



## SAFETY DATA SHEET

Section 1: Identification	
<b>Material</b>	<b>Oxcarbazepine Oral Suspension USP, 300mg/5ml</b>
<b>Recommended use</b>	Indicated in the treatment of partial seizures
<b>Manufacturer</b>	<b>Hetero Labs Limited, Unit-III</b> 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc., Piscataway, NJ 08854</b>
Section 2: Hazard(s) Identification	
<b>Physical hazards</b>	Not classified
<b>Health hazards</b>	Not classified
<b>OSHA defined hazards</b>	Not classified
<b>Hazard symbol</b>	None
<b>Signal word</b>	Warning
<b>Hazard statement</b>	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
<b>Prevention</b>	Observe good industrial hygiene practices
<b>Response</b>	Wash hands after handling
<b>Storage</b>	Store at 20 – 25 °C (68 - 77°F).
<b>Disposal</b>	Incineration of waste at an approved USEPA incinerator is recommended
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	<b>CAS</b>
Oxcarbazepine	28721-07-5
Saccharin sodium	6155-57-3
Ascorbic Acid USP (Fine powder)	50-81-7



Microcrystalline cellulose and Carboxymethylcellulose sodium	9004-34-6
Lemon Flavor 051124AP0551	8008-56-8
Methylparaben	99-76-3
Propylparaben	94-13-3
Sorbic acid	110-44-1
Polyoxyl 8 Stearate Type I	9004-99-3

#### Section 4: First-Aid Measures

<b>Inhalation</b>	Get medical attention if symptoms occur.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately
<b>Most important symptoms/effects, acute and delayed</b>	The most commonly observed adverse experiences were: dizziness, somnolence, diplopia, fatigue, nausea, vomiting, ataxia, abnormal vision, abdominal pain, tremor, dyspepsia, abnormal gait, infections and infestations
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidote known. Provide general supportive measures and treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves

#### Section 5: Fire-Fighting Measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.



<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8)
<b>Methods and materials for containment and cleaning up</b>	Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of Waste at an approved USEPA incinerator is recommended.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>Section 7: Handling and Storage</b>	
<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
<b>Conditions for safe storage, including any incompatibilities</b>	Store at 20 – 25 °C (68 - 77°F). Use within 7 weeks of first opening bottle. Store away from Incompatible materials (see Section 10 of the SDS).
<b>Section 8: Exposure Controls/Personal Protection</b>	
<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Ventilation should be matched to conditions.
<b>Eye/face protection</b>	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
<b>Skin protection Hand protection</b>	For consumer use, no unusual precautions are necessary.
<b>Other</b>	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for

	specific information
<b>Respiratory protection</b>	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	Liquid.
<b>Colour</b>	Off-white to slightly brown or red.
<b>Description</b>	<p>Oxcarbazepine Oral Suspension USP, 300 mg/5 mL (60 mg/mL) is an off-white to slightly brown or slightly red suspension with lemon flavor.</p> <p>Available in amber glass bottles containing 250 mL of oral suspension. Supplied with a 10 mL dosing syringe and press-in bottle adapter. Bottle containing 250 mL of oral suspension NDC 31722-687-25</p> <p>Store oxcarbazepine oral suspension, USP in the original container. Shake well before using. Use within 7 weeks of first opening the bottle.</p> <p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p>
<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity</b>	The product is stable and non-reactive under normal

	conditions of use, storage and transport
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Exposure to light
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.
<b>Section 11: Toxicological Information</b>	
<b>Inhalation</b>	Not expected to be hazardous in final pharmaceutical form.
<b>Skin contact</b>	Not expected to be hazardous in final pharmaceutical form.
<b>Eye contact</b>	Not expected to be hazardous in final pharmaceutical form. Contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Ingestion may cause irritation and stomach discomfort.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	The most commonly observed adverse experiences were: dizziness, somnolence, diplopia, fatigue, nausea, vomiting, ataxia, abnormal vision, abdominal pain, tremor, dyspepsia, abnormal gait, infections and infestations
<b>Acute toxicity</b>	May be harmful if swallowed in large quantities
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.
<b>Serious eye damage/eye irritation</b>	May cause temporary eye irritation.
<b>Respiratory sensitization</b>	Not a respiratory sensitizer.
<b>Skin sensitization</b>	Not expected to be a skin sensitizer.
<b>Germ cell mutagenicity</b>	Positive in vitro, but negative in vivo assays.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>Reproductive toxicity</b>	Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Drug is present in breast milk. A decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.
<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.
<b>Aspiration hazard</b>	Not classified.
<b>Further information</b>	See package insert.

<b>Section 12: Ecological Information</b>	
<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous.
<b>Persistence and degradability</b>	No data is available on the degradability of this product
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	Expected to be mobile in soil.
<b>Other adverse effects</b>	None.
<b>Section 13: Disposal Considerations</b>	
<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
<b>Section 14: Transport Information</b>	
<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable
<b>Section 15: Regulatory Information</b>	
<b>US federal regulations</b>	<p>This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&amp;D or drug use.</p> <p>Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.</p> <p>OSHA GHS: GHS symbols in consumer-packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and</p>



	OSHA 29 CFR 1910.1200(b)(5)(iii).
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories</b>	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	No
<b>SARA 313 (TRI reporting)</b>	Not regulated
<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	Not regulated.
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>	Not regulated
<b>Safe Drinking Water Act (SDWA)</b>	Not regulated
<b>US. Massachusetts RTK - Substance List</b>	Not regulated
<b>US. New Jersey Worker and Community Right-to-Know Act</b>	Not listed.
<b>US. Pennsylvania Worker and Community Right-to-Know Law</b>	Not listed
<b>US. Rhode Island RTK</b>	Not regulated.
<b>US. California Proposition 65</b>	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories****Country(s) or region Inventory name On inventory (yes/no)\***

Australia Australian Inventory of Chemical Substances (AICS) No

Canada Domestic Substances List (DSL) No

Canada Non-Domestic Substances List (NDSL) No

China Inventory of Existing Chemical Substances in China (IECSC) No

European Inventory of Existing Commercial Chemical Substances (EINECS)

Europe Yes

Europe European List of Notified Chemical Substances (ELINCS) No

Japan Inventory of Existing and New Chemical Substances (ENCS) No

Korea Existing Chemicals List (ECL) No

New Zealand New Zealand Inventory No

Philippine Inventory of Chemicals and Chemical Substances (PICCS)

Philippines No

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**Section 16: Other Information**

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**Further information**

**Revision date: New issue**

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The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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 product for any particular purpose.

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