



## MATERIAL SAFETY DATA SHEET

**Product Name: Methylprednisolone Sodium Succinate Injection**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hemofarm Group Beogradski put bb 26300 Vrsac Serbia and Montenegro Telephone:+381 13 803 100 Fax: +381 13 803 100 Contact person: Tanja Tomic Contact person telephone number: +381 13 803 272 Contact person fax number: +381 13 803 424 24 hour contact tel. number: +381 64 833 5071
--------------------------------------	--	--

<b>Emergency Telephone Hospira, Inc., Non-Emergency</b>	CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887 224 212-2055
---	--

<b>Product Name</b>	Methylprednisolone Sodium Succinate Injection, Powder, Lyophilized, For Solution
---------------------	--

<b>Synonyms</b>	Methylprednisolone Sodium Succinate HEMOFARM 40 mg Methylprednisolone Sodium Succinate HEMOFARM 125 mg A-Methapred; Pregna-1,4-diene-3,20-dione,21-(3-carboxy-1-oxo-propoxy)-11,17-dihydroxy-6-methyl-monosodium salt, (6 $\alpha$ , 11 $\beta$ ).
-----------------	--

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

<b>Active Ingredient Name</b>	Methylprednisolone Sodium Succinate
<b>Chemical Formula</b>	C <sub>26</sub> H <sub>33</sub> NaO <sub>8</sub>

Component	HEMOFARM 40 mg Approximate Percent by Weight	HEMOFARM 125 mg Approximate Percent by Weight	CAS Number	RTECS Number
Methylprednisolone Sodium Succinate	50(5.3)*	82(8.3)*	2375-03-3	TU4154060
Monobasic Sodium Phosphate, Anhydrous	1.5(0.16)*	0.8(0.08)*	7558-80-7	WA1900000
Dibasic Sodium Phosphate, Anhydrous	16.5(1.7)*	8.6(0.9)*	7558-79-4	WC4500000
Benzyl Alcohol	8.3(0.88)*	8.6(0.9)*	100-51-6	DN3150000

Non-hazardous ingredients include water for injection and lactose. Hazardous ingredients present at less than 1% include sodium hydroxide (which is added to adjust the pH).

\*Numbers in parentheses represent approximate weight percents after reconstitution in water for injection.

### 3. HAZARD INFORMATION

<b>Emergency Overview</b>	Methylprednisolone Sodium Succinate Injection, Powder, Lyophilized, For Solution is a two compartment vial containing water and methylprednisolone sodium succinate, an anti-inflammatory glucocorticoid. Methylprednisolone sodium succinate is a steroid that depresses the immune system and may cause elevated blood pressure and swelling. In the workplace, this material should be considered a potent drug, and possibly irritating to the eyes and respiratory system. Based on clinical use, possible target organs may include the gastrointestinal system, eyes, the nervous system, immune system, endocrine system, and the cardiovascular system.
---------------------------	--



**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 USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.

**Special Precautions** None required for hazard control. For product integrity, protect from freezing, light, and extreme heat.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Exposure limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Methylprednisolone Sodium Succinate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: 20 mcg/m <sup>3</sup>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL : Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.  
 STEL: 15-minute Short Term Exposure Limit.

**Respiratory Protection** Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, or respiratory protection is desired, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin Protection** If skin contact is likely, the use of latex or nitrile gloves is recommended.

**Eye Protection** Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls** Engineering controls are normally not needed during the normal use of this product.

**9. PHYSICAL/CHEMICAL PROPERTIES**

**Appearance/Physical State** White or nearly white odorless, hygroscopic amorphous solid and water.

**Odor** NA

**Odor Threshold:** NA

**pH:** 7.0 to 8.0 when reconstituted

**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 (Air =1)** NA

**9. PHYSICAL/CHEMICAL PROPERTIES:** continued

<b>Evaporation Rate</b>	NA
<b>Specific Gravity</b>	NA
<b>Solubility</b>	Very soluble in water and in alcohol; it is insoluble in chloroform and is very slightly soluble in acetone.
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature</b>	NA
<b>Decomposition temperature</b>	NA

**10. STABILITY AND REACTIVITY**

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to avoid</b>	Not determined
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and sodium oxides (NaOx).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

**11. TOXICOLOGICAL INFORMATION**

**Acute Toxicity**

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

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Route of Administration</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Methylprednisolone Sodium Succinate	100	LD50	Oral	>5,000	mg/kg mg/kg	Rat Mouse
Methylprednisolone Sodium Succinate	100	LD50	Intravenous	640 750	mg/kg mg/kg	Rat Mouse
Methylprednisolone Sodium Succinate	100	LD50	Intraperitoneal	640 880	mg/kg mg/kg	Rat Mouse

LD 50: Dosage that produces 50% mortality.

<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce redness and discomfort.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. However, allergic reactions have been reported during the clinical use of this product.

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Reproductive Effects</b>	As with other glucocorticoids, high doses of methylprednisolone have produced cleft palate in some animal species. Other animal experiments, as well as clinical observations, suggest that prenatal exposure to methyl-prednisolone may retard fetal growth, and be associated with an increased incidence of low birth weight among offspring.
<b>Mutagenicity</b>	Methylprednisolone sodium succinate was negative in an alkaline elution assay for DNA damage.
<b>Carcinogenicity</b>	Long-term studies to evaluate the carcinogenic potential have not been conducted.
<b>Target Organ Effects</b>	Based on clinical use, possible target organs may include muscle, the gastrointestinal system, eyes, the nervous system, immune system, endocrine system, and the cardiovascular system.

**12. ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity</b>	Not determined for product  LC50(96 hr) = 460 mg/L in Pimephales promelas for benzyl alcohol LC50 = 640 mg/L in Leuciscus idus for benzyl alcohol EC50(24 hr) = 400 mg/L in Daphnia magna for benzyl alcohol EC50 = 95 mg/L in Chlorella pyrenoidosa for benzyl alcohol
<b>Persistence/Biodegradability</b>	Not determined for product. Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

**13. DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	All waste materials must be properly characterized by the waste generator. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

**14. TRANSPORTATION INFORMATION**

<b>DOT STATUS:</b>	Not regulated
<b>Proper Shipping Name:</b>	NA
<b>Hazard Class:</b>	NA
<b>UN Number:</b>	NA
<b>Packing Group:</b>	NA
<b>Reportable Quantity:</b>	NA

**14. TRANSPORTATION INFORMATION: continued**

**ICAO/IATA STATUS** Not regulated  
**Proper Shipping Name:** NA  
**Hazard Class:** NA  
**UN Number:** NA  
**Packing Group:** NA  
**Reportable Quantity:** NA

**IMDG STATUS** Not regulated  
**Proper Shipping Name:** NA  
**Hazard Class:** NA  
**UN Number:** NA  
**Packing Group:** NA  
**Reportable Quantity:** NA

Notes: DOT - US Department of Transportation Regulations


**15. REGULATORY INFORMATION**

**U.S. TSCA Status** Exempt  
**U.S. CERCLA Status** Not listed  
**U.S. SARA 302 Status** Not listed  
**U.S. SARA 313 Status** Not listed  
**U.S. RCRA Status** Not listed  
**U.S. PROP 65 (Calif.)** Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

**U.S. OSHA Classification** Possible Irritant  
 Target Organ Toxin

**GHS Classification\*** \*In circumstances where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
<b>Hazard Category</b>	Not Classified	2B	2
<b>Symbol</b>	NA	NA	
<b>Signal Word</b>	NA	Warning	Warning
<b>Hazard Statement</b>	NA	Causes eye irritation	Based on clinical use, possible target organs may include muscle, the gastrointestinal system, eyes, the nervous system, immune system, endocrine system, and the cardiovascular system.
<b>Prevention:</b>	Wear protective gloves and eye/face protection Take precautionary measures against static discharge. Wash hands after handling.		
<b>Response:</b>	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.		

**15. REGULATORY INFORMATION: continued**

**EU Classification\***

\*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance methylprednisolone sodium succinate.

**Classification(s):** Irritant

**Symbol:**



**Indication of Danger** Xi

**Risk Phrases:** R36/37 - Irritating to eyes and respiratory system

**Safety Phrases:** S24: Avoid contact with the skin  
S25: Avoid contact with eyes  
S37/39 Wear suitable gloves and eye/face protection.

**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
LD <sub>50</sub>	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

MSDS Coordinator: Global Occupational Toxicology  
Date Prepared: September 15, 2005  
Dates Revised: October 21, 2009  
May 6, 2009

**Disclaimer:**

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.