

## 1. Product and Company Identification

www.rxmarine.com

Product Name RXSOL-60-6605-171  
Product Type PANCREATIN (ACTIVITY EQ. TO INF)  
Revised date

### Company Details:

RX MARINE INTERNATIONAL  
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## 2. Composition / Information on ingredients

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Substance / Preparation : PANCREATIN (activity eq. to INF)

CAS No :8049-47-6

Substance.

Contains no other components or impurities which will influence the classification of the product.

## 3. Hazards Identification

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### 3.1. Classification of the substance or mixture

Classification EC 67/548 or EC 1999/45

Classification : Xi; R36/37/38

Xn ; R42/43

Hazard Class and Category Code(s), Regulation (EC) No 1272/2008 (CLP)

Health hazards : Specific Target Organ Toxicity - Single exposure - Respiratory tract  
irritation - Category 3 - Warning (CLP : STOT SE 3) H335

Eye irritation - Category 2A - Warning (CLP : Eye Irrit. 2) H319

Respiratory sensitization - Category 1 - Danger (CLP : Resp. Sens. 1) H334

Skin irritation - Category 2 - Warning (CLP : Skin Corr. 2) H315

### 3.2. Label elements

Labelling EC 67/548 or EC 1999/45

Symbol(s) : Xn : Harmful

R Phrase(s) : R36/37/38 : Irritating to eyes, respiratory system and skin.

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

S Phrase(s) : S22 : Do not breathe dust.

S24 : Avoid contact with skin.

S26 : In case of contact with eyes, rinse immediately with plenty of water  
and seek medical advice.

S36/37 : Wear suitable protective clothing and gloves.

S45 : In case off accident or if you feel unwell, seek medical advice immediately. (show  
the label where possible)

Labelling Regulation EC 1272/2008 (CLP)

Hazard pictograms

Signal words : Danger

Hazard statements : H319 : Causes serious eye irritation.

H315 : Causes skin 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

 Prevention : P285: In case of inadequate ventilation wear respiratory protection.

P280: Wear protective gloves, protective clothing, eye protection, face protection.

P271: Use only outdoors or in a well-ventilated area.

P261: Avoid breathing dust, fume, gas, mist, vapours, spray.

P264: Wash thoroughly after handling.

P272: Contaminated work clothing should not be allowed out of the workplace.

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

P305+P351+P338: IF IN EYES : Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.


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

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

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

P363: Wash contaminated clothing before reuse.

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

P405: Store locked up.

 Disposal considerations : P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

### 3.3. Other hazards

Other hazards : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

## 4. First Aid Measures

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### 4.1. Description of first aid measures

Inhalation : Call a POISON CENTER or doctor if you feel unwell. Remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms:

Skin contact : If skin irritation or rash occurs : Get medical advice. Specific treatment (see on this label). Wash contaminated clothing before reuse. Wash with plenty of soap and water.

Eye contact : Get medical advice. If eye irritation persists : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes.

Ingestion : Obtain emergency medical attention. Do NOT induce vomiting. Rinse mouth.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms relating to use : Causes serious eye irritation. Causes skin irritation.

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. May cause respiratory irritation.

### 4.3. Indication of any immediate medical attention and special treatment needed

General information : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

## 5. Fire-fighting Measures

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### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

Surrounding fires : Use water spray or fog for cooling exposed containers.

### 5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Under fire conditions, hazardous fumes will be present.

### 5.3. Advice for fire-fighters

Protection against fire : Do not enter fire area without proper protective equipment, including respiratory protection.

Special procedures : Exercise caution when fighting any chemical fire. Avoid (reject) fire-fighting water to enter environment.

## 6. Accidental Release Measures

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### 6.1. Personal precautions, protective equipment and emergency procedures

For emergency responders : Equip cleanup crew with proper protection.

Ventilate area.

For non-emergency personnel : Evacuate unnecessary personnel.

### 6.2. Environmental precautions

Environmental precautions : Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Clean up methods : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

### 6.4. Reference to other sections

See section 8. Exposure controls/personal protection

## 7. Handling and Storage

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### 7.1. Precautions for safe handling

Handling : Use only outdoors or in a well-ventilated area. Avoid breathing dust, fume, gas, mist, vapours, spray. Wash thoroughly after handling. Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Wash thoroughly after handling. Wash thoroughly after handling.

Technical protective measures : Provide good ventilation in process area to prevent formation of vapour.

Special precautions : Avoid breathing dust, fume, gas, mist, vapours, spray.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage : Keep only in the original container in a cool, well ventilated place. Keep container tightly closed.

Storage - away from : Strong bases. Strong acids. Sources of ignition. Direct sunlight.

### 7.3. Specific end use(s)

Specific end use(s) : None.

## 8. Exposure controls and personal protection

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### 8.1. Exposure controls

Personal protection : Avoid all unnecessary exposure.

☒ Respiratory protection : In case of inadequate ventilation wear respiratory protection.

☒ Hand protection : Wear protective gloves.

☒ Skin protection : Wear suitable protective clothing.

☒ Eye protection : Chemical goggles or safety glasses.

☒ Others : When using, do not eat, drink or smoke.

### 8.2. Control parameters

Occupational Exposure Limits : No data available.

### 9.1. Information on basic physical and chemical properties

Physical state at 20 °C : Solid.

Odour threshold : No data available.

pH value : Not applicable.

Melting point [°C] : No data available.

Decomposition point [°C] : N/A

Critical temperature [°C] : N/A

Auto-ignition temperature [°C] : N/A

Flammability (solid, gas) : N/A

Flash point [°C] : N/A

Boiling point [°C] : N/A

Initial boiling point [°C] : N/A

Final boiling point [°C] : N/A

Evaporation rate : N/A

Vapour pressure [20°C] : N/A

Vapour pressure mm/Hg : N/A

Vapour density : N/A

Density [g/cm<sup>3</sup>] : N/A

Relative density, gas (air=1) : N/A

Relative density, liquid (water=1) : N/A

Solubility in water [% weight] : N/A

Solubility in water : N/A

Log Pow octanol / water at 20°C : No data available.

Solubility : N/A

Viscosity at 40°C [mm<sup>2</sup>/s] : N/A

### 9.2. Other information

Explosive properties : N/A

Explosion limits - upper [%] : N/A

Explosion limits - lower [%] : N/A

## 10. Stability and reactivity

### 10.1. Reactivity

Reactivity : Not established.

### 10.2. Chemical stability

Chemical stability : Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

Hazardous reactions : Not established.

### 10.4. Conditions to avoid

Conditions to avoid : Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Materials to avoid : Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

Hazardous decomposition products : Fumes. Carbon monoxide. Carbon dioxide.

## 11. Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity

☒ Inhalation : Based on available data, the classification criteria are not met.

☒ Dermal : Based on available data, the classification criteria are not met.

☒ Ingestion : Based on available data, the classification criteria are not met.

Corrosion : Based on available data, the classification criteria are not met.

Irritation : Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation.

Sensitization : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Mutagenicity : Based on available data, the classification criteria are not met.

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Carcinogenicity : Based on available data, the classification criteria are not met.

Toxic for reproduction : Based on available data, the classification criteria are not met.

STOT-single exposure : Based on available data, the classification criteria are not met.

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.

## 12. Ecological information

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### 12.1. Toxicity

Toxicity information : Not established.

### 12.2. Persistence - degradability

Persistence - degradability : Biodegradable.

### 12.3. Bioaccumulative potential

Bioaccumulative potential : Not established.

### 12.4. Mobility in soil

Mobility in soil : Not established.

### 12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : The substance does not fulfil the criteria to be identified as PBT substance or vPvB substance according to Annex XIII of Regulation REACH.

### 12.6. Other adverse effects

Environmental precautions : Avoid release to the environment.

## 13. Disposal considerations

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### 13.1. Waste treatment methods

General : Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations. Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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## 14. Transport information

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### 14.1. Land transport (ADR-RID)

General information : Not regulated.

### 14.2. Sea transport (IMDG) [English only]

General information : Not regulated.

### 14.3. Air transport (ICAO-IATA) [English only]

General information : Not regulated.

## 15. Regulatory information

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

Safety, health and environmental : Ensure all national/local regulations are observed.

regulations/legislation specific for the substance or mixture

REACH Restrictions - Annex XVII : The components of this product are not subject to restrictions.

REACH Authorisation - Annex XIV : The components of this product are not subject to authorization.

### 15.2. Chemical Safety Assessment

Chemical Safety Assessment : It has not been carried out.

## 16. Other information

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Abbreviations and acronyms : PBT: persistent, bioaccumulative and toxic.

vPvB: very persistent and very bioaccumulative

Sources of key data used : REGULATION (EC) No 1272/2008 OF THE EUROPEAN

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PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification,

labelling and packaging of substances and mixtures, amending and repealing Directives

67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Further information : None.

In accordance with REACH Regulation (CE) N° 1907/2006 and with CLP Regulation

(CE) N° 1272/2008

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