

Endoproteinase Lys-C Sequencing grd. 5ugVersion
1.1Revision Date:
11-05-2015Date of last issue: 08-13-2015
Date of first issue: 08-13-2015**SECTION 1. IDENTIFICATION**

Product name : Endoproteinase Lys-C Sequencing grd. 5ug
Mat.-No./ Genisys-No. : 11420429001

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 Canada)
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**

Respiratory sensitization : Category 1

GHS Label element

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/ vapors/ spray.
P285 In case of inadequate ventilation wear respiratory protection.
Response:
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

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None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Substance name : Endoproteinase Lys-C Sequencing Grade

Hazardous ingredients

Chemical Name	CAS-No.	Concentration (% w/w)
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	>= 10 - < 20
Endoproteinase Lys-C from Lysobacter enzymes	72561-05-8	>= 0.1 - < 1

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 on skin, rinse well with water.

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 : 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.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

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| 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 | : | In case of fire hazardous decomposition products may be produced such as:
Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides |
| 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. |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.
Ensure adequate ventilation. |
| Environmental precautions | : | Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities. |
| Methods and materials for containment and cleaning up | : | Keep in suitable, closed containers for disposal. |
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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.
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 |

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used.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
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.
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6
Endoproteinase Lys-C from <i>Lysobacter enzymogenes</i>	72561-05-8

Engineering measures : No data available

Personal protective equipment

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/m³.
Effective dust mask

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

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 : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid, (lyophilized)

Color : white

Odor : odorless

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Odor Threshold	: Not applicable
pH	: 8.0, (as aqueous solution)
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
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.
Conditions to avoid	: Exposure to moisture.

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Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: 2,655 mg/kg
Method: Calculation methodAcute inhalation toxicity : Acute toxicity estimate: 8.36 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method**Ingredients:****Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg
Test substance: anhydrous substance

LD50 Oral (Rabbit): 2,300 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1 - 5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Test substance: anhydrous substance

Acute toxicity estimate: 1.5 mg/l

Test atmosphere: dust/mist

Method: Expert judgment

Skin corrosion/irritation

Not classified based on available information.

Ingredients:**Endoproteinase Lys-C from Lysobacter enzymogenes:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks: Product dust may be irritating to eyes, skin and respiratory system.

Ingredients:**Endoproteinase Lys-C from Lysobacter enzymogenes:**

Result: Irritating to eyes.

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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:**Endoproteinase Lys-C from Lysobacter enzymogenes:**

Result: May cause sensitization by inhalation.

Germ cell mutagenicity

Not classified based on available information.

Ingredients:**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**

Genotoxicity in vitro : Test Type: Ames test

Remarks: In vitro tests did not show mutagenic effects

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

Not classified based on available information.

Ingredients:**Endoproteinase Lys-C from Lysobacter enzymogenes:**

Assessment: May cause respiratory irritation.

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Endoproteinase Lys-C from Lysobacter enzymogenes:**

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

Aspiration toxicity

Not classified based on available information.

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Ingredients:

Endoproteinase Lys-C from Lysobacter enzymogenes:

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:

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): ca. 320 mg/l
Exposure time: 96 h
Test substance: anhydrous substance

LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia): > 100 mg/l
Exposure time: 24 h

Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l
Exposure time: 8 h
Test substance: anhydrous substance

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

Endoproteinase Lys-C from Lysobacter enzymogenes:

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

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Persistence and degradability**Ingredients:****Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**

Biodegradability : Biodegradation: 3 %
Testing period: 30 d
Method: Directive 67/548/EEC Annex V, C.4.C.
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Biochemical Oxygen Demand (BOD) : 10 mg/g
Incubation time: 5 d

Bioaccumulative potential**Ingredients:****Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**

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

Endoproteinase Lys-C from Lysobacter enzymogenes:

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.

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.

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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.**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.

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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

HEPES	7365-45-9	50 - 70 %
Raffinose pentahydrate	17629-30-0	20 - 30 %
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	10 - 20 %

New Jersey Right To Know

HEPES	7365-45-9	50 - 70 %
Raffinose pentahydrate	17629-30-0	20 - 30 %
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	10 - 20 %

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 Endoproteinase Lys-C from Lysobacter enzymogenes
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Endoproteinase Lys-C from Lysobacter enzymogenes
AICS	: Not in compliance with the inventory Endoproteinase Lys-C from Lysobacter enzymogenes
NZIoC	: Not in compliance with the inventory Endoproteinase Lys-C from Lysobacter enzymogenes
ENCS	: Not in compliance with the inventory HEPES Raffinose pentahydrate Endoproteinase Lys-C from Lysobacter enzymogenes
ISHL	: Not in compliance with the inventory HEPES Raffinose pentahydrate Endoproteinase Lys-C from Lysobacter enzymogenes
KECI	: Not in compliance with the inventory HEPES Raffinose pentahydrate Endoproteinase Lys-C from Lysobacter enzymogenes
PICCS	: Not in compliance with the inventory

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Endoproteinase Lys-C from Lysobacter enzymogenes

IECSC : Not in compliance with the inventory
Endoproteinase Lys-C from Lysobacter enzymogenes**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

SAFETY DATA SHEET



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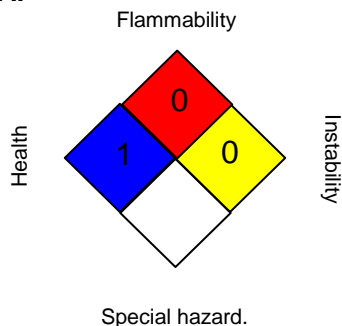
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Further information

NFPA:



HMIS III:

HEALTH	1*
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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