

# SAFETY DATA SHEET

Section 1: Identification		
Material	Mexiletine Capsules 150 mg, 200 mg and 250 mg	
Manufacturer	Hetero Labs Limited	
	Unit-III, 22-110, IDA, Jeedimetla,	
	Hyderabad, India	
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854	
Section 2: Hazard(s) Identification		
Hazard statement(s)	Harmful if swallowed.	
Precautionary statement(s)	Wash skin thoroughly after handling.	
	Do not eat, drink or smoke when using this product.	
,	IF SWALLOWED: Call a POISON CENTER/ doctor	
	if you feel unwell.	
Section 3: Composition/Information on Ingredients		
Ingredients	CAS	
Mexiletine Hydrochloride	5370-01-4	
Corn starch	9005-25-8	
Colloidal silicon dioxide	112926-00-8	
Magnesium Stearate	557-04-0	
Section 4: First-Aid Measures		
General advice	Consult a physician. Show this material safety data sheet to the doctor in attendance	
If inhaled	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.	
In case of skin contact	Wash off with soap and plenty of water. Consult a physician.	



In case of eye contact	Flush eyes with water as a precaution.
If swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Section 5: 1	Fire-Fighting Measures
Extinguishing media Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Special hazards arising from the substance or mixture	Carbon oxides Nitrogen oxides (NOx) Hydrogen chloride gas
Advice for firefighters	Wear self-contained breathing apparatus for firefighting if necessary
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.
Environmental precautions	Do not let product enter drains
Methods and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.
Section 7: Handling and Storage	
Precautions for safe handling Advice on safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols
Advice on protection against fire and explosion	Provide appropriate exhaust ventilation at places where dust is formed.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Storage conditions	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].



Section 8: Exposure Controls/Personal Protection		
Eye/face protection	Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).	
Skin protection	Handle with gloves. 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.  The selected protective gloves have to satisfy the	
	specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.	
<b>Body Protection</b>	Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.	
Respiratory protection	For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).	
Control of environmental exposure	Do not let product enter drains	
Section 9: Physical and Chemical Properties		
Physical Form	Capsule	
Description	Mexiletine hydrochloride capsules USP, 150 mg are white opaque/light blue opaque colored size '2', hard	
	gelatin capsules, imprinted with "V1" on cap and "30" on body, filled with white to off white granular powder. They are supplied as follows:	
	Bottles of 100 NDC 31722-036-01	



Mexiletine hydrochloride capsules USP, 200 mg are white opaque/light blue opaque colored size '1', hard gelatin capsules, imprinted with "V1" on cap and "33" on body, filled with white to off white granular powder. They are supplied as follows:

Bottles of 100

NDC 31722-037-01

Mexiletine hydrochloride capsules USP, 250 mg are white opaque/light blue opaque colored size '0', hard gelatin capsules, imprinted with "V1" on cap and "34" on body, filled with white to off white granular powder. They are supplied as follows:

Bottles of 100

NDC 31722-038-01

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Section 10: Stability and Reactivity		
Reactivity	No data available	
Chemical stability	Stable under recommended storage conditions	

## **Section 11: Toxicological Information**

## **Acute toxicity**

Acute toxicity estimate Oral - 320 mg/kg

(Calculation method)

LD50 Oral - Mouse - 320 mg/kg

### **Additional Information**

Central nervous system depression, Dizziness, Blurred vision, Tremors, Drowsiness, Convulsions, Unconsciousness



## **Section 12: Ecological Information**

### Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

## **Endocrine disrupting properties**

No data available

## Other adverse effects

No data available

## **Section 13: Disposal Considerations**

#### Waste treatment methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste, chemical waste generators must also consult local, regional and national hazardous waste regulations to ensure complete and accurate classification.

## **Section 14: Transport Information**

#### UN number

ADR/RID: - IMDG: - IATA: -

## UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

## Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

### Packaging group

ADR/RID: - IMDG: - IATA: -

## **Environmental hazards**

ADR/RID: no IMDG Marine pollutant: no IATA: no

## **Special precautions for user**

### **Further information**

Not classified as dangerous in the meaning of transport regulations



## **Section 15: Regulatory Information**

Safety, health and environmental regulations/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

## **Section 16: Other Information**

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Issue Date: 01-02-2023

Version: 00

**Further information** 

Revision date: NA

**Revision note: NA** 

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