

# SAFETY DATA SHEET



## Pancrelipase Formulation



Version 2.1      Revision Date: 30.09.2023      SDS Number: 5322032-00009      Date of last issue: 04.04.2023  
Date of first issue: 22.11.2019

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### SECTION 1. IDENTIFICATION

Product name : Pancrelipase Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 1-551-430-6000

Emergency telephone : 1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Respiratory sensitization : Category 1

Short-term (acute) aquatic hazard : Category 2

#### 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.  
H401 Toxic to aquatic life.

Precautionary Statements : **Prevention:**

## Pancrelipase Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	5322032-00009	Date of first issue: 22.11.2019

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ 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.

**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**

Chemical name	CAS-No.	Concentration (% w/w)
Pancrelipase	53608-75-6	>= 50 -< 70
Starch	9005-25-8	>= 30 -< 50

**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.

# SAFETY DATA SHEET



## Pancrelipase Formulation



Version 2.1      Revision Date: 30.09.2023      SDS Number: 5322032-00009      Date of last issue: 04.04.2023  
Date of first issue: 22.11.2019

---

- In case of eye contact : Thoroughly clean shoes before reuse.  
: 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.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 (NO<sub>x</sub>)  
Sulfur oxides  
Metal 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.
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### 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).

## Pancrelipase Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	5322032-00009	Date of first issue: 22.11.2019

---

- 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 : Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.  
Add excess liquid to allow the material to enter into solution.  
Soak up with inert absorbent material.  
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.  
Clean up remaining materials from spill with suitable absorbent.  
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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, 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.
- 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:

## Pancrelipase Formulation

Version 2.1      Revision Date: 30.09.2023      SDS Number: 5322032-00009      Date of last issue: 04.04.2023  
Date of first issue: 22.11.2019

Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pancrelipase	53608-75-6	TWA	OEB 3 ( $\geq 10 < 100 \mu\text{g}/\text{m}^3$ )	Internal
Starch	9005-25-8	CMP	10 mg/m <sup>3</sup>	AR OEL
Further information: A4 - Not classifiable as a human carcinogen				
		TWA	10 mg/m <sup>3</sup>	ACGIH

**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 : Particulates 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,

# SAFETY DATA SHEET



## Pancrelipase Formulation



Version 2.1      Revision Date: 30.09.2023      SDS Number: 5322032-00009      Date of last issue: 04.04.2023  
Date of first issue: 22.11.2019

---

industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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### 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

# SAFETY DATA SHEET



## Pancrelipase Formulation



Version 2.1      Revision Date: 30.09.2023      SDS Number: 5322032-00009      Date of last issue: 04.04.2023  
Date of first issue: 22.11.2019

---

Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : No data available  
Particle size : No data available

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### 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.

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### 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

##### Starch:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 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

---

## Pancrelipase Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	5322032-00009	Date of first issue: 22.11.2019

---

**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

**Starch:**

Species : Rabbit  
Result : No eye irritation

**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.

**Starch:**

Test Type : Maximization 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



## Pancrelipase Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	5322032-00009	Date of first issue: 22.11.2019

---

Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

### Starch:

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

### Carcinogenicity

Not classified based on available information.

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

### 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

# SAFETY DATA SHEET



## Pancrelipase Formulation



Version 2.1      Revision Date: 30.09.2023      SDS Number: 5322032-00009      Date of last issue: 04.04.2023  
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---

### Aspiration toxicity

Not classified based on available information.

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## 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

### Persistence and degradability

#### Components:

##### **Pancrelipase:**

Biodegradability : Result: Readily biodegradable.

### Bioaccumulative potential

#### Components:

##### **Pancrelipase:**

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

### Mobility in soil

No data available

### Other adverse effects

No data available



# SAFETY DATA SHEET



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Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	5322032-00009	Date of first issue: 22.11.2019

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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