



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 C₂₄ H₂₆ N₂ O₄

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

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

5. FIRE-FIGHTING MEASURES

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

6. ACCIDENTAL RELEASE MEASURES

Environmental Precautions	Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas.
Personal Precautions	Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.
Methods for Cleaning up	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.
Other Information	See Section 12 for additional information.

7. HANDLING AND STORAGE

Handling	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.
Storage	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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

Appearance	White off-white Powder Nonhygroscopic
Odour	No information available

Important Health, Safety and Environmental Information

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

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

Other Information

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

Stability	Stable under normal conditions. Thermal degradation suspected at > 200 deg C.
Conditions to Avoid	Moisture. All sources of ignition.
Materials to Avoid	Strong oxidizing agents.
Hazardous Decomposition Products	Toxic fumes of: Nitrogen oxides (NOx), Carbon oxides.
Hazardous Polymerization	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

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

RID

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

ADR

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

ICAO

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

IATA

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

DOT

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

NFPA

Health Hazard 2 **Flammability** 0 **Stability** 0

15. REGULATORY INFORMATION

LabellingEU 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

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

<u>HMIS</u>	Health Hazard	2	Flammability	0	Reactivity	0	Protective Equipment	D
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16. OTHER INFORMATION**EU Directive 2001/58/EC****R-phrase(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-phrase(s)

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GHS - Regulation**Hazards Statements**

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Revision Note

Not applicable.

LEGEND

DIRECTIVES 1999/45/CE, 67/548/CEE AND SUCCESSIONS 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