# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

078904890

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

078572713

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).

078904889 078905723



# MATERIAL SAFETY DATA SHEET

Product Name: LEVOPHED (norepinephrine bitartrate) Injection, USP

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And

Hospira Inc.

Address

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** 

LEVOPHED (norepinephrine bitartrate) Injection, USP

**Synonyms** 

Levarterenol bitartrate; (-)-α-(aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt) monohydrate; (-)-Norepinephrine bitartrate salt monohydrate; L-

Noradrenaline bitartrate monohydrate.

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** L-Norepinephrine Bitartrate Monohydrate

**Chemical Formula**  $C_8H_{11}NO_3 \bullet C_4H_6O_6 \bullet H_2O$ 

Preparation

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride and sodium metabisulfite.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
L-Norepinephrine Bitartrate Monohydrate	0.1	108341-18-0	NA

### 3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
L-Norepinephrine Bitartrate Monohydrate	Not Listed	Not Listed	Not Listed

**Emergency Overview** 

LEVOPHED (norepinephrine bitartrate) Injection, USP is a solution containing norepinephrine bitartrate, a vasoconstrictor agent, and sodium metabisulfite, a preservative. In the workplace, this material should be considered possibly irritating to the skin, eyes and respiratory tract. The metabisulfite preservative may induce allergic reactions in people sensitive to sulfites. Possible target organs include the nervous system, cardiovascular system, respiratory system, and skin.

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

None known from occupational exposure. This product contains sodium metabisulfite which may cause allergic-type reactions, including anaphylactic symptoms and/or life-threatening asthmatic episodes in susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown, but occurs more frequently in asthmatics than in non-asthmatics. In clinical use, adverse effects may include hypertension, bradycardia, restlessness,



palpitations, tremor, weakness, headache and elevated blood pressure. Overdosage can result in severe hypertension, bradycardia, increased peripheral resistance, decreased cardiac output and potentially fatal arrhythmias including ventricular tachycardia and fibrillation. Prolonged administration can result in depletion of plasma volume and electrolyte imbalance. Administration to pregnant women can cause fetal anoxia by provoking uterine contractions; therefore, the drug should not be used during pregnancy.

**Medical Conditions Aggravated by Exposure** 

Pre-existing hypersensitivity to sulfites or related materials; concurrent therapy with monoamine oxidase inhibitors or related drugs. Pre-existing nervous system, cardiovascular system, respiratory system, or skin 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 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 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

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.

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines** 

	Exposure limits				
Component	Type	mg/m3	ppm	μg/m3	Note
L-Norepinephrine Bitartrate Monohydrate	Hospira EEL	N/A	N/A	0.5	
L-Norepinephrine Bitartrate Monohydrate	Hospira STEL	N/A	N/A	5	

**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 the product formulation 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 Liquid

**Color** Clear, Colorless

Odor None
Odor Threshold: NA
pH: 3 - 4.5
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point
NA

Range:

Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or NA

**Explosive Limits:** 

Vapor Pressure:

NA
Vapor Density:

NA
Specific Gravity:

NA

**Solubility:** Norepinephrine is sparingly soluble in water, very slightly soluble in alcohol

and ether, and readily soluble in acids.

**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 nitrogen

oxides (NOx).

**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
1-Norepinephrine bitartrate	100	LD50	Intravenous	210	mcg/kg	Rat
1-Norepinephrine bitartrate	100	LD50	Intravenous	1.03	mg/kg	Mouse
1-Norepinephrine bitartrate	100	LD50	Intraperitoneal	26.8	mg/kg	Mouse
1-Norepinephrine	100	LD50	Oral	20	mg/kg	Rat
l-Norepinephrine	100	LD50	Intravenous	550 250	mcg/kg mcg/kg	Mouse Rabbit
l-Norepinephrine	100	LD50	Intraperitoneal	6	mcg/kg mg/kg	Rat Mouse
1-Norepinephrine	100	LD50	Subcutaneous	5	mg/kg	Mouse

**Aspiration Hazard** None anticipated from normal handling of this product.

**Dermal Irritation/Corrosion** None anticipated from normal handling of this product. However, inadvertent

contact with this product may be irritating to mucous membranes.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent

contact of this product with eyes may produce irritation.

**Dermal or Respiratory** 

Sensitization

None anticipated from normal handling of this product. However, this product contains sodium metabisulfite and may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes, in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown, but sulfite sensitivity occurs more frequently in asthmatic than in non-asthmatic people.

**Reproductive Effects**No studies have been conducted in animals with norepinephrine bitartrate.

However, administration to pregnant women can cause fetal anoxia by



provoking uterine contractions; therefore, the drug should not be used during

pregnancy.

Mutagenicity Studies to evaluate the genotoxic potential of norepinephrine bitartrate have

not been conducted.

Carcinogenicity Long-term studies in animals to evaluate the carcinogenic potential of

norepinephrine bitartrate have not been conducted.

Target Organ Effects

Based on clinical use, possible target organs include the nervous system,

cardiovascular system, respiratory system, or 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. 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

**IMDG STATUS:** Not regulated

ICAO/IATA STATUS: Not regulated

**Transport Comments:** None

### 15. REGULATORY INFORMATION

### **USA Regulations**

Substance	TSCA	CERCLA	SARA 302	SARA 313	PROP 65
	Status	Status	Status	Status	Status
L-Norepinephrine Bitartrate Monohydrate	Not Listed				

RCRA Status Not Listed

<u>U.S. OSHA</u> Target Organ Toxin Classification 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/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 L-Norepinephrine Bitartrate Monohydrate

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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 vapors.

S24 - Avoid contact with 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: Hospira GEHS

Date Prepared: 10/13/2011 Obsolete Date: 01/07/2008

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#### SAFETY DATA SHEET

Product Name: LEVOPHED (norepinephrine bitartrate) Injection, USP

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And

Hospira, Inc.

Address

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

**Product Name** 

LEVOPHED (norepinephrine bitartrate) Injection, USP

Synonyms

(-)-α-(aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt) monohydrate

# 2. HAZARD(S) IDENTIFICATION

Emergency Overview LEVOPHED (norepinephrine bitartrate) Injection, USP is a solution containing

norepinephrine bitartrate, a vasoconstrictor agent. Clinically, it is indicated for blood pressure control in certain acute hypotensive states. In the workplace, this material should be considered a potent drug, and possibly irritating to the skin, eyes and respiratory tract, and a possible sensitizer. Based on clinical use, possible target organs

include the nervous system, cardiovascular system, and respiratory system.

### **U.S. OSHA GHS Classification**

Physical Hazards Hazard Class Hazard Category

Not Classified Not Classified

Health Hazards Hazard Class Hazard Category

Not Classified Not Classified

Label Element(s)

Pictogram NA

Signal Word NA

Hazard Statement(s) NA

**Precautionary Statement(s)** 

**Prevention** Do not breathe vapor or spray

Wash hands thoroughly after handling

**Response** Get medical attention if you feel unwell

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.



## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name (-)-Norepinephrine bitartrate salt monohydrate

Chemical Formula C<sub>8</sub>H<sub>11</sub>NO<sub>3</sub> •C<sub>4</sub>H<sub>6</sub>O<sub>6</sub> •H<sub>2</sub>O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
L-Norepinephrine Bitartrate Monohydrate	0.1	108341-18-0	NA

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride and sodium metabisulfite.

### 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** 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

No special provisions required beyond normal firefighting equipment such as flame

applicable federal, state, or local regulations.

# 7. HANDLING AND STORAGE

Handling No special handling required for hazard control 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.



### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure Guidelines** 

Exposure Limits					
Component	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL	
Nagaria anhaira Ditartuata	8-hr TWA: Not	8-hr TWA: Not	8-hr TWA: Not	8 hr TWA: Not	
Norepinephrine Bitartrate	Established	Established	Established	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 the product formulation 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 Clear, colorless liquid.

Odor NA **Odor Threshold** NA рH 3 - 4.5Melting 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 NA Vapor Density (Air =1)

Solubility Norepinephrine is sparingly soluble in water, very slightly soluble in

alcohol and ether, and readily soluble in acids.

Partition Coefficient: n-octanol/water NA
Auto-ignition Temperature NA
Decomposition Temperature NA
Viscosity NA

**Relative Density** 



## 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 nitrogen oxides

(NOx).

**Hazardous Polymerization** Not anticipated to occur with this product.

### 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
l-Norepinephrine bitartrate	100	LD50	Intravenous	210	mcg/kg	Rat
l-Norepinephrine bitartrate	100	LD50	Intravenous	1.03	mg/kg	Mouse
l-Norepinephrine bitartrate	100	LD50	Intraperitoneal	26.8	mg/kg	Mouse
1-Norepinephrine	100	LD50	Oral	20	mg/kg	Rat
1-Norepinephrine	100	LD50	Intravenous	550 250 100	mcg/kg mcg/kg mcg/kg	Mouse Rabbit Rat
1-Norepinephrine	100	LD50	Intraperitoneal	6	mg/kg	Mouse
1-Norepinephrine	100	LD50	Subcutaneous	5	mg/kg	Mouse

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential

Some literature reports indicate that norepinephrine may be absorbed by inhalation. Information on the absorption of this product via skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

None anticipated from normal handling of this product. In clinical use, adverse effects may include hypertension, bradycardia, restlessness, palpitations, tremor, weakness, headache and elevated blood pressure. Overdosage can result in severe hypertension, bradycardia, increased peripheral resistance, decreased cardiac output and potentially fatal arrhythmias including ventricular tachycardia and fibrillation. Prolonged administration can result in depletion of plasma volume and electrolyte imbalance. Administration to pregnant women can cause fetal anoxia by provoking uterine contractions; therefore, the drug should not be used during pregnancy.

**Aspiration Hazard** None anticipated from normal handling of this product.

**Dermal Irritation/ Corrosion** None anticipated from normal handling of this product. However, inadvertent contact

with this product may be irritating to mucous membranes.

Ocular Irritation/ Corrosion None anticipated from normal handling of this product. However, inadvertent contact

of this product with eyes may produce irritation.

Dermal or Respiratory

Sensitization

None anticipated from normal handling of this product. However, this product contains sodium metabisulfite and may cause allergic-type reactions, in persons

sensitive to sulfites.



# 11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects None anticipated from normal handling of this product. Animal reproduction studies

have not been conducted with norepinephrine bitartrate. However, administration to pregnant women can cause fetal anoxia by provoking uterine contractions; therefore,

the drug should not be used during pregnancy.

**Mutagenicity** The genotoxic potential of norepinephrine bitartrate has not been evaluated.

Carcinogenicity Long-term studies in animals to evaluate the carcinogenic potential of norepinephrine

bitartrate have not been conducted.

Carcinogen Lists IARC: Not listed NTP: Not listed OSHA: Not listed

**Specific Target Organ Toxicity** 

- Single Exposure

Specific Target Organ Toxicity Based on clinical use, possible target organs include the nervous system, cardio-

- **Repeat Exposure** vascular system, and respiratory system.

NA

# 12. ECOLOGICAL INFORMATION

Aquatic ToxicityNot determined for product.Persistence/BiodegradabilityNot 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
Hazard Class
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

# **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 vapor wash hands thorough						
Response	Get medical attention if you feel unwell						
	IF IN EYES: Rinse ca if present and easy to attention.	•		. Remove contact lenses, persists, get medical			
EU Classification*	*Medicinal products a Preparations Directive		e requirements of the	EU Dangerous			
Classification(s) Symbol	NA NA						

Classific **Symbol Indication of Danger** NA **Risk Phrases** 

**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<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

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

MSDS Coordinator: Hospira GEHS
Date Prepared: October 18, 2012
Date Revised: June 02, 2014

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