SAFETY DATA SHEET
Pancrelipase (High / Low Lipase) Formulation

Version: 1.2  Revision Date: 10.10.2020  SDS Number: 5322078-00003  Date of last issue: 23.03.2020  Date of first issue: 22.11.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Pancrelipase (High / Low Lipase) Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Skin irritation: Category 2
Eye irritation: Category 2A
Respiratory sensitization: Category 1
Short-term (acute) aquatic hazard: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
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.
H401 Toxic to aquatic life.

Precautionary Statements: Prevention:
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.
SAFETY DATA SHEET

Pancrelipase (High / Low Lipase) Formulation

Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pancrelipase</td>
<td>53608-75-6</td>
<td>Skin irritation, Category 2</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2A</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Respiratory sensitization, Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Short-term (acute) aquatic hazard, Category 2</td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td></td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Diethyl phthalate</td>
<td>84-66-2</td>
<td>Short-term (acute) aquatic hazard, Category 3</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>

SECTION 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
High volume water jet

Specific hazards during fire fighting:
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)
Sulfur 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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.

SECTION 7. HANDLING AND STORAGE

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, vapors 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 assessment.
- Keep container tightly closed.
- Already sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers.
- 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.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
- When using do not eat, drink or smoke.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
- Keep in properly labeled 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>TWA</td>
<td>2 mg/m³ (Respirable particulate matter)</td>
<td>ACGI-H</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGI-H</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGI-H</td>
</tr>
<tr>
<td>Diethyl phthalate</td>
<td>84-66-2</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>ACGI-H</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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapor type

Hand protection: Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES
### Appearance
- solid

### Color
- No data available

### Odor
- No data available

### Odor 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

### Vapor pressure
- Not applicable

### Relative vapor 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

### Autoignition 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

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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: vapor
- 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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Components:

Pancrelipase:
- Routes of exposure: Inhalation
- Species: Humans
- Result: positive
- Remarks: Based on data from similar materials
- Assessment: May cause sensitization by inhalation.

Talc:
- Routes of exposure: Skin contact
- Species: Humans
- Result: negative

Starch:
- Test Type: Maximization Test
- Routes of exposure: Skin contact
- Species: Guinea pig
- Result: negative

Diethyl phthalate:
- Test Type: Buehler Test
- Routes of exposure: 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

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

- Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials

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

Pancrelipase (High / Low Lipase) Formulation

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

**Talc**:

**Effects on fetal development**:  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Diethyl phthalate**:

**Effects on fertility**:  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Method: OECD Test Guideline 416

**Effects on fetal development**:  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Species: Rabbit  
Application Route: Skin contact  
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**:  

---

**SAFETY DATA SHEET**

Pancrelipase (High / Low Lipase) Formulation

**Version**: 1.2  
**Revision Date**: 10.10.2020  
**SDS Number**: 5322078-00003  
**Date of last issue**: 23.03.2020  
**Date of first issue**: 22.11.2019
SAFETY DATA SHEET

Pancrelipase (High / Low Lipase) Formulation

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.

SECTION 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

SECTION 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
SECTION 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.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.