SAFETY DATA SHEET
Pancrelipase (High / Low Lipase) Formulation

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

GHS Classification
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2
Respiratory sensitisation : Category 1

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.

Precautionary statements : Prevention:
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
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
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Version 1.2  Revision Date: 10.10.2020  SDS Number: 5322087-00003  Date of last issue: 23.03.2020  Date of first issue: 22.11.2019

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.
P332 + P313 If respiratory irritation occurs: 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.

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; 10</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:
- Sweep up or vacuum up spillage and collect in suitable con-
containment and cleaning up
- 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

**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 assessment.
- 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.

**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

### 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 (≥ 10 &lt; 100 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>PEL (long)</td>
<td>2 mg/m3</td>
<td>SG OEL</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 vapour 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.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</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>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form combustible dust concentrations in air.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Relative vapour density</td>
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<tr>
<td>Relative density</td>
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<tr>
<td>Density</td>
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<td>Solubility(ies)</td>
<td>Water solubility</td>
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<td></td>
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<tr>
<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Auto-ignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
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

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
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>10.10.2020</td>
<td>5322087-00003</td>
<td>23.03.2020</td>
<td>22.11.2019</td>
</tr>
</tbody>
</table>

- 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
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

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
   Test Type: Embryo-foetal development
   Species: Rat
   Application Route: Ingestion
   Result: negative
   Remarks: Based on data from similar materials

Talc:
Effects on foetal development
   Test Type: Embryo-foetal development
   Species: Rat
   Application Route: Ingestion
   Result: negative

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
   Test Type: Embryo-foetal development
   Species: Rat
   Application Route: Ingestion
   Result: negative

Test Type: Embryo-foetal development
   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

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

Exposure time: 28 Days
Method: OECD Test Guideline 410

Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact

Diethyl phthalate:

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

Aspiration toxicity
Not classified based on available information.

Talc:

Toxicity to fish: LC50 (Brachydanoerio (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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
- Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
- Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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
Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
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.

SG / EN