

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Suxa-AUS/DP-001

Effective Date: 26th April 2021

Suxamethonium Chloride Injection 50 mg/mL, 2 mL PFS

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Suxamethonium Chloride Injection 50 mg/mL, 2 mL PFS

Synonyms	Suxamethonium Chloride
Details of the Supplier of the Safety Data Sheet	
Manufacturer: Plot Numbers 457 and 458 Sarkhej Bavla Highway, Matoda, Sanand, Ahmedabad - 382 210, India.	Sponsor: Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active Ingredient Name : Succinylcholine Chloride.
Chemical Formula : C₁₄H₃₀Cl₂N₂O₄

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Succinylcholine Chloride	≤10	71-27-2	GA2360000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride; methylparaben and 0.02% propylparaben may also be added as preservatives in multi-dose solutions; sodium hydroxide and/or hydrochloric acid may be used to adjust the pH.

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview : Succinylcholine Chloride Injection, is a solution containing succinylcholine chloride, a depolarizing neuromuscular blocking agent used to relax muscles during anesthesia and other clinical procedures. In the workplace, this product should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the muscular system, nervous system, cardiovascular system, and respiratory system.

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U.S. OSHA GHS Classification

Physical Hazards

Hazard Class : Not Classified
Hazard Category : Not Classified

Health Hazards

Hazard Class : Acute Toxicity – Oral
: Eye Damage / Irritation
Hazard Category : 4
: 2B

Label Element(s)

Pictogram



Signal Word : Warning

Hazard Statement(s) : Harmful if swallowed
Causes eye irritation

Precautionary Statement(s)

Prevention

: Do not breathe vapor or spray
Wash hands thoroughly after handling
Do not eat, drink or smoke when using this product.

Response

: Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

IF SWALLOWED: Call a poison center/doctor if you feel unwell. Rinse mouth.

SECTION 4 - FIRST AID MEASURES

Eye Contact : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact : Remove from source of exposure. Flush with

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copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

SECTION 5 - FIRE FIGHTING MEASURES

Flammability : None anticipated for this aqueous product.

Fire & Explosion Hazard : None anticipated for this aqueous product.

Extinguishing Media : As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures : No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal : Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

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SECTION 7 - HANDLING AND STORAGE

- Handling** : No special handling required for hazard control under conditions of normal product use.
- Storage** : No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
- Special Precautions** : No special precautions required for hazard control.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Succinylcholine Chloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit

ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.

AIHA WEEL: Workplace Environmental Exposure Level

EEL: Employee Exposure Limit.

TWA: 8-hour Time Weighted Average.

- Respiratory Protection** : Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

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- Skin Protection** : If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
- Eye Protection** : Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
- Engineering Controls** : Engineering controls are normally not needed during the normal use of this product.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

- Appearance/Physical State** : A clear, colorless solution
- Odor** : NA
- Odor Threshold** : NA
- pH** : 3.5 to 5.0)
- Melting point/Freezing Point** : NA
- Initial Boiling Point/Boiling Point Range** : NA
- Flash Point** : NA
- Evaporation Rate** : NA
- Flammability (solid, gas)** : NA
- Upper/Lower Flammability or Explosive Limits** : NA
- Vapor Pressure** : NA
- Vapor Density (Air =1)** : NA
- Relative Density** : NA
- Solubility** : NA
- Partition Coefficient: n-octanol/water** : NA
- Auto-ignition Temperature** : NA
- Decomposition Temperature** : NA
- Viscosity** : NA

SECTION 10 - STABILITY AND REACTIVITY

- Reactivity** : Not determined.
- Chemical stability** : Stable under standard use and storage conditions.
- Hazardous Reactions** : Not determined

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- Conditions to avoid** : Not determined
- Incompatibilities** : Not determined
- Hazardous decomposition products** : Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO_x), nitrogen oxides (NO_x), and hydrogen chloride.
- Hazardous Polymerization** : Not anticipated to occur with this product.

SECTION 11 - TOXICOLOGY INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Succinylcholine	100	LD50	Oral	125	mg/kg	Mouse
Succinylcholine Chloride	100	LD50	Intravenous	0.43 0.24	mg/kg mg/kg	Mouse Rabbit

LD 50: Dosage that produces 50% mortality.

- Occupational Exposure Potential** : Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

- Signs and Symptoms** : None anticipated from normal handling of this product. In clinical use, adverse reactions are primarily an extension of the pharmacological activity. Succinylcholine chloride can cause profound muscle relaxation, and may produce prolonged respiratory depression to the point of apnea. Infrequently, adverse reactions such as cardiac arrest, malignant hyperthermia, arrhythmias, bradycardia, tachycardia, hypertension, hypotension, hyperkalemia, prolonged respiratory depression or apnea, increased intraocular pressure, muscle fasciculation, jaw rigidity, postoperative muscle pain, rhabdomyolysis with possible myoglobinuric acute renal failure, excessive salivation, and rash have also been reported. Hypersensitivity reactions, including anaphylaxis, may also occur.

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Aspiration Hazard	: None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	: None anticipated from normal handling of this product.
Ocular Irritation/ Corrosion	: None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Dermal or Respiratory Sensitization	: None anticipated from normal handling of this product.
Reproductive Effects	: None anticipated from normal handling of this product. Animal reproduction studies have not been conducted with succinylcholine chloride. The genotoxic potential of succinylcholine chloride has not been evaluated.
Mutagenicity	: The genotoxic potential of succinylcholine chloride has not been evaluated.
Carcinogenicity	: The genotoxic potential of succinylcholine chloride has not been evaluated.
Carcinogen Lists	Not listed
IARC	: Not listed
NTP	: Not listed
OSHA	:
Specific Target Organ Toxicity	NA
Single Exposure	: Based on clinical use, possible target organs
Repeat Exposure	: include the muscular system, nervous system, cardiovascular system, and respiratory system.

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Aquatic Toxicity	: Not determined for product.
Persistence/Biodegradability	: Not determined for product
Bioaccumulation	: Not determined for product
Mobility in soil	: Not determined for product

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SECTION 13 - DISPOSAL INFORMATION

- Waste disposal** : All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
- Container Handling and Disposal** : Dispose of container and unused contents in accordance with federal, state and local regulations.

SECTION 14 - TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS : Not regulated

Proper shipping name : NA
Hazard class : NA
UN Number : NA
Packing Group : NA
Reportable Quantity : NA

ICAO/IATA STATUS : Not regulated

Proper Shipping Name : NA
Hazard Class : NA
UN Number : NA
Packing Group : NA
Reportable Quantity : NA

IMDG STATUS : Not regulated

Proper Shipping Name : NA
Hazard Class : NA
UN Number : NA
Packing Group : NA
Reportable Quantity : NA

Notes: DOT - US Department of Transportation Regulations

SECTION 15 - REGULATORY INFORMATION

US TSCA Status : Exempt
US CERCLA Status : Not listed

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US SARA 302 Status : Not listed
US SARA 313 Status : Not listed
US RCRA Status : Not listed
US PROP 65 (Calif.) : Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification* : *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention : Do not breathe vapor or spray
Wash hands thoroughly after handling
Do not eat, drink or smoke when using this product.

Response : Get medical attention if you feel unwell.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

IF SWALLOWED: Call a poison center/doctor if you feel unwell. Rinse mouth.

EU Classification* : *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) : NA
Symbol : NA
Indication of Danger : NA
Risk Phrases : NA
Safety Phrases : S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

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SECTION 16 - OTHER DATA

Notes:

ACGIH TLV	: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	: Chemical Abstracts Service Number
CERCLA	: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	: US Department of Transportation Regulations
EEL	: Employee Exposure Limit
IATA	: International Air Transport Association
LD50	: Dosage producing 50% mortality
NA	: Not applicable/Not available
NE	: Not established
NIOSH	: National Institute for Occupational Safety and Health
OSHA PEL	: US Occupational Safety and Health Administration –
Prop 65	: Permissible Exposure Limit
RCRA	: California Proposition 65
RTECS	: US EPA, Resource Conservation and Recovery Act
SARA	: Registry of Toxic Effects of Chemical Substances
STEL	: Superfund Amendments and Reauthorization Act
STOT - SE	: 15-minute Short Term Exposure Limit
STOT - RE	: Specific Target Organ Toxicity – Single Exposure
TSCA	: Specific Target Organ Toxicity – Repeated Exposure Toxic Substance Control Act
TWA	: 8-hour Time Weighted Average

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

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