



# SAFETY DATA SHEET

Complying with 1907/2006/EC Regulation of 18 December 2006.

Issuing Date 26-Aug-2009

Revision Date 26-Aug-2009

Revision Number 1

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Product Name**

**CARVEDILOL**

**Synonyms**

BM 14190; 1-(9H-Carbazol-4-yloxy)-3-((2-(2-methoxyphenoxy)ethyl)amino)-2-propanol; (+)-Carvedilol; Coreg; DQ 2466; SKF 105517; DIMITONE; SFK 105517; KREDEX

**Identified Use**

Active Pharmaceutical Ingredient

**Manufacturer, Supplier**

Teva Plantex  
API Production  
PO Box 160  
Old Industrial Zone  
Netanya 47101  
Tel: 972(9) 860-4333  
Fax: 972(9) 833-9063

Contact for timely inquires in regards to this product

**Emergency Telephone Number**

972 (9)-8604300; 972 (9)-8826604

## 2. HAZARDS IDENTIFICATION

**According to EC Directive 2001/58/EC**

**Most Important Hazards**

Possible risk of harm to the unborn child

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

**Classification**

Xn - Harmful

N - Dangerous for the environment

**GHS-Classification**

**Hazards Statements**

Suspected of damaging fertility or the unborn child

Very toxic to aquatic life

Very toxic to aquatic life with long lasting effects

**Signal Word**

Warning

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical Name:**  $\pm$ 1-(Carbazol-4-yloxy)-3-[[2-(o-methoxyphenoxy)ethyl]amino]-2-propanol

**Formula** C<sub>24</sub> H<sub>26</sub> N<sub>2</sub> O<sub>4</sub>

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %	EU Classification	GHS Classification
CARVEDILOL	-	Not available	72956-09-3	100	Repr. Cat. 3; R63 N; R50/53	Repr. 2 H361 Aquatic Acute 1 H400 Aquatic Chronic 1 H410

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
<b>Ingestion</b>	Get medical attention. Clean mouth with water, only if the person is in conscious.
<b>Inhalation</b>	Remove from exposure, lie down. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
<b>Notes to Physician</b>	Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media</b>	Water spray. Carbon dioxide (CO <sub>2</sub> ). Foam. Dry powder.
<b>Extinguishing media which must not be used for safety reasons</b>	No information available.
<b>Special exposure hazards arising from the substance/preparation including combustion products and gases</b>	Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.
<b>Special protective equipment for firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Environmental Precautions</b>	Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.
<b>Personal Precautions</b>	Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.
<b>Methods for Cleaning up</b>	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). If emergency, enforce internal emergency plan.
<b>Other Information</b>	See Section 12 for additional information.

## 7. HANDLING AND STORAGE

<b>Handling</b>	Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.
<b>Storage</b>	Keep tightly closed in a dry and cool place. Keep at temperatures 25°C. Excursion permitted between 15°C and 40°C. Store in accordance with local regulations.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Exposure Limits</b>	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
<b>Occupational Exposure Controls</b>	
<b>Engineering Measures</b>	Provide engineering control, according to Teva Guidelines.
<b>Special Requirements</b>	Employment of pregnant women is permitted subject to protective measures required by local regulations and Teva policy .
<b>Personal Protective Equipment</b>	
<b>Respiratory Protection</b>	Approved full face respirator P3 or airline respirator.
<b>Eye Protection</b>	Approved safety goggles/glasses.
<b>Skin and Body Protection</b>	Long sleeved clothing.
<b>Hand Protection</b>	Rubber/latex/neoprene or other suitable chemical resistant gloves.
<b>Hygiene Measures</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Environmental exposure controls</b>	No information available.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### General Information

<b>Appearance</b>	White off-white Powder Nonhygroscopic
<b>Odour</b>	No information available

### Important Health, Safety and Environmental Information

<b>Flash Point</b>	Expected to be > 55 °C	<b>Boiling Point/Range</b>	No information available.
<b>pH</b>	No information available.	<b>Vapor Pressure</b>	No information available.
<b>VOC Content</b>	No information available.	<b>Viscosity</b>	No information available

<b>Solubility</b>	Freely Soluble in Dimethylsulfoxide. Soluble in Methanol, Methylene chloride. Sparingly soluble in 95% ethanol, Isopropanol. Slightly soluble in Ethyl ether.	<b>Water Solubility</b>	Practically insoluble
<b>Molecular Weight</b>	406.5	<b>Specific Gravity</b>	No information available
<b>Octanol/water Partition Coefficient ( Log Kow )</b>	3.8	<b>Evaporation Rate</b>	No information available
<b>Vapor Density</b>	No information available.	<b>Relative Density</b>	No information available.

**Other Information**

<b>Melting Point/Range</b>	114-115 °C	<b>Autoignition Temperature</b>	No information available
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**10. STABILITY AND REACTIVITY**

<b>Stability</b>	Stable under normal conditions. Thermal degradation suspected at > 200 deg C.
<b>Conditions to Avoid</b>	Moisture. All sources of ignition.
<b>Materials to Avoid</b>	Strong oxidizing agents.
<b>Hazardous Decomposition Products</b>	Toxic fumes of: Nitrogen oxides (NOx), Carbon oxides.
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur.

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

#### Product Information

**LD50 Oral rat** 8000 mg/kg

**Irritation:** May be irritant to eyes, skin and respiratory system  
**Corrosivity:** No information available.  
**Sensitization** No information available

**Eyes:** Visual abnormalities  
**Skin:** May cause: Irritation  
**Inhalation:** May cause: Angina.  
**Ingestion:** May cause: Nausea, Vomiting, Diarrhea

#### Other information:

**Central nervous system:** May cause headache, May cause dizziness, May cause insomnia  
**Cardiovascular system:** Decreased/irregular heart rate , Hypo/hypertension  
**Body as a whole** May cause: Fatigue

### Chronic toxicity

**Carcinogenicity** Not listed by IARC. Rats 75 mg/kg/day (12 times the maximum recommended human dose MRHD) or in mice given up to 200 mg/kg/day (16 times the MRHD): no carcinogenic effect.

**Mutagenic Effects** Negative when tested in a battery of genotoxicity assays, including the Ames and the CHO/HGPRT assays for mutagenicity and the in vitro hamster micronucleus and in vivo human lymphocyte cell tests for clastogenicity.

**Reproductive Toxicity** Rat 200 mg/ kg/ day: toxic (sedation, reduced weight gain), reduced number of successful matings, reduced sperm fertility, prolonged mating time, significantly fewer corpora lutea and implants per dam, complete resorption of 18% of the litters; NOEL: 60 mg/ kg/D. Rats 300 mg/kg/day (50 times the MRHD ), rabbits 75 mg/kg/day (25 times the MRHD ): increased post-implantation loss

**Target Organ Effects** Central nervous system (CNS).

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Microtox	Daphnia Magna (Water Flea)
CARVEDILOL	NOEL (78h): 0.46 mg/l	LC50 (96h): 0.95 mg/l NOEL (96h): <0.43 mg/l		EC50 (48 h): >2.8 mg/l NOEL (48h): <0.37 mg/l

**Persistence and Degradability** No information available.  
**Bioaccumulation** Expected to bioaccumulate. Half-Life Elimination in Human: 7-10h.  
**Mobility** No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste from Residues/Unused Products** Dispose of in accordance with local regulations.

**Contaminated Packaging** Empty containers should be taken for local recycling, recovery or waste disposal.

**14. TRANSPORT INFORMATION****IMDG/IMO**

<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s (Carvedilol)
<b>Hazard Class</b>	9
<b>UN-No</b>	3077
<b>Packing Group</b>	III
<b>EmS No.</b>	F-A, S-F
<b>Marine Pollutant</b>	This product contains a chemical which is listed as a marine pollutant according to IMDG/IMO (P)

**RID**

<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s (Carvedilol)
<b>Hazard Class</b>	9
<b>UN-No</b>	3077
<b>Packing Group</b>	III
<b>Classification Code</b>	M7

**ADR**

<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s (Carvedilol)
<b>Hazard Class</b>	9
<b>UN-No</b>	3077
<b>Packing Group</b>	III
<b>Classification Code</b>	M7

**ICAO**

<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s (Carvedilol)
<b>Hazard Class</b>	9
<b>UN-No</b>	3077
<b>Packing Group</b>	III

**IATA**

<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s (Carvedilol)
<b>Hazard Class</b>	9
<b>UN-No</b>	3077
<b>Packing Group</b>	III

**DOT**

<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s (Carvedilol)
<b>Hazard Class</b>	9
<b>UN-No</b>	3077
<b>Packing Group</b>	III

**NFPA**

<b>Health Hazard</b>	2	<b>Flammability</b>	0	<b>Stability</b>	0
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## 15. REGULATORY INFORMATION

**Labelling**EU Directive 2001/58/EC classification**Contains****Symbol(s)**

Xn - Harmful. N - Dangerous for the environment.

**R-phrases(s)**

R63 - Possible risk of harm to the unborn child

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

**S-phrases(s)**

S22 - Do not breathe dust

S61 - Avoid release to the environment. Refer to special instructions/safety data sheets

S60 - This material and its container must be disposed of as hazardous waste

S 7/8 - Keep container tightly closed and dry

S24/25 - Avoid contact with skin and eyes

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection

**GHS-Classification****Signal Word**

Warning

**Hazards Statements**

H361 - Suspected of damaging fertility or the unborn child

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

**Precautionary Statements**

P402 + P404 - Store in a dry place. Store in a closed container

P260 - Do not breathe dust

P262 - Do not get in eyes, on skin, or on clothing

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P501 - Dispose of contents/container to an approved waste disposal plant.

P273 - Avoid release to the environment

**International Inventories****TSCA** Not Listed**EINECS/ELINCS** Not Listed**DSL/NDSL** Not Listed**PICCS** Not Listed**ENCS** Not Listed**IECSC** Not Listed**AICS** Not Listed**KECL** Not Listed**Legend****TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List**PICCS** - Philippines Inventory of Chemicals and Chemical Substances**ENCS** - Japan Existing and New Chemical Substances

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**IECSC** - China Inventory of Existing Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances

<b>HMIS</b>	Health Hazard	2	Flammability	0	Reactivity	0	Protective Equipment	D
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## 16. OTHER INFORMATION

### **EU Directive 2001/58/EC**

#### **R-phrases**

R63 - Possible risk of harm to the unborn child

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

#### **S-phrases**

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### **GHS - Regulation**

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<b>Issuing Date</b>	26-Aug-2009
<b>Revision Date</b>	26-Aug-2009
<b>Revision Note</b>	Not applicable.

#### **LEGEND**

DIRECTIVES 1999/45/CE, 67/548/CEE AND SUCCESSION MODIFICATIONS

REGULATIONS (CE) 1907/2006 (REACH) AND 1272/2008 (CLP) OF EUROPEAN PARLIAMENT

SAX'S - DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS

VERSCHUEREN - HANDBOOK OF ENVIRONMENTAL DATA ON ORGANIC CHEMICALS

THE MERCK INDEX

KLEEMANN - PHARMACEUTICAL SUBSTANCES

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

STN DATA BANK

BRETHERRICK'S - HANDBOOK OF REACTIVE CHEMICAL HAZARDS

A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

N.L.M. - NATIONAL LIBRARY OF MEDICINE

H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK

N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

N.T.P. - NATIONAL TOXICOLOGY PROGRAM

I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

A.D.R. - INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD

R.I.D. - TRANSPORT OF DANGEROUS GOODS BY RAIL

I.A.T.A. - INTERNATIONAL AIR TRANSPORT ASSOCIATION - DANGEROUS GOODS REG.

I.M.D.G. - INTERNATIONAL MARITIME DANGEROUS GOODS CODE

### **GHS classification for informational use only**

#### **Disclaimer**

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

End of Safety Data Sheet