

Pronase,Lyo. 5 gVersion
1.2Revision Date:
01-18-2016Date of last issue: 11-04-2015
Date of first issue: 09-24-2015**SECTION 1. IDENTIFICATION**

Product name : Pronase,Lyo. 5 g

Mat.-No./ Genisys-No. : 11459643001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone:

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Ca-
nada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Skin irritation : Category 2

Eye irritation : Category 2A

Respiratory sensitization : Category 1

Specific target organ system-
ic toxicity - single exposure : Category 3 (Respiratory system)**GHS Label element**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.Precautionary Statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.

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P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.

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

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

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

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

P362 Take off contaminated clothing and wash before reuse.

Storage:

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Substance name : Pronase from Streptomyces griseus

Hazardous ingredients

Chemical Name	CAS-No.	Concentration (% w/w)
Pronase from Streptomyces griseus	9036-06-0	>= 70 - < 90

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Call a physician or poison control center immediately.
Move to fresh air.
If unconscious place in recovery position and seek medical advice.

In case of skin contact : If skin irritation persists, call a physician.
If on skin, rinse well with water.

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- If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Causes skin irritation.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause respiratory irritation.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water
Carbon dioxide (CO₂)
Foam
Dry powder
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency measures : Use personal protective equipment.
Avoid dust formation.

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Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

Technical measures/Precautions : See label, package insert or internal guidelines

Personal protective equipment

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Respiratory protection	: In the case of dust or aerosol formation use respirator with an approved filter. Dust safety masks are recommended when the dust concentration is more than 10 mg/m ³ . Effective dust mask
Hand protection	In case of full contact: Material : Nitrile rubber Break through time : > 480 min Glove thickness : 0.11 mm In case of contact through splashing: Material : Nitrile rubber Break through time : > 480 min Glove thickness : 0.11 mm
Remarks	: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly. Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	: Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
Skin and body protection	: Dust impervious protective suit Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: powder
Color	: white light brown
Odor	: characteristic
Odor Threshold	: Not applicable
pH	: Not applicable
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available

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Flammability (solid, gas)	: Sustains combustion
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: Not applicable
Relative density	: No data available
Solubility(ies)	
Water solubility	: 10 - 20 g/l soluble
Solubility in other solvents	: insoluble Solvent: Alcohol
Partition coefficient: n-octanol/water	: No data available
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: Not applicable
Viscosity, kinematic	: Not applicable
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed. Dust may form explosive mixture in air.
Conditions to avoid	: Heat, flames and sparks. Extremes of temperature and direct sunlight. Exposure to moisture. Exposure to light. Heat.
Incompatible materials	: Strong oxidizing agents Water
Hazardous decomposition products	: No decomposition if stored and applied as directed.

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Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: 3,492 mg/kg
Method: Calculation method**Ingredients:****Pronase from Streptomyces griseus:**

Acute oral toxicity : LD50 Oral (Rat): 3,290 mg/kg

Acute inhalation toxicity : Symptoms: Shortness of breath, Local irritation

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks: May cause skin irritation in susceptible persons.

Ingredients:**Pronase from Streptomyces griseus:**

Result: Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks: May cause irreversible eye damage.

Ingredients:**Pronase from Streptomyces griseus:**

Result: Irritating to eyes.

Respiratory or skin sensitization

Skin sensitization: Not classified based on available information.

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

Ingredients:**Pronase from Streptomyces griseus:**

Result: May cause sensitization by inhalation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed

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human carcinogen by IARC.

OSHA

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

May cause respiratory irritation.

Ingredients:**Pronase from *Streptomyces griseus*:**

Assessment: May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Pronase from *Streptomyces griseus*:**

Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Ingredients:**Pronase from *Streptomyces griseus*:**

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:**

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Ingredients:**Pronase from *Streptomyces griseus*:**

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

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Persistence and degradability

No data available

Bioaccumulative potential

Ingredients:

Pronase from *Streptomyces griseus*:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulation

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : Acute Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Pronase from Streptomyces griseus	9036-06-0	70 - 90 %
Calcium acetate monohydrate	5743-26-0	20 - 30 %

New Jersey Right To Know

Pronase from Streptomyces griseus	9036-06-0	70 - 90 %
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Calcium acetate monohydrate

5743-26-0

20 - 30 %

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

CH INV	: On the inventory, or in compliance with the inventory
TSCA	: Not On TSCA Inventory Pronase from Streptomyces griseus
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Pronase from Streptomyces griseus
AICS	: Not in compliance with the inventory Pronase from Streptomyces griseus
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory Pronase from Streptomyces griseus
ISHL	: Not in compliance with the inventory Pronase from Streptomyces griseus
KECI	: Not in compliance with the inventory Pronase from Streptomyces griseus
PICCS	: Not in compliance with the inventory Pronase from Streptomyces griseus
IECSC	: On the inventory, or in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION
Full text of other abbreviations

(Q)SAR - (Quantitative) Structure Activity Relationship; ASTM - American Society for the Testing of Materials; bw - Body weight; DIN - Standard of the German Institute for Standardisation; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; 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; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISO - International Organisation for Standardization; 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

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Roche

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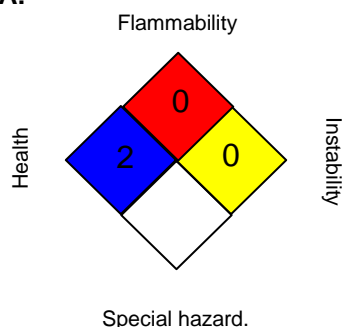
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Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative; DSL - Domestic Substances List (Canada); KECI - Korea Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); AICS - Australian Inventory of Chemical Substances; IECSC - Inventory of Existing Chemical Substances in China; ENCS - Existing and New Chemical Substances (Japan); ISHL - Industrial Safety and Health Law (Japan); PICCS - Philippines Inventory of Chemicals and Chemical Substances; NZIoC - New Zealand Inventory of Chemicals; TCSI - Taiwan Chemical Substance Inventory; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; DOT - Department of Transportation; EHS - Extremely Hazardous Substance; HMIS - Hazardous Materials Identification System; MSHA - Mine Safety and Health Administration; NFPA - National Fire Protection Association; RCRA - Resource Conservation and Recovery Act; RQ - Reportable Quantity; SARA - Superfund Amendments and Reauthorization Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; GLP - Good Laboratory Practice; ERG - Emergency Response Guide; NTP - National Toxicology Program; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods

Further information

NFPA:



HMIS III:

HEALTH	3*
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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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.

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