

# Safety Data Sheet for Drug Products (EU)



Date of issue: 13-JUN-2017

Replaces version of:

TEGRETOL TAB 400MG.003 850721 (MARS)

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

**Product name** TEGRETOL TAB 400MG.003  
**Chemical Class** dibenzazepine derivative  
**Generic Name** Carbamazepine  
**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
Carbamazepine	22 - 72 %	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** 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:

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)

## 9. Physical and chemical properties

**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
<b>Irritation, Corrosion</b>	no data available
<b>Sensitisation</b>	no data available
<b>Mutagenicity</b>	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
<b>Chronic Effects</b>	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
<b>Reproduction Toxicity</b>	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
<b>Human Pharmacokinetics</b>	Data of Carbamazepine
	Tablet (Human pharmacokinetics and metabolism)
	Absorption: approx. 100 %
	Half Life (T <sub>1/2</sub> ): 9 - 10 hours
	Tmax: 12 hours
	Availability: 85 - 100 %
	Route: oral
	Species: human
	Dose: 400 mg

## 12. Ecological information

<b>Biological Elimination</b>	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
<b>Fish acute toxicity</b>	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
<b>Aquatic invertebrate acute toxicity</b>	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)
<b>Aquatic invertebrate chronic toxicity</b>	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:	9 / M7	3077	III	9, M	5 kg
IMDG-Code:	9	3077	III	9, M	5 kg
ICAO/IATA-DGR:	9	3077	III	9, M	

M = Environmentally Hazardous

**ICAO/IATA-DGR:** classified

**Proper shipping name:** Environmentally hazardous substance, solid, n.o.s. ( Carbamazepine)

## 15. Regulatory information

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## Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Carbamazepine	22 - 72 %	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

Henry Delima  
Delima Associates  
1227 Providence Terr  
McLean, VA  
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.