



MSDS: Physostigmine Salicylate Injection, 0.1%

Material Safety Data Sheet

Manufacturer: Akorn Incorporated
Address: 150 S. Wyckles Road, Decatur, IL 62522
Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

TRADE NAME: Physostigmine Salicylate Injection, 0.1%
Description: Physostigmine Salicylate is a derivative of the Calabar bean, and its active moiety, physostigmine, is also known as eserine. Physostigmine Salicylate Injection is used to reverse the effect upon the central nervous system, caused by clinical or toxic dosage of drugs capable of producing the anticholinergic syndrome.

Composition	CAS#	TLV (mg/m³)	PEL (mg/m³)	Content
Physostigmine Salicylate, USP	57-64-7	Not Established	Not Established	0.1 %
Sodium Metabisulfite, NF	7681-57-4	Not Established	Not Established	0.1 %
Benzyl Alcohol, NF	100-51-6	Not Established	Not Established	2.0 %
Water for Injection, USP	7732-18-5	Not Established	Not Established	QS

Common name of active ingredient: Physostigmine Salicylate
Chemical Formula: $C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$
Molecular Weight: 413.47 g/mole
Legal Category: Prescription Only

Section 2 - HAZARDOUS INGREDIENTS

Physostigmine salicylate is toxic to the nervous system.

POTENTIAL HEALTH HAZARDS

Carcinogenicity: No
Mutagenicity: Not available
Teratogenicity: Not available
Developmental toxicity: Not available
Eye: Very hazardous, irritant
Skin: Slightly hazardous, irritant
Ingestion: Extremely hazardous
Inhalation: Very hazardous



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Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance	Clear, colorless solution
Boiling Point (C°)	Not Established
Vapor Pressure (mmHg at 20°C)	Not Established
Vapor Density (g/m ³)	Not Established
Viscosity	Comparable to water
Osmolality	Not Established
pH	2.2 to 5.0
Specific Gravity:	~1.00 @ 25°
Solubility in Water	Soluble
Latex Free:	Yes

Section 4 - FIRE AND EXPLOSION HAZARD DATA

Flammable Properties	Flash point: Not Established	Method: Not Established
Auto-Ignition Temperature:	Not Available	
Fire Hazards in Presence of Various Substances:		Not available
Explosion Hazards in Presence of Various Substances:		
Risks of explosion of the product in presence of mechanical impact:		Not available
Risks of explosion of the product in presence of static discharge:		Not available
Fire Fighting Media and Instructions:	Use dry chemical powder, water spray, fog or foam. Do not use water jet. Wear self-contained breathing apparatus and protective clothing. Emits toxic fumes.	

Section 5 - STABILITY AND REACTIVITY DATA

Chemical Stability:	Stable
Conditions to avoid:	Exposure to light and air
Incompatibility:	Not available
Hazardous Polymerization:	Will not occur

Section 6 - HEALTH HAZARDS

Chemical Listed as Carcinogen or Potential Carcinogen

National Toxicology Program (NTP):	No
International Agency for Research on Cancer (IARC):	No
Occupational Safety and Health Administration (OSHA):	No
American Conference of Governmental Industrial Hygienists (ACGIH):	Not Established
Environmental Protection Agency (EPA):	Not Established



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First Aid:

- Eye Contact: Flush eyes with copious amounts of water for at least 15 minutes. Seek medical attention.
- Skin Contact: Remove contaminated clothing. Wash with soap and water. Seek medical attention.
- Inhalation: Seek medical attention after removing person to fresh air.
- Ingestion: Flush mouth with water. Seek immediate medical attention. May be fatal if swallowed.

Section 7 - PROTECTION INFORMATION

- Engineering Controls:** No special procedures are required in a clinical/home environment.
- Eye Protection:** Goggles or chemical safety glasses
- Skin Protection:** Gloves and protective clothing (disposable)
- Respiratory Protection:** Wear appropriate respirator when ventilation is inadequate.
- Ventilation:** Local exhaust recommended
- Contaminated Equipment:** Wash contaminated clothing and equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.
- Exposure Limits:** Not available

Section 8 - HANDLING AND STORAGE

- Handling:** Avoid contact with product and use caution to prevent breaking container. No special protective equipment or procedures are required in the clinical or home environment. Use of gloves, lab coat, splash goggles, dust respirator is recommended.
- Storage:** Store at controlled room temperature from 20° to 25°C (68° to 77°F)

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

Section 9 - SPILL, LEAK and DISPOSAL PROCEDURES

- Large / Small Spills:** Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Wipe working surfaces to dryness, then wash with soap and water.
- Waste Management:** Dispose of all waste in accordance with Federal, State and Local regulations.



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Section 10 - TOXICOLOGY INFORMATION

Routes of Entry: Eye contact, inhalation, ingestion, injection, absorption

Toxicity to Animals: Oral (LD₅₀): 2.5 mg/kg, mice

Intraperitoneal (LD₅₀): 0.64 mg/kg, mice

Chronic Effects on Humans: The substance is toxic to the nervous system.

Usage in Pregnancy:

Safe use in pregnancy and lactation has not been established; therefore, use in pregnant women, nursing mothers or women who may become pregnant requires that possible benefits be weighed against possible hazards to mother and child.

Adverse Reactions:

Nausea, vomiting and salivation can be offset by reducing dosage. Bradycardia, respiratory distress and convulsions may occur if intravenous administration is too rapid. Can cause a cholinergic crisis.

Precautions:

Because of possibility of hypersensitivity in an occasional patient, atropine sulfate injection should always be at hand since it is an antagonist and antidote for physostigmine.

Section 11 - ECOLOGICAL INFORMATION

Ecotoxicity: Not available

Chemical Fate: Product administered to patients presents a negligible impact on the environment.

Section 12 - REGULATORY INFORMATION

Federal and State Regulations:

Pennsylvania RTK

Massachusetts RTK

TSCA 8(b) inventory

SARA 302/304/311/312 extremely hazardous substance

CERCLA Hazardous substance

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200)

WHMIS (Canada):

CLASS D -1A: Material causing immediate and serious toxic effects (VERY TOXIC)

CLASS D - 2B: Material causing other toxic effects (TOXIC)

DSCL (EEC): R41- Risk of serious damage to eyes.

HMIS (USA): Health Hazard: 4 Fire Hazard: 1 Reactivity: 0 Personal Protection: E

National Fire Protection Association: Health: 4 Flammability: 1 Reactivity: 0



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Section 13 - TRANSPORTATION INFORMATION
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DOT Classification: CLASS 6.1: Poisonous material.

Identification: Toxic solid, organic, n.o.s. (Physostigmine salicylate): UN2811 PG: I

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