



MATERIAL SAFETY DATA SHEET

Revision date: 22-Jun-2012

Version: 2.0

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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 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
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3. COMPOSITION/INFORMATION ON INGREDIENTS

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU 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.

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.

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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. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Propylene glycol

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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
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
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

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.

Chlorhexidine Gluconate

Pfizer Occupational Exposure OEB 4 (control exposure to the range of >1ug/m³ to <10ug/m³)
Band (OEB):

Lidocaine Hydrochloride

Pfizer Occupational Exposure OEB 2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)
Band (OEB):

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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		

10. STABILITY AND REACTIVITY

Chemical 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	Para-periosteal	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	Para-periosteal	LD50	24.2 mg/kg
Mouse	Oral	LD50	1260 mg/kg
Mouse	Intravenous	LD50	12.9 mg/kg

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

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11. TOXICOLOGICAL INFORMATION

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	NOAEL	Not teratogenic
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

Chlorhexidine Gluconate

Embryo / Fetal Development Rat Oral 68 mg/kg/day NOAEL Not teratogenic

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

Chlorhexidine Gluconate

In Vivo Cytogenetics Hamster Negative
In Vivo 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

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.

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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

EU Indication of danger: Not classified

OSHA Label:

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.

Chlorhexidine Gluconate

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

Lidocaine Hydrochloride

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

Propylene glycol

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

Hydroxyethyl cellulose

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Acetic acid USP - glacial	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
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
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

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. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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