



SAFETY DATA SHEET

Oracit®

SDS DATE: 03-Nov-2015

SECTION 1: IDENTIFICATION

PRODUCT NAME: Oracit®
SYNONYMS: Oral Citrate (Shohl's) Solution
NDC Number: 46287-014-15, 46287-014-30, and 46287-014-01
MANUFACTURER: CMP Pharma, Inc.
ADDRESS: PO Box 147
8026 US Hwy. 264A
Farmville, NC 27828

EMERGENCY PHONE: 1-800-227-6637
CHEMTREC PHONE: 1-908-859-2151
OTHER CALLS: 1-252-753-7111

PRODUCT USE: Renal acidosis

SECTION 2: HAZARD(S) IDENTIFICATION

PHYSICAL HAZARDS: May be irritating to eyes. May cause mild mechanical irritation.

HEALTH HAZARDS: None classified.

SIGNAL WORD: Warning

HAZARD STATEMENT: May form combustible dust concentrations in air.

HAZARD SYMBOLS:



PRECAUTIONARY STATEMENTS:

Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.

HAZARDS NOT OTHERWISE CLASSIFIED: None classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT:</u>	<u>CAS NO.</u>
Sodium Citrate Dihydrate, USP	6132-04-3
Citric Acid, USP	77-92-9
Methylparaben NF	99-76-3
Propylparaben NF	94-13-3
USP Alcohol	9003-99-0



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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. Seek medical attention if irritation persists.
- SKIN CONTACT:** Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.
- INGESTION:** Clean mouth with water then drink plenty of water to dilute drug. Do not induce vomiting. If irritation causes breathing difficulty, seek medical attention.
- INHALATION:** This product is not expected to be an inhalation hazard under normal use conditions.

MOST IMPORTANT SYMPTOMS/EFFECTS

ACUTE OR DELAYED:
May cause mild skin irritation. May be irritating to eyes. May cause irritation of the respiratory tract.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:
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.
- UNSUITABLE EXTINGUISHING MEDIA:** None known.
- UNUSUAL FIRE AND EXPLOSION HAZARDS:** None known.
- SPECIAL FIRE FIGHTING PROCEDURES:** Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- PERSONAL PRECAUTIONS:** Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Contaminated surfaces may be slippery. Remove all sources of heat and ignition.
- METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING:** Use appropriate tools to collect spilled product into a disposal container. 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:** 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.
- 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. Maintain an appropriate temperature during storage.



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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	HSE WEL (TWA)
Sodium Citrate Dihydrate, USP	N/A	5 mg/m ³	3 mg/m ³	N/A
Citric Acid, USP	N/A	5 mg/m ³	3 mg/m ³	N/A
Methylparaben NF	N/A	N/A	N/A	N/A
Propylparaben NF	N/A	N/A	N/A	N/A
USP Alcohol	N/A	N/A	N/A	N/A

ENGINEERING CONTROLS: The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces.

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:** Wear gloves impervious to conditions of use. A safety shower should be located in the work area.
- RESPIRATORY PROTECTION:** In case of insufficient ventilation wear suitable respiratory equipment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR: This product is a clear, colorless liquid with no discernible aroma.

FLASH POINT:	Not established.	% VOLATILE:	Not established.
AUTOIGNITION TEMP:	Not established.	VISCOSITY:	Not established.
BOILING POINT:	Not established.	pH:	3.0-4.0
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):	1.100-1.110
LOWER FLAMMABILITY LIMIT:	Not established.	UPPER FLAMMABILITY LIMIT:	Not established.

SECTION 10: STABILITY AND REACTIVITY

- REACTIVITY:** Material may be corrosive to copper, zinc, aluminum and their alloys.
- CHEMICAL STABILITY:** Material is stable under normal conditions.
- POSSIBILITY OF HAZARDOUS REACTIONS:** No dangerous reaction known under conditions of normal use.
- CONDITIONS TO AVOID:** Avoid dust formation, heat, flames and sparks.
- INCOMPATIBLE MATERIALS:** Strong oxidizers and strong bases.
- HAZARDOUS DECOMPOSITION PRODUCTS:** Under fire conditions, thermal decomposition may generate carbon oxide vapors.



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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: Inhalation of vapors may slightly irritate the nose, throat, and lungs.

SKIN CONTACT: May cause mild irritation.

EYE CONTACT: Avoid contact with eyes. May cause irritation of the eyes.

CHRONIC EFFECTS:

May include itching, redness, or mechanical irritation.

ACUTE TOXICITY VALUES: Not available.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility.

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. Solutions with low pH value should be neutralized prior to disposal.

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

This product is in conformance with the GHS Standard.

SECTION 16: OTHER INFORMATION

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) RATINGS:

Health: 1 Flammability: 1 Reactivity: 0 Other: 0

CREATION DATE: 03Nov2015 **REVISION DATE:** N/A

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