

Safety data sheet
according to Regulation (EC) No 1907/2006, Article 31

Printing date 10.02.2025

Version number 2 (replaces version 1)

Revision: 10.02.2025

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

· **1.1 Product identifier**

· **Trade name:** Reagent P

· **Product variants:** KIT230007 (Ref. A 500 12)

· **CAS Number:**

39450-01-6

· **EC number:**

254-457-8

· **Index number:**

647-014-00-9

· **UFI:** JJ10-907R-9002-RRVM

· **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 and analytical use / additional solutions

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Hygiena Diagnostics GmbH

Hermannswerder 17

14473 Potsdam

GERMANY

Phone: +49 (0) 331-23 00 200

www.hygiena.com

BIOTECON Diagnostics GmbH

Hermannswerder 17

14473 Potsdam

GERMANY

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

Office hours: 09:30 - 16:00

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

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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.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

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

Hazard pictograms



GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:

Proteinase K

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/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P312 Call a POISON CENTER/doctor if you feel unwell.
 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.

Additional information:

Packaging of whatever capacity that is delivered to the general public shall be fitted with a tactile warning of danger according to EN ISO 11683.

Please refer to further labelling elements in section 15 of this safety data sheet, if applicable.

2.3 Other hazards

Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

Determination of endocrine-disrupting properties

The product does not contain substances with endocrine disrupting properties.

SECTION 3: Composition/information on ingredients

3.1 Substances

CAS No. Designation:

39450-01-6 Proteinase, Tritirachium album serine

Identification number(s):

· **EC number:** 254-457-8· **Index number:** 647-014-00-9

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SECTION 4: First aid measures

· 4.1 Description of first aid measures

· **General information** Remove contaminated clothing immediately.

· 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

If skin irritation continues, consult a doctor.

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.

Remove contact lenses if possible.

· After swallowing

Rinse out mouth and then drink plenty of water.

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** Use fire fighting measures that suit the environment.

· **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:** Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Observe information for safe handling (item 7) and personal protective equipment (item 8).

· 6.2 Environmental precautions:

Do not allow to enter drainage system, surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Send for recovery or disposal in suitable containers.

Complete cleaning with water.

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

Store in cool, dry place in tightly closed containers.

Keep away from heat and direct sunlight.

Avoid contact with eyes and skin.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

· **Information about protection against explosions and fires:** No special measures required.

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- **Handling**
Do not eat, drink or smoke while working.
Wash hands during breaks and at the end of the work.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
 - **Requirements to be met by storerooms and containers:**
Store only in the original container.
Prevent any penetration into the ground.
 - **Information about storage in one common storage facility:**
Keep away from strong oxidizing, alkalis and acidic materials.
 - **Further information about storage conditions:**
Store in the dark.
Protect from the effects of light.
Keep container tightly sealed.
- **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:** Not required.
- **Additional information:** The lists that were valid during the compilation were used as basis.
- **8.2 Exposure controls**
- **Individual protection measures, such as personal protective equipment**
- **Breathing equipment:**
Not necessary if room is well-ventilated.
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.
- **Hand protection**



Protective gloves.

Only use chemical-protective gloves with CE-labelling of category III (EN 374).
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **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.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **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
- **Eye/face protection**



Tightly sealed safety glasses.

- **Body protection:** Wear suitable protective clothing.

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Solid
· Colour:	White
· Odour:	odourless
· Odour threshold:	Not determined.
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	Not determined
· Flammability	Product is not inflammable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable
· Auto-ignition temperature:	Not determined.
· Decomposition temperature:	Not determined.
· SADT	
· pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· dynamic:	Not applicable.
· Solubility	
· Water:	Soluble
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density at 20 °C	1.153 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	See section 3.

· 9.2 Other information

· Appearance:	
· Form:	Powder
· Important information on protection of health and environment, and on safety.	
· Self-inflammability:	Not determined.
· Explosive properties:	Product is not explosive.
· Change in condition	
· Evaporation rate	Not applicable.

· Information with regard to physical hazard classes

· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void

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· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **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 hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **Primary irritant effect:**
 - **Skin corrosion/irritation**
Causes skin irritation.
 - **Serious eye damage/irritation** Causes serious eye irritation.
 - **Respiratory or skin sensitisation**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** May cause respiratory irritation.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

Substance is not listed.

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.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects** No further relevant information available.

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- **Additional ecological information:**

- **General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Proceed according to local, official regulations.

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 hazardous substances
HP4	Irritant - skin irritation and eye damage
HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP13	Sensitising

- **Uncleaned packagings:**

- **Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

Non contaminated packagings can be used for recycling.

Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

- **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

<ul style="list-style-type: none"> · 14.1 UN number or ID number · ADR/RID, IMDG, IATA 	Void
<ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID, IMDG, IATA 	Void
<ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR/RID, ADN, IMDG · Class 	Void
<ul style="list-style-type: none"> · IATA · Class 	Void Not Restricted.
<ul style="list-style-type: none"> · 14.4 Packing group · ADR/RID, IMDG, IATA 	Void
<ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: 	No
<ul style="list-style-type: none"> · 14.6 Special precautions for user 	Not applicable.
<ul style="list-style-type: none"> · 14.7 Maritime transport in bulk according to IMO instruments 	Not applicable.

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· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

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

· Directive 2012/18/EU

· **Named dangerous substances - ANNEX I** Substance is not listed.

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

Substance is not listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

Substance is not listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

Substance is not listed.

· **Regulation (EC) No 273/2004 on drug precursors**

Substance is not listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

Substance is not listed.

· **National regulations**

· **Water hazard class:**

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

Substance is not listed.

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

SECTION 16: Other information

This data sheet considers labelling requirements of Regulation (EU) 2022/692 adapting Regulation (EC) No 1272/2008 (18th ATP of the CLP Regulation).

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.

This safety data sheet meets the requirements of Regulation (EU) 2015/830 and 2020/878 amending Annex II of Regulation (EC) 1907/2006.

· **Relevant phrases**

The phrases specified here are no labelling elements for the product but repeat the properties of the ingredients from section 3.

· **Department issuing data specification sheet:**



This Safety Data Sheet has been drawn up in cooperation with:
DEKRA Assurance Services GmbH, Hanomagstr. 12, D-30449 Hanover, Germany,
phone: (+49) 511 42079 - 0, reach@dekra.com.

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- **Version number of previous version: 1**

- **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 relatif au transport international 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

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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

EU