

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Proteinase K,recomb.,PCR Grd.lyo.,100 mg

Version 1.0

Revision Date 26.10.2011

Print Date 20.11.2012

### 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Commercial Product Name : Proteinase K,recomb.,PCR Grd.lyo.,100 mg  
Mat.-No./ Genisys-No. : 03115879001

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

Recommended restrictions : For professional users only.  
on use

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
-  
Sandhoferstrasse 116  
68305 Mannheim  
E-mail address : mannheim.umweltschutz@roche.com  
Telephone : +496217590  
Telefax : +496217592890  
Responsible Department : +49(0)621-759-2012 +49(0)621-759-4848+49(0)8856-60-2629  
In case of emergencies: : Central Works Security +49(0)621-759-2203  
Roche Diagnostics GmbH  
Centre for detoxification: : Mainz +49(0)6131-19240  
Munich +49(0)89-19240

### 2. Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|  |  |
|--|--|
| Skin irritation, Category 2                                  | H315: Causes skin irritation.  |
| Eye irritation, Category 2                                   | H319: Causes serious eye irritation.   |
| Respiratory sensitization, Category 1                        | H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Skin sensitization, Category 1                               | H317: May cause an allergic skin reaction.                                       |
| Specific target organ toxicity - single exposure, Category 3 | H335: May cause respiratory irritation.  |

##### Classification (67/548/EEC, 1999/45/EC)

|          |  |
|----------|--|
| Harmful  | R42: May cause sensitization by inhalation.  |
| Irritant | R43, R36/37/38: May cause sensitization by skin contact., Irritating to eyes, respiratory system and skin. |

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### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word : Danger

Hazard statements

|      |  |
|------|--|
| H315 | Causes skin irritation.  |
| H317 | May cause an allergic skin reaction.                                       |
| H319 | Causes serious eye irritation.   |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | May cause respiratory irritation.  |

Precautionary statements

|                    |  |
|--------------------|--|
| <b>Prevention:</b> |  |
| P261               | Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.                           |
| P280               | Wear protective gloves/ eye protection/ face protection.                         |
| P285               | In case of inadequate ventilation wear respiratory protection.                   |
| <b>Response:</b>   |  |
| P333 + P313        | If skin irritation or rash 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. |

Hazardous components which must be listed on the label:  
39450-01-6 Proteinase, Tritirachium album serine

### 2.3 Other hazards

No information available.

## 3. Composition/information on ingredients

### 3.2 Mixtures

Hazardous components

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| Chemical Name                            | CAS-No.<br>EC-No.<br>Registration<br>number | Classification<br>(67/548/EEC) | Classification<br>(REGULATION<br>(EC) No<br>1272/2008)   | Concentration<br>[%] |
|--|---|--------------------------------|--|----------------------|
| Proteinase, Triticachium<br>album serine | 39450-01-6<br>254-457-8                     | Xi; R36/37/38-R43<br>Xn; R42   | Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Resp. Sens. 1;<br>H334<br>Skin Sens. 1; H317<br>STOT SE 3; H335 | >= 50 - <= 100       |

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

### 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.  
Do not leave the victim unattended.
- If inhaled : Call a physician or poison control centre 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.  
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.

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

- Symptoms : No information available.

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

- Treatment : The first aid procedure should be established in consultation

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with the doctor responsible for industrial medicine.

### 5. Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water  
Dry powder  
Carbon dioxide (CO<sub>2</sub>)  
Foam

Unsuitable extinguishing media : High volume water jet

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

Specific hazards during firefighting : No information available.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self contained breathing apparatus for fire fighting if necessary.

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

### 6. Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.  
Ensure adequate ventilation.

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and materials for containment and cleaning up

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

#### 6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

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### 7. Handling and storage

#### 7.1 Precautions for safe handling

- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapours/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 sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.

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

- Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label or package insert
- German storage class : 11 Combustible Solids
- Other data : No decomposition if stored and applied as directed.

#### 7.3 Specific end uses

- Specific use(s) : Laboratory chemicals

### 8. Exposure controls/personal protection

#### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

#### 8.2 Exposure controls

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### 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/m<sup>3</sup>.
- Hand protection : In case of full contact:  
Nitrile rubber  
Break through time: > 480 min  
Glove thickness: 0,11 mm
- : In case of contact through splashing:  
Nitrile rubber  
Break through time: > 480 min  
Glove thickness: 0,11 mm
- : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.  
This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us.  
Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.  
The suitability for a specific workplace should be discussed with the producers of the protective gloves.
- 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.

### Environmental exposure controls

- General advice : 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.

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### 9. Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|  |                              |
|--|------------------------------|
| Appearance                             | : solid                      |
| Colour                                 | : white                      |
| Odour                                  | : very faint                 |
| pH                                     | : 6,5, (as aqueous solution) |
| Melting point/range                    | : no data available          |
| Flash point                            | : not applicable             |
| Lower explosion limit                  | : no data available          |
| Upper explosion limit                  | : no data available          |
| Vapour pressure                        | : no data available          |
| Water solubility                       | : soluble                    |
| Partition coefficient: n-octanol/water | : no data available          |
| Ignition temperature                   | : no data available          |
| Thermal decomposition                  | : Decomposes on heating.     |
| Viscosity, dynamic                     | : no data available          |

#### 9.2 Other information

|                     |                            |
|---------------------|----------------------------|
| Conductivity        | : no data available        |
| Oxidising potential | : no data available        |
| Bulk density        | : ca. 35 kg/m <sup>3</sup> |
| Surface tension     | : no data available        |

### 10. Stability and reactivity

#### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

#### 10.2 Chemical stability

Decomposes on heating., Sensitive to air.

#### 10.3 Possibility of hazardous reactions

|                     |  |
|---------------------|--|
| Hazardous reactions | : No dangerous reaction known under conditions of normal use.    |
|                     | : Further information: No decomposition if stored and applied as |

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directed.

### 10.4 Conditions to avoid

Conditions to avoid : Heat.

### 10.5 Incompatible materials

Materials to avoid : no data available

### 10.6 Hazardous decomposition products

Hazardous decomposition products : no data available

## 11. Toxicological information

### 11.1 Information on toxicological effects

#### Product

Acute oral toxicity : no data available

Acute inhalation toxicity : no data available

Acute dermal toxicity : no data available

Acute toxicity (other routes of administration) : no data available

Skin corrosion/irritation : May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation : May cause irreversible eye damage.

Respiratory or skin sensitization : Causes sensitization.

Aspiration toxicity : no data available

Further information : no data available

#### Components:

##### **Proteinase, Tritirachium album serine:**

Acute oral toxicity : no data available

Acute inhalation toxicity : no data available

Acute dermal toxicity : no data available

Acute toxicity (other routes of administration) : no data available



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administration)

|                                   |   |
|-----------------------------------|---|
| Skin corrosion/irritation         | : Result: Irritating to skin., May cause skin irritation and/or dermatitis.   |
| Serious eye damage/eye irritation | : Result: Irritating to eyes., May cause irreversible eye damage.   |
| Respiratory or skin sensitization | : Classification: May cause sensitization by skin contact., Causes sensitization.<br>: Classification: May cause sensitization by inhalation. |
| STOT - single exposure            | : Assessment: May cause respiratory irritation.   |
| STOT - repeated exposure          | : Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.                                |
| Aspiration toxicity               | : no data available   |
| Further information               | : no data available   |

## 12. Ecological information

### 12.1 Toxicity

#### Product:

Toxicity to fish : no data available  
Toxicity to daphnia and other aquatic invertebrates. : no data available

Toxicity to algae : no data available

Toxicity to bacteria : no data available

#### **Ecotoxicology Assessment**

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

Other organisms relevant to the environment : no data available

#### Components:

##### **Proteinase, Triticachium album serine:**

Toxicity to fish : no data available

Toxicity to daphnia and other aquatic invertebrates. : no data available

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Toxicity to algae : no data available

Toxicity to bacteria : no data available

### Ecotoxicology Assessment

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

Other organisms relevant to the environment : no data available

### 12.2 Persistence and degradability

#### Product:

Biodegradability : no data available

#### Components:

##### Proteinase, *Tritirachium album* serine:

Biodegradability : no data available

### 12.3 Bioaccumulative potential

#### Product:

Bioaccumulation : no data available

#### Components:

##### Proteinase, *Tritirachium album* serine:

Bioaccumulation : no data available

### 12.4 Mobility in soil

#### Product:

Mobility : no data available

Distribution among environmental compartments : no data available

Environmental fate and pathways : no data available

Physico-chemical removability : no data available

#### Components:

##### Proteinase, *Tritirachium album* serine:

Mobility : no data available

Distribution among environmental compartments : no data available

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Environmental fate and pathways : no data available

Physico-chemical removability : no data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance is not considered to be persistent, bioaccumulating nor toxic (PBT)., This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

#### Components:

##### **Proteinase, Tritirachium album serine:**

Assessment : This substance is not considered to be persistent, bioaccumulating nor toxic (PBT)., This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

### 12.6 Other adverse effects

#### Product:

Biochemical Oxygen Demand (BOD) : no data available

Dissolved organic carbon (DOC) : no data available

Chemical Oxygen Demand (COD) : no data available

Adsorbed organic bound halogens (AOX) : no data available

Additional ecological information : no data available

#### Components:

##### **Proteinase, Tritirachium album serine:**

Biochemical Oxygen Demand (BOD) : no data available

Dissolved organic carbon (DOC) : no data available

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Chemical Oxygen Demand (COD) : no data available

Adsorbed organic bound halogens (AOX) : no data available

### 13. Disposal considerations

#### 13.1 Waste treatment methods

Product : 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.

### 14. Transport information

#### 14.1 UN number

##### ADR

Not dangerous goods

##### IMDG

Not dangerous goods

##### IATA

Not dangerous goods

#### 14.2 Proper shipping name

##### ADR

Not dangerous goods

##### IMDG

Not dangerous goods



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### IATA

Not dangerous goods

### 14.3 Transport hazard class

#### ADR

Not dangerous goods

#### IMDG

Not dangerous goods

#### IATA

Not dangerous goods

### 14.4 Packing group

#### ADR

Not dangerous goods

#### IMDG

Not dangerous goods

#### IATA

Not dangerous goods

### 14.5 Environmental hazards

#### ADR

Not dangerous goods

#### IMDG

Not dangerous goods

#### IATA

Not dangerous goods

### 14.6 Special precautions for user

Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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

Remarks : not applicable

## 15. Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Major Accident Hazard : 96/82/EC Update: 2003  
Legislation Directive 96/82/EC does not apply

Water contaminating class : WGK 1 slightly water endangering  
(Germany) VWWWS A4

TA Luft List (Germany) : Total dust: not applicable  
Inorganic substances in powdered form: not applicable  
Inorganic substances in vapour or gaseous form: not applicable  
Organic Substances: not applicable  
Carcinogenic substances: not applicable  
Mutagenic: not applicable  
Toxic to reproduction: not applicable

### 15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

## 16. Other information

### Full text of R-phrases referred to under sections 2 and 3

R36/37/38 Irritating to eyes, respiratory system and skin.  
R42 May cause sensitization by inhalation.  
R43 May cause sensitization by skin contact.

### Full text of H-Statements referred to under sections 2 and 3.

H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H335 May cause respiratory irritation.

### Further information

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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.