MSDS: Methylene Blue Injection, USP 1%

Manufacturer: Akorn
1925 W. Field Court Suite 300
Lake Forest, IL 60045

Contact Telephone: 1-800-932-5676
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Section 1 - IDENTIFICATION

Common/Trade Name: Methylene Blue Injection, USP 1%
Chemical Names: Phenothiazin-5-ium, 3,7-bis (dimethylamino)-, chloride, trihydrarate
Chemical Formula: C_{216}H_{18}ClN_{3}S
Category: Prescription Only.

Section 2 – HAZARD(S) IDENTIFICATION

Routes of Entry: For intravenous injection.
Warning: Methylene blue should not be given by subcutaneous or intrathecal injection.

Statement of Hazard: This material is considered hazardous by OSHA Hazard Communication Standard (29 CFR 1910.1200).
Carcinogenicity: Does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Additional Hazard Information:
Routes of Exposure: Eye contact, skin contact, ingestion and inhalation.
Eye: Causes irritation of the eye.
Skin: May cause the irritation of the skin.
Inhalation: Causes irritation of the respiratory tract.
Ingestion: Causes irritation of the gastrointestinal tract.
Skin Adsorption: Not adsorbed through the skin.
Target Organs: Hemopoietic and central nervous system.

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS#</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylene Blue</td>
<td>7220-79-3</td>
<td>10 mg/mL</td>
</tr>
</tbody>
</table>
Inactive ingredients: Water for injection (qs), pH adjusted with hydrochloric acid and/or sodium hydroxide when necessary.

Section 4 – FIRST AID MEASURES

Eyes: Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin: Remove contaminated clothing. Flush area with large amounts of water. Seek medical attention.
Inhalation: Remove to fresh air and keep patient at rest. Remove contaminated clothing. Seek medical attention immediately.
Ingestion: Wash out mouth with water. Seek medical attention immediately.
Note to Physicians: Exposure to product may result in headache, confusion, dizziness and nausea. May cause precordial and abdominal pain and the formation of methemoglobin. See prescribing information.

Section 5 – FIRE FIGHTING MEASURES

Flash Point: NA
Auto ignition: NA
Lower Explosion Limit: NA
Upper Explosion Limit: NA
Suitable Extinguishing Media: Water spray, foam, dry chemical of carbon dioxide.
Caution: Carbon dioxide will displace air in confined spaces and may cause oxygen deficient atmosphere.
Unsuitable Extinguishing Media: None
Hazardous Combustion Particles: When heated methylene blue solution thermally decomposes to form toxic vapors. (i.e. Carbon monoxide, Carbon Dioxide, Halogenated Compounds and Oxides of Sulfur and nitrogen.)
Protection for Firefighters: Methylene blue solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin, and may be toxic to respiratory tract. Firefighters are to wear self contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.
Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water. Dispose of material according to Federal, State and Local regulations.

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Environmental Precautions: This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.

Methods of Containment: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.

Other Information: A spill of this material does not need to be reported to the National Response Center.

Section 7 – HANDLING AND STORAGE

Precautions: NA

General Handing: Avoid all contact and inhalation of mists or vapors associates with the product. Avoid contact with skin, eyes, and clothing. Do not mix with other drugs.

Storage Conditions: Store between 20°C and 25°C (68°F and 77°F).

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTIVE

Engineering Controls: Local exhaust or general ventilation is recommended.

Personal Protective Equipment

Eye Protection: Wear ANSI approved chemical splash goggles or safety glasses.

Skin Protection: When administering this product to patients wear nitrile or latex gloves. Use Tyvek SL or equivalent coveralls, PVC booties and nitrile gloves for cleanup activities.
Respiratory Protection: Under normal conditions of product use respiratory protection is not required. When required, use NIOSH approved air purifying respirator with P-100/organic vapor/acid gas cartridges.

Exposure Limits:

<table>
<thead>
<tr>
<th>Compound</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylene Blue</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>2 mg/m$^3$ – 8 hour TWA</td>
<td>2 mg/m$^3$ – Ceiling</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>5 ppm – Ceiling</td>
<td>2 ppm - Ceiling</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Physical Form/ Appearance: Dark blue solution.
Melting Point/Melting Range: NA
Freezing Point: Approximately 32°F
Boiling Point: Approximately 212°F
Flash Point: NA
Auto-ignition Temperature: NA
Evaporation Rate: NA
Flammability: Nonflammable, noncombustible.
Vapor Pressure: NA
Relative Vapor Density: NA
Specific Gravity: Approximately 1.0.

pH: 3.0 to 4.5
Solubility: Freely soluble in water and alcohol.
Latex Free: NA
Physical State: Liquid
Odor: Odorless.
Partition Coefficient: NA
%Volatile: 0%
Volatile Organic Compounds(%): 0%
Section 10 – STABILITY AND REACTIVITY

Reactivity: NA
Chemical Stability: Stable.
Possibility of Hazardous Reactions: NA
Conditions to Avoid: Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.

Hazardous Polymerization: Does not occur.
Hazardous Decomposition Product: Carbon monoxide, carbon dioxide, halogenated compounds, oxides of sulfur and nitrogen may be released by thermal decomposition.

Section 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity:
Oral (LD₅₀): No data available.
Intravenous (LD₅₀): No data available.
Intraperitoneal (LD₅₀): No data available.
Subcutaneous (LD₅₀): No data available.
Dermal (LD₅₀): No data available.
Inhalation: Respiratory inhalation is possible.
Eye Irritation: Causes eye irritation.
Skin Irritation: Skin irritation is possible.
Sensitization: No available data concerning sensitivity of this product.

Chronic Effects:
Organ Systems: May be toxic to lungs, eyes, hemopoietic and central nervous system.
Mutagenicity: Methylene blue is mutagenic in bacteria, yeast and somatic mammalian cells. No adequate and well controlled studies in humans concerning the mutagenic effects of Methylene Blue.
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Reproductive Effects: Animal studies concerning Methylene Blue illustrated adverse effects, decreased sperm motility. No adequate and well controlled studies in humans concerning the reproductive effects of Methylene Blue.

Developmental Effects: Methylene blue is not considered a teratogen; however, it may be teratogenic if used during amniocentesis.

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity : Data not yet available.
Biodegradable : Short term products of biodegradation are not likely. No data available on the long term degradation of the product.
Bioaccumulation : No applicable bioaccumulation is expected in the environment.
Environmental Overview: With respect to mobility in the environment, appreciable volatilization is not expected into the air or aquatic environment.

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dispose of waste in accordance to all applicable laws and regulations. Do not mix with other substances. Contact your state or local government environmental and/or sanitation department for guidance on disposal.

Section 14 – TRANSPORT INFORMATION

UN/NA Nimber: NA
Canadian TDG (ground): See US DOT
IATA (air): Not considered a DOT regulated material. Non hazardous for shipment.
Proper Shipping Name: NA
Shipping Label: NA
Section 15 – REGULATORY INFORMATION

California Safe Drinking Water & Toxic Enforcement Act (Prop 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.

RTECS Number: SO5600000
TSCA: 8b Inventory – Not listed.
NFPA Rating:
  Health – 1
  Fire – 1
  Reactivity – 0
WHMIS (Canada): Not Listed.

Section 16 – OTHER INFORMATION

Date of preparation or last revision: 10-13

Key to Abbreviations:
  NA = Not Available

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