# SAFETY DATA SHEET

#### 1. Identification

**Product identifier** Carvedilol

Other means of identification

Catalog number 1096622 **CAS** number 72956-09-3

**Chemical name** 2-Propanol, 1-(9H-carbazol-4-yloxy)-3-((2-(2-methoxyphenoxy)ethyl)amino)-, (+-)-

Recommended use Specified quality tests and assay use only.

Not for use as a drug. Not for administration to humans or animals. Recommended restrictions

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790

**United States** 

**RS Technical Services** Telephone 301-816-8129

Website www.usp.org E-mail RSTECH@usp.org

CHEMTREC within US & **Emergency phone number** 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

# 2. Hazard(s) identification

Physical hazards Not classified.

**Health hazards** Sensitization, skin Category 1

Specific target organ toxicity, single exposure Category 1 (cardiovascular system)

**Environmental hazards** Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word Danger

**Hazard statement** May cause an allergic skin reaction. Causes damage to organs (cardiovascular system).

**Precautionary statement** 

Do not breathe dust. Wash thoroughly after handling. Contaminated work clothing must not be Prevention

allowed out of the workplace. Wear protective gloves.

If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Response

Wash contaminated clothing before reuse. If exposed: Call a poison center/doctor.

Storage Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations. Disposal

Hazard(s) not otherwise This product is supplied in a small quantity which does not constitute a combustible dust hazard. classified (HNOC)

The physical properties of this material indicate that in large quantities accumulated dust may be

hazardous.

Supplemental information Potent pharmacologically active material.

#### 3. Composition/information on ingredients

#### **Substance**

Chemical name	Common name and synonyms	CAS number	%
Carvedilol		72956-09-3	100

#### 4. First-aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. Wash

contaminated clothing before reuse.

**Eye contact** Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion** Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important

symptoms/effects, acute and delayed

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Treatment for carvedilol overdose may include the following: Administer activated charcoal as a slurry. Place patient in a supine position. Use gastric lavage shortly after ingestion unless contraindicated. Protect airway and control seizures before initiating. For bradycardia: Administer atropine intravenously. If resistant, administer pacemaker therapy. To support cardiovascular function: Administer glucagon intravenously or sympathomimetics (dobutamine, isoproterenol, epinephrine). For peripheral vasodilation: Administer epinephrine or norepinephrine and monitor circulatory conditions. For bronchospasm: Administer intravenous or inhaled beta-sympathomimetics or intravenous aminophylline. For seizures: Administer slow intravenous injection of diazepam or clonazepam. For hypoglycemia: Administer intravenous dextrose. For hypotension: Infuse isotonic fluid. If persistent, administer dopamine or norepinephrine. Carvedilol is not cleared significantly by hemodialysis.

**General information** 

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and

in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**Cool containers exposed to flames with water until well after the fire is out.

General fire hazards No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, and postion 12 of the CDS

waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

Material name: Carvedilol usp sps us

#### 7. Handling and storage

#### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

#### 8. Exposure controls/personal protection

## Occupational exposure limits

**Exposure limit values** 

**Industrial Use** Value Material **Type** Carvedilol (CAS **TWA** 30 micrograms/m3 72956-09-3)

**Biological limit values** 

No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When Hand protection

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

> disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head Respiratory protection

cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice. Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

### 9. Physical and chemical properties

**Appearance** Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

**Form** Crystalline powder. White. Off-white. Color

Odor Odorless. Odor threshold Not available. Not available.

Melting point/freezing point 237.2 - 248 °F (114 - 120 °C)

Initial boiling point and boiling

range

Not available.

Not available. Flash point

Not available. **Evaporation rate** Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

(%)

Not available.

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available.

< 0.0000001 kPa at 25 °C Vapor pressure

Vapor density Not available. Not available. Relative density

Solubility(ies)

Solubility (water) Practically insoluble.

Solubility (other) Dimethylsulfoxide: Freely soluble.

Methylene chloride: Soluble.

Methanol: Soluble.

Ethanol: 95%: Sparingly soluble. Isopropanol: Sparingly soluble. Ethyl ether: Slightly soluble. Dilute acids: Practically insoluble.

Partition coefficient

4.19

(n-octanol/water)

Not available. **Auto-ignition temperature Decomposition temperature** Not available. **Viscosity** Not available.

Other information

Carbazole. **Chemical family** 

**Dust explosion properties** 

Kst 228 bar.m/s

St class 2 Strong explosion.

Minimum ignition energy (MIE) - dust

cloud

< 5 mJ

Molecular formula C24H26N2O4

406.47 Molecular weight

7.6 - 7.7 to 8.5 Suspension: 10% pH in aqueous solution

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Material is stable under normal conditions. **Chemical stability** 

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials None known.

**Hazardous decomposition** products

NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact May cause an allergic skin reaction.

Eye contact Knowledge about health hazard is incomplete.

Based on information from therapeutic use, this material may cause: Cardiovascular effects. Ingestion

Symptoms related to the physical, chemical, and toxicological characteristics

Beta-adrenergic blockers: Gastrointestinal disturbances. Headache. Mood or mental changes. Drowsiness. Weakness. Insomnia. Nervousness. Visual disturbances. Swelling of feet or legs. Muscle, joint, or chest paint. Seizures. Coma. Cardiovascular effects. Respiratory depression. Dizziness when standing. Fainting. Blue or pale lips, fingernails, and skin. Weight gain.

#### Information on toxicological effects

#### **Acute toxicity**

Product Species Test Results

Carvedilol (CAS 72956-09-3)

Acute Oral

LD50 Rat > 8000 mg/kg

**Skin corrosion/irritation**Based on available data, the classification criteria are not met. **Serious eye damage/eye**Based on available data, the classification criteria are not met.

irritation

Local effects

Eye irritation test Result: Negative. Recovery Period: 2 days

Skin irritation test, intact and abraded skin

Result: Negative.

Respiratory or skin sensitization

**Respiratory sensitization** Knowledge about health hazard is incomplete.

**Skin sensitization** May cause an allergic skin reaction.

Guinea pig maximization test

Result: Positive.

**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames assay Result: Negative.

In vitro micronucleus assay: in cells

Result: Negative. Species: Hamster

Mutagenicity: HGPRT in ovary cells

Result: Negative.

Species: Hamster, Chinese

Mutagenicity: In vivo human lymphocyte test

Result: Negative.

Carcinogenicity

Based on available data, the classification criteria are not met.

200 mg/kg/day Two-year carcinogenicity study

Result: No evidence of carcinogenicity.

Species: Mouse

75 mg/kg/day Two-year carcinogenicity study Result: No evidence of carcinogenicity.

Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

Reproductivity

15 - 75 mg/kg/day Reproductivity / Developmental

Result: Increased post-implantation loss but no teratogenicity

at high dose. NOEL = 15 mg/kg/day

Species: Rabbit

60 - 200 mg/kg/day Reproductive toxicity (fertility)

Result: Fertility impaired at high dose. NOEL = 60 mg/kg/day

Species: Rat

Material name: Carvedilol usp sps us

Reproductivity

60 - 300 mg/kg/day Reproductivity / Developmental

Result: Maternal toxicity and fetotoxicity at high dose. NOEL

= 60 mg/kg/day Species: Rat

Specific target organ toxicity -

single exposure

Causes damage to organs (cardiovascular system).

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

### 12. Ecological information

### **Ecotoxicity**

	Species	Test Results
i-09-3)		
EC50	Algae	< 0.17 mg/l, 72 hours
EC50	Daphnia magna	7.38 mg/l, 48 hours
EC50	Sunfish (Lepomis)	0.99 mg/l, 96 hours
	EC50 EC50	EC50 Algae EC50 Daphnia magna

Persistence and degradability

**Bioaccumulative potential** 

Not readily biodegradable.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

#### 13. Disposal considerations

**Disposal instructions**Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

6/8

emptied.

## 14. Transport information

DOT

UN number UN3077

UN proper shipping name E

Environmentally hazardous substance, solid, n.o.s. (Carvedilol)

Transport hazard class(es)
Class

Subsidiary risk -

Packing group

Ш

9

**IATA** 

UN number UN3077

**UN proper shipping name** 

Environmentally hazardous substance, solid, n.o.s. (Carvedilol)

Transport hazard class(es)

Class 9
Subsidiary risk Packing group III

Material name: Carvedilol usp sps us

1096622 Version #: 03 Revision date: 03-27-2019 Issue date: 04-17-2007

Other information

Passenger and cargo

aircraft

Cargo aircraft only

Transport in bulk according to Annex II of MARPOL 73/78 and

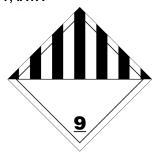
the IBC Code

Allowed with restrictions.

Not applicable.

Allowed with restrictions.

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US** federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Yes

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Combustible dust

**Classified hazard** categories

Respiratory or skin sensitization

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

## Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

**US state regulations** 

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories** 

Country(s) or region Inventory name On inventory (yes/no)\* Australian Inventory of Chemical Substances (AICS) Australia Nο

China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances	No

(PICCS)

Taiwan Chemical Substance Inventory (TCSI)

United States & Puerto Rico

Toxic Substances Control Act (TSCA) Inventory

No

# 16. Other information, including date of preparation or last revision

Inventory name

Domestic Substances List (DSL)
Non-Domestic Substances List (NDSL)

 Issue date
 04-17-2007

 Revision date
 03-27-2019

Version # 03

Country(s) or region

Canada

Canada

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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herein.

Material name: Carvedilol USP SDS US

On inventory (yes/no)\*

No

<sup>\*</sup>A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).