SAFETY DATA SHEET

Prednisolone Sodium Phosphate Oral Solution

Revised: 2/15/17
MF #: 1205 **Supersedes: 8/25/16**

I. IDENTIFICATION:

Recommended Use: Rx Pharmaceutical for human use

Chemical Name: Prednisolone Sodium Phosphate Oral Solution **MF#:** 1205

Distributor:
Edenbridge Pharmaceuticals, LLC
300 Interpace Parkway, Suite 360
Morris Corporate Center 1 - Building C
Parsippany, NJ 07054
Emergency: (201) 292-1292
Information: (877) 381-3336

Manufacturer:
Mikart, Incorporated
1750 Chattahoochee Ave., N.W.
Atlanta, GA 30318
Emergency: (404) 351-4510
Information: (404) 351-4510

II. HAZARDS IDENTIFICATION:

This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for hazardous ingredients. See section XI, *Toxicological Information* for additional data.



Health Hazard (e.g., carcinogenic, mutagenic, reproductive toxicity)

Signal Word:
WARNING

Inhalation:	Harmful if inhaled.
Ingestion:	May cause nausea, malaise, increased appetite and/or weight gain.
Skin Contact:	May be harmful if absorbed through skin. May cause increased sweating, thin fragile skin, urticaria and/or edema.
Eye Contact:	May be harmful if absorbed through this route. May also cause glaucoma and/or increased intraocular pressure.
Physical Hazards:	None known.
Chronic Exposure:	May cause irregular heartbeat, electrolyte imbalance, swelling, confusion, lightheadedness, numbness, tremors, back pain, stiffness, weakness, increased appetite, and/or mental or behavioral changes.

Conditions Aggravated by Exposure:	Hypersensitivity, heart disease, high blood pressure, diabetes, epilepsy, glaucoma, hypothyroidism, osteoporosis, peptic ulcer, mental disorders, impaired liver or kidney function.
Systemic Effects:	Anti-inflammatory. May produce an allergic reaction.

III. COMPOSITION / INFORMATION ON INGREDIENTS:

Contains:

Active Ingredient(s):	CAS Number:	Strength:
Prednisolone Sodium Phosphate	125-02-0	20 mg per 5 mL

Inactive Ingredient(s):	CAS Number:	Inactive Ingredient(s):	CAS Number:
Methylparaben	99-76-3	Monobasic Potassium	
Edetate Disodium	6381-92-6	Phosphate	7778-77-0
Hydroxyethyl Cellulose	N/A	Glycerin	56-81-5
High Fructose Corn Syrup	57-48-7	Artificial Grape Flavor	N/A
Saccharin Sodium	82385-42-0	Bitter Mask	N/A
Dibasic Potassium		Purified Water	7732-18-5
Phosphate	7758-11-4		

IV. FIRST AID MEASURES:

General: In case of accident involving illness, seek medical advice immediately.
Eye Contact: Remove contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Obtain medical attention.
Skin Contact: Remove contaminated clothing. Flush skin with plenty of water. Obtain medical attention.
Inhalation: Remove to fresh air. Seek medical advice immediately. If not breathing, trained personnel should give artificial respiration. If difficulty in breathing, trained personnel should give oxygen.
Ingestion: Seek medical advice immediately. Provide container labeling or SDS if possible.

V. FIRE FIGHTING MEASURES:

Extinguishing media: Use extinguishing media appropriate to the surrounding fire.
Special considerations: Toxic gases and vapors may be released if involved in a fire.

VI. ACCIDENTAL RELEASE MEASURES:

Small spill: Utilize appropriate personal protective equipment. Gather spilled material and place in a glass or plastic container. Assess and document the amount of material collected.
Large spill: Contain spill to the extent possible using available absorbents. Prevent entry into water systems, surface waters, or groundwater. Notify the appropriate emergency response personnel. Do not attempt clean-up without appropriate protective equipment.

VII. HANDLING AND STORAGE:

Store refrigerated, 2^{o}C to 8^{o}C (36^{o}F to 46^{o}F). This product is best stored in the original container.

VIII. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Exposure Limits: Not established.

Personal Protection Recommendations:

Ventilation: A local and/or general exhaust system is recommended to minimize airborne contaminants.

Respirator: Use a powered or air-purifying respirator meeting an approved standard if indicated by environmental assessment. Selection should be based upon anticipated exposure and capacity of respirator.

Gloves: Impervious gloves should be worn.

Clothing: Wear clean, body-covering protective clothing that is suitable for the task being performed.

Eye Protection: Utilize safety eyewear that complies with an approved standard when protection from splash, mist or dust is required.

IX. PHYSICAL AND CHEMICAL PROPERTIES:

Product Strength: Prednisolone Sodium Phosphate: 20 mg per 5 mL
Physical State: liquid
Color: Clear, translucent, colorless to yellowish
Shape: N/A
Deboss/Imprint: N/A
Aroma: Grape
pH: 6.0 – 7.5
Specific Gravity: 1.050 – 1.150
Boiling point: Unknown (25% of this mixture has a boiling point of 110 °C)
Flashpoint: Unknown (7% of this mixture has a flashpoint of 199°C)

Viscosity, Vapor pressure, Odor threshold, Vapor density, Upper/lower flammability or explosive limits, Relative density, Melting point/Freezing point, Solubility, Partition coefficient: n-octanol/water, Auto-ignition temperature, Evaporation rate, and Decomposition temperature: No information available

X. STABILITY AND REACTIVITY:

Stability: Stable under normal conditions of use.

Hazardous Decomposition Products: Toxic gases and vapors may be released if involved in a fire.

Incompatibilities: Not established. This product is a mixture that has not been tested as a whole.

XI. TOXICOLOGICAL INFORMATION:

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Toxicity data:	Prednisolone Sodium Phosphate: Oral LD50 = >2000 mg/kg (mouse)
Carcinogenicity:	No adequate or well-controlled studies have been conducted with this combination product.
Reproductive Effects:	Pregnancy Category C. No adequate or well-controlled studies have been conducted with this combination product.

XII. ECOLOGICAL INFORMATION:
Not established. This product is a mixture that has not been tested as a whole.

XIII. DISPOSAL CONSIDERATIONS:
Ensure compliance with local, state and federal regulations.

XIV. TRANSPORT INFORMATION:
Not regulated as dangerous goods.

XV. REGULATORY INFORMATION:
Individual containers are labeled in accordance with U.S. FDA regulations for finished pharmaceutical products.
Drug Status: Rx Only
Schedule: Non-Controlled
Product may be considered a hazardous material according to OSHA 29 CFR 1910.1200 regulatory standards.

XVI. OTHER INFORMATION:

NFPA (self-assessment):	**Health=**2	**Flammability=**1	**Reactivity=**0	
HMIS (self-assessment):	**Health=**2	**Flammability=**1	**Reactivity=**0	**PPE=**F

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