

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078949965

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078949963 078949964

## 1.0 Product Identification:

- 1.1 **Product Name:** **Mexiletine Hydrochloride Capsules (All Strengths)**
- 1.2 **CAS #:** 5370-01-4 (Active Ingredient)
- 1.3 **Chemical Name:** Mixture
- 1.4 **Chemical Formula:** Mixture
- 1.5 **Manufacturer:** Ingenus Pharmaceuticals NJ, LLC  
140 New Dutch Lane  
Fairfield, NJ 07004  
862-210-8536  
www.ingenus.com
- 1.6 **Intended Use:** Pharmaceutical Medication.
- 1.7 **Emergency Contact:** 862-250-3243

## 2.0 Hazard Identification:

- 2.1 **GHS Classification:** Exempt from requirements – regulated as medicinal product.
- 2.2 **GHS Label Elements:** Exempt from requirements – regulated as medicinal product.
- 2.3 **Hazards Not Otherwise Classified (HNOC):** None

## 3.0 Composition / Information on Ingredients:

- 3.1 **Hazardous Ingredients:** *No hazardous ingredients per 29 CFR 1910.1200 or GHS.*

| Chemical Name                 | CAS #     | % By Weight |
|-------------------------------|-----------|-------------|
| Mexiletine Hydrochloride, USP | 5370-01-4 | >45%        |

- 3.2 **Non-Hazardous Ingredients:**

| Chemical Name                 | CAS #       |
|-------------------------------|-------------|
| Pregelatinized Starch, NF     | 9005-25-8   |
| Colloidal Silicon Dioxide, NF | 112945-52-5 |
| Magnesium Stearate, NF        | 557-04-0    |

Empty Hard Gelatin Capsule

Not Applicable

## 4.0 **First Aid Measures:**

- 4.1 **General advice:** This pharmaceutical product is a capsule form. The most likely route of exposure is ingestion. If unintentionally ingested, immediately consult a physician. Provide this Safety Data Sheet to the doctor.
- 4.2 **In case of Eye Contact:** Rinse thoroughly with plenty of water. Consult a physician.
- 4.3 **In case of Skin Contact:** Wash off with soap and plenty of water. Consult a physician.
- 4.4 **If Inhaled:** If inhaled, move person to fresh air. If not breathing, give artificial respiration. Consult a physician.
- 4.5 **If Swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
- 4.6 **Special treatment required:** No specific antidote. Treat symptomatically and supportively.

## 5.0 **Firefighting Measures:**

- 5.1 **Extinguishing media:** Use water spray, foam, dry chemical or carbon dioxide.
- 5.2 **Special hazards from fire:** Formation of irritating gases and vapors possible under fire conditions.
- 5.3 **Advice for firefighters:** Wear self-contained breathing apparatus (SCBA) under fire conditions.
- 5.4 **Further information:** Fine particles or dusts may fuel fires or explosions.

## 6.0 **Accidental Release Measures:**

- 6.1 **Protective equipment and emergency procedures:** Avoid dust formation. Ensure adequate ventilation. Use personal protective equipment. Avoid breathing dusts.
- 6.2 **Environmental precautions:** Do not let product enter drains, sewers or waterways.
- 6.3 **Containment and clean-up:** Avoid creating dust. Sweep up and place into a suitable, closed container for disposal.
- 6.4 **Reference to other SDS Sections:** See Section 8 for Personal Protective Equipment (PPE). See Section 13 for waste handling and disposal.

## 7.0 **Handling and Storage:**

- 7.1 **Precautions for safe handling:** Handle in accordance with good industrial hygiene and safety practices. Avoid contact with eyes and skin. Avoid creating dust. Provide adequate exhaust ventilation where dust is present. Wash hands before breaks and at the end of the workday.
- 7.2 **Conditions for safe storage:** Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in tight, light-resistant container as defined in the USP with a child-resistant closure (as required). Keep this and all medications out of the reach of children.
- 7.3 **Incompatibilities:** None identified.
- 7.4 **Specific end uses:** Pharmaceutical medication.

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## 8.0 Exposure Controls:

- 8.1 **Engineering Controls:** Use local exhaust ventilation when airborne dusts are present.
- 8.2 **Eye / Face Protection:** Safety glasses with side-shields. Use only approved eye protection.
- 8.3 **Hand / Skin Protection:** Handle using protective gloves. Nitrile gloves are recommended.
- 8.4 **Body Protection:** Work uniform or lab coat.
- 8.5 **Respiratory Protection:** Particle respirator or dust mask. Use only approved respiratory protection.

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## 9.0 Physical and Chemical Properties:

- 9.1 **State:** Solid
- 9.2 **Appearance:** Capsule
- 9.3 **Color:** 150 mg (Opaque tan cap and opaque orange body)  
200 mg (Opaque orange cap and opaque orange body)  
250 mg (Opaque green cap and opaque orange body)
- 9.4 **Odor:** No data available
- 9.5 **pH:** No data available
- 9.6 **Melting Point:** No data available
- 9.7 **Freezing Point:** No data available
- 9.8 **Boiling Point:** No data available
- 9.9 **Flash Point:** No data available
- 9.10 **Lower Explosive Limit (LEL):** No data available
- 9.11 **Upper Explosive Limit (UEL):** No data available
- 9.12 **Vapor Pressure:** No data available

- 9.13 **Vapor Density:** No data available
- 9.14 **Water Solubility:** No data available
- 9.15 **Auto-Ignition Temperature:** No data available
- 9.16 **Viscosity:** No data available

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## 10.0 **Stability and Reactivity:**

- 10.1 **Reactivity:** No information available.
- 10.2 **Chemical stability:** Stable under recommended storage conditions.
- 10.3 **Possibility of hazardous reactions:** None under normal processing.
- 10.4 **Conditions to avoid:** Heat, flames and sparks.
- 10.5 **Incompatible materials:** None known.
- 10.6 **Hazardous decomposition products:** None known.

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## 11.0 **Toxicological Information:**

- 11.1 **Toxicological effects:** No data available.
- 11.2 **Skin corrosion / irritation:** No known effects.
- 11.3 **Serious eye damage / irritation:** No known effects.
- 11.4 **Respiratory or Skin Sensitization:** No known effects.
- 11.5 **Germ Cell Mutagenicity:** No known effects.
- 11.6 **Carcinogenicity:** No known effects.
- 11.7 **Reproductive toxicity:** No known effects.
- 11.8 **Specific Target Organ Toxicity (STOT) – Single Exposure:** No known effects.
- 11.9 **Specific Target Organ Toxicity (STOT) – Repeated Exposure:** No known effects.
- 11.10 **Aspiration Hazard:** No known effects.
- 11.11 **Additional Information:** No data available.

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## 12.0 **Ecological Information:**

- 12.1 **Toxicity:** No data available.
- 12.2 **Persistence and degradability:** No data available.

12.3 **Possibility of hazardous reactions:** No data available.

12.4 **Bioaccumulative potential:** No data available.

12.5 **Mobility in soil:** No data available.

12.6 **Results of PBT and vPvB assessment:** No data available.

12.7 **Other adverse effects:** No data available.

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## 13.0 Disposal Consideration:

13.1 **Waste Classification:** Not classified as RCRA Hazardous Waste.

13.2 **Waste treatment methods:** Incineration at a licensed waste handling facility.

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## 14.0 Transportation Information:

14.1 **DOT (US):** Not classified as a Hazardous Material for ground transport.

14.2 **IATA:** Not classified as a Dangerous Good for air transport.

14.3 **IMDG:** Not classified as a Dangerous Good for maritime transport.

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## 15.0 Regulatory Information:

15.1 **SARA 302 Components:** No data available.

15.2 **SARA 313 Components:** No data available.

15.3 **SARA 311 / 312 Hazards:** No data available.

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## 16.0 Other Information:

16.1 **HMIS Ratings:** Health Hazard = 0  
Chronic Health = N/A  
Flammability = 0  
Physical Hazard = 0

16.2 **NFPA Ratings:** Health Hazard = 0  
Fire Hazard = 0  
Reactivity Hazard = 0

16.3 **SDS Preparation Information:** Ingenus Environmental, Health and Safety Department

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or the product for any particular purpose.

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