



MSDS: Physostigmine Salicylate Injection, 0.1%

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Section 1 - IDENTIFICATION

Common/Trade Name: Physostigmine Salicylate Injection, 0.1%
Common Name of Active Ingredient: Physostigmine Salicylate, Eserine salicylate
Chemical Formula: $C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$
Legal Category: Prescription only

Section 2 – HAZARD(S) IDENTIFICATION

Routes of Entry: For intramuscular or intravenous injection
Physostigmine salicylate is toxic to the nervous system.

Potential Health Hazards:

Mutagenicity: NA
Teratogenicity: NA
Developmental toxicity: NA
Eye: Very hazardous, irritant.
Skin: Slightly Hazardous, irritant.
Ingestion: Extremely hazardous.
Inhalation: Very hazardous.

Carcinogenicity:

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): NE
Environmental Protection Agency (API): NE

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Component	CAS	Amount
Physostigmine Salicylate, USP	57-64-7	0.1 %
Sodium Metabisulfite, NF	7681-57-4	0.1 %
Benzyl Alcohol, NF	100-51-6	2.0 %
Water for Injection, USP	7732-18-5	QS

Section 4 – FIRST AID MEASURES

- Eye Contact:** Flush eyes with copious quantities of water for at least 15 minutes. Seek medical attention.
- Skin Contact:** May cause irritation. Product may be absorbed through the skin. Remove contaminated clothing and clean before reuse. Wash with soap and water. Get medical attention.
- Inhalation:** Move individual to fresh air. Get medical attention immediately.
- Ingestion:** Flush mouth with water. Seek immediate medical attention.
May be fatal if swallowed.

Section 5 – FIRE FIGHTING MEASURES

- Flash Point:** Not Established
- Auto ignition:** Not Available
- Lower Explosion Limit:** Not Established
- Upper Explosion Limit:** Not Established
- Fire Hazards in Presence of Various Substances:**
- Risk of explosion of the product in presence of mechanical impact:** NA
- Risk of explosion of the product in presence of static discharge:** NA
- General Hazard:** Not Established
- Fire Fighting Instructions:** Use water, carbon dioxide, dry chemical, foam, or Halon. Do not use water jet. Solution thermally decomposes to form toxic vapors. Use caution.
- Fire Fighting Equipment:** Firefighters should wear self-contained breathing apparatus and full protective gear.
- Hazardous Combustion Products:** Toxic Fumes may be emitted.

Section 6 – ACCIDENTAL RELEASE MEASURES

Use of personal protective equipment such as gloves, lab coat, splash goggles, dust respirator is recommended. Contain any spills to prevent drainage into sewers or streams. Absorb spilled solution with suitable materials such as clay absorbent or absorbent pads for aqueous solutions. Wipe working surfaces to dryness then wash with soap and water.

Dispose of all waste in accordance with federal, state and local regulations.

Section 7 – HANDLING AND STORAGE

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

General Handling: No special protective equipment or procedures are required in the clinical or home environment. As a general rule, while handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes, clothing. Do not mix with other drugs.

Storage Conditions: Store at controlled room temperature 20° to 25°C (68° to 77° F)

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Local exhaust or general ventilation is recommended.

Personal Protective Equipment

Eye Protection: Wear chemical splash goggles or safety glasses.
Hand Protection: When administering this product to patients, wear nitrile or latex gloves.
Respiratory Protection: Under normal conditions of product use, respiratory protection is not required. 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 in accordance with federal, state and local regulations.
Skin Protection: Use coveralls, booties and gloves for clean-up activities.

Section 9 – PHYSICAL / CHEMICAL CHARACTERISTICS

Physical Form/ Appearance: Clear, colorless solution
Boiling Point/Boiling Range: NE
Melting Point/Melting Range: Not Applicable
Freezing Point: Aqueous
Vapor Pressure: Not Established
Relative Vapor Density: Not Established
Percent Volatiles: Not Established
Viscosity: Comparable to water
Osmolality: Not Established

pH:	2.2 to 5.0
Molecular Weight:	413.47 g/mole for active pharmaceutical ingredient
Solvent Solubility:	Soluble in water and ethanol
Specific Gravity:	~1.00 @ 25°C
Latex Free:	Yes

Section 10 – STABILITY AND REACTIVITY

Reactivity:	Not Established
Chemical Stability:	Stable at normal temperatures and pressures
Possibility of Hazardous Reactions:	May be reactive with strong oxidizing agents
Hazardous Polymerization:	Will not occur
Conditions to avoid:	Exposure to light and air.

Section 11 – TOXICOLOGICAL INFORMATION

Signs/Symptoms of Exposure & Overexposure: Can cause a cholinergic crisis
Appropriate antidote is atropine sulfate

Medical Conditions Aggravated by Accidental Exposure: Not Established

Acute Effects

Oral LD₅₀:	2.5 mg/kg, in mice
Intraperitoneal LD₅₀:	0.64 mg/kg, in mice

Chronic Effects

Organ Systems: Toxic to the central nervous system

No adequate and well controlled studies in humans have been conducted to fully determine the mutagenic, teratogenic or adverse reproductive effects of physostigmine salicylate.
Classified as Pregnancy Category C.

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 cholinergic crisis.

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity: Not Established

Mobility in Environment: Appreciable volatilization into the air is not expected.
Product administered to patients presents a negligible impact on the environment.

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dispose of material according to Federal, State, and Local regulations

Section 14 – TRANSPORTATION INFORMATION

UN/NA Number: 1851

Proper Shipping Name: Medicine, liquid, toxic, n.o.s.

DOT Hazard Class Class 6.1 - poisonous material
Packaging Group PGII

Section 15 – REGULATORY INFORMATION

Right to Know: Pennsylvania, Massachusetts

FDA (Food & Drug Administration): Prescription only
NDC No. 17478-510-02 (2 ml)

TSCA (Toxic Substance Control Act): 8b Inventory

SARA: 302/304/311/312
extremely hazardous substance

HMIS (Hazardous Materials Information System (USA)): Health Hazard 4
Fire Hazard 1
Reactivity Hazard 0

National Fire Protection Association (NFPA): Health Hazard 4
Fire Hazard 1
Reactivity Hazard 0

WHMIS (Workplace Hazardous Materials): Class D-1A, D-2B
Very Toxic

CERCLA: Hazardous Substance

DSCL: R41 – Risk of serious damage to eyes

OSHA: This material is considered hazardous by definition within Hazard Communications Standard 29CFR 1910.1200.

Section 16 – OTHER INFORMATION**Date of preparation or last revision: 09-2013**

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