

Safety Data Sheet

ASCOR[®]

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: ASCOR[®]

Synonyms: Ascorbic Acid Injection, USP, Vitamin C, Sodium Ascorbate

Manufacturer: McGuff Pharmaceuticals, Inc.
2921 West McArthur Blvd, Suite 141
Santa Ana, CA 92704

Revision Date: March 15, 2018

Information Telephone Number: (714) 918-7277

Fax number: (877) 444-1155

Emergency Telephone Number: (714) 918-7277

CHEMTREC: 1-800-424-9300

SECTION 2. HAZARD IDENTIFICATION

Appearance/Odor:

Clear, light yellow to yellow solution.

Skin, eye and respiratory irritant:

Cause irritation of the eyes, skin and respiratory tract.

Toxicity to fish/aquatic organism:

Product is not known to be toxic to fish.

Likely Routes of Exposure:

Eye contact, skin contact, inhalation and ingestion.

Eye:

Causes slight irritation.

Skin:

Contact during a long period may causes irritation of the skin.

Inhalation:

The risk of inhalation exposure is negligible when product is in its final packaged form.

Ingestion:

Ingestion of large amounts may cause irritation of the gastrointestinal tract.

Skin Absorption:

Not absorbed through the skin.

This material is not considered hazardous by the OSHA hazard communication Standard (29 CFR 1910.1200)

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SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Ingredients:

<u>Component</u>	<u>CAS #</u>
Ascorbic Acid, 500 mg/mL	50-81-7
Edetate Disodium	139-33-3
Sodium Bicarbonate	144-55-8
Water	7732-18-5

SECTION 4. FIRST AID MEASURES

EMERGENCY OVERVIEW:

Remove any contamination from the skin, eyes, or clothing.

Inhalation:

The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, remove to fresh air and get medical attention if symptoms persist.

Ingestion:

Can cause irritation. Flush mouth out with water. Do not induce vomiting unless directed by emergency medical personnel. Seek medical attention.

Skin Contact:

If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing and seek medical attention.

Eye Contact:

Can cause irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.

Chronic Exposure:

Not expected to be a chronic health hazard.

Aggravation of Pre-existing Conditions:

No information found.

SECTION 5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media:

Water spray, foam, dry chemical or Carbon Dioxide (CO₂).

Caution:

CO₂ will displace air in confined spaces and may cause an Oxygen deficient atmosphere.

Unsuitable Extinguishing Media:

None

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SECTION 5. FIRE FIGHTING MEASURES (continued)

Hazardous combustion Products:

When heated, Ascorbic Acid solution thermally decomposes to form acrid and toxic vapors. (i.e. Carbon Monoxide and Carbon Dioxide).

Protection for firefighters: As in any fire, wear a self contained breathing apparatus in pressure demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personnel Precautions:

Use personal protective equipment recommended in section 8 of this document and isolate the hazard area.

Environmental precautions:

This material is not known to be a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.

Methods of Containment:

Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.

Methods of Clean Up:

Vacuum spillage with vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

Other Information:

A spill of this material does not need to be reported to the National Response Center.

SECTION 7. HANDLING AND STORAGE

Store at 2°C to 8°C. Pressure may develop within the vial upon long storage. Precautions should be taken when product is being withdrawn from vial. Internal pressure may expel plunger from syringes and other devices upon insertion into the stoppered vial. Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agencies.

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:

None established

Engineering Controls:

Not expected to require any special ventilation.

Respiratory Protection:

Not expected to require personal respirator usage.

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SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION (continued)

Skin Protection:

Wear protective gloves and clean body-covering clothing. When administering this product to patients, wear appropriate gloves. Wear Tyvek[™] SL or equivalent coveralls, PVC booties and nitrile gloves for clean-up activities.

Eye/Face Protection:

Safety glasses

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Color:

Clear, light yellow to yellow solution.

Odor:

May have slight odor

Physical State:

Liquid

pH:

5.6 to 6.6

Freezing Point:

Approximately -20 degrees Celsius

Boiling Point:

Approximately 212 degrees Celsius

Flash Point:

Not applicable

Evaporation Rate:

Not applicable

Flammability:

Nonflammable, noncombustible

Vapor Pressure:

Not applicable

Vapor Density:

Not applicable

Specific Gravity:

Approximately 1.3

Solubility (water):

Freely soluble in water

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES (continued)

Auto-ignition Temperature:

Not applicable

Percent Volatile:

0 Percent

Volatile Organic Compounds (%):

0 Percent

SECTION 10. STABILITY AND REACTIVITY

Stability:

Stable under normal conditions.

Hazardous Decomposition Products:

When heated to decomposition, ascorbic acid emits acrid smoke and irritating fumes.

Hazardous Polymerization:

Hazardous Polymerization will not occur.

Incompatibilities:

Strong acids. Strong bases.

SECTION 11. TOXICOLOGICAL INFORMATION

Ascor[®] is formulated as an Injectable Drug Product and approved by the United States Food and Drug Administration. Refer to the Drug Products FDA approved "full prescribing information" (Package Insert) and labeling for further information. In its prepared form, Ascor[®] is not considered a significant toxicological threat. ASCOR[®] as formulated contains various base ingredients as listed in section 2. Toxicological information on specific components may be obtained by submitting a written request to McGuff Pharmaceuticals, Inc. at the address listed in Section 1 - Attn: Customer Service Department.

Base Ingredient - Ascorbic Acid (500mg/mL):

RTECS#: CI7650000 CAS# 50-81-7

LD50/LC50: Reference: Registry of Toxic Effects of Chemical Substances (RTECS)

CAS# 50-81-7:

Oral, mouse: LD50 = 3367 mg/kg;

Oral, rat: LD50 = 11900 mg/kg;

Carcinogenicity: L(+)Ascorbic acid - Not listed as a carcinogen by the International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), or CA Prop 65.

Other:

See RTECS for complete information.

The toxicological properties have not been fully investigated.

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SECTION 12. ECOLOGICAL INFORMATION

ASCOR[®] is intended for use by hospital or pharmacy professionals, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13. DISPOSAL CONSIDERATIONS

ASCOR[®] is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

DOT (Department of Transportation):

Not Regulated

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantities:

None

SARA Title III

302 Extremely Hazardous Substances:

None

311/312 Hazard Categories:

None

313 Toxic substances subject to annual release reporting requirements:

None

RCRA Hazardous Waste Status

Non-hazardous (See Section 13 for additional details.)

California Proposition 65 Warning

This product does not contain substances known to the State of California to cause cancer.

WHMIS: This SDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

SECTION 16. OTHER INFORMATION

NFPA Ratings:

Health: 0 Flammability: 0 Reactivity: 0

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SECTION 16. OTHER INFORMATION (continued)
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Product Use:

Refer to package insert supplied with product for detail use information. Generally, Ascor[®] is a solution of Ascorbic Acid (Vitamin C) in Water for Injection intended for use in hospital or pharmacy admixture programs.

Revision Information:

March 2018

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