SAFETY DATA SHEET

1. Identification
Product identifier: Oxcarbazepine Oral Suspension USP, 300mg/5ml
Other means of identification: None.
Recommended use: Indicated in the treatment of partial seizures
Recommended restrictions: None known.
Manufacturer/Importer/Supplier/Distributor information:
- Company name: West-Ward Pharmaceuticals Corporation
- Address: 1809 Wilson Road Columbus, Ohio 43228
- Telephone: (614) 276-4000
- Emergency phone number: (614) 276-4000

2. Hazard(s) identification
Physical hazards: Not classified.
Health hazards: Not classified.
OSHA defined hazards: Not classified.
Label elements:
- Hazard symbol: None.
- Signal word: Warning
- Hazard statement: 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.

Precautionary statement:
- Prevention: Observe good industrial hygiene practices.
- Response: Wash hands after handling.
- Storage: Store at 20 – 25 ºC (68 - 77ºF).
- Disposal: Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC): None known.

3. Composition/information on ingredients
Substances

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxcarbazepine</td>
<td></td>
<td>28721-07-5</td>
<td>300mg/5mL</td>
</tr>
</tbody>
</table>

Composition comments: Refer to Physician's Desk Reference for common components present at <1%

4. First-aid measures
Inhalation: Get medical attention if symptoms occur.
Skin contact: Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact: Rinse with water. Get medical attention if irritation develops and persists.
Ingestion: Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed:
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.
No specific antidote known. Provide general supportive measures and treat symptomatically.

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media
Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Use water spray to cool unopened containers.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).

Methods and materials for containment and cleaning up
Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities
Store at 20 – 25 ºC (68 - 77ºF). Use within 7 weeks of first opening bottle. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits
No exposure limits noted for ingredient(s).

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
Ventilation should be matched to conditions.

Individual protection measures, such as personal protective equipment

Eye/face protection
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.

Skin protection

Hand protection
For consumer use, no unusual precautions are necessary.

Other
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.

Respiratory protection
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.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.
General hygiene
considerations
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.

9. Physical and chemical properties

Appearance
- Physical state: Liquid.
- Form: Liquid.
- Color: Off-white to slightly brown or red.
- Odor: Not available.
- Odor threshold: Not available.
- pH: Not available.
- Melting point/freezing point: Not available.
- Initial boiling point and boiling range: Not available.
- Flash point: Not available.
- Evaporation rate: Not available.
- Flammability (solid, gas): Not available.

Upper/lower flammability or explosive limits
- Flammability limit - lower (%): Not available.
- Flammability limit - upper (%): Not available.
- Explosive limit - lower (%): Not available.
- Explosive limit - upper (%): Not available.
- Vapor pressure: Not available.
- Vapor density: Not available.
- Relative density: Not available.
- Solubility(ies)
  - Solubility (water): Insoluble
  - Partition coefficient (n-octanol/water): Not available.
- Auto-ignition temperature: Not available.
- Decomposition temperature: Not available.
- Viscosity: Not available.

10. Stability and reactivity

Reactivity
The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
Contact with incompatible materials. Exposure to light.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure
- Inhalation: Not expected to be hazardous in final pharmaceutical form.
- Skin contact: Not expected to be hazardous in final pharmaceutical form.
- Eye contact: Not expected to be hazardous in final pharmaceutical form. Contact with eyes may cause temporary irritation.
- Ingestion: Ingestion may cause irritation and stomach discomfort.
### Symptoms related to the physical, chemical and toxicological characteristics

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.

### Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>May be harmful if swallowed in large quantities.</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Prolonged skin contact may cause temporary irritation.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>May cause temporary eye irritation.</td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td>Not a respiratory sensitizer.</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Not expected to be a skin sensitizer.</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Positive in vitro, but negative in vivo assays.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not a respiratory sensitizer.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Mice and rats were administered high doses in a 2 year carcinogenicity study. Hepatocellular adenomas, hepatocellular carcinomas and tumors of the cervix, vagina, and testicular interstitial cells were observed.</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>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.</td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Not classified.</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Not classified.</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified.</td>
</tr>
<tr>
<td>Further information</td>
<td>See package insert.</td>
</tr>
</tbody>
</table>

### 12. Ecological information

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecotoxicity</td>
<td>The product is not classified as environmentally hazardous.</td>
</tr>
<tr>
<td>Persistence and degradability</td>
<td>No data is available on the degradability of this product.</td>
</tr>
<tr>
<td>Bioaccumulative potential</td>
<td>No data available.</td>
</tr>
<tr>
<td>Mobility in soil</td>
<td>Expected to be mobile in soil.</td>
</tr>
<tr>
<td>Other adverse effects</td>
<td>None.</td>
</tr>
</tbody>
</table>

### 13. Disposal considerations

<table>
<thead>
<tr>
<th>Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disposal instructions</td>
<td>Collect and reclaim or dispose in sealed containers at licensed waste disposal site.</td>
</tr>
<tr>
<td>Local disposal regulations</td>
<td>Dispose in accordance with all applicable regulations.</td>
</tr>
<tr>
<td>Hazardous waste code</td>
<td>The waste code should be assigned in discussion between the user, the producer and the waste disposal company.</td>
</tr>
<tr>
<td>Waste from residues / unused products</td>
<td>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).</td>
</tr>
<tr>
<td>Contaminated packaging</td>
<td>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.</td>
</tr>
</tbody>
</table>

### 14. Transport information

**DOT**

- Not regulated as dangerous goods.

**IATA**

- Not regulated as dangerous goods.

**IMDG**

- Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

- Not applicable.
15. Regulatory information

US federal regulations

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

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.


TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.

US. Rhode Island RTK
Not regulated.

US. California Proposition 65
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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Oxcarbazepine Oral Suspension USP, 300mg/5ml
926318   Version #: 01   Revision date: -   Issue date: 25-April-2015

SDS US
### Country(s) or region
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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).

### 16. Other information, including date of preparation or last revision

**Issue date** 25-April-2015  
**Revision date** -  
**Version #** 01  
**References**  
1) Oxcarbazepine Oral Suspension USP, 300mg/5mL, Package Insert, West-Ward Pharmaceuticals Corporation, Columbus, Ohio  
2) PDR – Physicians Desk Reference.  

**Disclaimer**  
West-Ward Pharmaceuticals Corporation cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user’s responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.