

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 22.02.2013

Version 4.8

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

1.1 Product identifier

Catalogue No.	107130
Product name	Pancreatin (from porcine pancreas) 350 FIP-U/g Protease, 6000 FIP-U/g Lipase, 7500 FIP-U/g Amylase, suitable for use as excipient EMPROVE® exp USP
REACH Registration Number	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.

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

Identified uses	Biochemical research/analysis For additional information on uses please refer to the Merck Chemicals portal (www.merck-chemicals.com).
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1.3 Details of the supplier of the safety data sheet

Responsible Department	LS-QHC * e-mail: prodsafe@merckgroup.com
Regional representation	Merck Chemicals Ltd * Boulevard Industrial Park * Padge Road * Beeston * Nottingham * NG9 2JR * Tel. 01159 430840 * information@merckchem.co.uk .

1.4 Emergency telephone number	+49 (0) 6151 722440
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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
Specific target organ toxicity - single exposure, Category 3, H335
Respiratory sensitisation, Category 1, H334
Skin sensitisation, Category 1, H317

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

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

		R42/43
Xi	Irritant	R36/37/38

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

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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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.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H317 May cause an allergic skin reaction.

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

Precautionary statements

Prevention

P280 Wear protective gloves.

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.

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

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

Reduced labelling (≤125 ml)

Hazard pictograms



Signal word

Danger

Hazard statements

H317 May cause an allergic skin reaction.

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

Precautionary statements

P280 Wear protective gloves.


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.

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

CAS-No. 8049-47-6

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

Symbol(s)  Xn Harmful


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Catalogue No. 107130
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R-phrase(s) 36/37/38-42/43 Irritating to eyes, respiratory system and skin. May cause sensitisation by inhalation and skin contact.
S-phrase(s) 22-24-37-45 Do not breathe dust. Avoid contact with skin. Wear suitable gloves. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

EC-No. 232-468-9

Reduced labelling (≤125 ml)

Symbol(s)  Xn

Harmful

R-phrase(s) 42/43

S-phrase(s) 22-24-37-45

May cause sensitisation by inhalation and skin contact.
Do not breathe dust. Avoid contact with skin. Wear suitable gloves. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature Substances which occur in nature

3.1 Substance

CAS-No. 8049-47-6

EC-No. 232-468-9

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

Chemical Name (Concentration)

CAS-No. Registration number Classification

pancreatin (≤ 100 %)

8049-47-6 *)

Skin irritation, Category 2, H315

Eye irritation, Category 2, H319

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

Respiratory sensitisation, Category 1, H334

Skin sensitisation, Category 1, H317

*) 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

pancreatin (≤ 100 %)

8049-47-6 R42/43

Xi, Irritant; R36/37/38

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

3.2 Mixture

not applicable

SECTION 4. First aid measures

4.1 Description of first aid measures

The Safety Data Sheets for catalogue items are available at www.merckgroup.com

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After inhalation: fresh air. Call in physician.

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

After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects, Allergic reactions

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Carbon dioxide (CO₂), 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.

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

5.3 Advice for firefighters

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

Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Avoid substance contact. Avoid inhalation of dusts. 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 dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

Indications about waste treatment see section 13.

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7500 FIP-U/g Amylase, suitable for use as excipient EMPROVE® exp USP

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. Dry.

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.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

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.

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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).

Other protective equipment
protective clothing

Respiratory protection
required when dusts are generated.
Recommended Filter type: Filter P 2 (acc. to DIN 3181) for solid and liquid particles of harmful substances
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.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid
Colour	light yellow
Odour	characteristic
Odour Threshold	No information available.
pH	ca. 5 - 6 at 10 g/l 20 °C
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	at 20 °C not applicable
Relative vapour density	No information available.

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Relative density	No information available.
Water solubility	at 20 °C partly soluble
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

Ignition temperature	> 360 °C
Bulk density	ca.400 kg/m ³

SECTION 10. Stability and reactivity

10.1 Reactivity

The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

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

Heating.

10.5 Incompatible materials

no information available

10.6 Hazardous decomposition products

no information available

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SECTION 11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 rat: > 10,000 mg/kg (RTECS)

Symptoms: Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract.

Acute inhalation toxicity

This information is not available.

Acute dermal toxicity

This information is not available.

Skin irritation

Irritations

Causes skin irritation.

Eye irritation

Irritations

Causes serious eye irritation.

Sensitisation

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

May cause an allergic skin reaction.

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Result: negative

(Lit.)

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

May cause respiratory irritation.

Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Substance which occurs in the human body under physiological conditions.

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. Ecological information

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

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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.

SECTION 13. Disposal considerations

Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

SECTION 14. Transport information

Land transport (ADR/RID)

14.1 - 14.6	Not classified as dangerous in the meaning of transport regulations.
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Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 - 14.6	Not classified as dangerous in the meaning of transport regulations.
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Sea transport (IMDG)

14.1 - 14.6	Not classified as dangerous in the meaning of transport regulations.
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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

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

Storage class	10 - 13
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15.2 Chemical Safety Assessment

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

SECTION 16. Other information

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.

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

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

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.

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.