



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 17.06.2013

Version 3.6

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

### 1.1 Product identifier

Catalogue No. 107138  
Product name Auxillase® liquid standardized protease concentrate (Carica papaya)  
REACH Registration Number This product is a mixture. REACH Registration Number see section 3.

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

Identified uses Pharmaceutical production, Reagent for development and research  
For additional information on uses please refer to the Merck Chemicals portal ([www.merck-chemicals.com](http://www.merck-chemicals.com)).

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

Company Merck KGaA \* 64271 Darmstadt \* Germany \* Phone:+49 6151 72-0  
Responsible Department EQ-RS \* e-mail: [prodsafe@merckgroup.com](mailto:prodsafe@merckgroup.com)

1.4 Emergency telephone number Please contact the regional company representation in your country.

## SECTION 2. Hazards identification

### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2, H315  
Eye irritation, Category 2, H319  
Respiratory sensitisation, Category 1, H334  
For the full text of the H-Statements mentioned in this Section, see Section 16.

Classification (67/548/EEC or 1999/45/EC)

Sensitising R42

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

### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



Signal word  
Danger

Hazard statements

H315 Causes skin irritation.  
H319 Causes serious eye irritation.

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

*Precautionary statements*

Response

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

P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position 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.

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

**Reduced labelling (≤125 ml)**

*Hazard pictograms*



*Signal word*

Danger

*Hazard statements*

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

*Precautionary statements*

P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

**Labelling (67/548/EEC or 1999/45/EC)**

*Symbol(s)*  Xn Harmful

*R-phrase(s)* 42 May cause sensitisation by inhalation.

*S-phrase(s)* 23-45 Do not breathe vapour. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

**2.3 Other hazards**

None known.

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**SECTION 3. Composition/information on ingredients**

Chemical nature Mixture of inorganic and organic compounds

**3.1 Substance**

not applicable

**3.2 Mixture**

**Hazardous components (REGULATION (EC) No 1272/2008)**

*Chemical Name (Concentration)*

CAS-No. Registration number Classification

Papain (>= 10 % - < 20 % )

9001-73-4 \*)

Eye irritation, Category 2, H319

Specific target organ toxicity - single exposure, Category 3, H335

Skin irritation, Category 2, H315

Respiratory sensitisation, Category 1, H334

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sodium hydrogensulphite...% ( $\geq 1\%$  -  $< 10\%$ )  
7631-90-5 \*) Acute toxicity, Category 4, H302

\*) A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

**Hazardous components (1999/45/EC)**

*Chemical Name (Concentration)*

CAS-No.	Classification
Papain ( $\geq 10\%$ - $< 20\%$ )	
9001-73-4	Xi, Irritant; R36/37/38 R42

sodium hydrogensulphite...% ( $\geq 1\%$  -  $< 10\%$ )  
7631-90-5 R31  
Xn, Harmful; R22

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

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**SECTION 4. First aid measures**

**4.1 Description of first aid measures**

After inhalation: fresh air. Call in physician.

After skin contact: wash off with plenty of water. Remove contaminated clothing.

Immediately call in ophthalmologist. Call in ophthalmologist.

After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.

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

irritant effects

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

No information available.

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**SECTION 5. Firefighting measures**

**5.1 Extinguishing media**

*Suitable extinguishing media*

Water, Carbon dioxide (CO<sub>2</sub>), Foam, Dry powder

*Unsuitable extinguishing media*

For this substance/mixture no limitations of extinguishing agents are given.

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

Combustible.

Vapours are heavier than air and may spread along floors.

Development of hazardous combustion gases or vapours possible in the event of fire.

Fire may cause evolution of:

nitrogen oxides, Sulphur oxides

**5.3 Advice for firefighters**

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*Special protective equipment for firefighters*

Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

*Further information*

Suppress (knock down) gases/vapours/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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**SECTION 6. Accidental release measures**

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

Advice for non-emergency personnel: Avoid substance contact. Do not breathe vapours, aerosols. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders: Protective equipment see section 8.

**6.2 Environmental precautions**

Do not empty into drains.

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

Cover drains. Collect, bind, and pump off spills.

Observe possible material restrictions (see sections 7 and 10).

Take up with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

**6.4 Reference to other sections**

Indications about waste treatment see section 13.

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**SECTION 7. Handling and storage**

**7.1 Precautions for safe handling**

*Advice on safe handling*

Observe label precautions.

*Hygiene measures*

Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

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

*Storage conditions*

Tightly closed.

Store below +15°C.

**7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

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**SECTION 8. Exposure controls/personal protection**

**8.1 Control parameters**

**8.2 Exposure controls**

**Engineering measures**

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Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

**Individual protection measures**

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

*Eye/face protection*

Safety glasses

*Hand protection*

full contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	> 480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0,11 mm
Break through time:	> 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 741 Dermatril® L (full contact), KCL 741 Dermatril® L (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet (>,<) supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: [www.kcl.de](http://www.kcl.de)).

*Other protective equipment*

protective clothing

*Respiratory protection*

required when vapours/aerosols are generated.

Recommended Filter type: filter ABEK

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

**Environmental exposure controls**

Do not empty into drains.

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**SECTION 9. Physical and chemical properties**

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

Form	liquid
Colour	yellow
Odour	No strong odour known.

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Odour Threshold	No information available.
pH	No information available.
Melting point	No information available.
Boiling point	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.
Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Relative density	1,22 g/cm <sup>3</sup> at 20 °C
Water solubility	No information available.
Partition coefficient: n- octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

## 9.2 Other data

none

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## SECTION 10. Stability and reactivity

### 10.1 Reactivity

See section 10.3

### 10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

### 10.3 Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidizing agents

### 10.4 Conditions to avoid

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no information available

**10.5 Incompatible materials**

no information available

**10.6 Hazardous decomposition products**

in the event of fire: See section 5.

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**SECTION 11. Toxicological information**

**11.1 Information on toxicological effects**

**Mixture**

*Acute oral toxicity*

Symptoms: Swallowing may result in damage to the following: , oesophagus

Acute toxicity estimate: > 2.000 mg/kg

Calculation method

*Acute inhalation toxicity*

Symptoms: Possible damages: , mucosal irritations

*Acute dermal toxicity*

This information is not available.

*Skin irritation*

Mixture causes skin irritation.

*Eye irritation*

Mixture causes serious eye irritation.

*Sensitisation*

Mixture may cause allergy or asthma symptoms or breathing difficulties if inhaled.

*Germ cell mutagenicity*

This information is not available.

*Carcinogenicity*

This information is not available.

*Reproductive toxicity*

This information is not available.

*Teratogenicity*

This information is not available.

*Specific target organ toxicity - single exposure*

This information is not available.

*Specific target organ toxicity - repeated exposure*

This information is not available.

*Aspiration hazard*

This information is not available.

**11.2 Further information**

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

**Components**

*Papain*

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*Acute oral toxicity*  
LD50 rat: > 4.000 mg/kg (RTECS)

*Sensitisation*  
Human experience  
Result: positive  
(Lit.)

*Germ cell mutagenicity*  
*Genotoxicity in vitro*  
Result: negative  
(Lit.)

*sodium hydrogensulphite... %*  
*Acute oral toxicity*  
Acute toxicity estimate: 500,1 mg/kg  
Expert judgement

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## SECTION 12. Ecological information

### Mixture

#### 12.1 Toxicity

No information available.

#### 12.2 Persistence and degradability

No information available.

#### 12.3 Bioaccumulative potential

No information available.

#### 12.4 Mobility in soil

No information available.

#### 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

#### 12.6 Other adverse effects

Discharge into the environment must be avoided.

### Components

#### *Papain*

No information available.

#### *sodium hydrogensulphite... %*

No information available.

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## SECTION 13. Disposal considerations

### *Waste treatment methods*

See [www.retrologistik.com](http://www.retrologistik.com) for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

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## SECTION 14. Transport information

### Land transport (ADR/RID)

#### 14.1 - 14.6

Not classified as dangerous in the meaning of transport regulations.

### Inland waterway transport (ADN)

Not relevant

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**Air transport (IATA)**

**14.1 - 14.6** Not classified as dangerous in the meaning of transport regulations.

**Sea transport (IMDG)**

**14.1 - 14.6** Not classified as dangerous in the meaning of transport regulations.

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**  
Not relevant

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**SECTION 15. Regulatory information**

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

*EU regulations*

Major Accident Hazard 96/82/EC  
Legislation Directive 96/82/EC does not apply  
Occupational restrictions Take note of Dir 94/33/EC on the protection of young people at work.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC not regulated

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals not regulated

Substances of very high concern (SVHC) This product does not contain substances of very high concern above the respective regulatory limit (> 0.1 % (w/w) Regulation (EC) No 1907/2006 (REACH), Article 57).

*National legislation*

Storage class 10 - 13

**15.2 Chemical Safety Assessment**

For this product a chemical safety assessment was not carried out.

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**SECTION 16. Other information**

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

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

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

R22	Harmful if swallowed.
R31	Contact with acids liberates toxic gas.
R36/37/38	Irritating to eyes, respiratory system and skin.
R42	May cause sensitisation by inhalation.

**Training advice**

Provide adequate information, instruction and training for operators.

**Key or legend to abbreviations and acronyms used in the safety data sheet**

Used abbreviations and acronyms can be looked up at [www.wikipedia.org](http://www.wikipedia.org).

**Regional representation**

This information is given on the authorised Safety Data Sheet for your country.

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*The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.*