



MATERIAL SAFETY DATA SHEET

Revision date: 14-Nov-2007

Version: 1.2

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

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Material Name: Lidocaine Hydrochloride, Chlorhexidine Gluconate Topical Gel

Trade Name:	Lignocaine Gel With Chlorhexidine
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as anesthetic agent

2. HAZARDS IDENTIFICATION

Appearance:	Clear, Colorless gel
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	
Short Term:	May cause mild eye irritation. May cause slight irritation . Harmful if swallowed (based on components) . May cause numbing effects to skin .
Known Clinical Effects:	Adverse effects associated with the therapeutic use include dizziness, nervousness, agitation, drowsiness, apprehension, euphoria, blurred/double vision, slurred speech, tremors, convulsions, and seizure. Respiratory depression and arrest may follow. Other, more serious effects seen with IV use of this drug, particularly when it is administered rapidly, are cardiovascular collapse, central nervous system depression, and/or hypotension.
EU Indication of danger:	Not classified
Australian Hazard Classification (NOHSC):	Hazardous Substance. Non-Dangerous Goods.
Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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

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Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lidocaine Hydrochloride	73-78-9	200-803-8	Xn;R22	1-2
Chlorhexidine Gluconate	18472-51-0	242-354-0	Xn;R22	<1.0
Acetic acid USP - glacial	64-19-7	200-580-7	C;R35 R10	<1.0
Propylene glycol	57-55-6	200-338-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Hydroxyethyl cellulose	9004-62-0	Not listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

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Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Contain the source of the spill or leak if it is safe to do so. Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal.

7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Contents under pressure, do not puncture or incinerate. Releases to the environment should be avoided.

Storage Conditions: Protect from light. Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Acetic acid USP - glacial

ACGIH Threshold Limit Value (TWA)	= 10 ppm TWA
ACGIH Threshold Limit Value (STEL)	= 15 ppm STEL
Australia STEL	= 15 ppm STEL
	= 37 mg/m ³ STEL
Australia TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Austria OEL - MAKs	= 10 ppm MAK
	= 25 mg/m ³ MAK
Belgium OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Bulgaria OEL - TWA	= 25.0 mg/m ³ TWA
Cyprus OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Czech Republic OEL - TWA	= 25 mg/m ³ TWA
Denmark OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Estonia OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Finland OEL - TWA	= 13 mg/m ³ TWA
	= 5 ppm TWA
Greece OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Hungary OEL - TWA	= 25 mg/m ³ TWA
Ireland OEL - TWAs	= 10 ppm TWA
	= 25 mg/m ³ TWA
Latvia OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Lithuania OEL - TWA	= 10 ppm IPRV
	= 25 mg/m ³ IPRV
Luxembourg OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
OSHA - Final PELs - TWAs:	= 10 ppm TWA
	= 25 mg/m ³ TWA

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Poland OEL - TWA	= 15 mg/m ³ NDS
Portugal OEL - TWA	= 10 ppm TWA
Romania OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Slovakia OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Slovenia OEL - TWA	= 10 ppm TWA
	= 25 mg/m ³ TWA
Spain OEL - TWA	= 10 ppm VLA-ED
	= 25 mg/m ³ VLA-ED
Sweden OEL - TWAs	= 13 mg/m ³ LLV
	= 5 ppm LLV

Propylene glycol

Australia TWA	= 10 mg/m ³ TWA
	= 150 ppm TWA
	= 474 mg/m ³ TWA
Ireland OEL - TWAs	= 10 mg/m ³ TWA
	= 150 ppm TWA
	= 470 mg/m ³ TWA
Latvia OEL - TWA	= 7 mg/m ³ TWA
Lithuania OEL - TWA	= 7 mg/m ³ IPRV

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

Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Gel	Color:	Clear, colorless
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Soluble: Water		
pH:	6-7		

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10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
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

11. TOXICOLOGICAL INFORMATION

General Information: 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 Intravenous LD50 25 mg/kg
Rat Intraperitoneal LD50 133 mg/kg
Mouse Oral LD50 292 mg/kg
Mouse Intravenous LD50 19.5 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Chlorhexidine Gluconate

Rat Oral LD50 2000 mg/kg
Rat Intravenous LD50 24.2 mg/kg
Mouse Oral LD50 1260 mg/kg
Mouse Intravenous LD50 12.9 mg/kg

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

Lidocaine Hydrochloride

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Chlorhexidine Gluconate

Eye Irritation Rabbit Moderate

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Lidocaine Hydrochloride

Embryo / Fetal Development	Rat	Subcutaneous	30 mg/kg	NOEL	Not teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	56 mg/kg	NOEL	Not Teratogenic
Embryo / Fetal Development	Rat	Intraperitoneal	72 mg/kg/day	NOEL	Not Teratogenic

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Embryo / Fetal Development	Rat	Intravenous	500 mg/kg/day	LOAEL	Fetotoxicity
Embryo / Fetal Development	Rat	Intraperitoneal	6 mg/kg	LOAEL	Developmental toxicity

Chlorhexidine Gluconate

Embryo / Fetal Development	Rat	Oral	68 mg/kg/day	NOAEL	Not teratogenic
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Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Lidocaine Hydrochloride

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

Chlorhexidine Gluconate

<i>In Vivo</i> Cytogenetics	Hamster	Negative
<i>In Vivo</i> Dominant Lethal Assay	Mouse	Negative

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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

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Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-803-8

Chlorhexidine Gluconate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	242-354-0

Acetic acid USP - glacial

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
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
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 40.
EU EINECS/ELINCS List	200-580-7

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Hydroxyethyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Water

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

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16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R10 - Flammable.

R22 - Harmful if swallowed.

R35 - Causes severe burns.

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision:

Updated Section 2 - Hazard Identification. Updated Section 15 - Regulatory Information.

Prepared by:

Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material 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