MSDS: Physostigmine Salicylate Injection, 0.1%

Material Safety Data Sheet

Manufacturer: Akorn Incorporated
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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.

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

Common name of active ingredient: Physostigmine Salicylate
Chemical Formula: C₁₅H₂₁N₃O₂ · C₇H₆O₃
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/m³)**: 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
- **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
- **Explosion Hazards in Presence of Various Substances**: 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


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

DOT Classification:  CLASS 6.1: Poisonous material.
Identification:  Toxic solid, organic, n.o.s. (Physostigmine salicylate): UN2811 PG: I

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