### **SAFETY DATA SHEET**



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

1.1. Product identifier

Product Name Axtra® PRO 301 TPT

Product Code A01059
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

Genencor International, B.V.

Archimedesweg 30 2333 CN Leiden The Netherlands

Tel.: +31 71 5686 168 Fax: +31 71 5686 169

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

regulation (LO) to the known	
Serious eye damage/eye irritation	Category 2 - (H319)
Respiratory sensitisation	Category 1 - (H334)
Chronic aquatic toxicity	Category 3 - (H412)

# 2.2. Label elements

Contains: Subtilisin



Signal word DANGER

### Hazard statements

H412 - Harmful to aquatic life with long lasting effects

H319 - Causes serious eye irritation

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

## **Precautionary Statements**

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

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

P337 + P313 - If eye irritation persists: Get medical advice/attention

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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

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

P273 - Avoid release to the environment

### 2.3. Other hazards

None known

# Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Description

Preparation.

Chemical Name	CAS No	%	EINECS	IUB Code	REACH Reg. No	CLP Classification
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-<5	232-752-2	3.4.21.62		Acute Oral 4 (H302) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Resp. Sens. 1 (H334) STOT SE 3 (H335) Acute Aquatic 1 (H400) Chronic Aquatic 2 (H411)

# 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

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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. 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.

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

Avoid generation of dust and aerosols. Ensure adequate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing dust or spray mist. Wear suitable gloves and eye/face protection.

# **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:
Talc	None known	3 mg/m³ STEL	None known	TWA: 2 mg/m <sup>3</sup>	Category 3B
		(calculated, respirable		_	
		dust)			
		1 mg/m³ respirable			
		dust			

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Subtilisin	None known	TWA= 0.00004 mg/m <sup>3</sup>	None known	STEL: 0.00006 mg/m <sup>3</sup>	None known
Starch	None known	30 mg/m³ STEL	None known	TWA: 10 mg/m <sup>3</sup>	None known
		(calculated, total			
		inhalable); 12 mg/m <sup>3</sup>			
		STEL (calculated,			
		respirable)		]	
ĺ		10 mg/m³ total		1	
		inhalable			
	!	4 mg/m³ respirable			

Chemical Name	Italy	Portugal	The Netherlands	Finland	Denmark
Talc	None known	TWA: 2 mg/m <sup>3</sup>	TWA: 0.25 mg/m <sup>3</sup>	TWA: 0.5 fiber/cm3	TWA: 0.3 fiber/cm3
				STEL: 2 ppm	
				STEL: 1 ppm	
Subtilisin	None known	Ceiling= 0.00006	None known	None known	Ceiling= 0.00006
		mg/m³			mg/m³
Starch	None known	TWA: 10 mg/m <sup>3</sup>	None known	None known	None known

Chemical Name	Austria	Switzerland	Poland	Norway	freland
Talc	TWA: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup>	TWA: 4.0 mg/m <sup>3</sup>	TWA: 6 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
			TWA: 1.0 mg/m <sup>3</sup>	TWA: 2 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>
Subtilisin	None known	STEL= 0.00006 mg/m <sup>3</sup>	None known	None known	TWA= 0.00006
***************************************		1			mg/m³= 0.00006
					mg/m³
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>

## 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 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. 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.

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

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P3 filters are recommended.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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**Appearance** Granules **Physical State** Colour Brown Odour No data available **Odour Threshold** No data available рΗ 5.1-5.3 Melting point / freezing point No data available Bolling 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 No data available Lower Flammability Limit 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** No data available (n-octanol/water) **Autoignition Temperature** No data available **Decomposition Temperature** No data available No data available Dynamic viscosity **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

None known.

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 Causes serious eye irritation.
Skin Contact: Not expected to cause irritation.

Ingestion Toxicity: Not expected

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May cause sensitisation in susceptible persons. Repeated inhalation of enzyme containing Sensitisation

aerosol (dust or mist) can cause a respiratory allergy in some individuals.

Mutagenic effects No data available. No data available. Carcinogenic effects Reproductive effects No data available. STOT - single exposure No data available. No data available. STOT - repeated exposure Aspiration hazard Not expected.

Component Information

Eye irritation May cause slight irritation Skin irritation May cause slight irritation May cause slight irritation Respiratory irritation Sensitisation Not a skin sensitiser

Reproductive effects No Developmental toxicity In rats

Negative in the chromosomal aberration assay. Negative in dominant lethal assay in rat up **Mutagenic effects** 

Classification based on data available for ingredients.

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.

Subtilisin

Oral LD50 (rat) =1800 mg/kg Oral LC50/inhalation/4h/rat 0.8 mg/l Inhalation Causes severe eye irritation Eye irritation Skin irritation May cause skin irritation

Respiratory irritation May cause irritation of respiratory tract

Patch test on human volunteers did not demonstrate sensitisation properties. May cause Sensitisation

sensitisation in susceptible persons. Repeated inhalation of enzyme containing aerosol

(dust or mist) can cause a respiratory allergy in some individuals.

Reproductive effects This product does not contain any known or suspected reproductive hazards

Negative in chromosomal aberration using human lymphocytes. Negative in Ames assay **Mutagenic effects** 

with and without metabolic activation up to 5000 µg/plate.

In a 90-day feeding study with rats, no evidence of toxicity attributed to treatment was seen Systemic Toxicity

at levels up to 50000 ppm/d. A NOAEL was established at > 50000 ppm/d

Starch

Mild eye irritation Eye irritation Skin irritation Mild skin irritation Respiratory irritation May cause slight irritation

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

69,231.00 mg/kg ATEmix (oral)

## 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
F			

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ļ	Talc	No data	Brachydanio rerio LC50 = 100000	No data
ı	14807-96-6		mg/L.	
	Subtilisin	NOEC = 0.041 mg protein/l (72	LC50; 8.2 mg/L (96 h) Rainbow	EC0/48hr/daphnia 0.17 mg/L.
1	9014-01-1	h). (Pseudokirchneriella	trout.	
		subcapitata).		

## 12.2. Persistence and degradability

Based on data available for ingredients.

Chemical Name	Biodegradation
Talc	No data
14807-96-6	
Subtilisin	Readily biodegradable (102 % after 29 days).
9014-01-1	

### 12.3. Bioaccumulative potential

No bioaccumulation potential.

## 12.4. Mobility in soil

Soluble in water.

### 12.5. Results of PBT and vPvB assessment

No data available.

### 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
14.4. Packing Group
Not regulated
14.5. Marine Pollutant
None
14.6. Special Provisions
None
14.7. Transport in bulk according to None
Annex II of MARPOL 73/78 and the

**IBC Code** 

<u>RID</u>

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. 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)
Starch	1
Subtilisin	1

# 15.2. Chemical safety assessment

No information available.

# Section 16: OTHER INFORMATION

# 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

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SDS sections updated First edition in this format.

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

### Disclaimer

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**End of Safety Data Sheet**