



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Methylprednisolone Acetate Injectable Suspension, USP

### 1. PRODUCT IDENTIFICATION

**Product Name** Methylprednisolone Acetate Injectable Suspension, USP (Multi-Dose)  
**Product Use** Medical Treatment; Corticosteroid (anti-inflammatory)  
**Manufacturer** Teva Parenteral Medicines, Inc.  
**Address** 11 Hughes  
 Irvine, CA 92618-1902

**Chemtrec Emergency No.** 1-800-424-9300 (United States)  
 1-202-483-7617 (International Collect)  
**Business Phone** 1-800-729-9991  
**Website Address** <http://www.tevausa.com>

**Common Names** Depo-Medrol™  
 RU 3533  
**Chemical Name** pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-6-methyl-,(6α,11β)-  
**Chemical Formula** C<sub>24</sub>H<sub>32</sub>O<sub>6</sub>  
**Chemical Family** Glucocorticoid (corticosteroid)  
**How Supplied** 40mg/ml: 5 ml in 5ml vial  
 40 mg/ml: 10 ml in 10ml vial  
 80mg/ml: 5 ml in 5 ml vial

**Date of Preparation:** November 27, 2000

### 2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	40 mg/ml	80 mg/ml	EXPOSURE LIMITS IN AIR				
		%	%	ACGIH		OSHA		Other
		by weight	by weight	TLV	CEIL	PEL	CEIL	TWA*
Methylprednisolone acetate	53-36-1	4	8	NE	NE	NE	NE	4ug/m <sup>3</sup>
Polyethylene glycol 3350	None	2.91	2.82	NE	NE	NE	NE	NE
Polysorbate 80	2748-88-1	0.194	0.188	NE	NE	NE	NE	NE
Monobasic Sodium Phosphate	7558-80-7	0.68	0.659	NE	NE	NE	NE	NE
Dibasic Sodium Phosphate	7558-79-4	0.142	0.137	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	0.916	0.888	NE	NE	NE	NE	NE
Water for Injection	7732-18-5	Balance	Balance	NE	NE	NE	NE	NE
Sodium Chloride (to adj. tonicity)	7647-14-5	Trace	Trace	NE	NE	NE	NE	NE
Sodium hydroxide and/or	1310-73-2	Trace	Trace	NE	2mg/m <sup>3</sup>	2mg/m <sup>3</sup>	NE	NE
Hydrochloric acid (for pH adjustment)	7647-01-0	Trace	Trace	NE	5ppm	NE	5ppm	NE

NE - Not Established

C - Ceiling Limit

\* Pharmacia and Upjohn Derived Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 – 1998 format

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this

# Methylprednisolone Acetate Injectable Suspension, USP

## 3. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:** Material is a white suspension. May cause allergic reactions. Overexposure may cause damage to the kidneys, pituitary, cardiovascular, immune and nervous systems. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact may cause mild irritation. Effects may include stinging, watering, and redness of the eyes and redness and a burning sensation on the skin. Hypersensitive (allergic) reactions have been observed following clinical use of the product.

Ingestion: Although ingestion is not an anticipated route of occupational exposure, this material has a low degree of toxicity. Harmful effects from swallowing are not expected. Symptoms similar to those identified under injection may occur.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

### Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as hypertension, headaches, abdominal pain, pancreatitis, visual disturbances (including cataracts, glaucoma and blindness), muscle weakness and fatigue, acne, menstrual disorders, peptic ulcers, fluid retention, heart failure, susceptibility to infection, and fluctuation in electrolyte levels may occur.

Cancer: Methylprednisolone acetate was negative in the DNA-cell-binding (DCB) assay. Ingredients are not listed as carcinogenic by NTP, IARC or OSHA.

Chronic: Corticosteroids are generally teratogenic in laboratory animals (see Section 11).

Target Organs: This product may produce adverse effects on the kidneys, pituitary, cardiovascular, immune and nervous systems. (see Section 11).

Other: This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissues.

Multi-dose use from a single vial requires special care to avoid contamination.

See package insert for additional information.



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Methylprednisolone Acetate Injectable Suspension, USP

### 3. HAZARD IDENTIFICATION cont.

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include kidney, pituitary, cardiovascular, immune and nervous systems disorders. Corticosteroids may increase susceptibility to infection (including reactivation of latent tuberculosis and enhancement of secondary eye infections due to fungi or viruses) or mask some signs of infection. Recent immunization procedures may result in a lack of antibody response and neurological disorders. This material is contraindicated for intrathecal administration, systemic fungal infections and in patients with clinically significant hypersensitivity to it. Corticosteroids exhibit enhanced effects on persons with hypothyroidism or cirrhosis.

### 4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Eye Exposure: If irritation or redness develops, move victim away from exposure and into fresh air. Flush eyes with clean water and seek medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

### 5. FIRE-FIGHTING MEASURES

Flash Point: Non-flammable      Autoignition Temperature: Not applicable

Flammable Limits (in air by volume, %): Lower: Not applicable    Upper: Not applicable

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK    Carbon Dioxide: OK    Halon: OK  
Foam: OK    Dry Chemical: OK    Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Methylprednisolone Acetate Injectable Suspension, USP

### 5. FIRE-FIGHTING MEASURES cont.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS:	Health:	1 (Slight)
	Flammability:	0 (Least)
	Reactivity:	0 (Least)

### 6. ACCIDENTAL RELEASE MEASURES

#### Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

### 7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from sources of ignition and any incompatible materials or conditions (see Section 10).

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Methylprednisolone Acetate Injectable Suspension, USP

### 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

### 9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	ND	Evaporation Rate (n-BuAc=1):	ND
Specific Gravity (water = 1):	~1	Melting/Freezing Point:	ND
Solubility in Water:	insoluble	Boiling Point:	ND
Vapor Pressure, mm Hg @ 25°C.	ND	pH:	3.5-7.0
Odor Threshold: Odorless			
Appearance and Color: White suspension			

ND = No Data

### 10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling. The recommended storage temperature is 20° – 25°C (68° – 77°F)

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility.

Hazardous Polymerization: Will not occur.

Hazardous Combustion Products: Carbon monoxide and carbon dioxide.

## Methylprednisolone Acetate Injectable Suspension, USP

### 11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Methylprednisolone Acetate

Oral LD50(rat) =10 g/kg

IP LD50(mouse) >1409 mg/kg

SubQ LD50(rat) =265 mg/kg

SubQ LD50(mouse) =1320 mg/kg

Suspected Cancer Agent: This product 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.

Target Organ(s): The active ingredient, Methylprednisolone Acetate, is a glucocorticoid. Glucocorticoids affect carbohydrate, protein and fat metabolism; functions of the cardiovascular system, kidney, skeletal muscle, nervous system and other organ and tissues. It may modify the body's immune response to diverse stimuli. Chronic overexposure to glucocorticoids may produce pituitary-adrenal suppression, Cushing's syndrome (redistribution of body fat to face, and back of the neck and trunk, causing "moon face"), increased susceptibility to infections with suppression of inflammatory response, osteoporosis, cataracts, glaucoma with possible damage to the optic nerve, mental symptoms, hyperglycemia and glycosuria.

Reproductive Toxicity Information: Listed below is information concerning the effects of Methylprednisolone Acetate on human and animal reproductive systems. This material is classified as a Pregnancy Category C: Risk cannot be ruled out.

Mutagenicity: Methylprednisolone Acetate was negative in the DNA damage/alkaline elution assay.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Corticosteroids are generally teratogenic in laboratory animals; there are no well-controlled studies in women. The safety of their use in pregnant women has not been absolutely established. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.



TEVA PARENTERAL MEDICINES

## Materials Safety Data Sheet

# Methylprednisolone Acetate Injectable Suspension, USP

### 12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Methylprednisolone Acetate on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Methylprednisolone Acetate on plants or animals in the aquatic environment.

### 13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None

### 14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable





TEVA PARENTERAL MEDICINES

## Materials Safety Data Sheet

# Methylprednisolone Acetate Injectable Suspension, USP

### 15. REGULATORY INFORMATION

#### U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Methylprednisolone Acetate is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):

**WARNING!** MAY CAUSE ALLERGIC REACTIONS. OVEREXPOSURE MAY CAUSE DAMAGE TO THE KIDNEYS, PITUITARY, CARDIVASCULAR, IMMUNE and NERVOUS SYSTEMS.

Methylprednisolone Acetate should be administered under the supervision of a qualified physician.

Avoid over-exposure. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Methylprednisolone Acetate. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

#### CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Methylprednisolone Acetate is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

### 16. OTHER INFORMATION

Issue Date: 1/23/09

Previous Issue Date: 11/27/00

The information in this document is believed to be correct as of the date issued. **HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THIS INFORMATION, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE.** This information and product are furnished on the condition that the person receiving them shall make his own determination as to the suitability of the product for his particular purpose and on the condition that he assume the risk of his use thereof.