1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Pancrelipase (High / Low Lipase) Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A  07302
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>solid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Toxic to aquatic life.

GHS Classification

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2A</td>
</tr>
<tr>
<td>Respiratory sensitisation</td>
<td>Category 1</td>
</tr>
<tr>
<td>Short-term (acute) aquatic hazard</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

GHS label elements

Hazard pictograms: 
Signal word: Danger

Hazard statements:
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. Toxic to aquatic life.
Precautionary statements:

**Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.
P284 Wear respiratory protection.

**Response:**
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.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

### Physical and chemical hazards
Not classified based on available information.

### Health hazards
Causes skin irritation. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Environmental hazards
Toxic to aquatic life.

### Other hazards which do not result in classification
May form combustible dust concentrations in air.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancrelipase</td>
<td>53608-75-6</td>
<td>&gt;= 70 -&lt; 90</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Diethyl phthalate</td>
<td>84-66-2</td>
<td>&gt;= 1 -&lt; 2.5</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

General advice
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled
If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact
In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed
If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed
Causes skin irritation.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

Protection of first-aiders
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media
High volume water jet

Specific hazards during firefighting
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Do not use a solid water stream as it may scatter and spread fire.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products
Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

**Handling**

**Technical measures**:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

**Local/Total ventilation**:
- Use only with adequate ventilation.

**Advice on safe handling**:
- Do not get on skin or clothing.
- Avoid breathing dust, fume, gas, mist, vapours or spray.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
sessment
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact : Oxidizing agents

Storage
Conditions for safe storage : Keep in properly labelled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancrelipase</td>
<td>53608-75-6</td>
<td>TWA</td>
<td>OEB 3 (&gt;= 10 &lt; 100 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>PC-TWA (Total dust)</td>
<td>3 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-TWA (Respirable dust)</td>
<td>1 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>2 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Diethyl phthalate</td>
<td>84-66-2</td>
<td>TWA</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment
Respiratory protection : If adequate local exhaust ventilation is not available or expo-
9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form combustible dust concentrations in air.
Flammability (liquids) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
   May form combustible dust concentrations in air.
   Can react with strong oxidizing agents.
Conditions to avoid
   Heat, flames and sparks.
   Avoid dust formation.
Incompatible materials
   Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Pancrelipase:
Acute oral toxicity: LD50 (Rat): > 10,000 mg/kg

Talc:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Starch:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Sucrose:
Acute oral toxicity: LD50 (Rat): 29,700 mg/kg

Diethyl phthalate:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 4.64 mg/l
Exposure time: 6 h
Test atmosphere: vapour
Acute dermal toxicity: LD50 (Rat): > 11,181 mg/kg

Skin corrosion/irritation
Causes skin irritation.

Components:

Pancrelipase:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Skin irritation
Remarks: Based on data from similar materials

Talc:
Species: Rabbit
Result: No skin irritation

Diethyl phthalate:
Species: Rabbit
Result : No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Pancrelipase:
Result : Irritation to eyes, reversing within 21 days
Remarks : Based on data from similar materials

Talc:
Species : Rabbit
Result : No eye irritation

Starch:
Species : Rabbit
Result : No eye irritation

Diethyl phthalate:
Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

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

Components:

Pancrelipase:
Exposure routes : Inhalation
Species : Humans
Result : positive
Remarks : Based on data from similar materials
Assessment : May cause sensitisation by inhalation.

Talc:
Exposure routes : Skin contact
Species : Humans
Result : negative

Starch:
Test Type : Maximisation Test
Exposure routes : Skin contact
Species: Guinea pig
Result: negative

**Diethyl phthalate:**
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Pancrelipase:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Species: Rat
Application Route: Ingestion
Result: negative

**Talc:**
Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro
Species: Rat
Application Route: Ingestion
Result: negative

**Starch:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

**Sucrose:**
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

**Diethyl phthalate:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Talc:
Species: Mouse
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Result: negative

Diethyl phthalate:
Species: Rat
Application Route: Skin contact
Exposure time: 103 weeks
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Pancrelipase:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Talc:
Effects on foetal development
Species: Rat
Application Route: Ingestion
Result: negative
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Pancrelipase (High / Low Lipase) Formulation

Version 1.2  Revision Date: 2020/10/10  SDS Number: 5322075-00003  Date of last issue: 2020/03/23  Date of first issue: 2019/11/22

Diethyl phthalate:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on foetal development:
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Pancrelipase:
Species: Rat
NOAEL: > 100 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Method: OECD Test Guideline 408
Remarks: Based on data from similar materials

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

Diethyl phthalate:
Species: Rat
NOAEL: 150 mg/kg
Application Route: Ingestion
Exposure time: 16 Weeks

Aspiration toxicity
Not classified based on available information.
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Pancrelipase:
- Toxicity to fish
  : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: Based on data from similar materials

- Toxicity to daphnia and other aquatic invertebrates
  : EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
  Remarks: Based on data from similar materials

- Toxicity to algae/aquatic plants
  : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
    Exposure time: 72 h
    Method: OECD Test Guideline 201
    Remarks: Based on data from similar materials

  NOEC (Desmodesmus subspicatus (green algae)): > 1 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  Remarks: Based on data from similar materials

Talc:
- Toxicity to fish
  : LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
    Exposure time: 24 h

Diethyl phthalate:
- Toxicity to fish
  : LC50 (Oncorhynchus mykiss (rainbow trout)): 12 mg/l
    Exposure time: 96 h

- Toxicity to daphnia and other aquatic invertebrates
  : LC50 (Daphnia magna (Water flea)): 90 mg/l
    Exposure time: 48 h

- Toxicity to algae/aquatic plants
  : ErC50 (Desmodesmus subspicatus (green algae)): 45 mg/l
    Exposure time: 72 h
    EC10 (Desmodesmus subspicatus (green algae)): 9 mg/l
    Exposure time: 72 h

- Toxicity to fish (Chronic toxicity)
  : NOEC (Cyprinus carpio (Carp)): 5 mg/l
    Exposure time: 28 d

- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
  : NOEC (Daphnia magna (Water flea)): 25 mg/l
    Exposure time: 21 d
Persistence and degradability

**Components:**

**Pancrelipase:**
Biodegradability: Result: Readily biodegradable.

**Diethyl phthalate:**
Biodegradability: Result: Readily biodegradable.

Biodegradation: 94.6%
Exposure time: 28 d

Bioaccumulative potential

**Components:**

**Pancrelipase:**
Partition coefficient: n-octanol/water: log Pow: < 4

**Sucrose:**
Partition coefficient: n-octanol/water: Pow: < 1

**Diethyl phthalate:**
Partition coefficient: n-octanol/water: log Pow: 2.2

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; ACGIH Threshold Limit Values (TLV); ACGIH - American Conference of Governmental Industrial Hygienists; 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SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Pancrêlipase (High / Low Lipase) Formulation

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