

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product Identifier**Product name : ChloroPrep[®] Solutions**1.2. Relevant identified uses of the substance or mixture and uses advised against**

Use of the substance/mixture : Antimicrobial

1.3. Details of the supplier of the safety data sheetCareFusion
75 N. Fairway Drive
Vernon Hills, IL 60061
T 800-523-0502 - F 855-329-6985**1.4. Emergency telephone number**

Emergency number : Chemtrec 1 800 424 9300

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****GHS-US classification**Flam. Liq. 2 H225
Eye Irrit. 2A H319
STOT SE 3 H336
STOT SE 3 H335**2.2. Label elements****GHS-US labelling**

Hazard pictograms (GHS-US) :



GHS02



GHS07

Signal word (GHS-US) :

: Danger

Hazard statements (GHS-US) :

: H225 - Highly flammable liquid and vapor
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H336 - May cause drowsiness or dizziness

Precautionary statements (GHS-US) :

: P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/... equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash ... thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P312 - Call a POISON CENTER/doctor/physician if you feel unwell
P337+P313 - If eye irritation persists: Get medical advice/attention
P370+P378 - In case of fire: Use ... for extinction
P403+P233 - Store in a well-ventilated place. Keep container tightly closed
P403+P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up
P501 - Dispose of contents/container to ...

ChloraPrep® Solutions

Safety Data Sheet

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

ChloraPrep® Clear

Name	Product Identifier	%	GHS-US classification
Isopropyl alcohol	(CAS No) 67-63-0	70	Flam. Liq. 2, H225
Chlorhexidine digluconate	(CAS No) 18472-51-0	2	Acute Tox. 4 (Oral), H302

ChloraPrep® Teal Green

Name	Product Identifier	%	GHS-US classification
Isopropyl alcohol	(CAS No) 67-63-0	70	Flam. Liq. 2, H225
Chlorhexidine digluconate	(CAS No) 18472-51-0	2	Acute Tox. 4 (Oral), H302
C.I. Food Green 3	(CAS No) 2353-45-9	0 - 0.1	Muta. 2, H341

ChloraPrep® Hi-Lite Orange

Name	Product Identifier	%	GHS-US classification
Isopropyl alcohol	(CAS No) 67-63-0	70	Flam. Liq. 2, H225
Chlorhexidine digluconate	(CAS No) 18472-51-0	2	Acute Tox. 4 (Oral), H302
FD and C Yellow No. 6	(CAS No) 2783-94-0	0 - 0.1	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: If symptoms of exposure develop, move to fresh air. Seek medical attention if symptoms persist.
First-aid measures after skin contact	: Wash material off the skin with copious amounts of water. If redness or a burning sensation develops, seek medical attention and discontinue use.
First-aid measures after eye contact	: Flush with copious amounts of water. After initial flushing remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and treated by medical personnel immediately.
First-aid measures after ingestion	: Give individual one to two glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person).

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: Inhalation of vapors may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness and drowsiness.
Symptoms/injuries after skin contact	: May cause irritation, drying, defatting of the skin. Prolonged contact may cause dermatitis.
Symptoms/injuries after eye contact	: Contact may cause severe irritation with redness, tearing and pain with possible eye damage.
Symptoms/injuries after ingestion	: Ingestion may cause mucous membrane and gastrointestinal irritation, abdominal pain, nausea, vomiting, dizziness and drowsiness.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water fog, alcohol-resistant foam, carbon dioxide or dry chemical. Water spray can be used to cool exposed containers and structures, dilute spills and disperse flammable vapors.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Highly flammable liquid and vapor. Ampoules may explode if exposed to extreme heat or flame. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back.
Explosion hazard	: None known.

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Safety Data Sheet

5.3. Advice for firefighters

Protection during firefighting : Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Wear skin, eye and respiratory protection during cleanup. For small spills, wipe or mop up and rinse to sewer serviced by a wastewater treatment facility. For large spills, eliminate sources of ignition and ventilate spill area. Soak up liquid with inert absorbent and collect into a suitable waste container. Wash residue from spill area with water and flush to sewer serviced by a wastewater treatment facility if permitted.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged exposure (ingestion, inhalation, or skin contact). Avoid breathing vapors. Use in well-ventilated areas. Keep product away from heat, sparks and flames.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a cool, dry, well-ventilated area away from incompatible chemicals and all sources of ignition.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Isopropyl alcohol (67-63-0)		
USA ACGIH	ACGIH TWA (ppm)	200 ppm
USA ACGIH	ACGIH STEL (ppm)	400 ppm
USA OSHA	OSHA PEL (TWA) (mg/m³)	980 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	400 ppm

8.2. Exposure controls

Appropriate engineering controls : Use with adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. Use explosion proof equipment where required.

Hand protection : Latex rubber for limited contact. Butyl rubber or nitrile recommended for prolonged contact.

Eye protection : Safety glasses or goggles recommended if eye contact is possible.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : If the exposure limits are exceeded a NIOSH/EN approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Appearance : Clear in product; when activated, clear orange, teal

ChloraPrep® Solutions

Safety Data Sheet

Color	: Clear, orange, or teal
Odor	: Odorless
Odor threshold	: No data available
pH	: 7 - 7.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 67 °F
Self ignition temperature	: 2 - 12.7
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Specific gravity	: 0.88
Solubility	: Water: Complete
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosive limits	: No data available

9.2. Other Information

VOC content : 100 %

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Extreme heat, sparks or flame.

10.5. Incompatible materials

Oxidizing materials

10.6. Hazardous decomposition products

Carbon dioxide, carbon monoxide, nitrogen oxides, ammonia, chlorine compounds.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Isopropyl alcohol (67-63-0)	
LD50 oral rat	4396 mg/kg
LD50 dermal rabbit	12800 mg/kg
LC50 inhalation rat (ppm)	16000 ppm (Exposure time: 8 h)

Chlorhexidine digluconate (18472-51-0)	
ATE (oral)	500.000 mg/kg

Skin corrosion/irritation : Not classified

ChloraPrep® Solutions

Safety Data Sheet

Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Isopropyl alcohol (67-63-0)	
IARC group	3 - Not classifiable

C.I. Food Green 3 (2353-45-9)	
IARC group	3 - Not classifiable

FD and C Yellow No. 6 (2783-94-0)	
IARC group	3 - Not classifiable

Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: May cause drowsiness or dizziness. May cause respiratory irritation.
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Isopropyl alcohol (67-63-0)	
LC50 fishes 1	9640 mg/l (Exposure time: 96 h - Species: Pimephales promelas (flow-through))
EC50 Daphnia 1	13299 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	> 1000 mg/l (Exposure time: 96 h - Species: Desmodesmus subspicatus)
LC50 fish 2	11130 mg/l (Exposure time: 96 h - Species: Pimephales promelas (static))
EC50 other aquatic organisms 2	> 1000 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Isopropyl alcohol (67-63-0)	
Log Pow	0.05 (at 25 °C)

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT

Transport document description	: UN1219 Isopropanol Solution, 3, II
UN-No.(DOT)	: 1219
DOT NA no.	: UN1219
DOT Proper Shipping Name	: Isopropanol Solution
Department of Transportation (DOT) Hazard Classes	: 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

ChloraPrep® Solutions

Safety Data Sheet

Hazard labels (DOT) : 3 - Flammable liquid



Packing group (DOT) : II - Medium Danger
 DOT Special Provisions (49 CFR 172.102) : IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized.
 T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3)
 TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = $97 / (1 + a (t_r - t_f))$ Where: t_r is the maximum mean bulk temperature during transport, and t_f is the temperature in degrees celsius of the liquid during filling.
 DOT Packaging Exceptions (49 CFR 173.xxx) : 4b;150
 DOT Packaging Non Bulk (49 CFR 173.xxx) : 202
 DOT Packaging Bulk (49 CFR 173.xxx) : 242
 DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 5 L
 DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 60 L
 DOT Vessel Stowage Location : B - (i) The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel carrying a number of passengers limited to not more than the larger of 25 passengers, or one passenger per each 3 m of overall vessel length; and (ii) "On deck only" on passenger vessels in which the number of passengers specified in paragraph (k)(2)(i) of this section is exceeded.

SECTION 15: Regulatory information

15.1. US Federal regulations

Isopropyl alcohol (67-63-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on SARA Section 313 (Specific toxic chemical listings)

EPA TSCA Regulatory Flag : T - T - indicates a substance that is the subject of a Section 4 test rule under TSCA.

SARA Section 313 - Emission Reporting : 1.0 % (only if manufactured by the strong acid process, no supplier notification)

C.I. Food Green 3 (2353-45-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Chlorhexidine digluconate (18472-51-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

FD and C Yellow No. 6 (2783-94-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Isopropyl alcohol (67-63-0)

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Flam. Liq. 2	Flammable liquids, Category 2
Muta. 2	Germ cell mutagenicity, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Narcosis

ChloroPrep[®] Solutions

Safety Data Sheet

STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapor
H302	Harmful if swallowed
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H341	Suspected of causing genetic defects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product



SAFETY DATA SHEET

Product Name: Lidocaine Hydrochloride Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Lidocaine Hydrochloride Injection
Synonyms	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxydide, 2-(diethylamino)-, hydrochloride

2. HAZARD(S) IDENTIFICATION

Emergency Overview	Lidocaine Hydrochloride Injection is a solution containing lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management. In the workplace, this product should be considered potentially irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.
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U.S. OSHA GHS Classification

Physical Hazards	Hazard Class	Hazard Category
	Not Classified	Not Classified
Health Hazards	Hazard Class	Hazard Category
	STOT – RE	2

Label Element(s)

Pictogram



Signal Word

Warning

Hazard Statement(s)

May cause damage to organs through prolonged or repeated exposures

**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.

Product Name: Lidocaine Hydrochloride Injection**3. COMPOSITION/INFORMATION ON INGREDIENTS**

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

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Lidocaine Hydrochloride	≤ 5.0%	73-78-9	AN7600000

Non-hazardous ingredients include Water for Injection; some preparation may contain up to 7.5% dextrose. Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are used to adjust the pH. Multiple-dose vials contain 0.1% of methylparaben added as a preservative.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.
Special Fire Fighting Procedures	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb 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.
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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 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

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Lidocaine Hydrochloride	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
 AIHA WEEL: Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit
 TWA: 8 hour Time Weighted Average.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection

If skin contact with 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
pH	Between 5.0 and 7.0
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	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 (COx), 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 active ingredient 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.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Published reports suggest that some local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. 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, 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.

Product Name: Lidocaine Hydrochloride Injection



11. TOXICOLOGICAL INFORMATION: continued

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. Rarely, allergic-type reactions have been reported during the clinical use of lidocaine.
Reproductive Effects	None anticipated from normal handling of this product. In a fertility study in rats, lidocaine given subcutaneously at a dosage of 30 mg/kg (180 mg/m ²) 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 <i>in vitro</i> chromosome aberrations assay in human lymphocytes and in an <i>in vivo</i> 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.
Carcinogen Lists	IARC: Not listed NTP: Not listed OSHA: Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the 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.

Product Name: Lidocaine Hydrochloride Injection



13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

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

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt. However, lidocaine hydrochloride is listed on the TSCA inventory.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

GHS/CLP Classification*

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

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

Prevention

Do not breathe 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.

EU Classification*

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

Classification(s)
Symbol
Indication of Danger
Risk Phrases
Safety Phrases

NA
NA
NA
NA
S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD ₅₀	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
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