

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 08.05.2015

Version number 2

Revision: 08.05.2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
 - **Trade name: Reagent P**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
 - **Application of the substance / the mixture**
Laboratory chemicals
Detection System Solutions
- **1.3 Details of the supplier of the safety data sheet**
 - **Manufacturer/Supplier:**
BIOTECON Diagnostics GmbH
Hermannswerder Haus 17
14473 Potsdam
Phone: +49 (0) 331-23 00 200
www.bc-diagnostics.com
 - **Informing department:**
Phone: +49 (0) 331-23 00 200
Fax: +49 (0) 331-23 00 299
- **1.4 Emergency telephone number:** Phone: +49 (0) 331-23 00 200

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2 H319 Causes serious eye irritation.
 Skin Sens. 1 H317 May cause an allergic skin reaction.
 STOT SE 3 H335 May cause respiratory irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xn; Sensitising

R42/43: May cause sensitisation by inhalation and skin contact.



Xi; Irritant

R36/37/38: Irritating to eyes, respiratory system and skin.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

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- **Classification system:**

The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

- **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger

- **Hazard-determining components of labelling:**

Proteinase, Tritirachium album serine

- **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

- **Precautionary statements**

P261 Avoid breathing dust.

P280 Wear protective gloves / eye protection.

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

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

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**

- **Description:**

Mixture of the substances listed below including additives not requiring identification.

- **Dangerous components:**

CAS: 39450-01-6	Proteinase, Tritirachium album serine	50-100%
EINECS: 254-457-8	<ul style="list-style-type: none"> ☒ Xn R42/43; ☒ Xi R36/37/38 ☒ Resp. Sens. 1, H334; ☒ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 	

- **Additional information** For the wording of the listed risk phrases refer to section 16.

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SECTION 4: First aid measures

- **4.1 Description of first aid measures**
 - **General information** Instantly remove any clothing contaminated by the product.
 - **After inhalation**
Supply fresh air and call for doctor for safety reasons.
In case of unconsciousness bring patient into stable side position for transport.
 - **After skin contact** Instantly wash with water and soap and rinse thoroughly.
 - **After eye contact**
Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
 - **After swallowing** In case of persistent symptoms consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
 - **Suitable extinguishing agents**
Extinguishing powder, foam or water jet. Fight larger fires with water jet or alcohol-resistant foam.
 - **For safety reasons unsuitable extinguishing agents** None known.
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
 - **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid causing dust.
Avoid contact with the product.
- **6.2 Environmental precautions:**
No special measures required.
Do not allow to enter drainage system, surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose of contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Prevent formation of dust.
Avoid contact with eyes and skin.
 - **Information about protection against explosions and fires:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** Keep container tightly sealed.

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- **Storage class** 11 (Combustible solids) according TRGS 510 (German Regulation)
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
 - **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
 - **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
Keep away from foodstuffs, beverages and food.
Take off all contaminated clothing immediately.
Wash hands during breaks and at the end of the work.
Avoid contact with the eyes and skin.
 - **Breathing equipment:**
In case of brief exposure or low pollution use breathing filter apparatus. In case of intensive or longer exposure use breathing apparatus that is independent of circulating air.
 - **Protection of hands:**



Protective gloves.

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
With solid dry substances permeation is not to be expected. Therefore the breakthrough-time for this protective glove has not been measured.
- **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
Nitrile rubber, NBR
Neoprene gloves
- **Eye protection:** Tightly sealed safety glasses.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Powder
 - **Colour:** White
 - **Odour:** odourless
 - **Odour threshold:** Not determined.
 - **pH-value:** Not applicable.
 - **Change in condition**
 - **Melting point/Melting range:** Not determined
 - **Boiling point/Boiling range:** Not determined

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· Flash point:	Not applicable
· Inflammability (solid, gaseous)	Not determined.
· Ignition temperature:	
· Decomposition temperature:	Not determined.
· Self-inflammability:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive.
· Vapour pressure:	Not applicable.
· Density	Not determined
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
· Water:	Soluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
· dynamic:	Not applicable.
· kinematic:	Not applicable.
· Solvent content:	
· Organic solvents:	0.0 %
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **10.2 Chemical stability**
 - **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**
None in case of intended use and storage in compliance with instructions.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
 - **Acute toxicity**
 - **Primary irritant effect:**
 - **Skin corrosion/irritation** Irritant to skin and mucous membranes.
 - **Serious eye damage/irritation** Strongly irritant
 - **Respiratory or skin sensitisation**
Sensitization possible by inhalation.
Sensitization possible by skin contact.
 - **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version:
Harmful
Irritant

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SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
 - **Other information:** There are no data available about the preparation.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
 - **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
The waste code numbers mentioned are recommendations based on the probable use of the product.

· European waste catalogue

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 02 00	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 05*	chemicals consisting of or containing dangerous substances

- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.
 - **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- | | |
|---|------|
| · 14.1 UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards:
· Marine pollutant: | No |

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- | | |
|---|--|
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · UN "Model Regulation": | - |

SECTION 15: Regulatory information

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

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger

- **Hazard-determining components of labelling:**

Proteinase, Tritirachium album serine

- **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

- **Precautionary statements**

P261 Avoid breathing dust.

P280 Wear protective gloves / eye protection.

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

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

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER/doctor if you feel unwell.

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

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **National regulations**

- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

- **Substances of very high concern (SVHC) according to REACH, Article 57**

None of the ingredients is contained.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

- 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.
- R36/37/38 Irritating to eyes, respiratory system and skin.
- R42/43 May cause sensitisation by inhalation and skin contact.

· **Department issuing data specification sheet:**

This Material Safety Data Sheet has been drawn up in cooperation with:
 DEKRA Assurance Services GmbH, Hanomagstr. 12, D-30449 Hanover, Germany,
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· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 ICAO: International Civil Aviation Organisation
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 IATA: International Air Transport Association
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
 Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2
 Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
 Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**

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