

Safety Data Sheet for Drug product



Date of issue: 19-JAN-2016

Replaces version of: 23-NOV-2015

TEGRETOL XR FCT 400MG 1X4 US S 135179 (MARS)

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

Product name TEGRETOL XR FCT 400MG 1X4 US S
Chemical Class dibenzazepine derivative
Generic Name Carbamazepine
Pharmacological Action antiepileptic, Anticonvulsant
Usage no data available
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
Carbamazepine	60 - 70 %	298-46-4

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 carbon oxides, 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 precautions Must not be released into sewers, drains or wells.

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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:

Carbamazepine

List type	Value	Unit	
Internal exposure limit	240	µg/m3	HHA Database

Personal protection for open handling

Health care personnel	 	Safety glasses (EN166) Lab coat Disposable gloves (EN374)
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9. Physical and chemical properties

Formulation Tablet
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 Carbamazepine
LC50: > 2160 mg/m3
Route: inhalative
Species: rat
Exp. time: 4 hours

Data of Carbamazepine
LD50: > 3850 - 4025 mg/kg
Route: oral
Species: rat

Data of Carbamazepine
LD50: > 5620 mg/kg
Route: oral
Species: dog

Data of Carbamazepine
LD50: 1100 - 3750 mg/kg
Route: oral
Species: mouse

Data of Carbamazepine
LD50: 1500 - 2680 mg/kg
Route: oral
Species: rabbit

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	Data of Carbamazepine LD50: 920 mg/kg Route: oral Species: guinea pig
Irritation, Corrosion	no data available
Sensitisation	no data available
Mutagenicity	Data of Carbamazepine Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of salmonella typhimurium. Data of Carbamazepine Negative (Mouse Lymphoma Mutagenicity Assay in vitro) in vitroCell: Lymphoma cells L5178Y of the mouse Data of Carbamazepine Negative (Dominant lethal test) in vivo, Species: mouse, Cell: Germ cells Data of Carbamazepine Negative (Chromosome Aberration Study) in vivo, Species: mouse, Cell: Germ cells Data of Carbamazepine Negative (Micronucleus Test) in vivo, Species: chinese hamster, Cell: Bone marrow
Chronic Effects	Data of Carbamazepine Severe toxicity - reversible (Repeated Dose Toxicity) NOAEL: 50 mg/kg/d Route: oral Species: rat, Organ: Male reproductive system Duration: 52 weeks Data of Carbamazepine Severe toxicity - reversible (Repeated Dose Toxicity) NOAEL: 100 mg/kg/d Route: oral Species: dog, Organ: Liver Duration: 52 weeks Data of Carbamazepine Evidence for tumour promotion (Carcinogenesis) NOAEL: 25 mg/kg/d Route: Dietary Species: rat, Organ: Liver Duration: 104 weeks
Reproduction Toxicity	Data of Carbamazepine Negative (Fertility and early Embryonic Development) LOAEL: 30 mg/kg/d Route: oral Species: rat Data of Carbamazepine No teratogenicity at maternally non toxic dose (Embryo-Fetal Development) NOAEL: 30 mg/kg/d Route: oral Species: rat Data of Carbamazepine No Teratogenicity (Embryo-Fetal Development) NOAEL: 75 mg/kg/d Route: oral Species: mouse Data of Carbamazepine Negative (Peri- and Postnatal Development) NOAEL: 192 mg/kg/d

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	Route: oral
	Species: rat
	Data of Carbamazepine
	Embryotoxicity at maternally toxic dose (Embryo-Fetal Development)
	Route: oral
	Species: rabbit
Human Pharmacokinetics	Data of Carbamazepine
	Tablet (Human pharmacokinetics and metabolism)
	Absorption: approx. 100 %
	Half Life ($T_{1/2}$): 9 - 10 hours
	Tmax: 12 hours
	Availability: 85 - 100 %
	Route: oral
	Species: human
	Dose: 400 mg

12. Ecological information

Biological Elimination Data of Carbamazepine
Degradation: = 0 % (aerobic: Temperature: 21 - 25 °C DOC)
not degradable in biol. waste water treatment plant
Initial conc.: 20 mg DOC/l, Duration: 28 days
Method: OECD 301E * 1981

Fish acute toxicity Data of Carbamazepine
LC0: 32 mg/l
LC50: 43 mg/l
LC100: 58 mg/l
Species: zebra fish (danio rerio)
Exp. time: 96 hours
Method: OECD 203 * 1984 * acute toxicity

Data of Carbamazepine
LC50: 13.3 mg/l
NOEC: 12.5 mg/l
Species: zebra fish (danio rerio)
Exp. time: 96 hours
Method: OECD (1998a) Zebrafish embryo toxicity test

Aquatic invertebrate acute toxicity Data of Carbamazepine
EC0: 32 mg/l
EC50: 92 mg/l
EC100: > 100 mg/l
Species: daphnia magna (water flea)
Exp. time: 24 hours
Method: OECD 202 * 2004

Data of Carbamazepine
EC50: 71 mg/l
Species: Ceriodaphnia dubia
Exp. time: 48 hours
Method: EPA-821-R-02-013 (2002) * Chronic toxicity
(derived value)

Aquatic invertebrate chronic toxicity Data of Carbamazepine
LOEC: 0.1 mg/l
NOEC: NOEC: 0.025 mg/l
Species: Ceriodaphnia dubia
Exp. time: 7 days
Method: AFNOR T 90-376 (2000)

Data of Carbamazepine
LOEC: 1.26 mg/l
NOEC: NOEC: 0.4 mg/l

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Species: daphnia magna (water flea)
Exp. time: 21 days
Method: OECD 211 * 2008
Data of Carbamazepine
LOEC: 31 mg/l
NOEC: NOEC: 17 mg/l
Species: Ceriodaphnia dubia
Exp. time: 7 days
Method: EPA-821-R-02-013 (2002) * Chronic toxicity
Data of Carbamazepine
EC10: 24 mg/l
EC50: 41 mg/l
Species: Ceriodaphnia dubia
Exp. time: 7 days
Method: EPA-821-R-02-013 (2002) * Chronic toxicity

Algae Toxicity

Data of Carbamazepine
NOEC: 20 mg/l
Species: Pseudokirchneriella subcapitata/Selenastrum capricornutum (Green algae)
Exp. time: 96 hours
Data of Carbamazepine
LOEC: > 100 mg/l
NOEC: 100 mg/l
Species: Green algae - fresh water (Pseudokirchneriella subcapitata)
Exp. time: 96 hours
Method: OECD 201 * 1984 * Growth inhibition
Data of Carbamazepine
EC50: 74 mg/l
Species: Desmodesmus subspicatus/Scenedesmus subspicatus (Green algae)
Exp. time: 3 days
Method: 92/69/EC (L383) C.3

Bacterial Respiration Inhibition

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

Ecotoxicity Summary

Data of Carbamazepine
Avoid release into soil, rivers or drains.

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

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

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Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Carbamazepine	60 - 70 %	298-46-4		W	H303, H351, H361d, H402, H410

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H303: May be harmful if swallowed.(in EU not leading to classification as hazardous)

H351: Suspected of causing cancer.

H361d: Suspected of damaging the unborn child.

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

H410: Very 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.