



SAFETY DATA SHEET

Carospir® (Spironolactone Oral Suspension, 25 mg/5 mL)

SDS DATE: 27-Mar-2018

SECTION 1: IDENTIFICATION

PRODUCT NAME: Carospir®
SYNONYMS: Spironolactone Oral Suspension, 25 mg/5 mL
NDC Number: 46287-020-01, 46287-020-04, 46287-020-20, and 46287-020-50
MANUFACTURER: CMP Pharma, Inc.
ADDRESS: PO Box 147
8026 US Hwy. 264A
Farmville, NC 27828

CHEMTREC PHONE: 1-800-424-9300
OTHER CALLS: 1-252-753-7111

CHEMICAL NAME (for active ingredient): 7- α -acetylthio-3-oxo-17- α -pregn-4-ene-21,17 β -carbolactone (IUPAC)
CHEMICAL FORMULA (for active ingredient): C₂₄H₃₂O₄S
PHARMACOLOGICAL PROPERTIES (for active ingredient): Potassium sparing diuretic

PRODUCT USE: Treatment of heart failure and hypertension and management of edema.

SECTION 2: HAZARD(S) IDENTIFICATION

HEALTH HAZARDS: May cause damage to organs through prolonged or repeated exposure. May damage fertility or the unborn child. May cause harm to breast-fed children.

SIGNAL WORD: Danger

HAZARD SYMBOLS:



PRECAUTIONARY STATEMENTS:

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Keep away from heat, sparks and open flames. Do not eat, drink, or smoke when using this product. Do not breathe dust/fume/gas/mist/vapors/spray.

HAZARDS NOT OTHERWISE CLASSIFIED: None classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT:	CAS NO.	Amount
Spironolactone	52-01-7	0.5%

*Product also contains Xanthan Gum, Simethicone Emulsion, Sorbic Acid, Potassium Sorbate, Sodium Saccharin, Citric Acid, Sodium Citrate Dihydrate, Magnasweet 110, Glycerin, Banana Flavor, Purified Water.



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SECTION 4: FIRST AID MEASURES

EYE CONTACT: Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.

SKIN CONTACT: Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.

INGESTION: Do not induce vomiting. Wash out mouth with copious amounts of water. Seek medical attention immediately.

INHALATION: Remove affected person to fresh air and keep patient at rest. Seek medical attention immediately.

MOST IMPORTANT SYMPTOMS/EFFECTS

ACUTE OR DELAYED:

Repeated or prolonged exposure may cause hypercalcaemia, hyponatremia and other renal dysfunction.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

This product should only be given to patients by medical professionals educated in the therapy intended for this product. Treat any symptoms and eliminate exposure.

SECTION 5: FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

MEDIA:

UNSUITABLE EXTINGUISHING MEDIA: None known.

UNUSUAL FIRE AND EXPLOSION HAZARDS: May form sulfur and/or carbon oxides under combustion.

SPECIAL FIRE FIGHTING PROCEDURES:

Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize the generation of aerosols. Remove all sources of heat and ignition.

METHODS/MATERIALS USED

FOR CONTAINMENT & CLEANING:

Use an inert absorbent material to remove and collect spillage. Minimize the generation of aerosols. Dampen remaining residue with water, then clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

SECTION 7: HANDLING AND STORAGE

HANDLING PRECAUTIONS: 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. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse.



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STORAGE PRECAUTIONS:

When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	HSE WEL (TWA)
Spironolactone	N/A	90 µg/m ³	N/A	N/A

ENGINEERING CONTROLS:

In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

EYE PROTECTION:

Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

SKIN PROTECTION:

Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

RESPIRATORY PROTECTION:

If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR:

This product is a white to off-white opaque suspension with a banana odor.

FLASH POINT:

Not established.

% VOLATILE:

Not established.

AUTOIGNITION TEMP:

Not established.

VISCOSITY:

Not established.

BOILING POINT:

Not established.

pH:

4.5 – 5.5

MELTING POINT:

Not established.

Octanol/H₂O PART. COEFFICIENT:

Not established.

VAPOR PRESSURE (mmHg):

Not established.

POUR POINT:

Not established.

EVAPORATION RATE (H₂O = 1):

Not established.

% SOLUBILITY IN WATER:

Not established.

VAPOR DENSITY (AIR = 1):

Not established.

SPECIFIC GRAVITY (H₂O = 1):

0.950 – 1.050

LOWER FLAMMABILITY LIMIT:

Not established.

UPPER FLAMMABILITY LIMIT:

Not established.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY:

No available data.

CHEMICAL STABILITY:

Material is stable under normal conditions.

POSSIBILITY OF HAZARDOUS REACTIONS:

Danger of dust explosion when handling solid drug substance.

CONDITIONS TO AVOID:

Intense heat.



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INCOMPATIBLE MATERIALS: Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS: Under fire conditions, thermal decomposition may generate sulfur and/or carbon oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

- INGESTION:** In an occupational setting, ingestion of this product is unlikely. Ingestion may cause irritation.
- INHALATION:** Although unlikely due to product form, inhalation of vapors may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon exposure to fresh air.
- SKIN CONTACT:** May be absorbed through the skin. Active ingredient has blood pressure lowering effects.
- EYE CONTACT:** Avoid contact with eyes. May cause irritation of the eyes.

SIGNS AND SYMPTOMS OF OVEREXPOSURE:

Possible gastrointestinal discomfort, dizziness, and/or headache.

CHRONIC EFFECTS:

May include possible hypersensitivity, gastrointestinal discomfort, or effects on blood and blood forming organs.

ACUTE TOXICITY VALUES: LD 50 for active ingredient (oral, rat) = > 1 g/kg

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility. Care should be taken to avoid environmental release.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All components of this product are included on the TSCA inventory.



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SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

There are no ingredients in this mixture listed under SARA.

SECTION 16: OTHER INFORMATION

CREATION DATE: 21Jan2016

REVISION DATE: 27Mar2018

DISCLAIMER: CMP Pharma, Inc. believes that the information contained in this Safety Data Sheet (SDS) is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.

The information contained herein is designated only as guidance for safe handling and storage of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment, should handle all chemicals. CMP Pharma, Inc. shall not be held liable for any loss, injury, or damage from contact with the product.