

Safety Data Sheet

acc. to OSHA HCS

Printing date 01/08/2025

Reviewed on 01/08/2025

1 Identification

- **Product identifier**
- **Trade name:** Simulated Intestinal Fluid
Prepared to USP 42/NF 37 (pH 6.80 +- 0.10)
- **Article number:** SPE510
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Aqua Solutions, Inc.
6913 Highway 225
DEER PARK, TX 77536
USA
800-256-2586
- **Information department:**
Technical Coordinator
Sherman Nelson shermann@aquasolutions.org
- **Emergency telephone number:**
Chemtrec: 800-424-9300
Canutec: 613-996-6666



2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Not Applicable
- **Hazard pictograms** Not Applicable
- **Signal word** Not Applicable
- **Hazard statements** Not Applicable
- **Precautionary statements**
If swallowed: Call a poison center/doctor if you feel unwell.
If on skin: Wash with plenty of water.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Store in a closed container.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**


Health = 0
 Fire = 0
 Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

HEALTH	0
FIRE	0
REACTIVITY	0

Health = 0
 Fire = 0
 Reactivity = 0
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

- **Chemical characterization:** *Mixtures*
- **Description:** *Mixture of the substances listed below with nonhazardous additions.*
- **Dangerous components:** *Not Applicable*

· Table of Nonhazardous Ingredients

CAS: 7732-18-5	Water	<99.258%
CAS: 7778-77-0	Potassium Phosphate Monobasic	0.68%
CAS: 1310-73-2	Sodium Hydroxide	0.061%
CAS: 7647-01-0	Hydrochloric Acid	<0.001%

4 First-aid measures

- **Description of first aid measures**
- **General information:** *No special measures required.*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints.*
- **After skin contact:** *Immediately rinse with water.*
- **After eye contact:** *Rinse opened eye for several minutes under running water. Then consult a doctor.*
- **After swallowing:** *If symptoms persist consult 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**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** *Use fire fighting measures that suit the environment.*
- **Special hazards arising from the substance or mixture** *No further relevant information available.*
- **Advice for firefighters**
- **Protective equipment:** *No special measures required.*

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** *Not required.*
- **Environmental precautions:** *Dilute with plenty of water.*
- **Methods and material for containment and cleaning up:**
*Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.*
- **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.*
- **Protective Action Criteria for Chemicals**

· PAC-I:

CAS: 7778-77-0	Potassium Phosphate Monobasic	9.6 mg/m ³
CAS: 1310-73-2	Sodium Hydroxide	0.5 mg/m ³

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CAS: 7647-01-0	Hydrochloric Acid	1.8 ppm
· PAC-2:		
CAS: 7778-77-0	Potassium Phosphate Monobasic	110 mg/m ³
CAS: 1310-73-2	Sodium Hydroxide	5 mg/m ³
CAS: 7647-01-0	Hydrochloric Acid	22 ppm
· PAC-3:		
CAS: 7778-77-0	Potassium Phosphate Monobasic	630 mg/m ³
CAS: 1310-73-2	Sodium Hydroxide	50 mg/m ³
CAS: 7647-01-0	Hydrochloric Acid	100 ppm

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **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:** No special requirements.
- **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 limit values that require monitoring at the workplace:**
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 were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **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.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **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 can not be calculated in advance and has therefore to be checked prior to the application.

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- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** *Goggles recommended during refilling.*
- **Body protection:** *Protective work clothing*

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Liquid
Color:	Colorless
Odor:	Odorless
Odor threshold:	Not determined.

· **pH-value at 20 °C (68 °F):** 6.8

· Change in condition

Melting point/Melting range:	0 °C (32 °F)
Boiling point/Boiling range:	100 °C (212 °F)

· **Flash point:** Not applicable.

· **Flammability:** Not applicable.

· **Decomposition temperature:** Not determined.

· **Ignition temperature:** Product is not selfigniting.

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

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure at 20 °C (68 °F):** 23 hPa (17.3 mm Hg)

· **Density at 20 °C (68 °F):** >1.00943 g/cm³ (>8.42369 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:

Water:	<99.3 %
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal

Solids content: <0.7 %

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

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations.
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is 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.*
- **Additional ecological information:**
- **General notes:** *Not hazardous for water.*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

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· **Other adverse effects** *No further relevant information available.*

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** *Smaller quantities can be disposed of with household waste.*
- **Uncleaned packagings:**
- **Recommendation:** *Disposal must be made according to official regulations.*
- **Recommended cleansing agent:** *Water, if necessary with cleansing agents.*

14 Transport information

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

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

Water	ACTIVE
Potassium Phosphate Monobasic	ACTIVE
Sodium Hydroxide	ACTIVE

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Hydrochloric Acid

ACTIVE

· **Hazardous Air Pollutants**

CAS: 7647-01-0 Hydrochloric Acid

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements** Not Applicable

· **Hazard pictograms** Not Applicable

· **Signal word** Not Applicable

· **Hazard statements** Not Applicable

· **Precautionary statements**

If swallowed: Call a poison center/doctor if you feel unwell.

If on skin: Wash with plenty of water.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Store in a closed container.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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

*

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** Environment protection department.

· **Contact:**

Date of Preparation / Last Revision:

· **Date of preparation / last revision**

Revision 1.1, 01-08-2025: .Updated USP version to 42. STN
01/08/2025 / -

· **Abbreviations and acronyms:**

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

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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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

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

US