

Safety Data Sheet for Drug product



Date of issue: 17-OCT-2016

Replaces version of: 30-NOV-2015

TRILEPTAL SSP 60MG/ML.004 138793 (MARS)

1. Identification of the substance/preparation and of the company

Product name TRILEPTAL SSP 60MG/ML.004
Chemical Class dibenzazepine derivative
Generic Name Oxcarbazepine
Pharmacological Action antiepileptic, Anticonvulsant
Usage Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name NIBR East Hanover
One Health Plaza
East Hanover, NJ 07936
sds.support@novartis.com
Emergency phone number CHEMTEL (US/Canada) 1-800-255-3924

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
Oxcarbazepine	5 - 10 %	28721-07-5

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

4. First aid measures

Eye Contact Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Skin Contact Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation Remove the victim from danger zone, avoid further exposure.
Ingestion If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media No restrictions
Dangerous Combustion Products nitrogen oxides
Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions Avoid contact with skin, eyes and clothing.
Environmental Must not be released into sewers, drains or wells.

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precautions

Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components

Contains:

Oxcarbazepine

List type	Value	Unit	
Internal exposure limit	360	µg/m3	HHA Database

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Formulation suspension

Flash Point not applicable

10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity Data of Oxcarbazepine

LD50: > 6000 mg/kg

Route: oral

Species: rat

Irritation, Corrosion Data of Oxcarbazepine

Eyes (Species: rabbit) non irritant

Method: FDA 1964

Data of Oxcarbazepine

Skin (Species: rabbit) non irritant

Method: Draize test

Sensitisation Data of Oxcarbazepine

Skin (Species: mouse) not sensitizing

Data of Oxcarbazepine

Skin (Species: guinea pig) not sensitizing

Mutagenicity Data of Oxcarbazepine

Negative (AMES-Test (reverse mutation assay))

in vitroCell: Strains of salmonella typhimurium.

Data of Oxcarbazepine

Negative (Gene Mutation Assay in Vitro)

in vitroCell: V79 cells (embryonic lung fibroblasts) of the Chinese hamster

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	Data of Oxcarbazepine Negative (Micronucleus Test) in vivo, Species: rat, Cell: Bone marrow
Chronic Effects	Data of Oxcarbazepine Minimal toxicity - irreversible (Repeated Dose Toxicity) NTEL: 20 mg/kg/d Route: oral Species: rat, Organ: Liver, kidneys Dosage: <= 300 mg/kg/d, Duration: 13 weeks Data of Oxcarbazepine Pharmacological effects (Repeated Dose Toxicity) Route: oral Species: dog, Organ: Central nervous system Dosage: <= 600 mg/kg/d, Duration: 52 weeks Data of Oxcarbazepine Increased incidence of liver adenoma (Carcinogenesis) Route: oral Species: mouse, Organ: Liver Dosage: <= 100 mg/kg/d, Duration: 2 years Data of Oxcarbazepine Carcinogen in animals (Carcinogenesis) Route: oral Species: rat, Organ: Liver Dosage: <= 250 mg/kg/d, Duration: 2 years
Reproduction Toxicity	Data of Oxcarbazepine Embryotoxicity at maternally toxic dose (Embryo-Fetal Development) Route: oral Species: rat Data of Oxcarbazepine Negative (Fertility and early Embryonic Development) NOEL: 150 mg/kg/d Route: oral Species: rat Data of Oxcarbazepine Teratogenicity was found (Embryo-Fetal Development) LOEL: 30 mg/kg/d Route: oral Species: mouse Data of Oxcarbazepine Negative (Embryo-Fetal Development) NOEL: 75 mg/kg/d Route: oral Species: rabbit Data of Oxcarbazepine Peri-Postnatal developmental effects (Peri- and Postnatal Development) NOAEL: 25 mg/kg/d Route: oral Species: rat
Human Pharmacokinetics	Data of Oxcarbazepine suspension Absorption: 95 % Half Life (T _{1/2}): 1.3 - 2.3 hours T _{max} : 6 hours Route: oral Species: man Dose: 600 mg Data of Oxcarbazepine Tablet

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Absorption: 95 %
Half Life (T_{1/2}): 1.3 - 2.3 hours
Tmax: 5 hours
Route: oral
Species: man
Dose: 600 mg

12. Ecological information

Biological Elimination Data of Oxcarbazepine
Degradation: 2 % (aerobic: Temperature: 20 - 25 °C DOC)
Not readily degradable
Initial conc.: 20 mg DOC/l, Duration: 28 days
Method: OECD 301E * 1981

Data of Oxcarbazepine
Degradation: 8 % (aerobic: Temperature: 20 - 24 °C CO₂)
Not readily degradable
Initial conc.: 10 mg/l, Duration: 28 days
Method: OECD 301B * 1981

Fish acute toxicity Data of Oxcarbazepine
LC0: > 100 mg/l
LC50: > 100 mg/l
Species: zebra fish (danio rerio)
Exp. time: 96 hours
Method: OECD 203 * 1984 * acute toxicity

Aquatic invertebrate acute toxicity Data of Oxcarbazepine
EC0: 58 mg/l
EC50: > 100 mg/l
Species: daphnia magna (water flea)
Exp. time: 24 hours
Method: EEC L251,C.2. 1984 * acute tox.

Algae Toxicity Data of Oxcarbazepine
ErC50: 12.8 mg/l
ErC10: 1.02 mg/l
LOEC: 1.34 mg/l
NOEC: 0.534 mg/l
Species: Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)
Exp. time: 72 hours
Method: OECD 201 * 2011 * ALGAE GROWTH INHIBITION

Bacterial Respiration Inhibition Data of Oxcarbazepine
EC50: > 320 mg/l
Species: activated sludge
Exp. time: 3 hours
Method: OECD 209 * 1984

Ecotoxicity Summary Data of Oxcarbazepine
When low concentrations are discharged correctly into adapted biological sewage treatment plants, interference with the degradation activity of activated sludge is not likely.
Data of Oxcarbazepine
Bioaccumulation in water organisms is not likely based on the n-octanol/water partition coefficient (log Pow < 3.0).

13. Disposal considerations

Disposal Requirements Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information

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Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Classification
Oxcarbazepine	5 - 10 %	28721-07-5		H402, H411

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H402: Harmful to aquatic life.(in EU not leading to classification as hazardous)

H411: Toxic to aquatic life with long lasting effects.

Recipient

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USA

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.