MATERIAL SAFETY DATA SHEET

Product Name: Sodium Chloride Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Note:	Hospira, formerly the Hospital Products Division of Abbott Laboratories, was created as an independent company in May 2004.
Emergency Telephone Hospira, Inc.	CHEMTREC: 800 424-9300 224 212-2055
Product Name	Sodium Chloride
Synonyms	None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Sodium Chloride
Chemical Formula NaCl

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Sodium Chloride	1-24	7647-14-5	VZ4725000
Water	76-99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview	In clinical use, this material is used to replace sodium. Possible target organs include the eyes.
Occupational Exposure Potential	Information on the absorption of this compound via ingestion, 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. Clinical data suggest the following: electrolytes imbalance, gastrointestinal upset, increased blood pressure.
Medical Conditions Aggravated by Exposure	Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: cardiovascular system and gastrointestinal system.

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: Non-flammable

Fire & Explosion Hazard: None

Extinguishing Media: 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 Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required.

Storage No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).

Special Precautions Protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**
Sodium Chloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established STEL: 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.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless solution
Odor	Not Determined
Boiling Point	Not Determined
Freezing Point	Not Determined
Vapor Pressure	Not Determined
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	1.151 gm/cm3 at 25 °C for 23.4%
Specific Gravity	1.0971 gm/mL at 25 °C for 14.6%
Solubility	Water
pH	4.5 – 7.0

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	None
Hazardous Decomposition Products	Toxic fumes of Cl and Na2O.
Hazardous Polymerization	Not Determined.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Sodium Chloride	100	LD50	4000	mg/kg	Rats, Mice, Rabbits

LD50: Dosage needed to produce 50% mortality.
Product contains between approximately 1-24% Sodium Chloride.

Acute Toxicity – Dermal:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Sodium Chloride	100	LD50(sc)	10,000	mg/kg	Rabbits

LD50 (sc) is the value for skin contact

Acute Toxicity – Inhalation:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Sodium Chloride	100	LC50	42	mg/L	Rats

LC50 is the concentration in air that produces 50% mortality.

Mutagenicity	Not Determined
Target Organ Effects	In clinical use target organ effects include parasympathetic nervous system, the cardiovascular system, gastrointestinal tract.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity	Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	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	Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Sodium Chloride is listed on the TSCA inventory
CERCLA Status	Not Regulated
SARA Status	Not Regulated
RCRA Status	Not Regulated
PROP 65 (Calif.)	Not Regulated

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

16. OTHER INFORMATION:

MSDS Coordinator	T. Straits MPH, CIH
Date Prepared	September 15, 2005

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MATERIAL SAFETY DATA SHEET

Product Name: **Lidocaine Hydrochloride and Epinephrine Injection, USP**

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880
Hospira, Inc., Non-Emergency	224 212-2055
Product Name	Lidocaine Hydrochloride and Epinephrine Injection, USP
Synonyms	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride; (-)-3,4-Dihydroxy-a-[(methylamino) methyl] benzyl alcohol

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Lidocaine Hydrochloride	Epinephrine
Chemical Formula	$C_{14}H_{22}N_2O \bullet HCl$	$C_9H_{13}NO_3$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Lidocaine Hydrochloride	≤ 2.0%	73-78-9	AN7600000
Epinephrine	≤ 0.002	51-43-4	DO2625000

Non-hazardous ingredients include water and sodium chloride. Hazardous ingredients present at less than 1% include sodium hydroxide and/or hydrochloric acid (used to adjust the pH), citric acid, and sodium metabisulfite.

3. HAZARD INFORMATION

Emergency Overview

Lidocaine hydrochloride and Epinephrine Injection, USP, contains lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management, and epinephrine, a vasoconstrictor agent. In the workplace, this material should be considered possibly irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Published reports have indicated that similar local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal, edema), tachycardia, sneezing, nausea,

3. HAZARD INFORMATION: continued

Signs and Symptoms: continued	vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.
Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to lidocaine or related amide-type anesthetics. Pre-existing nervous system or cardiovascular ailments.
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 from this aqueous product.
Fire & Explosion Hazard	None anticipated from 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 any 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	No special precautions are required for hazard controls.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**
Lidocaine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 500 mcg/m3 STEL: 5 mg/m3
Epinephrine	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 1 mcg/m3 STEL: 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.
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 or vapors 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	Not determined.
Odor Threshold:	NA
pH:	The pH of a 2% solution is between 3.3 and 5.5..
Melting point/Freezing point:	Approximately that of water (0 °C, 32 °F).
Initial Boiling Point/Boiling Point Range	Approximately that of water (100 °C, 212 °F).
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure	Approximately that of water (17.5 mm Hg at 20 °C).
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Specific Gravity	Approximately that of water (1.0).
Solubility	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.
Log 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 Strongly alkaline conditions. Methyl vinyl ether; zinc.

Hazardous Decomposition Products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides and nitrogen oxides (NOx), and hydrogen chloride.

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
Lidocaine Hydrochloride	100	LD50	Oral	220 292	mg/kg mg/kg	Mouse
Lidocaine Hydrochloride	100	LD50	Intraperitoneal	122 63	mg/kg mg/kg	Rat Mouse
Lidocaine Hydrochloride	100	LD50	Intravenous	21 15 25.6 24.5	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Guinea Pig
Lidocaine Hydrochloride	100	LD50	Intratracheal	28	mg/kg	Rabbit
L-Epinephrine	100	LD50	Intravenous	150 217	mcg/kg mcg/kg	Rat Mouse
L-Epinephrine	100	LD50	Dermal	62	mg/kg	Rat
Epinephrine Hydrochloride	100	LD50	Oral	90	mg/kg	Mouse
Epinephrine Hydrochloride	100	LD50	Intravenous	70	mcg/kg	Rat
Epinephrine Hydrochloride	100	LD50	Intraperitoneal	1.25 7.8	mg/kg mg/kg	Rat Mouse
L-Epinephrine Hydrochloride	100	LD50	Oral	24	mg/kg	Rat

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. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.

11. TOXICOLOGICAL INFORMATION: continued

Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of lidocaine.
Reproductive Effects	In a fertility study in rats, lidocaine given subcutaneously at a dosage of 30 mg/kg (180 mg/m2) to mating pairs did not produce alterations in fertility or general reproductive performance of rats. Subcutaneous administration of lidocaine to pregnant rats at a dosage of to 50 mg/kg did not produce evidence of harm to the fetus. In rabbits, there was no evidence of harm to the fetus at a subcutaneous dosage of 5 mg/kg. Treatment of rabbits with a subcutaneous dosage of 25 mg/kg produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight and an increase in minor skeletal anomalies. The effect of lidocaine on post-natal development was evaluated in rats by treating pregnant female rats daily subcutaneously at dosages of 2, 10, and 50 mg/kg from day 15 of pregnancy and up to 20 days post partum. No signs of adverse effects were seen either in dams or in the pups up to and including the dose of 10 mg/kg; however, the number of surviving pups was reduced at 50 mg/kg, both at birth and the duration of lactation period; this effect is most likely secondary to maternal toxicity. A second study evaluated the effects of lidocaine on post-natal development in the rat that included assessment of the pups from weaning to sexual maturity. Rats were treated subcutaneously for 8 months with 10 or 30 mg/kg lidocaine, a treatment duration that included 3 mating periods. There was no evidence of altered post-natal development in any offspring; however, both doses of lidocaine significantly reduced the average number of pups per litter surviving until weaning of offspring from the first 2 mating periods.
Mutagenicity	The mutagenic potential of lidocaine was evaluated in the Ames Salmonella reverse mutation assay, an *in vitro* chromosome aberrations assay in human lymphocytes and in an *in vivo* mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.
Carcinogenicity	Long-term studies in animals to evaluate the carcinogenic potential of most local anesthetics, including lidocaine, have not been conducted.
Target Organ Effects	Based on clinical use, possible target organs include the nervous system and the cardiovascular system.

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	Epinephrine is listed as a hazardous waste. However, it is not the sole active ingredient in this product. All wastes must be properly characterized by the waste generator. 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
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

TSCA Status	This product is exempt. However, lidocaine hydrochloride is listed on the TSCA inventory.
CERCLA Status	Epinephrine - Listed
SARA 302 Status	Not listed
SARA 313 Status	Not listed
RCRA Status	Epinephrine - Listed
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

U.S. OSHA Classification Possible Irritant
Target Organ Toxin

GHS Classification *Where medicinal products are not exempt, the recommended GHS workplace classification for this product is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	Unclassified	2B	2
Symbol	NA	NA	
Signal Word	NA	Warning	Warning
Hazard Statement	NA	Causes eye irritation	May cause damage to the nervous system and cardiovascular system through prolonged or repeated exposure.

Prevention: Do not breathe vapor or spray.

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 Classifications*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance lidocaine hydrochloride.

Classification(s):	Harmful	Irritant
Symbol:		
Indication of Danger	Xn	Xi

Risk Phrases: R22 – Harmful if swallowed
R36/37 - Irritating to eyes and respiratory system

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
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator:	Global Occupational Toxicology
Date Prepared:	November 16, 2007
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Date Revised:	December 30, 2009

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