MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT Oxcarbazepine Tablets, 150 mg, PRODUCT No.:

NAME: 300 mg and 600 mg 150 mg 51672-4105

> 300 mg 51672-4106

> 600 mg 51672-4107

MOLECULAR

252.27 FORMULA:

CAS #:

28721-07-5

SECTION 2: PHYSICAL/CHEMICAL DATA

BOILING POINT: Not Applicable MELTING/FREEZING POINT: Not Applicable

PHYSICAL STATE (liquid/solid/gas): Solid

SPECIFIC GRAVITY (H₂O=1): Not Applicable **BULK DENSITY** Not Established

SOLUBILITY: Slightly soluble in chloroform, acetone and

methanol. Insoluble in ethanol, ether and water

APPEARANCE: Pale peach, oval, slightly biconvex tablets,

scored on both sides

ODOR DESCRIPTION: Not Applicable

SECTION 3: FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: Not Applicable

FLAMMABLE LIMITS:

Upper Explosion Limit (UEL%): Not established Lower Explosion Limit (LEL%): Not established **AUTO-IGNITION TEMPERATURE:** Not Applicable

EXTINGUISHING MEDIA: Water, Foam, Dry Chemical

SPECIAL FIRE FIGHTING Evacuate area and fight fire from safe distance.

PROCEDURES:

FIRE AND EXPLOSION HAZARDS: Not available

HAZARDOUS COMBUSTION

PRODUCTS: COx,NOx

SECTION 4: STABILITY AND REACTIVITY DATA

CHEMICAL STABILITY:

Stable

CONDITIONS TO AVOID:

Protect from light.

SUBSTANCES TO AVOID

Not known.

DECOMPOSITION PRODUCTS:

Not known

HAZARDOUS POLYMERIZATION:

Will not occur

SECTION 5: HEALTH HAZARD DATA

EMERGENCY OVERVIEW FIRST AID MEASURES

Eye:

Use safety glasses if there is a potential for splashing. Flush with running

water for 15 minutes holding eyelids open.

Skin:

Wash contaminated area with soap and water.

Ingestion:

Get medical attention immediately.

Inhalation:

No specific treatment is necessary as this product is not likely to be inhaled.

SECTION 6: SPILL OR RELEASE PROCEDURES and WASTE DISPOSAL

STEPS TO BE TAKEN IF

Using appropriate protective equipment, clean up and

MATERIAL IS RELEASED OR

SPILLED:

containerize spilled material.

WASTE DISPOSAL METHOD:

Using appropriate protective equipment, clean up and

containerize spilled material. Consult local water

regulations prior to disposal.

SECTION 7: HANDLING AND STORAGE

HANDLING:

Keep this and all drugs out of the reach of children. Containers should be

kept tightly closed to prevent contamination. Use normal precautions for storage of a drug. Avoid contact with eyes. Avoid contact with skin or

clothing.

STORAGE:

Store at 20°C -25°C (68° - 77°F); excursions permitted to 15°C -30°C (59°

- 86°F) [see USP Controlled Room Temperature]

SHELF LIFE:

Do not use after expiration date.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

GENERAL EFFECTS OF EXPOSURE:

Routes of entry: Ingestion, Skin Contact, Inhalation

Acute Effects of Exposure: Overdosing can include nausea, vomiting and fatigue.

CARCINOGENIC COMPONENTS: Increased hepatocellular adenomas and carcinomas

NTP: None IARC: None OSHA: None

Therapeutic side effects by

Exposure:

Hyponatremia, nausea, headaches, dizziness, fatigue, vomiting, somnolence, ataxia, rash, diplopia, vision abnormality, rash, abdominal pain, tremor. Alcohol may

increase sedative effects.

Human Health Effects

Postnote:

Use only as directed. See product packaging and the Physicians' Desk Reference (PDR) for further information concerning adverse effects and drug interaction precautions.

This is a pharmaceutical material.

SECTION 9: OTHER INFORMATION

ECOLOGICAL DATA: No data available for this product.

TRANSPORTATION INFORMATION: Not Regulated in Transportation.

CONTACT INFORMATION:

Taro Pharmaceuticals U.S.A., Inc. Attn: Regulatory Affairs Department 3 Skyline Drive Hawthorne, NY 10532 (914) 345-9001 (914) 593-0078 fax

SECTION 12: REGULATORY INFORMATION

United States Federal Regulation

OSHA:

This Material Safety Data Sheet contains the information required by the Federal

Hazard Communication Standard.

SCA:

Not applicable.

SARA Title III

Sara Section 302 Extremely Hazardous

Not Listed

Substances:

SARA Section 311/312 Hazard

Categories:

Not Listed

SARA Section 313 Reportable Ingredients

Not Listed

DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals U.S.A., Inc. assumes no legal responsibility for the use or reliance of this information.

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