SAFETY DATA SHEETS

This SDS packet was issued with item:

078830296

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078427468 078695442 078904888

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078904887

MATERIAL SAFETY DATA SHEET

Product Name: Clindamycin Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira Inc. 275 North Field Drive Lake Forest, Illinois USA 60045
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880
Hospira, Inc., Non-Emergency	224-212-2000
Product Name	Clindamycin Injection, USP
Synonyms	Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans -4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo -α-D-galacto -octopyranoside 2-(dihydrogen phosphate).

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Clindamycin Phosphate
Chemical Formula	$C_{18}H_{34}ClN_2O_8PS$
Preparation	Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include disodium edetate and benzyl alcohol; sodium hydroxide and/or hydrochloric acid are added to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Clindamycin Phosphate	15	24729-96-2	GF2625000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Clindamycin Phosphate	Not Listed	Not Listed	Not Listed

Emergency Overview	Clindamycin Injection, USP is a solution containing clindamycin phosphate, a water soluble ester of the semi-synthetic antibiotic clindamycin. Clinically, it is intended for oral, parenteral, and topical use and indicated for the treatment of serious respiratory tract infections, pelvic inflammatory disease, bacterial vaginosis, hematogenous osteomycelitis and endocarditis. In the workplace, this material should be considered a potential sensitizer and potentially irritating to the skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the gastrointestinal system, blood, liver, kidneys, and skin.
Occupational Exposure Potential	Information on the absorption of this material via inhalation or skin contact is not available. During topical use of formulated gels, clindamycin may be absorbed through skin and mucus membranes.
Signs and Symptoms	None known from workplace exposures. In clinical use, systemic clindamycin has produced

	diarrhea in up to 20% of patients. Other gastrointestinal effects include nausea, vomiting, abdominal pain or cramps, and esophagitis; an unpleasant or metallic taste has occasionally been reported after high intravenous doses. Pseudomembranous colitis may also occur. Hypersensitivity reactions such as skin rashes and urticaria occur in up to 10% of patients. Other adverse effects include transient leucopenia or occasionally agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, and abnormalities of liver function tests with some cases overt jaundice and hepatic damage that have been reported. Renal dysfunction may occur rarely. Topical use has been associated with local irritation and contact dermatitis; clindamycin may be absorbed through the skin to produce systemic effects.
Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to clindamycin phosphate or related antibiotics; pre-existing skin, eye, liver, blood, or gastrointestinal ailments.

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 aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous 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. 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 for hazard control under conditions of normal use.
Storage	No special storage is 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. Persons with known hypersensitivity to clindamycin phosphate or related antibiotics should consult a health professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits				
Component	**Type**	**mg/m3**	**ppm**	**µg/m3**	**Note**
Clindamycin Phosphate	Not Applicable	N/A	N/A	N/A	None Established

Respiratory protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, 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 under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection If skin contact with this material is likely, the use of latex or nitrile gloves is recommended.

Eye protection Eye protection is normally not required during intended material 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 material.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Clear aqueous based solution
Odor	NA
Odor Threshold:	NA
pH:	6.5 (range 5.5 to 7.0)
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:	Clindamycin phosphate is very soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, ether, or benzene.
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), nitrogen oxides (NOx), oxides of phosphate and sulfur, and hydrogen chloride.

Hazardous Polymerization Not anticipated to occur with this material.

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
Clindamycin Phosphate	100	LD50	Oral	1832 2539	mg/kg mg/kg	Rat Mouse
Clindamycin Phosphate	100	LD50	Intravenous	321 820	mg/kg mg/kg	Rat Mouse

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation with redness and itching.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation with redness and pain.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions such as skin rashes and urticaria occur in up to 10% of patients.

Reproductive Effects Fertility studies in rats treated orally with up to 300 mg/kg/day revealed no effects on fertility or mating ability. Reproduction studies performed in rats and mice using oral doses of clindamycin up to 600 mg/kg/day or subcutaneous doses of clindamycin up to 250 mg/kg/day revealed no evidence of teratogenicity.

Mutagenicity Clindamycin was negative for genotoxicity in a rat micronucleus test and an Ames Salmonella reversion test.

Carcinogenicity	Long term studies in animals with clindamycin to evaluate carcinogenic potential have not been conducted.
Target Organ Effects	Based on clinical use, possible target organs include the gastrointestinal system, blood, liver, kidneys, and skin.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product
Persistence/Biodegradability	Not determined for product
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 of all pharmaceuticals 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

ADR/ADG/ DOT STATUS:	Not regulated
IMDG STATUS:	Not regulated
ICAO/IATA STATUS:	Not regulated
Transport Comments:	None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Clindamycin Phosphate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed

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

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class	Not Applicable
Hazard Category	Not Applicable
Signal Word	Not Applicable
Symbol	Not Applicable
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapours/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 Clindamycin Phosphate

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Classification(s):	Not Applicable
Symbol:	Not Applicable
Indication of Danger:	Not Applicable
Risk Phrases:	Not Applicable
Safety Phrases:	S23 - Do not breathe vapour. S24/25 - Avoid contact with skin and 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
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

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/09/2011
Obsolete Date: 10/21/2008

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SAFETY DATA SHEET

Material Name: Clindamycin Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Material Name	Clindamycin Injection, USP
Synonyms	Methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans -4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L-threo -α-D-galacto -octopyranoside 2-(dihydrogen phosphate).

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Clindamycin Injection, USP is a solution containing clindamycin phosphate, a water soluble ester of the semi-synthetic antibiotic clindamycin. Clinically, it is intended for oral, parenteral, and topical use and indicated for the treatment of serious respiratory tract infections, pelvic inflammatory disease, bacterial vaginosis, hematogenous osteomycelitis and endocarditis. In the workplace, this material should be considered irritating to the skin, eyes, and respiratory tract, and a potential sensitizer. Based on clinical use, possible target organs include the gastrointestinal system, blood, liver, kidneys, and skin.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage/Irritation	2
	Sensitization – Skin	1
	Sensitization – Respiratory	1
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word

Danger

Hazard Statement(s)

Causes eye irritation
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled
Many cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Do not breathe vapors/spray.
In case of inadequate ventilation, wear respiratory protection.
Wear protective gloves.
Contaminated work clothing must not be allowed out of the workplace.
Wash hands thoroughly after handling.

Response

Get medical attention if you feel unwell.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Clindamycin Phosphate
Chemical Formula $C_{18}H_{34}ClN_2O_8PS$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Clindamycin Phosphate	15	24729-96-2	GF2625000

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

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 aqueous product.

Fire & Explosion Hazard

None anticipated for this aqueous product.

Extinguishing Media

As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures

No special provisions required beyond normal firefighting 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 control 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 for hazard control under conditions of normal use.

Storage No special storage is 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. Persons with known hypersensitivity to clindamycin phosphate or related antibiotics should consult a health professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Clindamycin Phosphate	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: Not Established

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.

Respiratory Protection Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, 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 under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

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

Eye Protection Eye protection is normally not required during intended material 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 material.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear aqueous-based solution
Odor	NA
Odor Threshold	NA
pH	6.5 (range 5.5 to 7.0)
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Clindamycin phosphate is very soluble in water; slightly soluble in dehydrated alcohol; very slightly soluble in acetone; practically insoluble in chloroform, ether, or benzene
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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), nitrogen oxides (NOx), oxides of phosphate and sulfur, and hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this material.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity – Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Clindamycin Phosphate	100	LD50	Oral	1832 2539	mg/kg mg/kg	Rat Mouse
Clindamycin Phosphate	100	LD50	Intravenous	321 820	mg/kg mg/kg	Rat Mouse

LD 50: Dosage that produces 50% mortality.

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	Information on the absorption of this material via inhalation or skin contact is not available. During topical use of formulated gels, clindamycin may be absorbed through skin and mucus membranes.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, systemic clindamycin has produced diarrhea in up to 20% of patients. Other gastrointestinal effects include nausea, vomiting, abdominal pain or cramps, and esophagitis; an unpleasant or metallic taste has occasionally been reported after high intravenous doses. Pseudomembranous colitis may also occur. Hypersensitivity reactions such as skin rashes and urticaria occur in up to 10% of patients. Other adverse effects include transient leucopenia or occasionally agranulocytosis, eosinophilia, thrombocytopenia, polyarthritis, and abnormalities of liver function tests with some cases overt jaundice and hepatic damage that have been reported. Renal dysfunction may occur rarely. Topical use has been associated with local irritation and contact dermatitis; clindamycin may be absorbed through the skin to produce systemic effects.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation with redness and itching.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation with redness and pain.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. In clinical use, hypersensitivity reactions such as skin rashes and urticaria occur in up to 10% of patients.
Reproductive Effects	None anticipated from normal handling of this product. Fertility studies in rats treated orally with up to 300 mg/kg/day revealed no effects on fertility or mating ability. Reproduction studies performed in rats and mice using oral dosages of clindamycin up to 600 mg/kg/day or subcutaneous dosages of clindamycin up to 250 mg/kg/day revealed no evidence of teratogenicity.
Mutagenicity	Clindamycin was negative for genotoxicity in a rat micronucleus test and an Ames Salmonella reversion test.
Carcinogenicity	Long term studies in animals with clindamycin to evaluate carcinogenic potential have not been conducted.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the gastrointestinal system, blood, liver, kidneys, and skin.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product
Mobility in Soil	Not determined for product

Notes:

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. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
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

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US 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

15. REGULATORY INFORMATION: continued

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapors/spray.
In case of inadequate ventilation, wear respiratory protection.
Wear protective gloves.
Wash hands thoroughly after handling.
Contaminated work clothing must not be allowed out of the workplace.

Response

Get medical attention if you feel unwell.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) NA
Symbol NA
Indication of Danger NA
Risk Phrases R42/43: May cause sensitization by inhalation and skin contact
Safety Phrases S23: Do not breathe vapor/spray
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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 17, 2012
Date Revised: June 02, 2014

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