

# Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) revised in 2012 and GHS Rev 03.

Issue date 02/20/2024

Reviewed on 02/20/2024

**\* 1 Identification**

- **Product Identifier**
- **Trade Name: USP Simulated Intestinal Fluid, Part 2**
- **Product Number:** 1700-0903
- **Relevant identified uses of the substance or mixture and uses advised against:**
- **Product Description:** USP Simulated Intestinal Fluid
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**  
 Pickering Laboratories, Inc.  
 1280 Space Park Way  
 Mountain View, CA 94043  
 Phone: (650) 694-6700  
 Fax: (650) 968-0749  
 www.pickeringlabs.com  
 support@pickeringlabs.com
- **Emergency telephone number:**  
 Clean Harbors Environmental Services  
 1-800-645-8265

**2 Hazard(s) Identification**

- **Classification of the substance or mixture:**



Health hazard

Sensitization - Respiratory 1

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



Skin Irritation 2

H315 Causes skin irritation.

Eye Irritation 2A

H319 Causes serious eye irritation.

Sensitization - Skin 1

H317 May cause an allergic skin reaction.

Specific Target Organ Toxicity - Single Exposure 3

H335 May cause respiratory irritation.

- **Label elements:**
- **Hazard pictograms:**



- **Signal word:** Danger
- **Hazard-determining components of labeling:**  
Pancreatin

- **Hazard statements:**  
 H315 Causes skin irritation.  
 H319 Causes serious eye 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.

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**Precautionary statements:**

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P264 Wash thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves / eye protection / face protection.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P302+P352 If on skin: Wash with plenty of water.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P304+P341 If inhaled: If breathing is difficult, 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.
- P312 Call a poison center/doctor if you feel unwell.
- P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P332+P313 If skin irritation occurs: Get medical advice/attention.
- P333+P313 If skin irritation or rash 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.
- P363 Wash contaminated clothing before reuse.
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Unknown acute toxicity:**

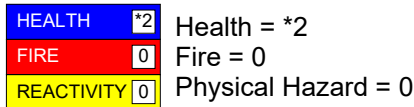
This value refers to knowledge of known, established toxicological or ecotoxicological values. 0 % of the mixture consists of component(s) of unknown toxicity.

**Classification system:** NFPA/HMIS Definitions: 0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme

**NFPA ratings (scale 0 - 4)**



**HMIS-ratings (scale 0 - 4)**



**Hazard(s) not otherwise classified (HNOC):** None known

**3 Composition/Information on Ingredients**

- Chemical characterization: Substance**
- Description:** Mixture of substances listed below with non-hazardous additions.

**Dangerous Components:**

8049-47-6	Pancreatin ⚠ Sensitization - Respiratory 1, H334; ⚠ Skin Irritation 2, H315; Eye Irritation 2A, H319; Sensitization - Skin 1, H317; Specific Target Organ Toxicity - Single Exposure 3, H335	100%
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**Additional information:**

The exact percentages of the ingredients of this mixture are considered to be proprietary and are withheld in accordance with the provisions of paragraph (i) of §1910.1200 of 29 CFR 1910.1200 Trade Secrets.

## 4 First-Aid Measures

- **Description of first aid measures**
- **General information:** If symptoms persist, call a physician.
- **After inhalation:** In case of unconsciousness place patient stably in the side position for transportation.
- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation occurs, consult a doctor.
- **After eye contact:**  
Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a doctor.  
If easy to do so, remove contact lenses if worn.
- **After swallowing:** If swallowed and symptoms occur, consult a doctor.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed:** Treat symptomatically.

## 5 Fire-Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** No further relevant information.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters**
- **Special protective equipment for firefighters:**  
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

## 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures:** Ensure adequate ventilation.
- **Environmental precautions:** Dilute with plenty of water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (i.e. sand, diatomite, acid binders, universal binders, sawdust).  
Dispose of contaminated material as waste according to section 13.  
Ensure adequate ventilation.  
Dispose of the collected material according to regulations.
- **Reference to other sections:**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

· <b>PAC-1:</b>	None of the ingredients are listed.
· <b>PAC-2:</b>	None of the ingredients are listed.
· <b>PAC-3:</b>	None of the ingredients are listed.

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### 7 Handling and Storage

- **Handling**
- **Precautions for safe handling:**  
Use normal laboratory hygiene procedures.  
Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**  
Store in a tightly closed container. Keep from contact with oxidizing materials. Store in a cool, dry, well-ventilated area away from incompatible substances. Do not store near alkaline substances.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s):** No further relevant information available.

### 8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**
- **Components with occupational exposure limits:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
- **Personal protective equipment**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing and wash before reuse.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves:**  
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material:**  
The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

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· **Eye protection:**



Tightly sealed goggles

· **Limitation and supervision of exposure into the environment:** None

### 9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Solid  
    **Color:** white to yellow white

· **Odor:** Characteristic

· **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

**Melting point/Melting range:** Not determined.  
    **Boiling point/Boiling range:** Not determined.

· **Flash point:** None

· **Flammability (solid, gaseous):** Not applicable.

· **Auto igniting:** Not applicable

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

**Lower:** Not determined.  
    **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density @ 20 °C (68 °F):** 0.62 g/cm<sup>3</sup> (5.1739 lbs/gal)

· **Relative density:** Not determined.

· **Vapor density:** Not determined.

· **Evaporation rate:** Not determined.

· **Solubility in / Miscibility with:**

**Water:** Fully miscible.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

**Dynamic:** Not determined.  
    **Kinematic:** Not determined.

· **Solvent content:**

**VOC content:** 0.00 %

**Solids content:** 0.0 %

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· **Other information:** No further relevant information available.

## 10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Product is stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:**  
Carbon monoxide in cases of incomplete combustion, carbon monoxide in cases of incomplete combustion, carbon dioxide.
- **Conditions to avoid:** Incompatible materials, dust generation, excess heat.
- **Incompatible materials:** Oxidizing agents.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological Information

- **Information on toxicological effects:**
- **Acute toxicity:**

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>8049-47-6 Pancreatin</b>		
Oral	LD50	10,000 mg/kg (Rat)

- **Primary irritant effect:**
- **On the skin:**  
Irritant to skin and mucous membranes.  
May cause an allergic skin reaction.
- **On the eye:** Irritating effect.
- **Sensitization:**  
Sensitization possible through inhalation.  
Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Harmful  
Irritant

· **Carcinogenic categories:**

· <b>IARC (International Agency for Research on Cancer):</b>
None of the ingredients are listed.

· <b>NTP (National Toxicology Program):</b>
None of the ingredients are listed.

· <b>OSHA-Ca (Occupational Safety &amp; Health Administration):</b>
None of the ingredients are listed.

## 12 Ecological Information

- **Toxicity:**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.

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- **Additional ecological information:**
- **General notes:** Generally not hazardous for water.
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

### 13 Disposal Considerations

- **Waste treatment methods**
- **Recommendation:**  
Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packaging**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### 14 Transport Information

- **UN-Number:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

### 15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**  
No further relevant information available.
- **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**  
None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**  
None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**  
All components have the value ACTIVE.

· **Hazardous Air Pollutants**  
None of the ingredients are listed.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**  
None of the ingredients are listed.

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· <b>Chemicals known to cause reproductive toxicity for females:</b>
None of the ingredients are listed.
· <b>Chemicals known to cause reproductive toxicity for males:</b>
None of the ingredients are listed.
· <b>Chemicals known to cause developmental toxicity:</b>
None of the ingredients are listed.
· <b>New Jersey Right-to-Know List:</b>
None of the ingredients are listed.
· <b>New Jersey Special Hazardous Substance List:</b>
None of the ingredients are listed.
· <b>Pennsylvania Right-to-Know List:</b>
None of the ingredients are listed.
· <b>Pennsylvania Special Hazardous Substance List:</b>
None of the ingredients are listed.
· <b>Carcinogenic categories:</b>
· <b>EPA (Environmental Protection Agency):</b>
None of the ingredients are listed.
· <b>TLV (Threshold Limit Value established by ACGIH):</b>
None of the ingredients are listed.
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health):</b>
None of the ingredients are listed.

· **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



· **Signal word:** Danger

· **Hazard-determining components of labeling:**

Pancreatin

· **Hazard statements:**

- H315 Causes skin irritation.
- H319 Causes serious eye 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:**

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P264 Wash thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves / eye protection / face protection.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P302+P352 If on skin: Wash with plenty of water.



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P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P304+P341	If inhaled: If breathing is difficult, 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.
P312	Call a poison center/doctor if you feel unwell.
P321	Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
P362+P364	Take off contaminated clothing and wash it before reuse.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P333+P313	If skin irritation or rash 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.
P363	Wash contaminated clothing before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

**· National regulations:**

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

**· Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

**· Contact:**

**· Abbreviations and acronyms:**

- ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
- ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- VOC: Volatile Organic Compounds (USA, EU)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- NIOSH: National Institute for Occupational Safety and Health
- OSHA: Occupational Safety & Health Administration
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Skin Irritation 2: Skin corrosion/irritation – Category 2
- Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
- Sensitization - Respiratory 1: Respiratory sensitisation – Category 1
- Sensitization - Skin 1: Skin sensitisation – Category 1
- Specific Target Organ Toxicity - Single Exposure 3: Specific target organ toxicity (single exposure) – Category 3

**· \* Data compared to the previous version altered.**

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