## Section 1 - Identification

**(a) Product Identifier:** Lidocaine Hydrochloride Injection, USP

**(b) Product Code:** 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. |

| | |
|---|---|
| **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. |

**(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 |

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

**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:**<br>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.<br><br>**Large Spill:**<br>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. |

## 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 µg/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$^3$ |

| | |
|---|---|
| OSHA PEL | 2 mg/m$^3$<br>(vacated) Ceiling: 2 g/m$^3$ |
| United Kingdom | STEL: 2 mg/m$^3$ |

**Sodium Chloride**

| | |
|---|---|
| Latvia | 5 mg/m$^3$ |
| Russia | MAC: 5 mg/m$^3$ |
| Occupational Exposure Band (OEB): | OEB 1 (control exposure to the range of 1000 ug/m$^3$ to 3000 ug/m$^3$) |

**Hydrochloric Acid**

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

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

| | |
|---|---|
| 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 |

| | | |
|---|---|---|
| **(r)** | **Viscosity** | Not available |

## 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. |

## (d) Acute Toxicity

| Component | Type | Route | Species | Dosage |
|---|---|---|---|---|
| Lidocaine Hydrochloride | $LD_{50}$<br>$LD_{50}$<br>$LD_{50}$<br>$LD_{50}$<br>$LD_{50}$ | Oral<br>Para-periosteal<br>Intraperitoneal<br>Oral<br>Intravenous | Rat<br>Rat<br>Rat<br>Mouse<br>Mouse | 317 mg/kg<br>25 mg/kg<br>133 mg/kg<br>292 mg/kg<br>19.5 mg/kg |
| Sodium Chloride | $LC_{50}$/1 hr<br>$LD_{50}$<br>$LD_{50}$<br>$LD_{50}$ | Sub-tenon injection (eye)<br>Oral<br>Oral<br>Dermal | Rat<br>Rat<br>Mouse<br>Rabbit | >42 g/m$^3$<br>3 g/kg<br>4 g/kg<br>>10 g/kg |
| Sodium Hydroxide | $LD_{50}$<br>$LD_{50}$<br>$LD_{50}$ | Intraperitoneal<br>Oral<br>Dermal | Mouse<br>Rat<br>Rabbit | 40 mg/kg<br>325 mg/kg<br>1,350 mg/kg |
| Hydrochloric Acid | $LD_{50}$<br>$LD_{50}$<br>$LC_{50}$ | Oral<br>Dermal<br>Inhalation | Rat<br>Rabbit<br>Rat | 238 – 277 mg/kg<br>>5,010 mg/kg<br>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 |

| | | | | |
|---|---|---|---|---|
| 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

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