

SAFETY DATA SHEET**Succinylcholine Chloride Injection, USP****1) PRODUCT AND COMPANY IDENTIFICATION**

Product name: Succinylcholine Chloride Injection

Synonyms: Succinylcholine Chloride Injection

Chemical Family: Not determined

Recommended Use: Pharmaceutical product

Manufacturer: Piramal Critical Care, Inc
3950 Schelden Circle
Bethlehem, PA 18017

Supplier: Piramal Critical Care, Inc.
3950 Schelden Circle
Bethlehem, PA 18017

24 Hour Emergency Number: CHEMTREC 1-703-527-3887

2) HAZARDS IDENTIFICATION**GHS Classification:**

Acute Oral Toxicity: Category 4

Label Elements:

Signal Word: Warning

Hazard Statements: H302 – Harmful if swallowed

Precautionary Statements: P264 – Wash hands thoroughly after handling
P270 – Do not eat, drink or smoke when using this product
P301 + P312 – IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P501 – Dispose of contents/container to an approved waste disposal site

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

3) COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Succinylcholine Chloride	71-27-2	200-747-4	Acute Tox 3 (H301)	2-
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
HYDROCHLORIC ACID	7647-01-0	231-595-7	Skin Corr. 1B (H314) STOT	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*

Additional Information:

* Proprietary
** to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4) FIRST AID MEASURES

- Eye Contact:** Rinse thoroughly with plenty of water, also under the eyelids. If irritation occurs or persists, get medical attention.
- Skin Contact:** Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5) FIRE FIGHTING MEASURES

Flash Point: Not determined

Special Hazards Arising from the Substance or Mixture:

Hazardous Combustion Products:

Formation of toxic gases is possible during heating or fire. May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

Extinguishing Media: As for primary cause of fire.

Fire Fighting Instructions: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire and Explosion Hazard: Not applicable

6) ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures:

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Measures for Cleaning / Collecting:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel

7) HANDLING AND STORAGE

Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage: Store as directed by product packaging.

8) EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye Protection: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin Protection: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory Protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Control Parameters: Refer to available public information for specific member state Occupational Exposure Limits.

SODIUM CHLORIDE

Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELs - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
Slovenia OEL - TWA 2 mg/m³
Sweden OEL - TWAs 1 mg/m³
Switzerland OEL - TWAs 2 mg/m³

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit: 2 ppm
Australia PEAK 5 ppm
7.5 mg/m³
Austria OEL - MAKs 5 ppm
8 mg/m³
Belgium OEL - TWA 5 ppm
8 mg/m³
Bulgaria OEL - TWA 5 ppm
8.0 mg/m³
Cyprus OEL - TWA 5 ppm
8 mg/m³
Czech Republic OEL - TWA 8 mg/m³
Estonia OEL - TWA 5 ppm
8 mg/m³
Germany - TRGS 900 - TWAs 2 ppm
3 mg/m³
Germany (DFG) - MAK 2 ppm
3.0 mg/m³
Greece OEL - TWA 5 ppm
7mg/m³
Hungary OEL - TWA 8 mg/m³
Ireland OEL - TWAs 5 ppm
8 mg/m³
Italy OEL - TWA 5 ppm
8 mg/m³
Japan - OELs - Ceilings 2 ppm
3.0 mg/m³
Latvia OEL - TWA 5 ppm
8 mg/m³
Lithuania OEL - TWA 5 ppm
8 mg/m³

Luxembourg OEL – TWA	5 ppm
	8 mg/m ³
Malta OEL – TWA	5 ppm
	8 mg/m ³
Netherlands OEL - TWA	8 mg/m ³
Poland OEL – TWA	5 mg/m ³
Portugal OEL - TWA	5 ppm
	8 mg/m ³
Romania OEL - TWA	5 ppm
	8 mg/m ³
Slovakia OEL - TWA	5 ppm
	8 mg/m ³
Slovenia OEL - TWA	5 ppm
	8 mg/m ³
Spain OEL - TWA	5 ppm
	7.6 mg/m ³
Switzerland OEL -TWAs	2 ppm
	3 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

9) PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Colorless
Odor:	No data available
Odor Threshold:	No data available
pH:	3.0-4.5
Molecular Weight:	Mixture
Boiling Point:	No data available
Melting/Freezing Point:	No data available
Vapor Pressure:	No data available
Vapor Density:	No data available
Relative Density:	No data available
Evaporation Rate:	No data available
Water Solubility:	Soluble
Specific Gravity:	No data available
Flash Point:	No data available
Explosive Limits:	No data available
Ignition Temperature:	No data available
Flammability (solid/gas):	No data available
Partition coefficient:	No data available
Viscosity:	No data available

10) STABILITY AND REACTIVITY

Stability:	Stable under normal conditions of use.
Reactivity:	No data available
Oxidizing Properties:	None
Conditions to Avoid:	None known
Incompatible Materials:	None known
Hazardous	
Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

11) TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Known Clinical Effects: The most common adverse effects seen during clinical use of this drug include increase in blood pressure (hypertension), decrease in blood pressure (hypotension), respiratory arrest, troubled breathing, irregular heartbeat (cardiac arrhythmia), slow heart rate (bradycardia), increased heart rate (tachycardia),

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat	Sub-tenon injection (eye)	LC50/1hr > 42 g/m3
Rat	Oral	LD 50 3g/kg
Mouse	Oral	LD 50 4g/kg
Rabbit	Dermal	LD 50 > 10g/kg

PROPYLPARABEN

Mouse	Oral	LD 50 6332 mg/kg
Mouse	Sub-tenon injection (eye)	LD 50 200 mg/kg

HYDROCHLORIC ACID

Rat	Oral	LD 50 238-277 mg/kg
-----	------	---------------------

SUCCINYLBCHOLINE CHLORIDE

Mouse	Oral	LD50 125 mg/kg
Mouse	IV	LD50 0.43mg/kg
Rabbit	IV	LD50 0.24mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin Irritation	Rabbit	Mild Eye Irritation	Rabbit	Mild
-----------------	--------	---------------------	--------	------

PROPYLPARABEN

3 Week(s)	Rat	Oral	27.1 g/kg	LOAEL	Endocrine system
4 Week(s)	Rat	Oral	347.2 mg/kg	LOAEL	Male reproductive system

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

HYDROCHLORIC ACID

Bacterial Mutagenicity (Ames)	Salmonella	Negative
In Vivo Micronucleus	Rat	Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

HYDROCHLORIC ACID

IARC: Group 3 (Not Classifiable)

12) ECOLOGICAL INFORMATION

Ecotoxicity Effects:	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Bioaccumulation:	No data available
Degradability:	No data available
Mobility:	No data available
Atmospheric Effects:	

13) DISPOSAL CONSIDERATIONS

Waste Disposal:	Comply with federal, state, and local regulations in the disposal of waste. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known
------------------------	---

environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14) TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15) REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SUCCINYLC HOLINE CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	200-747-4

SODIUM CHLORIDE

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

PROPYLPARABEN

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

WATER FOR INJECTION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

METHYLPARABEN

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

HYDROCHLORIC ACID

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb
California Proposition 65	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS/ELINCS List	Schedule 5
	Schedule 6
	231-595-7

16) OTHER INFORMATION

The information above is believed to be accurate and is intended only as a guide. Piramal Inc. assumes no responsibility for any damages resulting from handling or contact with the above material.