Hospira

MATERIAL SAFETY DATA SHEET

Product Name: Lidocaine Hydrochloride Injection, USP, 1% & 2%

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone Hospira, Inc.	CHEMTREC: 800-424-9300 224 212-2055
Product Name	**Lidocaine Hydrochloride Injection, USP, 1% & 2%**
Synonyms	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

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

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Lidocaine Hydrochloride	$\leq 2.0\%$	73-78-9	AN7600000

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

3. HAZARD INFORMATION

Emergency Overview

Lidocaine Hydrochloride Injection, USP, 1% or 2%, contains lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management. In the workplace, this product 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

3. HAZARD INFORMATION: continued

Signs and Symptoms: continued	edema), tachycardia, sneezing nausea, 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	Non-flammable
Fire & Explosion Hazard	None
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, store at 20 to 25°C (68 to 77°F). See USP Controlled Room Temperature. Protect from light.
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

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 is likely and engineering controls are not adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (P100) is recommended. 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:	Between 5.0 and 7.0
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 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

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.
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.

11. TOXICOLOGICAL INFORMATION: continued

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	If discarded as produced, this product is not a RCRA "listed" or "characteristic" hazardous waste. However, uses resulting in a chemical or physical change of the product or contamination of the product with other materials may subject it to regulation as a hazardous waste. 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

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	Not listed
SARA 302 Status	Not listed
SARA 313 Status	Not listed
RCRA Status	Not 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

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	Unclassified	2B	2
Symbol			
Signal Word		Warning	Warning
Hazard Statement		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: February 22, 2008

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Hospira

MATERIAL SAFETY DATA SHEET

Product Name: Lidocaine Hydrochloride 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 Hospira, Inc.	CHEMTREC: 800 424-9300 224 212-2055
Product Name	Lidocaine Hydrochloride Injection/Topical Solution, USP
Synonyms	None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	Lidocaine Hydrochloride
Chemical Formula	$C_{14}H_{23}ClN_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Lidocaine Hydrochloride	0.05 – 0.5	73-78-9	AN7600000
Water	99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview	In clinical use, this material is used to numb body tissues. Lidocaine is toxic by ingestion and besides its numbing effects, can affect the central nervous system, respiratory system, and cardiovascular system.
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: numbness, lightheadedness, transient deafness, drowsiness, dizziness, restlessness, breathing difficulty, anxiety, vomiting, tremor, stupor, convulsions, respiratory distress, decreased blood pressure, slow heart rate.
Medical Conditions Aggravated by Exposure	Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: eyes, central nervous system, cardiovascular 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**
Lidocaine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 500 mcg/m3 STEL: 5 mg/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 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 liquid
Odor	Not Applicable
Boiling Point	Approximately that of water (100 °C, 212 °F).
Freezing Point	Approximately that of water (0 °C, 32 °F).
Vapor Pressure	Not Applicable
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Determined
Specific Gravity	Approximately that of water (1.0)
Solubility	Aqueous solution
pH	3.0 – 7.0

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	Not Determined
Hazardous Decomposition Products	Toxic fumes of nitrogen oxides and HCl
Hazardous Polymerization	Not Determined.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Lidocaine Hydrochloride	100	LD50	317 220	mg/kg	Rats Mice

LD50 is the dosage producing 50% mortality.
Product contains between approximately 0.05 – 0.5% Lidocaine Hydrochloride.

Mutagenicity	Not Determined
Target Organ Effects	In clinical use target organ effects include central nervous system, cardiovascular system.

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	Not Regulated
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	Global Occupational Toxicology
Date Prepared	September 15, 2005
Date Revised	October 21, 2008

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Hospira

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
Date Revised:	February 22, 2008
Date Revised:	December 30, 2009

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Safety Data Sheet

According to EC Directive 91/155/EEC

Date of issue: 01.04.2005
Supersedes edition of 28.10.2003

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product

Catalogue No.: 106400

Product name: Sodium chloride EMPROVE® Ph Eur,BP,USP

Use of the substance/preparation

Pharmaceutical production and analysis

Company/undertaking identification

Company: Merck KGaA * 64271 Darmstadt * Germany * Phone: +49 6151 72-0

Emergency telephone No.: Please contact the regional Merck representation in your country.

2. Composition/information on ingredients

CAS-No.: 7647-14-5

M: 58.44 g/mol EC-No.: 231-598-3

Formula Hill: ClNa

Chemical formula: NaCl

3. Hazards identification

No hazardous product as specified in Directive 67/548/EEC.

4. First aid measures

After inhalation: fresh air.
After skin contact: wash off with plenty of water. Remove contaminated clothing.
After eye contact: rinse out with plenty of water with the eyelid held wide open.
After swallowing: make victim drink plenty of water. Consult doctor if feeling unwell.

5. Fire-fighting measures

Suitable extinguishing media:
In adaption to materials stored in the immediate neighbourhood.

Special risks:
Non-combustible.

Other information:
Prevent fire-fighting water from entering surface water or groundwater.

6. Accidental release measures

Person-related precautionary measures:
Avoid generation of dusts; do not inhale dusts.

Environmental-protection measures:
Do not allow to enter sewerage system.

Procedures for cleaning / absorption:
Take up dry. Forward for disposal. Clean up affected area.

7. Handling and storage

Handling:

Store protected from solvents.

Storage:

Tightly closed. Dry. Storage temperature: no restrictions.

8. Exposure controls/personal protection

Personal protective equipment:

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

Respiratory protection: required when dusts are generated.

Eye protection: required

Hand protection:

In full contact:

Glove material:	nitrile rubber
Layer thickness:	0.11 mm
Breakthrough time:	> 480 Min.

In splash contact:

Glove material:	nitrile rubber
Layer thickness:	0.11 mm
Breakthrough time:	> 480 Min.

The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN374, for example KCL 741 Dermatril® L (full contact), 741 Dermatril® L (splash contact). The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.
This recommendation applies only to the product stated in the safety data sheet and supplied by us as well as to the purpose specified by us. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Industrial hygiene:
Change contaminated clothing. Wash hands after working with substance.

9. Physical and chemical properties

Form:		solid		
Colour:		colourless		
Odour:		odourless		
pH value at 100 g/l H_2O		(20 °C)	4.5-7.0	
Melting point			801	°C
Boiling point		(1013 hPa)	1461	°C
Ignition temperature			not applicable	
Flash point			not applicable	
Explosion limits	lower		not available	
	upper		not available	
Vapour pressure		(865 °C)	1.3	hPa
Density		(20 °C)	2.17	g/cm^3
Bulk density			~ 1140	kg/m^3
Solubility in water		(20 °C)	358	g/l

10. Stability and reactivity

Conditions to be avoided
no information available

Substances to be avoided

alkali metals.

Hazardous decomposition products
no information available

11. Toxicological information

Acute toxicity

LD_{50} (dermal, rabbit): >10000 mg/kg (RTECS).
LD_{50} (oral, rat): 3000 mg/kg (RTECS).

Specific symptoms in animal studies:
Eye irritation test (rabbit): Slight irritations (IUCLID).

Subacute to chronic toxicity

Noncarcinogenic in animal experiments.
No mutagenic effect in animal experiments.
Mutagenicity (mammal cell test): micronucleus nagative. (IUCLID)
Bacterial mutagenicity: Ames test: negative. (IUCLID)
No impairment of reproductive performance suspected.
No teratogenic effect in animal experiments.

Further toxicological information

After eye contact: Slight irritations.
After swallowing of large amounts: nausea, vomiting.

Further data

No toxic effects are to be expected when the product is handled appropriately.

12. Ecological information

Biologic degradation:
Methods for the determination of biodegradability are not applicable to inorganic substances.

Behavior in environmental compartments:
Concentration in organisms is not to be expected.

Ecotoxic effects:
Biological effects:
Fish toxicity: P.promelas LC_{50}: 7650 mg/l /96 h (IUCLID).
Daphnia toxicity: Daphnia magna EC_{50}: 1000 mg/l /48 h (IUCLID).

Further ecologic data:
No ecological problems are to be expected when the product is handled and used with due care and attention.

13. Disposal considerations

Product:

Chemicals must be disposed of in compliance with the respective national regulations. Under www.retrologistik.de you will find country- and substance-specific information as well as contact partners.

Packaging:

Merck product packaging must be disposed of in compliance with the country-specific regulations or must be passed to a packaging return system. Under www.retrologistik.de you will find special information on the respective national conditions as well as contact partners.

14. Transport information

Not subject to transport regulations.

15. Regulatory information

Labelling according to EC Directives

Symbol: ---
R-phrases: ---
S-phrases: ---

16. Other information

Catalogue No.: 106400
Product name: Sodium chloride EMPROVE® Ph Eur,BP,USP

Reason for alteration

Chapter 1:change in product name.

General update.

Regional representation:

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.