SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: LIDOCAINE TOPICAL 5% PATCH

CHEMICAL NAME: For Active Ingredients: 2-(Diethylamino)-N-(2,6-dimethylphenyl)-acetamide
CHEMICAL FAMILY: For Active Ingredients: Acetamide
HOW SUPPLIED: 700 mg/12HRx30 Lidocaine via transdermal patch delivery system
OTHER DESIGNATIONS: NDC: 00591352530
FORMULA (for active ingredient): $C_{14}H_{22}N_2O$
RELEVANT USE of the SUBSTANCE: Human Pharmaceuticals
USES ADVISED AGAINST: Non-Pharmaceutical Use

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**ACTAVIS, INC.**
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NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: August 32015 **DATE OF REVISION:** New

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW:

Product Description: This product consists is comprised of an adhesive material containing 5% Lidocaine in an aqueous base, which is applied to a non-woven polyester felt backing and covered with a polyethylene terephthalate (PET) film release liner, and is packaged in a foil-backed pouch.

Health Hazards: The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Prolonged skin contact may cause symptoms of therapeutic use. In therapeutic use, the most common adverse effects reported are mild irritation, redness, or swelling where the medication is applied; or numbness in places patch is supplied. Adverse effects on the central nervous and cardiovascular system have been reported. Persons who are allergic to amide-type local anesthetics such as Lidocaine, may experience allergic reactions to this product. Severe allergic reactions can occur and can include anaphylactic reactions and shock. More information on adverse effects from therapeutic use is described in Section 11 (Toxicological Information).

Reactivity Hazards: This product is not reactive.

Flammability Hazards: This product may be combustible and may ignite if involved in a fire and the water evaporates. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides, acrolein).

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENT				
Lidocaine	137-58-6	205-302-8	5.0%	SELF CLASSIFICATION EU 67/548 Classification: Harmful Risk Phrases: R22, R42 EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Acute Dermal Toxicity Cat. 5, Skin Sensitization Cat. 2 Hazard Statement Codes: H302, H313, H317
EXCIPIENTS				
Croscarmellose Sodium	9004-32-4	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Dihydroxyaluminum Aminoacetate	41354-48-7	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Disodium Edetate	139-33-3	205-358-3	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Harmful Risk Phrases: R22 EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 4 Hazard Statement Codes: H302
Gelatin	9000-70-8	232-554-6	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Glycerin	56-81-5	200-289-5	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Kaolin	1332-58-7	310-194-1	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Methylparaben	99-76-3	202-785-7	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Polyacrylic Acid	9003-01-4	Not Listed	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Not Applicable Risk Phrases: Not Applicable EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303
Polyvinyl Alcohol	9002-89-5	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Propylene Glycol	57-55-6	200-338-0	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Propylparaben	94-13-3	202-307-7	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Sodium Polyacrylate	9003-04-7	Not Listed	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
D-Sorbitol	50-70-4	200-061-5	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Tartaric Acid	87-69-4	201-766-0	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Urea	57-13-6	200-315-5	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable
Water, USP	7732-18-5	231-791-2	Proprietary	EU 67/548 Classification: Not Applicable EU/GHS CLP 1272/2008 Classification: Not Applicable

See Section 16 for full classification information for components.

4. FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of SDS to physician or other health professional with victim(s).

INHALATION: Not a possible route of exposure to components of this product due to its form.

SKIN EXPOSURE: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

EYE EXPOSURE: If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

INGESTION EXPOSURE: Not a likely route of ingestion for product. If poor hygiene results in ingestion of the drug mixture on the patch, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately.

4. FIRST-AID MEASURES (Continued)

DESCRIPTION OF FIRST AID MEASURES (continued):

INGESTION EXPOSURE (continued): Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, hepatic dysfunction, dermatitis and other skin disorders or sensitivity or allergic reactions to components may be aggravated by exposure to this product. Persons who may have hypersensitivity reactions to this product or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure. Persons handling the product in the workplace may experience adverse reaction under the same conditions.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. There is no specific antidote for this medication; treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established for product.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not established.

FIRE EXTINGUISHING MEDIA: In the event of a fire, use suppression methods for surrounding materials, including water spray (for cooling), dry extinguishing media, carbon dioxide, foam.

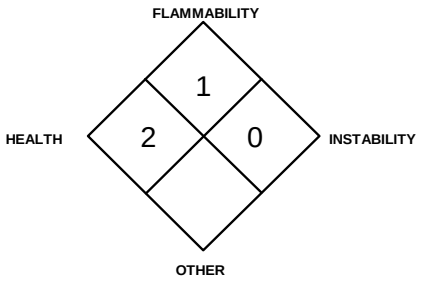
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: This product may be combustible and ignite if involved in a fire and the water evaporates. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon and nitrogen oxides, acrolein).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. Spills may be slippery.

PROTECTIVE EQUIPMENT:

All Spills: Wear double latex or nitrile disposable gloves and eye protection.

METHODS FOR CLEANUP AND CONTAINMENT:

All Spills: Sweep-up spilled patches and wipe area with damp sponge or polypad. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: See information in Section 8 (Exposure Controls – Personal Protection) and Section 13 (Disposal Considerations) for additional information.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. Ensure product is properly labeled.

CONDITIONS FOR SAFE STORAGE: Store this product away from incompatible materials. Store this product in original container. Store product at room temperature (20-28°C [68-77°F]).

7. HANDLING and USE (Continued)

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

SPECIFIC END USE(S): This product human pharmaceutical. Follow all industry standards for use of this product.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: Follow practices indicated in Section 6 (Accidental Release Measures). When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and all disposable items contaminated with this product and dispose of according to applicable local, national, and international regulations.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

OCCUPATIONAL/WORKPLACE EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Lidocaine	137-58-6	NE	NE	NE	NE	NE	NE	NE	NE
Croscarmellose Sodium	9004-32-4	NE	NE	NE	NE	NE	NE	NE	NE
Dihydroxyaluminum Aminoacetate	41354-48-7	NE	NE	NE	NE	NE	NE	NE	NE
Disodium Edetate	139-33-3	NE	NE	NE	NE	NE	NE	NE	NE
Gelatin	9000-70-8	NE	NE	NE	NE	NE	NE	NE	NE
Glycerin	56-81-5	Mist		Mist: 15 (total dust), 5 (resp. fraction) Vacated 1989 PEL: 10 (total dust)	Mist	NE	NE	NE	DFG MAKs: TWA = 50 (inhalable fraction) PEAK = 2•MAK 15 min. average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C
Kaolin	1332-58-7	2 (resp. fract.)	NE	15 (total dust), 5 (resp. fract.) Vacated 1989 PEL: 10 (total dust)	NE	10 (total dust), 5 resp. fract.)	NE	NE	Carcinogen: MAK-3B (quartz content must be considered separately), TLV-A4
Methylparaben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Polyacrylic Acid	9003-01-4	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Polyvinyl Alcohol	9002-89-5	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Propylene Glycol	55-57-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Propylparaben	94-13-3	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Polyacrylate	9003-04-7	NE	NE	NE	NE	NE	NE	NE	DFG MAKs: TWA = 0.05 (respirable fraction) PEAK = 1•MAK 15 min. average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C Carcinogen: MAK-4
D-Sorbitol	50-70-4	NE	NE	NE	NE	NE	NE	NE	NE
Tartaric Acid	87-69-4	NE	NE	NE	NE	NE	NE	NE	NE
Urea	57-13-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10 Carcinogen: EPA-II

NE = Not Established

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently the following international exposure limits are in place for some components of this product. Limits given may not be the most current and should be checked.

CARBOXYMETHYLCELLULOSE:
Russia: STEL = 10 mg/m^3, JUN 2003

EDETATE DISODIUM:
Russia: STEL = 2 mg/m^3, Skin, JUN 2003

GELATINS:
Russia: STEL = 10 mg/m^3, JUN 2003

GLYCERIN:
Belgium: TWA = 10 mg/m^3, MAR 2002
Finland: TWA = 20 mg/m^3, SEP 2009
France: VME = 10 mg/m^3, FEB 2006
Korea: TWA = 10 mg/m^3 (mist), 2006
Mexico: TWA = 10 mg/m^3 (inhalable), 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (mist), JAN 2002
Switzerland: MAK-W = 50 mg/m^3, KZG-W = 100 mg/m^3, DEC 2006
United Kingdom: TWA = 10 mg/m^3, 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

KAOLIN (CALCINED CLAY):
Belgium: TWA = 2 mg/m^3 (resp. dust), MA R 2002
Denmark: TWA = 2 mg/m^3 (respirable), MAY 2011
Finland: TWA = 2 mg/m^3, resp. dust, NOV 2011
France: VME = 10 mg/m^3, FEB 2006
Iceland: TWA 2 mg/m^3 (resp. dust), NOV 2011
Japan: OEL = 0.5 mg/m^3 (respirable), 2 mg/m^3 (total), APR 2007
Korea: TWA = 10 mg/m^3, 2006
Mexico: TWA = TWA 10 mg/m^3; STEL = 20 mg/m^3, 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
New Zealand: TWA = 2 mg/m^3 (respirable dust), JAN 2002
Peru: TWA 2 mg/m^3, JUL 2005
Switzerland: MAK-W =3 mg/m^3, DEC 2006
United Kingdom: TWA = 2 mg/m^3 (resp. dust), OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS (continued):

METHYL PARABEN:
Russia: STEL = 4 mg/m^3, JUN 2003

POLYACRYLIC ACID:
Belgium: TWA = 2 mg/m^3 (resp. dust), MAR 2002
Denmark: TWA = 2 mg/m^3 (respirable), MAY 2011
Finland: TWA = 2 mg/m^3, resp. dust, NOV 2011
France: VME = 10 mg/m^3, FEB 2006
Iceland: TWA = 2 mg/m^3 (resp. dust), NOV 2011
Korea: TWA = 10 mg/m^3, 2006
Mexico: TWA = 10 mg/m^3; STEL = 20 mg/m^3, 2004
The Netherlands: MAC-TGG = 0.05 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
New Zealand: TWA = 2 mg/m^3 (respirable dust), JAN 2002
Peru: TWA = 2 mg/m^3, JUL 2005
Switzerland: MAK-W = 0.05 mg/m^3, DEC 2006
United Kingdom: TWA 2 mg/m^3 (resp. dust), OCT 2007

POLYACRYLIC ACID (continued):
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

POLYVINYL ALCOHOL:
Russia: STEL = 10 mg/m^3, JUN 2003

PROPYLENE GLYCOL:
Australia: TWA = 10 mg/m^3 (particulates), JUL 2008
Australia: TWA = 150 ppm (474 mg/m^3) (total), JUL 2008
New Zealand: TWA = 10 mg/m^3 (particulates only), JAN 2002
New Zealand: TWA = 150 ppm (474 mg/m^3) (vapor and particulates), JAN 2002
Russia: STEL = 7 mg/m^3, JUN 2003
United Kingdom: TWA = 10 mg/m^3 (particulate), 2005
United Kingdom: TWA = 150 ppm (474 mg/m^3) (total vapor), 2005

SORBITOL:
Russia: STEL = 10 mg/m^3, JUN 2003

UREA:
Russia: STEL = 10 mg/m^3, JUN 2003

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

EYE PROTECTION: During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

HAND PROTECTION: During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

FORM: Adhesive material containing drug reservoir, which is applied to a non-woven polyester felt backing and covered with a polyethylene terephthalate (PET) film release liner, and is packaged in a foil-backed pouch

COLOR: Tan.

MOLECULAR WEIGHT: Mixture.

MOLECULAR FORMULA: Mixture.

ODOR: Faint odor.

ODOR THRESHOLD: Not applicable.

BOILING POINT: Not established.

FREEZING/MELTING POINT Not established.

EVAPORATION RATE (nBuAc = 1): Not established.

SOLUBILITY IN WATER: Partially soluble.

VAPOR PRESSURE (air = 1): Not available.

SPECIFIC GRAVITY (water = 1): Not available.

pH: Not established.

VAPOR DENSITY: Not available.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

VISCOSITY: Not available.

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance of this product may act as a distinguishing characteristic.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: *Combustion:* If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon and nitrogen oxides, ethanol, acetic acid, ammonia, hydrogen cyanide, nitriles, isocyanates, nitrosamines and formaldehyde). *Hydrolysis:* None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility.

POSSIBILITY OF HAZARDOUS REACTIONS OR POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Inhalation is not a likely route of exposure to this product.

CONTACT WITH SKIN or EYES: Prolonged contact with the skin may cause irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact of this product with the eyes may cause moderate to severe irritation, redness, and tearing.

SKIN ABSORPTION: This product is designed to be absorbed through the skin. Lidocaine toxicity could be expected at Lidocaine blood concentrations above 5 µg/mL. Contact with broken or inflamed skin (although not tested) may result in higher blood concentrations of Lidocaine from increased absorption.

INGESTION: Ingestion is not a significant route of occupational exposure. If ingestion of drug mixture occurs from poor hygiene, adverse effects as described under 'Other Potential Health Effects' may occur.

INJECTION: Not a likely route of exposure due to the form of this product.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effects reported are mild irritation, redness, or swelling where the medication is applied; or numbness in places patch is supplied. Adverse central nervous system reactions can occur and may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. See below for further details on possible central nervous system effects. Persons who are allergic to amide-type local anesthetics such as Lidocaine, may experience allergic reactions to this product. Severe allergic reactions can occur and can include anaphylactic reactions and shock. These effects may also be experienced from occupational exposure. Additional effects seen in therapeutic use have included the following.

- ***Body as a Whole:*** Weakness, metallic taste, alteration of taste.
- ***Cardiovascular:*** Rapid heart beat, low blood pressure and cardiovascular collapse leading to arrest.
- ***Central Nervous System:*** Excitation and/or depression (light headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, sensations of heat, cold or numbness, abnormal increase in sensitivity to sensory stimuli, reduced sense of touch, pain exacerbated, twitching, tremors, convulsions, unconsciousness.
- **Ears:** Ringing in ears.
- ***Eyes:*** Blurred or double vision.
- ***Gastrointestinal System:*** Nausea, vomiting.
- ***Reproductive System:*** Possible harm to fetus based on animal data.
- ***Respiratory System:*** Respiratory depression.
- ***Skin:*** Skin at the site of application may develop blisters, bruising, burning sensation, depigmentation or discoloration, dermatitis, swelling or raised swelling, exfoliation, irritation, rash with red, raised bumps, broken capillaries, itching, blisters, or may be the locus of abnormal sensation. These reactions are generally mild and transient, resolving spontaneously within a few minutes to hours.
- ***Vascular System:*** Flushing.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
3 = Serious **4** = Severe * = Chronic hazard

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. In the event of exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.

Chronic: Repeated skin contact may cause dermatitis (dry, red skin) or other effects described under 'Other Potential Health Effects'.

TARGET ORGANS: Acute: Workplace Exposure: Skin. Therapeutic Doses: Effects described under 'Other Potential Health Effects'. Chronic: Workplace Exposure: Skin. Therapeutic Doses: Effects described under 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue, especially if contact is prolonged.

SENSITIZATION OF PRODUCT: In therapeutic use, allergic and anaphylactoid reactions associated with Lidocaine, although rare, can occur and can include angioedema, bronchospasm, dermatitis, difficulty breathing, general hypersensitivity, laryngospasm, itching, shock and hives.

TOXICITY DATA: Currently, the following toxicity data is available for the active ingredient, Lidocaine. Data are available for the active ingredient and data are available for the excipient components, but are not presented in this SDS. Contact Actavis for more information.

LIDOCAINE:

TDLo (Oral-Child) 21 mg/kg: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: respiratory depression

TDLo (Oral-Child) 300 mg/kg/5 days-intermittent: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Nutritional and Gross Metabolic: body temperature increase

TDLo (Oral-Woman) 39 mg/kg: Behavioral: hallucinations, distorted perceptions, excitement; Cardiac: change in rate

TDLo (Intraspinal-Woman) 1 mL/kg: Behavioral: euphoria, hallucinations, distorted perceptions

TDLo (Intravenous-Woman) 16 mg/kg: Cardiac: change in rate; Respiration: dyspnea

TDLo (Intravenous-Man) 8643 µg/kg/4 hours-continuous: Behavioral: toxic psychosis

TDLo (Intravenous-Man) 1700 µg/kg/2 minutes-continuous: Behavioral: coma; Cardiac: pulse rate; Respiration: respiratory depression

TDLo (Intravenous-Human) 23 mg/kg: Behavioral: muscle contraction or spasticity; Lungs, Thorax, or Respiration: dyspnea

TDLo (Parenteral-Human) 0.71 mg/kg: Peripheral Nerve and Sensation: local anesthetic; Vascular: BP lowering not characterized in autonomic section

TDLo (Parenteral-Woman) 0.95 mg/kg: Peripheral Nerve and Sensation: local anesthetic; Vascular: regional or general arteriolar constriction

TDLo (Parenteral-Woman) 540 µg/kg: female 39 week(s) after conception: Reproductive: Specific Developmental Abnormalities: Central Nervous System

TDLo (Skin-Woman) 1.72 mg/kg: Local anesthetic; Vascular: regional or general arteriolar constriction

LIDOCAINE (continued):

TDLo (Subcutaneous-Human) 33.3 µg/kg: Behavioral: analgesia

LD_{50} (Oral-Rat) 317 mg/kg

LD_{50} (Oral-Mouse) 220 mg/kg: Behavioral: convulsions or effect on seizure threshold, rigidity (including catalepsy); Lungs, Thorax, or Respiration: respiratory stimulation

LD_{50} (Intraperitoneal-Rat) 133 mg/kg: Behavioral: somnolence (general depressed activity), convulsions or effect on seizure threshold; Lungs, Thorax, or Respiration: other changes

LD_{50} (Intraperitoneal-Mouse) 102 mg/kg: Peripheral Nerve & Sensation: local anesthetic; Behavioral: convulsions or effect on seizure threshold, ataxia

LD_{50} (Subcutaneous-Rat) 335 mg/kg

LD_{50} (Subcutaneous-Mouse) 238 mg/kg

LD_{50} (Subcutaneous-Guinea Pig) 120 mg/kg

LD_{50} (Intravenous-Rat) 18 mg/kg

LD_{50} (Intravenous-Mouse) 20 mg/kg: Behavioral: convulsions or effect on seizure threshold; Vascular: BP lowering not characterized in autonomic section; Lungs, Thorax, or Respiration: other changes

LD_{50} (Intravenous-Mouse) 39.4 mg/kg

LD_{50} (Unreported-Rat) 39,400 µg/kg

LDLo (Intravenous-Rabbit) 41 mg/kg

LDLo (Intravenous-Guinea Pig) 65 mg/kg

TDLo (Intradermal-Rabbit) 0.024 mg/kg

TDLo (Intravenous-Rat) 5 mg/kg: Vascular: BP lowering not characterized in autonomic section

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

LIDOCAINE (continued):

TDLo (Intravenous-Rat) 2343 µg/kg/5 minutes: Cardiac: change in rate
TDLo (Intravenous-Rat) 4688 µg/kg/5 minutes: Vascular: BP lowering not characterized in autonomic section
TDLo (Intravenous-Dog) 2 mg/kg: Cardiac: change in rate
TDLo (Intravenous-Dog) 5 mg/kg: Vascular: measurement of regional blood flow
TDLo (Intravenous-Mammal) 182.5 mg/kg/72 hr-continuous: Brain & Coverings: other degenerative changes
TDLo (Intraperitoneal-Rat) 2 mg/kg: Blood changes
TDLo (Subcutaneous-Mouse) 50 mg/kg: Local anesthetic4
TDLo (Parenteral-Rat) 6.67 mg/kg: Local anesthetic
TDLo (Parenteral-Rat) 6 mg/kg: female 11 days after conception: Reproductive: Effects on Newborn: sex ratio
TDLo (Parenteral-Rat) 6 mg/kg: female 18 days after conception: Behavioral Effects on Newborn

LIDOCAINE (continued):

TDLo (Intramuscular-Rat) 50 mg/kg/3 days-intermittent: Blood: change in clotting factors; Immunological Including Allergic: increased immune response; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects
TDLo (Intramuscular-Rat) 6 mg/kg: female 11 day(s) after conception: Reproductive: Effects on Newborn: behavioral
TDLo (Intraspinal-Rabbit) 5 mg/kg: Local anesthetic
TDLo (Intradermal-Rabbit) 0.024 mg/kg: Behavioral: general anesthetic, analgesia
TDLo (Implant-Rat) 7500 mg/kg: female 3-17 day(s) after conception: Reproductive: Effects on Fetus: fetotoxicity (except death, e.g., stunted fetus)
TDLo (Unreported-Rat) 0.5 pph: Local anesthetic
TDLo (Unreported-Guinea Pig) 0.25 pph: Local anesthetic
TDLo (Unreported-Frog) 0.1 pph: Local anesthetic
TCLo (Inhalation-Rabbit) 10,000 gm/m^3: Lungs, Thorax, or Respiration: structural or functional change in trachea or bronchi
Mutation in Microorganisms (Bacteria-*Salmonella typhimurium*) 50 µmol/plate

CARCINOGENIC POTENTIAL OF COMPONENTS: A minor metabolite, 2,6-xylidine, has been found to be carcinogenic in rats. The blood concentration of this metabolite is negligible following application of this product.

Components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

Kaolin: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); MAK-3B (Substances for Which In Vitro Tests or Animal Studies Have Yielded Evidence of Carcinogenic Effects that is not Sufficient for Classification of the Substance in One of the Other Categories. Further studies are required before a final classification can be made.)

Polyacrylic Acid and Polyvinyl Alcohol: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

Sodium Polyacrylate: MAK-4 (Substances with Carcinogenic and Potential for Which Genotoxicity Plays No or at Least a Minor Role)

Urea: EPA-II (Inadequate Information to Assess Carcinogenic Potential)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: This product is rated by the FDA as Pregnancy Category B (Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester). There are, however, no adequate and well-controlled studies in pregnant women. More specific details from animal testing of this compound are as follows.

Mutagenicity: Lidocaine is not mutagenic in Salmonella/mammalian microsome test nor clastogenic in chromosome aberration assay with human lymphocytes and mouse micronucleus test.

Embryotoxicity/Teratogenicity: Reproduction studies with Lidocaine have been performed in rats at doses up to 30 mg/kg subcutaneously and have revealed no evidence of harm to the fetus due to Lidocaine.

Reproductive Toxicity: Effects on fertility have not been studied. Lidocaine is excreted in human milk, and the milk: plasma ratio of Lidocaine is 0.4.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil. The drug mixture is expected to be somewhat mobile in soils.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No specific data is available for this product.

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

13. DISPOSAL CONSIDERATIONS (Continued)

U.S. EPA WASTE NUMBER: Not applicable.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is NOT classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods. Refer to current regulations for all additional provisions other information not given here.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: See the information under the UN ADR and IMO, in this section.

ENVIRONMENTAL HAZARDS: This product is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); components are not marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are NOT subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 Lists.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

ADDITIONAL CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

OTHER CANADIAN REGULATIONS: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

ADDITIONAL EUROPEAN UNION REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: When formulated in a finished medicinal compound for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! PROLONGED OR REPEATED SKIN CONTACT MAY CAUSE IRRITATION. SKIN CONTACT WITH THE DRUG PRODUCT MAY CAUSE ADVERSE EFFECTS TO THE CENTRAL NERVOUS AND CARDIOVASCULAR SYSTEM IN PERSONS SENSITIVE TO LIDOCAINE AND MAY CAUSE ALLERGIC REACTIONS. COMBUSTIBLE. May ignite in contact with flame or heated to high temperature for prolonged period. Keep away from heat, sparks, and flame. Avoid contact with skin, eyes, and clothing. Avoid breathing vapors. Keep container tightly closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. If swallowed, do NOT induce vomiting. If vomiting occurs, have person lean forward. Call physician or poison control center immediately. Never give anything by mouth to an unconscious person. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Wipe up spilled product. Place residue in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

16. OTHER INFORMATION (Continued)

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Lidocaine: This is a self-classification.
Classification: Acute Oral Toxicity Category 4, Acute Dermal Toxicity Category 5, Skin Sensitization Category 2
Hazard Statements: H302: Harmful by ingestion. H313: May be harmful in contact with skin. H317: May cause an allergic skin reaction.

Disodium Edetate: This is a self-classification.
Classification: Acute Oral Toxicity Category 4
Hazard Statement Codes: H302: Harmful if swallowed.

Polyacrylic Acid: This is a self-classification.
Classification: Acute Oral Toxicity Category 5
Hazard Statement Codes: H303: May be harmful if swallowed.

All Other Components: An official classification for these substances has not been published in the CLP 1272: 2008 and a self-classification is not applicable.

FULL TEXT EU 67/548/EEC:

67/548/EEC:

Lidocaine: This is a self-classification.
Hazard Classification: Reproductive Toxicity Category 3
Risk Phrases: R63: Possible risk of harm to the unborn child.

Disodium Edetate: This is a self-classification.
Classification: Harmful
Risk Phrases: R22: Harmful if swallowed.

All Other Components: An official classification for these substances has not been published in Commission Directives and a self-classification is not applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.
METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.
REVISION DETAILS: New.

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DATE OF PRINTING: October 6, 2015