

**RONOZYME® HiStarch(CT)****5015727**

Version 2.1

Revision Date 30.07.2021

Date of last issue: 27.01.2017

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : RONOZYME® HiStarch(CT)

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

Use of the Sub-stance/Mixture : Additive for animal nutrition to be used in feed

**1.3 Details of the supplier of the safety data sheet**Company : DSM Nutritional Products Ltd.  
PO Box 2676  
CH-4002 BaselTelephone : +41618158888  
E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com**1.4 Emergency telephone number**

+41 848 00 11 77 (Carechem 24 International)

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**Hazard pictograms : 

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
P284 Wear respiratory protection.

**Response:**  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

9000-90-2 amylase,  $\alpha$ -

**2.3 Other hazards**

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

None known.

**SECTION 3: Composition/information on ingredients**

Brief description of the product : Mixture (preparation) containing an enzyme and auxiliary substances

**3.2 Mixtures****Hazardous components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
amylase, $\alpha$ -	9000-90-2 232-565-6 647-015-00-4	Resp. Sens. 1; H334	$\geq 1 - < 10$

**Further ingredients**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
cellulose	9004-34-6 232-674-9		$\geq 10 - < 30$
kaolin	1332-58-7 310-194-1		$\geq 10 - < 30$
sucrose	57-50-1 200-334-9		$\geq 5 - < 10$

**SECTION 4: First aid measures****4.1 Description of first aid measures**

- General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.
- If inhaled : Move to fresh air.  
Consult a physician after significant exposure.
- In case of skin contact : Take off contaminated clothing and shoes immediately.  
Wash off with soap and plenty of water.  
If symptoms persist, call a physician.

- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Rinse mouth with water.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
Obtain medical attention.

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

- Symptoms : Inhalation may provoke the following symptoms:, Allergic reactions, Asthma

**4.3 Indication of any immediate medical attention and special treatment needed**

- Treatment : Treat symptomatically.
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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water  
Foam

**5.2 Special hazards arising from the substance or mixture**

- Specific hazards during fire-fighting : None known.

**5.3 Advice for firefighters**

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.  
Consider dust explosion hazard.
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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

- Personal precautions : Evacuate personnel to safe areas.  
Use personal protective equipment.  
Ensure adequate ventilation.  
Avoid dust formation.  
Avoid breathing dust.

**6.2 Environmental precautions**

- Environmental precautions : Do not flush into surface water or sanitary sewer system.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.

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**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Pick up and arrange disposal without creating dust.  
Keep in suitable, closed containers for disposal.  
Avoid formation of dust and aerosols.

**6.4 Reference to other sections**

For personal protection see section 8., For disposal considerations see section 13.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Advice on safe handling : Avoid formation of respirable particles.  
Avoid exceeding the given occupational exposure limits (see section 8).  
For personal protection see section 8.  
Provide sufficient air exchange and/or exhaust in work rooms.  
Dispose of rinse water in accordance with local and national regulations.  
Do not breathe vapours/dust.  
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.

Hygiene measures : When using do not eat or drink. When using do not smoke.  
Avoid contact with skin, eyes and clothing. Do not breathe dust or spray mist.

**7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight.

Keep container tightly closed and dry.

**7.3 Specific end use(s)**

Specific use(s) : Not applicable

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
		STEL (inhalable dust)	20 mg/m <sup>3</sup>	GB EH40
kaolin	1332-58-7	TWA (Respirable dust)	2 mg/m <sup>3</sup>	GB EH40
amylase, α-	9000-90-2	TLV-C	0.00006 mg/m <sup>3</sup>	DSM Internal Limit
	Recommended exposure limit			
sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	GB EH40

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		STEL	20 mg/m3	GB EH40
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**8.2 Exposure controls****Personal protective equipment**

- Eye protection : Safety glasses with side-shields
- Hand protection : Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.  
Glove material: for example nitrile rubber
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Respiratory protection : Suitable mask with particle filter P3 (European Norm 143)
- In the case of dust or aerosol formation use respirator with an approved filter.

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

- Appearance : granules
- Colour : beige - light brown
- Odour : slight
- Odour Threshold : No information available.
- pH : 5 - 8 (1%)  
(aqueous suspension)
- Melting point/range : Not applicable
- Boiling point/boiling range : Not applicable
- Flash point : Not applicable
- Flammability (solid, gas) : Not expected to form explosive dust-air mixtures.
- Vapour pressure : Not applicable
- Relative vapour density : Not applicable
- Density : not determined
- Water solubility : practically insoluble
- Partition coefficient: n-octanol/water : Not applicable
- Auto-ignition temperature : No data available
- Thermal decomposition : Not relevant
- Explosive properties : Not explosive
- Oxidizing properties : No data available

**9.2 Other information**

- Combustibility index for deposited dust : 3 ( 23 °C)
- : 3 ( 100 °C)

Dust explosion class	: The sample could not be ignited under test conditions (Hartmann tube). (Milled sample, Median value of the tested sample 0.071 mm, Loss on drying 1.2 %)
Minimum ignition energy	: > 1,000 mJ (Milled sample, Median value of the tested sample 0.071 mm, Loss on drying 1.2 %) The Minimum ignition energy (MIE) of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE.  : General remark: The indicated dust explosion characteristics are only valid for this product and are sensitive to the sample's parameters.
Powder volume resistivity	: ca. 1E+11 Ohmm (Product sample, Median value of the tested sample 0.63 mm, Loss on drying 0.9 %) The material can accumulate static charge and can therefore cause electrical ignition.
Minimum ignition temperature of a dust/air mix	: 420 °C (Median value of the tested sample 0.071 mm) determined in the BAM oven
Particle size	: 0.45 - 0.65 mm (average measurement value)
Bulk density	: ca. 1,090 kg/m <sup>3</sup>

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No hazards to be specially mentioned.

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

Dust may form explosive mixture in air.

### 10.4 Conditions to avoid

Heat

### 10.5 Incompatible materials

Strong acids and strong bases  
Strong oxidizing agents

### 10.6 Hazardous decomposition products

No decomposition if used as directed.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg (Calculation method)
Skin irritation	: Prolonged skin contact may cause skin irritation.

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Eye irritation	: Dust contact with the eyes can lead to mechanical irritation.
Sensitisation amylase, $\alpha$ -	: May cause sensitisation by inhalation.
Genotoxicity in vitro	: No indication for mutagenicity known.
Carcinogenicity	: No indication for carcinogenicity known.
Reproductive toxicity	: No indication for adverse effects on fertility known.
STOT - single exposure (A- cute exposure)	: The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	: This information is not available.
Aspiration toxicity	: No aspiration toxicity classification

**11.2 Information on other hazards****Endocrine disrupting properties****Product:**

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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**Experience with human exposure****Components:****amylase,  $\alpha$ -:**

Inhalation	: Remarks: Inhalation may induce sensitization and may cause allergic reactions in sensitized individuals.
Skin contact	: Remarks: Prolonged skin contact may cause skin irritation.

**SECTION 12: Ecological information****12.1 Toxicity**

Toxicity to daphnia and other aquatic invertebrates	: Daphnia (water flea) EC50 > 100 mg/l Test performed using a similar product.
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Toxicity to algae

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amylase, α- : Desmodesmus subspicatus (green algae)  
ErC50 (72 h) 5.2 mg/l  
(OECD Test Guideline 201)

**12.2 Persistence and degradability**

Biodegradability : The organic components of the product are biodegradable.

**12.3 Bioaccumulative potential**

Bioaccumulation : No data available

Partition coefficient: n-octanol/water : Not applicable

**12.4 Mobility in soil**

Distribution among environmental compartments : No data available

**12.5 Results of PBT and vPvB assessment**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Endocrine disrupting properties**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**12.7 Other adverse effects****Product:**

Additional ecological information : Harmful to aquatic organisms.

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Discharge into the environment must be avoided.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Do not dispose of waste into sewer.  
Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging : Dispose of as unused product.  
Do not re-use empty containers.

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**SECTION 14: Transport information****14.1 UN number or ID number**

Not regulated as a dangerous good

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**14.2 UN proper shipping name**

Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

Not regulated as a dangerous good

**14.4 Packing group**

Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Remarks : Not classified as dangerous in the meaning of transport regulations.

**14.7 Maritime transport in bulk according to IMO instruments**

Not applicable for product as supplied.

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**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. Not applicable

**15.2 Chemical safety assessment**

Not applicable

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**SECTION 16: Other information****Full text of H-Statements**

H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Full text of other abbreviations**

Resp. Sens. : Respiratory sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organiza-

tion; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative  
DNEL - Derived No-Effect Level; NFPA - National Fire Protection Association (USA); PNEC - Predicted No-Effect Concentration; STEL - Short term exposure limit; TLV-C - Ceiling Limit Value; TWA - Time Weighted Average; WEL - Workplace Exposure Limit.

**Further information****Classification of the mixture:**

Resp. Sens. 1

H334

**Classification procedure:**

Calculation method

The information provided in this 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.

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