SAFETY DATA SHEETS

This SDS packet was issued with item:

078905717

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

078682872 078829503 078923725

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

078924324 078924325

SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Lidocaine HCL and Epinephrine injection, USP

Trade Name: Lidocaine HCL 2%
Synonyms: Lidocaine 2% injection; Lidocaine - Epiniphrine injection
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as anesthetic agent
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: VMIPSrecords@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Liquid solution

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. May cause eye, skin and respiratory tract irritation

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Lidocaine Hydrochloride	73-78-9	200-803-8	Xn;R22	Acute Tox.4 (H302)	2
Sodium chloride	7647-14-5	231-598-3	Not Listed	Not Listed	<1
Sodium acetate trihydrate	6131-90-4	Not Listed	Not Listed	Not Listed	0.2
Acetic acid USP - glacial	64-19-7	200-580-7	R10 C; R35	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	<0.2
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	0.1
Sodium metabisulfite USP	7681-57-4	231-673-0	Xn; R22 R31 Xi; R41	Acute Tox. 4 (H302) Eye Dam. 1 (H318)	0.1
EDTA, disodium salt	139-33-3	205-358-3	Not Listed	Not Listed	0.01
Epinephrine	51-43-4	200-098-7	T;R24/25	Acute Tox. 2 (H300) Acute Tox. 2 (H310)	0.001
HYDROCHLORIC ACID	7647-01-0	231-595-7	T; R23 C; R35	Skin Corr.1B (H314) STOT SE 3 (H335)	##
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	Not Listed	>90

Additional Information: ## Trace
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Wipe up with a damp cloth and place in container for disposal. Clean contaminated surface thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Prevent environmental releases. Use appropriate personal protective equipment. Avoid accidental injection.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium chloride

Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3

Acetic acid USP - glacial

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm 37 mg/m^3
Australia TWA	10 ppm 25 mg/m^3
Austria OEL - MAKs	10 ppm 25 mg/m^3
Belgium OEL - TWA	10 ppm 25 mg/m^3
Bulgaria OEL - TWA	25.0 mg/m^3
Cyprus OEL - TWA	10 ppm 25 mg/m^3
Czech Republic OEL - TWA	25 mg/m^3
Denmark OEL - TWA	10 ppm 25 mg/m^3
Estonia OEL - TWA	10 ppm 25 mg/m^3
Finland OEL - TWA	5 ppm 13 mg/m^3
Germany - TRGS 900 - TWAs	10 ppm 25 mg/m^3
Germany (DFG) - MAK	10 ppm 25 mg/m^3
Greece OEL - TWA	10 ppm 25 mg/m^3
Hungary OEL - TWA	25 mg/m^3
Ireland OEL - TWAs	10 ppm 25 mg/m^3
Latvia OEL - TWA	10 ppm 25 mg/m^3
Lithuania OEL - TWA	10 ppm 25 mg/m^3
Luxembourg OEL - TWA	10 ppm 25 mg/m^3
Malta OEL - TWA	10 ppm 25 mg/m^3
Vietnam OEL - TWAs	25 mg/m^3
OSHA - Final PELS - TWAs:	10 ppm 25 mg/m^3
Poland OEL - TWA	15 mg/m^3
Portugal OEL - TWA	10 ppm
Romania OEL - TWA	10 ppm 25 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	10 ppm 25 mg/m^3
Slovenia OEL - TWA	10 ppm 25 mg/m^3
Spain OEL - TWA	10 ppm 25 mg/m^3
Sweden OEL - TWAs	5 ppm 13 mg/m^3
Switzerland OEL -TWAs	10 ppm 25 mg/m^3

Sodium metabisulfite USP

ACGIH Threshold Limit Value (TWA)	5 mg/m^3
Australia TWA	5 mg/m^3
Belgium OEL - TWA	5 mg/m^3
Denmark OEL - TWA	5 mg/m^3
France OEL - TWA	5 mg/m^3
Greece OEL - TWA	5 mg/m^3
Ireland OEL - TWAs	5 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3
Portugal OEL - TWA	5 mg/m^3
Spain OEL - TWA	5 mg/m^3
Switzerland OEL -TWAs	5 mg/m^3

HYDROCHLORIC ACID

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm 7.5 mg/m^3
Austria OEL - MAKs	5 ppm 8 mg/m^3
Belgium OEL - TWA	5 ppm 8 mg/m^3
Bulgaria OEL - TWA	8.0 mg/m^3 5 ppm
Cyprus OEL - TWA	5 ppm 8 mg/m^3
Czech Republic OEL - TWA	8 mg/m^3
Estonia OEL - TWA	5 ppm 8 mg/m^3
Germany - TRGS 900 - TWAs	2 ppm 3 mg/m^3
Germany (DFG) - MAK	2 ppm 3.0 mg/m^3
Greece OEL - TWA	5 ppm 7 mg/m^3
Hungary OEL - TWA	8 mg/m^3
Ireland OEL - TWAs	5 ppm 8 mg/m^3
Italy OEL - TWA	5 ppm 8 mg/m^3
Japan - OELs - Ceilings	5 ppm 7.5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	5 ppm 8 mg/m^3
Lithuania OEL - TWA	5 ppm 8 mg/m^3
Luxembourg OEL - TWA	5 ppm 8 mg/m^3
Malta OEL - TWA	5 ppm 8 mg/m^3
Netherlands OEL - TWA	8 mg/m^3
Vietnam OEL - TWAs	5 mg/m^3
Poland OEL - TWA	5 mg/m^3
Romania OEL - TWA	5 ppm 8 mg/m^3
Slovakia OEL - TWA	5 ppm 8.0 mg/m^3
Slovenia OEL - TWA	5 ppm 8 mg/m^3
Spain OEL - TWA	5 ppm 7.6 mg/m^3
Switzerland OEL -TWAs	2 ppm 3.0 mg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Lidocaine Hydrochloride

Zoetis OEB OEB 2 (control exposure to the range of 100ug/m^3 to < 1000ug/m^3)

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear impervious gloves if skin contact is possible.
Eyes: Safety glasses or goggles
Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture
Color: No data available.
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Lidocaine Hydrochloride
Rat Oral LD50 317 mg/kg
Rat Para-periosteal LD50 25mg/kg
Rat Intraperitoneal LD50 133mg/kg
Mouse Oral LD50 292mg/kg
Mouse Intravenous LD50 19.5mg/kg

Epinephrine
Rat Dermal LD50 62 mg/kg
Rat Oral LD50 30mg/kg

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

EDTA, disodium salt
Rat Oral LD50 > 5000 mg/kg

HYDROCHLORIC ACID
Rat Oral LD 50 238-277 mg/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Lidocaine Hydrochloride
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Lidocaine Hydrochloride
Embryo / Fetal Development Rat Subcutaneous 30 mg/kg NOAEL Not teratogenic

11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development	Rat	Intraperitoneal	56 mg/kg	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	72 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intravenous	500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	6 mg/kg	LOAEL	Developmental toxicity

Epinephrine

Embryo / Fetal Development	Rat	Intravenous	Dose not specified		Not teratogenic
Embryo / Fetal Development	Rabbit	Subcutaneous	30 times human dose	LOAEL	Developmental toxicity
Embryo / Fetal Development	Mouse	Subcutaneous	7 times human dose	LOAEL	Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Lidocaine Hydrochloride

Bacterial Mutagenicity (Ames)	*Salmonella* , *E. coli*	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative
In Vivo Micronucleus	Mouse	Negative

Epinephrine

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
Sister Chromatid Exchange	Negative with activation	
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Equivocal without activation

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Sodium metabisulfite USP
IARC: Group 3 (Not Classifiable)

HYDROCHLORIC ACID
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Epinephrine

RCRA - P Series Wastes	Listed

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Non-controlled
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Lidocaine Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-803-8

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Sodium acetate trihydrate

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Acetic acid USP - glacial

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

Methylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

Sodium metabisulfite USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS/ELINCS List	231-673-0

EDTA, disodium salt

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-358-3

Epinephrine

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	200-098-7

HYDROCHLORIC ACID

15. REGULATORY INFORMATION

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Sodium hydroxide

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H226 - Flammable liquid and vapor
H300 - Fatal if swallowed
H302 - Harmful if swallowed
H310 - Fatal in contact with skin
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

C - Corrosive
T - Toxic
Xi - Irritant
Xn - Harmful

R10 - Flammable.
R22 - Harmful if swallowed.
R23 - Toxic by inhalation.
R24 - Toxic in contact with skin.
R25 - Toxic if swallowed.
R31 - Contact with acids liberates toxic gas.
R35 - Causes severe burns.
R41 - Risk of serious damage to eyes.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET

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

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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 - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Lidocaine Hydrochloride and Epinephrine Injection
Synonyms	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride; (-)-3,4-Dihydroxy-a-[(methylamino) methyl] benzyl alcohol

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Lidocaine hydrochloride and Epinephrine Injection is a solution containing 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, and a potent drug. Based on clinical use, possible target organs include the nervous system and cardiovascular system.

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.

3. 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 for Injection. Hazardous ingredients present at less than 1% may include sodium chloride; sodium hydroxide and/or hydrochloric acid are added to adjust the pH; citric acid and sodium metabisulfite may be added as stabilizer. Multiple-dose vials contain methylparaben 1 mg/mL added as 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.

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 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**	**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
Epinephrine	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	The pH of a 2% solution is between 3.3 and 5.5
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 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.

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.

11. TOXICOLOGICAL INFORMATION: continued

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.
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. This product may contain sodium metabisulfite which may cause an allergic-type reaction in people sensitive to sulfites.
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/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.

11. TOXICOLOGICAL INFORMATION: continued

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.
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.

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. Epinephrine is listed as a hazardous waste. However, it is not the sole active ingredient in this product.
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	Epinephrine - Listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Epinephrine - Listed
US PROP 65 (Calif.)	Not listed

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

GHS/CLP Classification*

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

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

Prevention

Do not breathe vapor 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)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

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

MSDS Coordinator: Hospira GEHS
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