SAFETY DATA SHEET

1. Identification

Product Identifier: Methylene Blue Injection, USP 1%

Synonyms: Methylthioninium chloride * C.I. Basic Blue 9 trihydrate

National Drug Code (NDC): 17478-504-01
17478-504-10

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: Not classifiable.

Supplementary Information: This material is considered hazardous by OSHA Hazard Communication Standard (29 CFR 1910.1200).

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Methylene Blue	7220-79-3	Methylthioninium chloride * C.I. Basic Blue 9 trihydrate	$C_{16}H_{18}ClN_3S$	319.86	1%

*The formula also contains Water for Injection, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH.

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:	See package insert for more information.
Medical Conditions Aggravated by Exposure:	Personnel with central nervous system and hemopoietic disorders.
Notes to Physician:	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.

5. Firefighting Measures

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.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	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.)
Other Specific Hazards:	Not determined.
Special Protective Equipment/ Precautions 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.

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:	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.
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.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling:	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. 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 between 20°C – 25°C (68°F – 77°F). Store according to label and/or product insert information.
Specific End Use:	Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Methylene Blue	Not established.
Sodium Hydroxide	OSHA PEL 2 milligrams/cubic Meter – 8 hour TWA ACGIH TLV 2 milligrams/cubic meter – Ceiling
Hydrochloric Acid	OSHA PEL 5 parts per million – Ceiling ACGIH TLV 2 parts per million – Ceiling

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: 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: Not required for the normal use of this product. 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: Not required for the normal use of this product. 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: Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: Dark blue solution.
Odor: Odorless.
Odor Threshold: No data available.
pH: 3.0 - 4.5.
Melting Point: No data available.
Freezing Point: Approximately 32°F.
Boiling Point: Approximately 212°F.
Flash Point: No data available.
Evaporation Rate: No data available.
Flammability (solid, gas): Nonflammable, noncombustible.
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):	Freely soluble in water and alcohol.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials:	Reactive with strong Oxidizers and Alkalis.
Hazardous Decomposition Products:	Carbon monoxide, carbon dioxide, halogenated compounds, oxides of sulfur and nitrogen may be released by thermal decomposition.
Hazardous Polymerization:	Does not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	Cause irritation to the respiratory system.
Ingestion:	Causes irritation of the gastrointestinal tract.
Skin Contact:	May cause skin irritation.
Eye Contact:	Causes eye irritation.
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 – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.

Corrosivity:	No data available.
Dermal Irritation:	May cause skin irritation.
Eye Irritation:	Causes eye irritation.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	May be toxic to lungs, eyes, hemopoietic and central nervous system.
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.
Carcinogenicity:	Methylene Blue is not considered carcinogenic. No adequate and well controlled studies in humans concerning the carcinogenic effects of Methylene Blue.
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:	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.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	Short term products of biodegradation are not likely. No data available on the long term degradation of the product.
Bioaccumulative Potential:	No applicable bioaccumulation is expected in the environment.
Mobility in Soil:	No data available.
Mobility in Environment:	With respect to mobility in the environment, appreciable volatilization is not expected into the air or aquatic environment.

Other Adverse Effects: No data available.

13. Disposal Considerations

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

14. Transport Information

UN Number: Not applicable.
UN Proper Shipping Name: Not applicable.
Transport Hazard Class(es): Not applicable.
Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

NFPA Rating:
Health: 1
Fire: 1
Reactivity: 0

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