

SAFETY DATA SHEET

1. **Identification**

Product Identifier: Physostigmine Salicylate Injection

Synonyms: Eserine salicylate

National Drug Code (NDC): 17478-510-02

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. **Hazard(s) Identification**

Physical Hazards: Not classifiable.

Health Hazards: Not classifiable.

Symbol(s): None.

Signal Word: None.

Hazard Statement(s): None.

Precautionary Statement(s): None.

Hazards Not Otherwise Classified: None.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. **Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Physostigmine Salicylate Injection	57-64-7	Eserine salicylate	$C_{15}H_{21}N_3O_2 \cdot C_7H_6O_3$	413.47	0.1%

*The formula also contains Sodium Metabisulfite, 0.1%; Benzyl Alcohol, 2.0% as preservative and Water for Injection.

SDS: Physostigmine Salicylate Injection

4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Can cause a cholinergic crisis. Appropriate antidote is atropine sulfate.
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.
Medical Conditions Aggravated by Exposure:	Not determined.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use water, carbon dioxide, dry chemical, foam, or Halon. Do not use water jet. Solution thermally decomposes to form toxic vapors. Use caution.
Unsuitable Extinguishing Media:	Not determined.

SDS: Physostigmine Salicylate Injection

Specific Hazards Arising from the Chemical:

- Hazardous Combustion Products:** Toxic fumes may be emitted.
- Other Specific Hazards:** Not determined.
- Special Protective Equipment/ Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

- Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
- Personal Protective Equipment:** For personal protection see section 8.
- Methods for Cleaning Up:** Use of personal protective equipment such as gloves, lab coat, splash goggles, and 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.
- Environmental Precautions:** No data available.
- Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

- Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
- Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store at controlled room temperature 20°C – 25°C (68°F – 77°F).
- Specific End Use:** Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Physostigmine Salicylate Injection	Not established.
Sodium Metabisulfite	Not established.
Benzyl Alcohol	Not established.

SDS: Physostigmine Salicylate Injection

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Local exhaust or general ventilation is recommended.
Respiratory Protection:	Not required for the normal use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	When administering this product to patients, wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
Contaminated Equipment:	Wash contaminated clothing and equipment with soap and water. Release rinse water in accordance with federal, state and local regulations.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	5.8.
Melting Point:	No data available.
Freezing Point:	Aqueous.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water and ethanol.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.

SDS: Physostigmine Salicylate Injection

Viscosity: Comparable to water.
Specific Gravity: ~1.00 at 25°C.

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: May be reactive with strong oxidizing agents.

Conditions to Avoid (e.g., static discharge, shock, or vibration): Exposure to light and air.

Incompatible Materials: No data available.

Hazardous Decomposition Products: No data available.

Hazardous Polymerization: Will not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: Very hazardous.

Ingestion: Extremely hazardous. May be fatal if swallowed.

Skin Contact: Slightly hazardous, irritant.

Eye Contact: Very hazardous, irritant.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose
Physostigmine Salicylate	Mice	Oral	LD ₅₀	2.5 mg/kg
Physostigmine Salicylate	Mice	Intraperitoneal	LD ₅₀	0.64 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: Slightly hazardous, irritant.

Eye Irritation: Very hazardous, irritant.

Sensitization: No data available.

SDS: Physostigmine Salicylate Injection

Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	Toxic to the central nervous system.
Reproductive Effects:	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.
Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	Appreciable volatilization into the air is not expected. Product administered to patients presents a negligible impact on the environment.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	1851
UN Proper Shipping Name:	Medicine, liquid, toxic, n.o.s.
Transport Hazard Class(es):	Class 6.1 – poisonous material.
Packing Group:	PGII
Department of Transportation:	Regulated as a hazardous material.
International Air Transport Association (IATA):	Regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Regulated as a dangerous good.

15. **Regulatory Information**

US Federal Regulations:

Toxic Substance Control Act (TSCA):	8b Inventory.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Extremely hazardous substance.

State Regulations

Massachusetts:	Listed.
Pennsylvania:	Listed.
California Proposition 65:	Not listed.

16. **Other Information**

Not made with natural rubber latex.

NFPA Rating:		HMIS Classification:	
Health Hazard:	4	Health Hazard:	4
Fire Hazard:	1	Fire Hazard:	1
Reactivity Hazard:	0	Reactivity Hazard:	0

Revision Date: 05/11/2015

Revision Number: 1

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.