partition Coefficient (n-octanol/water)	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Oxidising Properties	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.

### 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	Not expected to cause eye irritation.
Skin Contact:	Not expected to cause irritation.
Ingestion	Toxicity: Not expected



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<b>Sensitisation</b>	May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol (dust or mist) can cause a respiratory allergy in some individuals.
<b>Mutagenic effects</b>	No data available.
<b>Carcinogenic effects</b>	No data available.
<b>Reproductive effects</b>	No data available.
<b>STOT - single exposure</b>	No data available.
<b>STOT - repeated exposure</b>	No data available.
<b>Aspiration hazard</b>	Not expected.

### Component Information

#### *Calcium carbonate*

<b>Oral</b>	Oral LD50 (rat) 6450 mg/kg
<b>Eye irritation</b>	May cause irritation
<b>Skin irritation</b>	May cause skin irritation
<b>Respiratory irritation</b>	Irritating to respiratory system

#### *Talc*

<b>Eye irritation</b>	May cause slight irritation
<b>Skin irritation</b>	May cause slight irritation
<b>Respiratory irritation</b>	May cause slight irritation
<b>Sensitisation</b>	Not a skin sensitiser.
<b>Reproductive effects</b>	No Developmental toxicity In rats
<b>Mutagenic effects</b>	Negative in the chromosomal aberration assay. Negative in dominant lethal assay in rat up to 5000 mg/kg . Negative in DNA Damage and Repair Assay. Negative in Ames assay with and without metabolic activation up to 20 mg/plate.

#### *Starch*

<b>Eye irritation</b>	Mild eye irritation
<b>Skin irritation</b>	Mild skin irritation
<b>Respiratory irritation</b>	May cause slight irritation

#### *Subtilisin*

<b>Oral</b>	Oral LD50 (rat) =1800 mg/kg
<b>Inhalation</b>	LC50/inhalation/4h/rat 0.8 mg/l
<b>Eye irritation</b>	Causes severe eye irritation
<b>Skin irritation</b>	May cause skin irritation
<b>Respiratory irritation</b>	May cause irritation of respiratory tract
<b>Sensitisation</b>	Patch test on human volunteers did not demonstrate sensitisation properties. May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol (dust or mist) can cause a respiratory allergy in some individuals.
<b>Reproductive effects</b>	This product does not contain any known or suspected reproductive hazards
<b>Mutagenic effects</b>	Negative in chromosomal aberration using human lymphocytes. Negative in Ames assay with and without metabolic activation up to 5000 µg/plate.
<b>Systemic Toxicity</b>	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

#### *Xylanase*

<b>Inhalation</b>	LC50/inhalation/4h/rat > 5.1 mg/l
<b>Eye irritation</b>	Non-irritant
<b>Skin irritation</b>	Non-irritant
<b>Sensitisation</b>	May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol (dust or mist) can cause a respiratory allergy in some individuals.
<b>Mutagenic effects</b>	Not mutagenic in bacterial assays in the presence and absence of metabolic activation up to 5,000 µg/plate. Negative in chromosomal aberration using human lymphocytes.
<b>Systemic Toxicity</b>	In a 90-day study in rats, there were no indications of toxicity or other changes attributed to treatment. A NOAEL can be established at 1140 mg/kg/d

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*Alpha Amylase*

<b>Oral</b>	Oral LD50 (rat) 2000 mg/kg
<b>Inhalation</b>	No data available
<b>Eye irritation</b>	Non-irritant
<b>Skin irritation</b>	Non-irritant
<b>Sensitisation</b>	May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol (dust or mist) can cause a respiratory allergy in some individuals.
<b>Mutagenic effects</b>	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.
<b>Systemic Toxicity</b>	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
<b>Carcinogenicity</b>	No data available

Chemical Name	Danish Carcinogens	UK	Italian Carcinogens (1827)
Talc	X		

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

ATEmix (oral) 12,881.00 mg/kg

**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
Calcium carbonate 471-34-1	No data	LC50/96hr/Gambusia affinis: 56000 mg/L.	No data
Talc 14807-96-6	No data	Brachydanio rerio LC50 = 100000 mg/L.	No data
Subtilisin 9014-01-1	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.

**12.2. Persistence and degradability**

Based on data available for ingredients.

Chemical Name	Biodegradation
Calcium carbonate	No data
Talc	No data
Subtilisin	Readily biodegradable (102 % after 29 days). Readily biodegradable (greater than 102 % by day 29).

**12.3. Bioaccumulative potential**

No bioaccumulation potential.

**12.4. Mobility in soil**

Soluble in water.

**12.5. Results of PBT and vPvB assessment**

The components in this formulation do not meet the criteria for classification as PBT or vPvB.

**12.6. Other adverse effects**

None known.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

<b>Disposal Methods</b>	Dispose of wastes in an approved waste disposal facility. Dispose of contents/containers in accordance with local regulations.
<b>Contaminated Packaging</b>	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
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 73/78 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



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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)
Starch	1
Subtilisin	1
Xylanase	1
Alpha Amylase	1

Chemical Name	TA Luft (German Air Pollution Control Regulation)	Occupational Illnesses (R-463-3, France)
Talc		RG 25
Subtilisin		RG63
Xylanase		RG63
Alpha Amylase		RG 63

### 15.2. Chemical safety assessment

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

## Section 16: OTHER INFORMATION

### Full text of H-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

H411 - Toxic to aquatic life with long lasting effects

Prepared By SDS.Genencor@DuPont.com

Issuing Date 13/05/2015

Revision Date 02/02/2016

Revision Number 2

SDS sections updated 1, 2, 3, 8, 11.

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

### 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