

Creation Date 13-Dec-2004

Revision Date 01-May-2012

Revision Number 2

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product Identifier

Product Description:

Pancreatin

Cat No.

416740000; 416745000

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

Recommended Use

Laboratory chemicals

Uses advised against

No Information available

Details of the supplier of the safety data sheet

Company

Acros Organics BVBA
Janssen Pharmaceuticaaan 3a
2440 Geel, Belgium

E-mail address

begel.sdsdesk@thermofisher.com

Emergency Telephone Number

For information in the US, call: 001-800-ACROS-01

For information in Europe, call: +32 14 57 52 11

Emergency Number, Europe: +32 14 57 52 99

Emergency Number, US: 001-201-796-7100

CHEMTREC Phone Number, US: 001-800-424-9300

CHEMTREC Phone Number, Europe: 001-703-527-3887

SECTION 2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Skin Corrosion/irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2
Respiratory Sensitization	Category 1
Skin Sensitization	Category 1
Specific target organ toxicity - (single exposure)	Category 3

Classification according to EU Directives 67/548/EEC or 1999/45/EC

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

Symbol(s)

Xn - Harmful

R-phrases

Risk Combination Phrases

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

R42/43 - May cause sensitization by inhalation and skin contact

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SECTION 2. HAZARDS IDENTIFICATION

Label Elements



Signal Word

Danger

Hazard Statements

H317 - May cause an allergic skin reaction

H315 - Causes skin irritation

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

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray

P304 + P341 - IF INHALED: If breathing is difficult, remove 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

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

P280 - Wear protective gloves/ protective clothing/ eye protection/ face 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

Other Hazards

No information available.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	EC-No.	Weight %	CAS-No	67/548/EEC Classification	CLP Classification - Regulation (EC) No 1272/2008	REACH No.
Pancreatin 8049-47-6	EEC No. 232-468-9	100	8049-47-6	Xi; R36/37/38 R42/43	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	-

For the full text of the R-phrases and H-Statements mentioned in this Section, see Section 16

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SECTION 4. FIRST AID MEASURES**Description of first aid measures****Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

Skin Contact

Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Obtain medical attention.

Ingestion

Clean mouth with water. Get medical attention.

Inhalation

Remove from exposure, lie down. Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Obtain medical attention.

Notes to Physician

Treat symptomatically

SECTION 5. FIRE-FIGHTING MEASURES**Extinguishing media****Suitable Extinguishing Media**

Water spray. Carbon dioxide (CO₂). Dry chemical. chemical foam.

Extinguishing media which must not be used for safety reasons

No information available.

Special hazards arising from the substance or mixture

Fine dust dispersed in air may ignite.

Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

Ensure adequate ventilation

Environmental precautions

Prevent further leakage or spillage if safe to do so

Methods and material for containment and cleaning up

Avoid dust formation. Sweep up or vacuum up spillage and collect in suitable container for disposal.

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SECTION 7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid contact with skin and eyes. Do not breathe dust. Do not breathe vapors or spray mist.

Conditions for safe storage, including any incompatibilities

Keep in a dry place. Keep container tightly closed. Keep refrigerated.

Specific End Uses

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Component Pancreatin

Russia - TWA	Slovak Republic	Slovenia	Sweden	Turkey
MAC: 1 mg/m ³				

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

Exposure controls

Engineering Measures

Ensure adequate ventilation, especially in confined areas Ensure that eyewash stations and safety showers are close to the workstation location

Personal protective equipment

Eye Protection

Goggles

Hand Protection

Protective gloves

Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure

Respiratory Protection

Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

Environmental exposure controls

No information available.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State Appearance

Powder, Solid
Off-white

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

odor	strong
pH	No information available.
Boiling Point/Range	No information available.
Melting Point/Range	No information available.
Flash Point	No information available.
Autoignition Temperature	No information available.
Water Solubility	Partly soluble

SECTION 10. STABILITY AND REACTIVITY

Reactivity

Chemical Stability

Stable under normal conditions.

Possibility of Hazardous Reactions

Hazardous Polymerization	Hazardous polymerization does not occur.
Hazardous Reactions .	No information available.

Conditions to Avoid

Incompatible products.

Incompatible Materials

Strong oxidizing agents.

Hazardous Decomposition Products

Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

Acute Toxicity

Component Information

Component
Pancreatin

LD50 Oral	LD50 Dermal	LC50 Inhalation
10 g/kg (Rat)		

Chronic Toxicity

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Carcinogenicity	There are no known carcinogenic chemicals in this product
Sensitization	May cause sensitization by inhalation and skin contact
Mutagenic Effects	No information available
Reproductive Effects	No information available.
Developmental Effects	No information available.
Target Organs	No information available.
Other Adverse Effects	The toxicological properties have not been fully investigated. See actual entry in RTECS for complete information
Endocrine Disruptor Information	None known

SECTION 12. ECOLOGICAL INFORMATION

Toxicity

Ecotoxicity effects Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants

Persistence and degradability

No information available

Bioaccumulative potential

No information available.

Mobility in soil

No information available.

Results of PBT and vPvB assessment

Other adverse effects

No information available

SECTION 13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from Residues / Unused Products Dispose of in accordance with local regulations

Contaminated Packaging Empty containers should be taken to local recyclers for disposal

SECTION 14. TRANSPORT INFORMATION

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SECTION 14. TRANSPORT INFORMATION

IMDG/IMO Not regulated

ADR Not regulated

IATA Not regulated

SECTION 15. REGULATORY INFORMATION

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

International Inventories

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	CHINA	AICS	KECL
Pancreatin	232-468-9	-		XU	-	-	X	-	X	X	X

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

CHINA - China Inventory of Existing Chemical Substances

AICS - Inventory of Chemical Substances

KECL - Existing and Evaluated Chemical Substances

Chemical Safety Assessment

SECTION 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

R42/43 - May cause sensitization by inhalation and skin contact

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Revision Summary

Reason for revision Not applicable

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SECTION 16. OTHER INFORMATION

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

The information provided on 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet