



SAFETY DATA SHEET

Creation Date 03-Mar-2020

Revision Date 00-000-0000

Revision Number 00

1. IDENTIFICATION

Product Name Methylprednisolone Acetate Injectable Suspension USP 40 mg/mL,
80 mg/mL

Type of Container Vials (1.185 mL) (40 mg / mL)
Vials (1.185 mL) (80 mg / mL)

Recommended Use Specified quality tests and assay use only.

Manufacturer Name And Address

Amneal Pharmaceuticals Pvt. Ltd.
Plot No.15, PHARMEZ-SEZ, Sarkhej-Bavla Highway,
Ta. Sanad, Dist. Ahmeddabad-382220, Gujarat, India.

Emergency Telephone number

+91-2714-671600

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

Carcinogen List

| Substance | IARC | NTP | OSHA |
|--------------------|------------|------------|------------|
| Methylprednisolone | Not Listed | Not Listed | Not Listed |

Hazard Class Not applicable

Signal word Not Classified

Symbol Not applicable

Hazard Statement Not classified in accordance with international standards for workplace safety.

Emergency Overview Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.



Product Name: Methylprednisolone Acetate Injectable Suspension USP

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Methylprednisolone Acetate
Chemical Family Mixer

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride; sodium hydroxide and/or hydrochloric acid are added to adjust the pH.

| Component | Approximate Percent by | CAS Number | RTECS Number |
|---|------------------------|------------|--------------|
| Sterile methylprednisolone acetate micronized USP | 5% to 8 % | 53-36-1 | NA |
| Polyethylene glycol | 2.8% to 2.9 % | None | NA |

4. FIRST-AID MEASURES

Eye contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact In case of contact, immediately flush skin with plenty of water. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Ingestion Ingestion of this material may cause effects similar to those seen in clinical use including chest pain, chills or fever, increased sweating, convulsions, dizziness, rapid, pounding, or irregular heart rhythm, hallucinations, headache, high or low blood pressure, nausea, or vomiting, troubled breathing, trembling, restlessness, or anxiety, blurred vision, difficult or painful urination, troubled sleeping, and weakness. May irritate digestive tract. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.



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5. FIRE-FIGHTING MEASURES

| | |
|---|--|
| Flammability | Non flammable |
| Flash point: | Non flammable |
| Auto ignition Temperature | Not applicable |
| Fire & Explosion Hazard | Not applicable |
| Extinguishing media | Use foam or all-purpose dry chemicals to extinguish. |
| Special Fire Fighting Procedures | No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus. |

6. ACCIDENTAL RELEASE MEASURES

| | |
|-----------------------------------|--|
| Personal precautions: | Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all firefighting procedures (Section 5). |
| Spill Cleanup and Disposal | Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations. |

7. HANDLING AND STORAGE

| | |
|----------------------------|--|
| Handling | No special handling required under conditions of normal product use. |
| Storage | No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary Container label, or the product insert. |
| Special Precautions | No special precautions required for hazard control. |
| Storage Conditions | Store your new, unused Methylprednisolone Acetate Injection in the original carton in a refrigerator at 68° to 77°F (20±5° C). Protect Methylprednisolone Acetate injection from light, store in carton until time of use. Follow instructions provided in packaging. |



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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Component | OSHA-Time Weighted Average: | OSHA-Short Term Exposur | OSHA-Ceiling Limits | ACGIH-Time Weighted Average: | ACGIH-Short Term Exposur | ACGIH-Ceiling Limit Value: |
|---|-----------------------------|-------------------------|---------------------|------------------------------|--------------------------|----------------------------|
| Sterile methylprednisolone acetate micronized USP 53-36-1 | None | None | None | None | None | None |
| Polyethylene glycol | None | None | None | None | None | None |
| Water 7732-18-5 | None | None | None | None | None | None |

Components with workplace control parameters

| Component | CAS No. | Value | Control parameters | Basis |
|---|---------|-------|--------------------|-------|
| Sterile methylprednisolone acetate micronized USP | 53-36-1 | N/A | N/A | N/A |

Engineering measures: No special containment is required. Provide general or local exhaust ventilation.

Personal protective equipment:

Respiratory protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR 1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Safety glasses with side-shields, Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

Engineering Controls Engineering controls are normally not needed during the normal use of this product. Handle product in a well-ventilated area.



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9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|---|
| Appearance/Physical State | Liquid |
| Color | White to off white homogeneous suspension |
| Odor | NA |
| Odor Threshold: | NA |
| pH: | NA |
| Melting point/Freezing point: | NA |
| Initial Boiling Point/Boiling Point Range: | NA |
| Evaporation Rate: | NA |
| Flammability (solid, gas): | NA |
| Upper/Lower Flammability or Explosive Limits: | NA |
| Vapor Pressure: | NA |
| Vapor Density: | NA |
| Specific Gravity: | NA |
| Solubility: | Soluble in water |
| Partition coefficient: n-octanol/water: | NA |
| Auto-ignition temperature: | NA |
| Decomposition temperature: | NA |

10. STABILITY AND REACTIVITY

| | |
|---|---|
| Stability | Stable under recommended storage conditions. |
| Reactivity | Not determined. |
| Chemical Stability | Stable under standard use and storage conditions. |
| Hazardous Reactions | Not determined. |
| Conditions to avoid | Oxidizing agent. |
| Incompatibilities | Not determined. |
| Hazardous Polymerization | Not applicable. |
| Hazardous decomposition products | Not determined. |



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11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

| Ingredient(s) | Percent | Test Type | Route of Administration | Value | Units | Species |
|---|---------|-----------|-------------------------|-------|-------|---------|
| Sterile methylprednisolone acetate micronized USP | 100 | LD50 | Oral | 10 | g/kg | Rat |
| | | LD50 | IP | >1409 | mg/kg | Mouse |

Acute Toxicity: Ingestion of this material may cause effects similar to those seen in clinical use including chest pain, chills or fever, increased sweating, convulsions, dizziness, rapid, pounding, or irregular heart rhythm, hallucinations, headache, high or low blood pressure, nausea, or vomiting, troubled breathing, trembling, restlessness, or anxiety, blurred vision, difficult or painful urination, troubled sleeping, and weakness.

Chronic Toxicity: Contains material which may cause damage to the following organs: skin, eye, lens or Cornea.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: No data available

Suspected Cancer Agent: These products as well as all components of this product have NOT been identified as Carcinogens by NTP, IARC or OSHA. Methylprednisolone Acetate was negative in the DNA-cell- binding (DCB) assay.

Irritancy of Product: This product is not expected to be irritating to contaminated skin, eyes and other tissues. The active ingredient is non-irritating to the eyes and the skin.

Sensitization to the Product: Hypersensitive reactions have been observed following clinical use of this product.



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12. ECOLOGICAL INFORMATION

Environmental properties:

| Component | Eco toxicity - Water Flea Data | Fish Species Eco toxicity | Eco toxicity - Freshwater Algae Data | Microtox Eotoxicity Data |
|--|-----------------------------------|------------------------------|--|--------------------------|
| Sterile methylprednisolone acetate micronized USP | No data available | No data available | No data available | No data available |

Ecotoxicity effects: No data available

Bioaccumulation: No data available

Mobility in Soil Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORT INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None



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15. REGULATORY INFORMATION

USA Regulations

| Substance | Weight % | TSCA Status | CERCLA Status | SARA 302 | SARA 313 | PROP 65 Status |
|---|------------|-------------|---------------|------------|------------|----------------|
| Sterile methylprednisolone acetate micronized USP | 5 % to 8 % | Not Listed | Not Listed | Not Listed | Not Listed | Not Listed |

RCRA Status Not Listed
U.S. OSHA Classification TSCA Inventory List: The product is exempt from TSCA, it is FDA Regulated
 Possible Irritant

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not applicable

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Ephedrine Sulfate.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
 S24/25 - Avoid contact with skin and eyes.
 S37/39 - Wear suitable gloves and eye/face protection.

WHMIS (Canada): Not controlled under WHMIS (Canada).



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16. OTHER INFORMATION:

Notes:

| | |
|-----------|---|
| ACGIH TLV | American Conference of Governmental Industrial Hygienists – Threshold Limit Value |
| CAS | Chemical Abstracts Service Number |
| CERCLA | US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act |
| DOT | US Department of Transportation Regulations |
| EEL | Employee Exposure Limit |
| IATA | International Air Transport Association |
| LD50 | Dosage producing 50% mortality |
| NA | Not applicable/Not available |
| NE | Not established |
| NIOSH | National Institute for Occupational Safety and Health |
| OSHA PEL | US Occupational Safety and Health Administration – Permissible Exposure Limit |
| Prop 65 | California Proposition 65 |
| RCRA | US EPA, Resource Conservation and Recovery Act |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| STEL | 15-minute Short Term Exposure Limit |
| TSCA | Toxic Substance Control Act |
| TWA | 8-hour Time Weighted Average |

| | |
|----------------------------|----------------|
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| Further information | Not available. |

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