MATERIAL SAFETY DATA SHEET

Product Name: Methylprednisolone Sodium Succinate Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	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
Emergency Telephone Hospira, Inc., Non-Emergency	CHEMTREC: North America: 800-424-9300; International: 1-703-527-3887 224 212-2055	
Product Name	Methylprednisolone Sodium Succinate Injection, Powder, Lyophilized, For Solution Methylprednisolone Sodium Succinate HEMOFARM 40 mg Methylprednisolone Sodium Succinate HEMOFARM 125 mg	
Synonyms	A-Methapred; Pregna-1,4-diene-3,20-dione,21-(3-carboxy-1-oxo-propoxy)-11,17-dihydroxy-6-methyl-monosodium salt, (6α, 11β).	

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Methylprednisolone Sodium Succinate
Chemical Formula $C_{26}H_{33}NaO_8$

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

Emergency Overview 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.

3. HAZARD INFORMATION: continued

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.
Signs and Symptoms	No signs or symptoms from occupational exposure are known. In clinical use, adverse effects include fluid and electrolyte disturbances, musculoskeletal weakness and myopathy, gastrointestinal disturbances (peptic ulcers), dermatologic reactions (allergic dermatitis), endocrine disturbances (adrenocortical suppression, suppression of growth in children), neurologic disturbances (vertigo, headache, psychosis), and ophthalmic disturbances (glaucoma, cataracts). Prolonged use of methylprednisolone sodium succinate may produce immune suppression, increasing the susceptibility to and masking the symptoms of infections. Prolonged use of methylprednisolone sodium succinate may result in a "withdrawal syndrome" characterized by fever, myalgia, and malaise.
Medical Conditions Aggravated by Exposure	Clinical data suggest glaucoma, peptic ulcer, hypertension, osteoporosis, myasthenia gravis, hyperthyroidism, pre-existing liver disease, and existing emotional instability or psychotic tendencies.
Carcinogen Lists:	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

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	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.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

5. FIRE FIGHTING MEASURES

Flammability	None anticipated for this product.
Fire & Explosion Hazard	None anticipated for this product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
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

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using techniques that minimize the creation of airborne dust. If the spill occurs after reconstitution, 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 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

	Exposure limits			
Component	**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/m3

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

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

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	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).
Hazardous Polymerization	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:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
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.

Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce redness and discomfort.
Dermal or Respiratory Sensitization	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

Reproductive Effects	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.
Mutagenicity	Methylprednisolone sodium succinate was negative in an alkaline elution assay for DNA damage.
Carcinogenicity	Long-term studies to evaluate the carcinogenic potential have not been conducted.
Target Organ Effects	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

Aquatic Toxicity	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
Persistence/Biodegradability	Not determined for product. Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORTATION INFORMATION

DOT STATUS:	Not regulated
Proper Shipping Name:	NA
Hazard Class:	NA
UN Number:	NA
Packing Group:	NA
Reportable Quantity:	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
Hazard Category	Not Classified	2B	2
Symbol	NA	NA	
Signal Word	NA	Warning	Warning
Hazard Statement	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.

Prevention: Wear protective gloves and eye/face protection
Take precautionary measures against static discharge.
Wash hands after handling.

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.

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_{50}	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
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