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Section 1 - Identification

- (a) **Product Identifier:** Lidocaine Hydrochloride Injection, USP
- (b) **Product Code:** 83634-653-41; 83634-653-42; 83634-653-43; 83634-653-02; 83634-653-05; 83634-653-30; 83634-651-50 and 83634-651-43
- Common/Trade Name:** Xylocaine, Lidocaine HCl
- Chemical Name:** acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride monohydrate
- Chemical Family:** Amide Local Anesthetic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Prefilled Liquid Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **Classification:** Not classified as hazardous.

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	None
Hazard Statements:	Not classified in accordance with international standards for workplace safety.
Precautionary Statements:	Harmful if swallowed. May cause mild eye irritation. May cause slight skin irritation. (based on components). Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

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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.
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(d) Unknown Acute Toxicity N/A

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-(diethylamino)-N-(2,6-dimethylphenyl)-, monohydrochloride monohydrate	Lidocaine Hydrochloride	10 mg/mL	73-78-9	NA
Sodium Chloride	Sodium Chloride	7 mg/mL	7647-14-5	NA
Methylparaben*	Methylparaben*	1 mg/mL	99-76-3	NA
Sodium Hydroxide	Sodium Hydroxide	pH adjustment	1310-73-2	NA
Hydrochloric Acid	Hydrochloric Acid	pH adjustment	7647-01-0	NA
Water	Water	q.s.	7732-18-5	NA

* Multi-Dose Vials contain methylparaben as a preservative. Single-Dose vials do not contain methylparaben and are preservative-free.

q.s. – quantity sufficient

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

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Additional Notes: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media:** Use extinguishing media appropriate to surrounding fire conditions, such as water spray, dry chemical, alcohol-resistant foam, carbon dioxide.
- (b) **Hazardous Combustion Products:** Not Flammable or Combustible.
- (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:**
- Small Spill:**
Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large Spill:**
Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor.
- Environmental Precautions:** Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
- For Emergency Responders:** If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For Non-Emergency Personnel"
- For Non-Emergency Personnel:** No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

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Section 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 wastewater 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.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

Lidocaine Hydrochloride

OEL TWA-8 Hr: 300 STEL 2500 $\mu\text{g}/\text{m}^3$, Skin

Sodium Hydroxide

ACGIH OEL (Ceiling)	2 mg/m^3
ACGIH TLV	Ceiling: 2 mg/m^3
Austria	2 mg/m^3 STEL 4 mg/m^3
Bulgaria	2.0 mg/m^3
Czech Republic	1 mg/m^3 Ceiling: 2 mg/m^3
Denmark	Ceiling: 2 mg/m^3
Estonia	1 mg/m^3 STEL: 2 mg/m^3
Finland	Ceiling: 2 mg/m^3
France	2 mg/m^3
Hungary	1 mg/m^3 STEL: 2 mg/m^3
Ireland	STEL: 2 mg/m^3
Ceiling Limit Value	2 mg/m^3
Latvia	0.5 mg/m^3
Poland	STEL: 1 mg/m^3 0.5 mg/m^3
Romania	1 mg/m^3 STEL: 3 mg/m^3
Slovakia	2 mg/m^3
Spain	STEL: 2 mg/m^3
Switzerland	2 mg/m^3 STEL: 2 mg/m^3

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OSHA PEL 2 mg/m³
(vacated) Ceiling: 2 g/m³
United Kingdom STEL: 2 mg/m³

Sodium Chloride

Latvia 5 mg/m³
Russia MAC: 5 mg/m³
Occupational Exposure Band OEB 1 (control exposure to the range of 1000 ug/m³
(OEB): to 3000 ug/m³)

Hydrochloric Acid

ACGIH OEL (Ceiling) 2 ppm
ACGIH TLV Ceiling: 2 ppm
Austria 5 ppm
8 mg/m³
STEL 10 ppm
STEL 15 mg/m³
Bulgaria STEL: 10 ppm
STEL: 15.0 mg/m³
5 ppm
8.0 mg/m³
Czech Republic 8 mg/m³
Ceiling: 15 mg/m³
Denmark Ceiling: 5 ppm
Ceiling: 8 mg/m³
Estonia 5 ppm
8 mg/m³
STEL: 10 ppm
STEL: 15 mg/m³
European Union TWA: 5 ppm
TWA: 8 mg/m³
STEL: 10 ppm
STEL: 15 mg/m³
Finland STEL: 5 ppm
STEL: 7.6 mg/m³
Germany 2 ppm
3.0 mg/m³
Ceiling / Peak: 4 ppm
Ceiling / Peak: 6 mg/m³
Germany 2 ppm
3 mg/m³
Hungary 8 mg/m³
STEL: 16 mg/m³
Ireland 8 mg/m³
5 ppm
STEL: 10 ppm
STEL: 15 mg/m³

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Italy	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Ceiling Limit Value	2 ppm 3.0 mg/m ³
Latvia	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Netherlands	8 mg/m ³ STEL: 15 mg/m ³
Poland	STEL: 10 mg/m ³ 5 mg/m ³
Romania	5 ppm 8 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Russia	MAC: 5 mg/m ³
Slovakia	5 ppm 8.0 mg/m ³
Spain	5 ppm 7.6 mg/m ³ STEL: 10 ppm STEL: 15 mg/m ³
Switzerland	2 ppm 3 mg/m ³ STEL: 4 ppm STEL: 6 mg/m ³
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m ³
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³ Ceiling: 5 ppm Ceiling: 7 mg/m ³
United Kingdom	TWA: 1 ppm TWA: 2 mg/m ³ STEL: 5 ppm STEL: 8 mg/m ³

(b) 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.

(c) Individual Protection Measures

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

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Respiratory Protection:	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, wear an appropriate respirator with a protection factor sufficient to control exposures.
Eye Protection:	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US).
Skin Protection:	Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly with water after handling this product.
Other Protective Equipment:	Protective gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Additional Exposure Precautions:	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Clear, colorless liquid
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	5-7
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not applicable
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available

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(r)	Viscosity	Not available
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Section 10 - Stability and Reactivity

(a)	Reactivity	No data available.
(b)	Chemical Stability	The product is stable under normal conditions of use.
(c)	Possibility of Hazardous Reactions	No data available.
(d)	Conditions to Avoid	Direct sunlight, conditions that might generate heat, and sources of ignition. Protect from freezing.
(e)	Incompatible Materials	No data available.
(f)	Hazardous Decomposition Products	No data available.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, skin and eye contact.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Harmful if swallowed. May cause mild eye irritation. May cause slight skin irritation. (based on components). Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	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.

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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Lidocaine Hydrochloride	LD ₅₀	Oral	Rat	317 mg/kg
	LD ₅₀	Para-periosteal	Rat	25 mg/kg
	LD ₅₀	Intraperitoneal	Rat	133 mg/kg
	LD ₅₀	Oral	Mouse	292 mg/kg
	LD ₅₀	Intravenous	Mouse	19.5 mg/kg
Sodium Chloride	LC ₅₀ /1 hr	Sub-tenon injection (eye)	Rat	>42 g/m ³
	LD ₅₀	Oral	Rat	3 g/kg
	LD ₅₀	Oral	Mouse	4 g/kg
	LD ₅₀	Dermal	Rabbit	>10 g/kg
Sodium Hydroxide	LD ₅₀	Intraperitoneal	Mouse	40 mg/kg
	LD ₅₀	Oral	Rat	325 mg/kg
	LD ₅₀	Dermal	Rabbit	1,350 mg/kg
Hydrochloric Acid	LD ₅₀	Oral	Rat	238 – 277 mg/kg
	LD ₅₀	Dermal	Rabbit	>5,010 mg/kg
	LC ₅₀	Inhalation	Rat	1.68 mg/L 1 hr
Water	LD ₅₀	Oral	Rat	>90 mL/kg

(e) Irritation/Sensitization

Lidocaine Hydrochloride

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

Sodium Chloride

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Sodium Hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

(f) Reproduction & Development Toxicity

Lidocaine Hydrochloride

Duration	Species	Route	Dose	End Point
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

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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

(g) Genetic Toxicity

Lidocaine Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

In Vitro Chromosome Aberration Human Lymphocytes Negative

In Vivo Micronucleus Mouse Negative

Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vivo Micronucleus Rat Negative

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

Hydrochloric Acid IARC Group 3 (Not Classifiable)

Information on other hazards

Endocrine disrupting properties No information available.

Other information

Other adverse effects No information available.

(h) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
(b)	Persistence and degradability	Not Available
(c)	Bioaccumulative potential	Not Available
(d)	Mobility in soil	Not Available
(e)	Other Adverse Effects	Not Available

Section 13 - Disposal Considerations

Waste Disposal: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with

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the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14 - Transport Information

- DOT:** Not regulated as a hazardous material.
- EUADR:** Not regulated as a hazardous material.
- IATA:** Not regulated as a hazardous material.
- IMDG:** Not regulated as a hazardous material.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy 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: Sodium Chloride is listed (Domestic Substance List)
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 304: Not regulated
- SARA 311/312 – Not on this list
- SARA 313 - Not on this list

Section 16 - Other Information

As of the date of effectiveness, 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.

For more information contact:

Avenacy
 10 N. Martingale Road, Suite 225
 Schaumburg, IL 60173
 847-773-4901

Glossary: This glossary contains definitions of general terms used in Safety Data Sheets (SDS).

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Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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)
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

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USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System