
	Sagent Pharmaceuticals, Inc.			
	GLYDO™ (Lidocaine HCl Jelly USP, 2%)		Safety Data Sheet (SDS)	
	SDS Issue Date: Sept 09, 2014	SDS No.: SDS 072	SDS Version No.: 1.0	Form No.: R-SOP-009-F001

Section 1 - Identification

- (a) **Product Identifier:** Lidocaine HCl Jelly USP, 2%
- (b) **Product Code:** 25021-673
Common/Trade Name: GLYDO™
Chemical Name: Acetamide, 2-(diethyl-amino)-N-(2,6-dimethylphenyl)-, monohydrochloride
- (c) **Product Use:** Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Single-use prefilled syringe
- (d) **Distributor:** Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** Non-hazardous in accordance with international standards for workplace safety.
- (b) **Signal Word,** Non-hazardous
Hazard statement(s),
Symbol(s), and/or
Precautionary
statement(s):
- (c) **Description of Hazards:** May cause slight irritation, harmful if swallowed (based on components). May cause mild eye irritation. May cause numbing effects on skin.
- (d) **Unknown Acute Toxicity:** NE

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Section 3 – Composition / Information on Ingredients


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Acetamide, 2-(diethyl-amino)- N-(2,6-dimethylphenyl)-, monohydrochloride	Lidocaine Hydrochloride	2%	73-78-9	N/A
Hydroxypropylmethylcellulose	Hypromellose	2 - 2.5%	9004-65-3	N/A
Purified Water USP	Water	qs	7732-18-5	N/A
Sodium Hydroxide 5N solution, NF	Sodium Hydroxide	< .01%	1310-73-2	N/A

Section 4 - First Aid Measures

- Eye Exposure:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
- Skin Exposure:** 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.
- Injection:** In cases of accidental injection, wash the affected area and seek medical attention.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use carbon dioxide, dry chemical, or water spray

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- (b) **Hazardous Combustion Products:** Oxides of carbon, nitrogen and sulfur. Formation of toxic gases is possible during heating or fire. Fine particles (such as dust and mists) may fuel fires/explosions.
- (c) **Special Protective Equipment / Precautions:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Use the appropriate personal protective equipment, see Section 8. Small spills may be absorbed with a disposable towel; larger spills may require use of an appropriate vacuum cleaner designed for drug disposal. Carefully collect with a non-combustible absorbent material and transfer to a suitable, properly labeled container for disposal. Clean area using soap and water.
- Release to Air:** If aerosolized, reduce exposures by ventilating area. Do not breathe mist.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.
- Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Refer to specific member state legislation for requirements under community environmental legislation.

Section 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 environment should be avoided.
- Storage Conditions:** Protect from light. Store at 20° to 25° C (68° to 77°F)

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Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
Lidocaine HCl	OSHA	PEL	N/E
	ACGIH	TLV	N/E

(b) Engineering Controls

Ventilation: General room ventilation is adequate unless the process generates dust, mist or fumes.

(c) Individual Protection Measures

Respiratory Protection:	If exposure to mist is possible, wear a NIOSH approved half-face respirator equipped with a dust/mist filter. Respiratory protection should be adjunct to and not a substitute for engineering controls.
Eye Protection:	Wear safety glasses or goggles if eye contact is possible. Emergency eyewash fountains should be available.
Skin Protection:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. Emergency shower should be available.
Other Protective Equipment:	None.
Additional Exposure Precautions:	Wash hands thoroughly following use. No eating, drinking, or smoking while handling this product. Do not smell or taste chemicals. Contaminated clothing should be laundered before reuse.


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Section 9 - Physical and Chemical Properties

(a)	Appearance	Nearly colorless, clear, viscous liquid.
(b)	Odor	No Odor
(c)	Odor Threshold	NE
(d)	pH	6.0 – 7.0
(e)	Melting Point:	NE
(f)	Initial Boiling Point:	NE
(g)	Flash Point	NE
(h)	Evaporation Rate:	NE
(i)	Flammability	NE
(j)	Upper Lower Flammability or Explosion Limits	NE
(k)	Vapor Pressure:	NE
(l)	Vapor Density:	NE
(m)	Relative Density	0.997 - 1.017 g/cm ³
(n)	Solubility(ies)	Soluble in Water
(o)	Partition Coefficient: n-octanol/water	NE
(p)	Auto-ignition Temperature	NE
(q)	Decomposition Temperature	NE
(r)	Viscosity	2000 - 6000 mPa's

Section 10 - Stability and Reactivity

(a)	Reactivity	Incompatible with water reactive materials
(b)	Chemical Stability	Stable under normal conditions of use.
(c)	Possibility of Hazardous Reactions	When heated to decomposition, product may emit oxides of carbon, nitrogen, and sulfur.
(d)	Conditions to Avoid	Keep away from strong oxidizers, extreme heat or cold.
(e)	Incompatible Materials	As a precaution, keep away from strong oxidizers.

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(f)	Hazardous Decomposition Products	NE
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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
(b)	Symptoms related to the physical, chemical and toxicological characteristics	<p>Effects noted after toxic doses include lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, blurred or double vision, hearing disturbances, cardiovascular depression, and slow heart rate. Nausea, vomiting, and abdominal discomfort may occur after ingestion.</p> <p>Massive over dosage can cause convulsions or seizures, cardiovascular and respiratory collapse, and heart stoppage.</p> <p>Lidocaine may cause allergic reactions in susceptible individuals.</p> <p>Lidocaine can cause methemoglobinemia in susceptible individuals. Since it is a local anesthetic, contact with the eyes or skin may cause temporary loss of feeling or sensation and transient blanching of the skin.</p> <p>Inhalation and ingestion of excessive amounts may result in toxic effects on the central and nervous system and cardiovascular system.</p>
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	<p>Inhalation Toxicity: Inhalation of mist may cause slight irritation and transient numbness to nose and throat, dizziness, and drowsiness. While unlikely with this formulation, overexposure may cause toxic effects on the central nervous system and cardiovascular system.</p> <p>Eye: Local anesthetics applied to the cornea may cause transient stinging, then numbness and loss of sensation. Local anesthesia suppresses automatic blinking and allows abnormal drying of the cornea.</p> <p>Skin: No dermal LD50 value was available. Lidocaine can be absorbed through broken or diseased skin. Skin</p>



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Delayed and immediate effects and also chronic effects from short and long term exposure (continued)


reactions after topical administration include transient blanching, paleness, redness, and dermal analgesia.

Sensitization: Allergic reactions are rare, but may occur in individuals hypersensitive to lidocaine, other amide-type local anesthetics, the preservatives, methyl- or propylparaben, or to other ingredients in the formulation. Allergic reactions are characterized by skin lesions, hives, edema, or anaphylactoid reactions.

Chronic/Carcinogenicity: No long term studies in animals have been conducted to evaluate the carcinogenic potential of lidocaine. Metabolites of lidocaine have been shown to be carcinogenic in laboratory animals. Rats, in a two-year oral toxicity study with 2,6-xylidine (lidocaine metabolite) at 15, 50, and 150 mg/kg/day developed carcinomas, adenomas, and rhabdomyosarcomas, in the nasal cavity, subcutaneous fibromas and/or fibrosarcomas, and neoplastic nodules of the liver at the high dose level.

Mutagenicity: Studies to evaluate the mutagenic potential of lidocaine base have not been performed. Lidocaine hydrochloride tested negative in the Ames, human lymphocyte chromosomal aberration, and in vivo mouse micronucleus assays. Mixed results have been noted in mutagenicity studies with the metabolite, 2, 6-xylidine.

Reproductive/Developmental Effects: Pregnancy Category B. Studies to evaluate the effects on fertility in humans have not been conducted. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine. There are, however, no adequate and well controlled studies in pregnant women. Animal reproductive studies are not always predictive of human response. Lidocaine is not contraindicated in labor and delivery. Lidocaine rapidly crosses the placenta in animal models and high

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		<p>doses may affect fetal heart rate. Lidocaine is distributed into human milk.</p> <p>Drug Interactions: B-adrenergic blocking agents, succinylcholine, other antiarrhythmic drugs, cimetidine.</p> <p>See package insert for additional information.</p>
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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Lidocaine HCl	LD ₅₀	Oral	Rat	317 mg/kg
Lidocaine HCl	LD ₅₀	Subcutaneous	Mouse	285 mg/kg
Lidocaine HCl	LD ₅₀	Oral	Mouse	220, 292 mg/kg
Lidocaine HCl	LD ₅₀	Subcutaneous	Rat	570 mg/kg
Lidocaine HCl	LD ₅₀	Intramuscular	Mouse	260 mg/kg
Lidocaine HCl	LD ₅₀	Intravenous	Mouse	22 mg/kg
Lidocaine HCl	LD ₅₀	Intraperitoneal	Mouse	119 mg/kg

(e) Hazardous Chemical Listings


NTP: No IARC: No OSHA: No

Section 12 - Ecological Information

(a)	Ecotoxicity	NE
(b)	Persistence and degradability	NE
(c)	Bioaccumulative potential	NE
(d)	Mobility in soil	NE
(e)	Other Adverse Effects	NE

Section 13 - Disposal Considerations

Dispose of material on-site in a licensed chemical incinerator, if allowed by the incinerator license or permit. If no on-site incinerator is available, dispose of material in a licensed

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commercial chemical incinerator. Disposal should be conducted in accordance with local, state and federal environmental regulations.

Section 14 - Transport Information

(a)	UN Number	NE
(b)	UN Proper Shipping Name	NE
(c)	Transport Hazard Class(es)	NE
(d)	Packing Group	NE
(e)	Environmental Hazards	NE
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	NE
(g)	Special Precautions	NE

DOT: Not Regulated
 ICAO/IATA: Not Regulated
 IMO: Not REgulated

Section 15 - Regulatory Information


Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: No
 CERCLA: Not established
 SARA 302: Not established
 SARA 313: Not established

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.


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For additional information contact:

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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)

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TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)