

# SAFETY DATA SHEET



## Collagenase P, 500mg

Version  
1.1

Revision Date:  
11-04-2015

Date of last issue: 07-30-2015  
Date of first issue: 07-30-2015

### SECTION 1. IDENTIFICATION

Product name : Collagenase P, 500mg  
Mat.-No./ Genisys-No. : 11213865001

#### 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 diffi-  
culties 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 : Collagenase A,B,D,H,P,Coll. I rec. Lyo.  
 CAS-No. : 647-014-00-9

**Hazardous ingredients**

Chemical Name	CAS-No.	Concentration (% w/w)
Collagenase	9001-12-1	>= 90 - <= 100

**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.

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In case of skin contact	: If skin irritation persists, call a physician. If on skin, rinse well with water. 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	: 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 procedures	: Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
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- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Provide sufficient air exchange and/or exhaust in work rooms.  
Dispose of rinse water in accordance with local and national regulations.  
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Observe label precautions.  
Electrical installations / working materials must comply with the technological safety standards.
- Technical measures/Precautions : See label, package insert or internal guidelines

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Hazardous components without workplace control parameters**

Ingredients	CAS-No.
Collagenase	9001-12-1

**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

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## Hand protection

Material : Protective gloves

Remarks : 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 : 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 : solid

Color : No data available

Odor : odorless

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

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 : soluble

Solubility in other solvents : No data available

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Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	Thermal sensitivity
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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**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.
Conditions to avoid	:	Direct sources of heat. Exposure to moisture.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NOx) Sulfur oxides

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Skin corrosion/irritation**

Causes skin irritation.

**Product:**

Remarks: May cause skin irritation in susceptible persons.

**Ingredients:****Collagenase:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

**Serious eye damage/eye irritation**

Causes serious eye irritation.

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### **Product:**

Remarks: May cause irreversible eye damage.

### **Ingredients:**

#### **Collagenase:**

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

### **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:**

#### **Collagenase:**

Assessment: 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 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:**

#### **Collagenase:**

Assessment: May cause respiratory irritation.

### **STOT-repeated exposure**

Not classified based on available information.

### **Ingredients:**

#### **Collagenase:**

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

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Not classified based on available information.

**Ingredients:****Collagenase:**

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:****Collagenase:**

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

Other organisms relevant to  
the environment : No data available**Persistence and degradability**

No data available

**Bioaccumulative potential****Ingredients:****Collagenase:**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).



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- 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**

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.



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**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 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**

Collagenase	9001-12-1	90 - 100 %
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**New Jersey Right To Know**

Collagenase	9001-12-1	90 - 100 %
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**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 : On TSCA Inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
Collagenase
- AICS : Not in compliance with the inventory  
Collagenase
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory  
Collagenase
- ISHL : Not in compliance with the inventory  
Collagenase
- KECI : Not in compliance with the inventory  
Collagenase

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Collagenase

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 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

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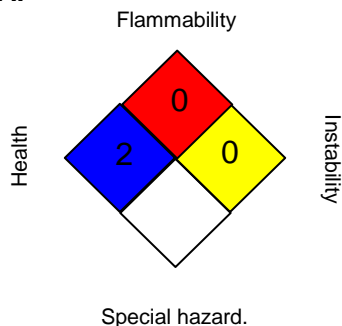
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### Further information

#### 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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