

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

## 1. Identification of the substance/preparation and the company/undertaking

### GHS product identifier

Product name: Prednisolone Sodium Phosphate Oral Solution

### Other means of identification

Product code(s): 0121-0773-08; 0121-0773-16

UN-Number: NA

Synonyms: 1-Dehydrohydrocortisone

### Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used for corticosteroid therapy.

Uses advised against: Do not use except as recommended.

### Supplier address/information

Pharmaceutical Associates, Inc.  
201 Delaware Street  
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

## 2. Hazards Identification

**Classification** This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

**Chemical family:** Mixture

**Statement of Hazard:** Product is safe when used as recommended.

### Additional Hazard Information:

**Short term:** Corticosteroids may mask some signs of infection, and new infections may appear during their use.

**Long term:** Prolonged use of corticosteroids may product posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses.

**Known Clinical Effects:** Prolonged use of the drug can produce mental symptoms, moon face, abnormal fat deposits, fluid retention, excessive appetite, weight gain, hypertrichosis, acne, striae, ecchymosis, increased sweating, pigmentation, dry scaly skin, thinning scalp hair, increased blood pressure, tachycardia, thrombophlebitis, decreased resistance to infection, negative nitrogen balance with delayed bone and wound healing, headache, weakness, menstrual disorders, accentuated menopausal symptoms, neuropathy, fractures, osteoporosis, peptic ulcer, decreased glucose tolerance, hypokalemia, and adrenal insufficiency. Hepatomegaly and abdominal distention have been observed in children.

**EU Indication of danger:** Not classified

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

## Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

## Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

## 3. Composition/Information on ingredients

| Chemical name                 | CAS-No    | mg/5 mL                     | Trade Secret |
|-------------------------------|-----------|-----------------------------|--------------|
| Prednisolone Sodium Phosphate | 125-02-0  | 10 mg/5 mL<br>(as the base) |              |
| Methylparaben                 | 99-76-3   |                             | X            |
| Edetate Disodium              | 6381-92-6 |                             | X            |
| Hydroxyethylcellulose         | 9004-62-0 |                             | X            |
| Glycerin                      | 56-81-5   |                             | X            |
| Sodium Saccharin              | 6155-57-3 |                             | X            |
| Potassium Phosphate Dibasic   | 7758-11-4 |                             | X            |
| Potassium Phosphate Monobasic | 7778-77-0 |                             | X            |
| High Fructose Corn Syrup      | Mixture   |                             | X            |
| Grape Flavor                  | Mixture   |                             | X            |

## 4. First aid measures

### Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

Overdosage or accidental ingestion –. Contact medical personnel or poison control center immediately if overdosage is suspected

## Most important symptoms/effects, acute and delayed

The effects of accidental ingestion of large quantities of prednisolone over a very short period of time have not been reported.

## Indication of immediate medical attention and special treatment needed, if necessary

No data available

Notes to Physician: NA

## 5. Fire-fighting measures

**Suitable extinguishing media:**

Use carbon dioxide, dry chemical or water spray.

**Specific hazards arising from the chemical**

Not applicable

**Explosion data:**

Not applicable

**Protective equipment and precautions for firefighter**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.

**Environmental precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and materials for containment and cleaning up**

- Methods for containment:
- Methods for cleaning up:

Isolate area around spill as specified by site procedures.  
Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

## 7. Handling and storage

**Precautions for safe handling**

Handling:

No special handling required for hazard control under conditions of normal product use.

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

## Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: As a precautionary measure, keep away from strong oxidizers.

## 8. Exposure controls/personal protection

### Control parameters

Exposure guidelines The exposure guidelines listed below are for the individual components and not the product itself.

| Chemical name                 | ACGIH TLV                | OSHA PEL                 | NIOSH IDLH    |
|-------------------------------|--------------------------|--------------------------|---------------|
| Prednisolone Sodium Phosphate | Not Available            | Not Available            | Not Available |
| Methylparaben                 | Not Available            | Not Available            | Not Available |
| Edetate Disodium              | Not Available            | Not Available            | Not Available |
| Hydroxyethylcellulose         | Not Available            | Not Available            | Not Available |
| Glycerin                      | 10 mg/m <sup>3</sup> TWA | 10 mg/m <sup>3</sup> TWA | Not Available |
| Sodium Saccharin              | Not Available            | Not Available            | Not Available |
| Potassium Phosphate Dibasic   | Not Available            | Not Available            | Not Available |
| Potassium Phosphate Monobasic | Not Available            | Not Available            | Not Available |
| Grape Flavor                  | Not Available            | Not Available            | Not Available |

### Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

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

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state: Solution  
 Odor: Faint grape  
 Appearance: Clear yellow liquid (may darken on storage)  
 Odor threshold: Not available

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

| Property                               | Values         | Remarks/Method |
|--|----------------|----------------|
| pH                                     | 4.0 – 5.0      | Current USP    |
| Melting point/range                    | Not applicable |                |
| Boiling point/boiling range            | Not available  |                |
| Flash point                            | Not applicable |                |
| Evaporation rate                       | Not applicable |                |
| Flammability (solid, gas)              | Not applicable |                |
| Flammability limits in air             | Not applicable |                |
| -upper flammability limit              | Not applicable |                |
| -lower flammability limit              | Not applicable |                |
| Vapor pressure                         | Not applicable |                |
| Vapor density                          | Not applicable |                |
| Specific gravity                       | 1.1            | Current USP    |
| Water solubility                       | Not applicable |                |
| Solubility in other solvents           | Not applicable |                |
| Partition coefficient: n-octanol/water | Not applicable |                |
| Autoignition temperature               | Not applicable |                |
| Decomposition temperature              | Not applicable |                |
| Viscosity                              | Not available  |                |
| Flammable properties                   | Not applicable |                |
| Explosive properties                   | Not applicable |                |
| Oxidizing properties                   | Not applicable |                |

Other information VOC content (%) NA

## 10. Stability and reactivity

|                                    |  |
|------------------------------------|--|
| Reactivity                         | Stable at normal conditions                                  |
| Chemical stability                 | Stable at normal conditions                                  |
| Possibility of hazardous reactions | Stable at normal conditions                                  |
| Conditions to avoid                | None known   |
| Incompatible materials             | As a precautionary measure, keep away from strong oxidizers. |
| Hazardous decomposition products   | None known   |

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

## 11. Toxicological information

### Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

| Chemical name                 | LD50 oral       | LD50 dermal                      | LC50 inhalation |
|-------------------------------|-----------------|----------------------------------|-----------------|
| Prednisolone Sodium Phosphate | Not Available   | Not Available                    | Not Available   |
| Methylparaben                 | 2100 mg/kg Rat  | No skin irritation 24 hr. Rabbit | Not Available   |
| Edetate Disodium              | >2000 mg/kg Rat | Not Available                    | Not Available   |
| Hydroxyethylcellulose         | Not Available   | Not Available                    | Not Available   |
| Glycerin                      | 12600 mg/kg Rat | 10000 mg/kg Rabbit               | Not Available   |
| Sodium Saccharin              | 14200 mg/kg Rat | Not Available                    | Not Available   |
| Potassium Phosphate Dibasic   | Not Available   | Not Available                    | Not Available   |
| Potassium Phosphate Monobasic | >2000 mg/kg Rat | >4640 mg/kg Rabbit               | Not Available   |
| High Fructose Corn Syrup      | Not Available   | Not Available                    | Not Available   |
| Grape Flavor                  | Not Available   | Not Available                    | Not Available   |

### Symptoms related to the physical, chemical and toxicological characteristics:

No data available

### Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available
- Numerical measures of toxicity – product No data available

## 12. Ecological information

### Ecotoxicity:

Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

### Persistence and Degradability

No data available

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

**Bioaccumulation**

No data available

**Other adverse effects:**

No data available

The following table lists the data for the individual components, if available.

| Chemical name                             | Toxicity to algae                                 | Toxicity to fish                   | Toxicity to micro-organisms | Daphnia Magna (water flea) |
|---|---|------------------------------------|-----------------------------|----------------------------|
| Prednisolone Sodium Phosphate             | Not Available                                     | Not Available                      | Not Available               | Not Available              |
| Methylparaben                             | 91 mg/L 72 hr.<br>Pseudokirchneriella subcapitata | 59.5 mg/L 89 hr<br>Oryzias latipes | Not Available               | 41.1 mg/L 48 hr            |
| Edetate Disodium<br>Hydroxyethylcellulose | 10 – 100 mg/L<br>72 hr                            | >500 mg/kg 96 hr<br>Leuciscus idus | Not Available               | >100 mg/L 24 hr.           |
| Glycerin                                  | Not Available                                     | 58.5 ppm 96 hr<br>Trout            | Not Available               | Not Available              |
| Sodium Saccharin                          | Not Available                                     | Not Available.                     | Not Available               | Not Available              |
| Potassium Phosphate Dibasic               | Not Available                                     | Not Available.                     | Not Available               | Not Available              |
| Potassium Phosphate Monobasic             | Not Available                                     | Not Available.                     | Not Available               | Not Available              |
| High Fructose Corn Syrup                  | Not Available                                     | Not Available.                     | Not Available               | Not Available              |
| Grape Flavor                              | Not Available                                     | Not Available.                     | Not Available               | Not Available              |

## 13. Disposal considerations

**Waste disposal methods**

Dispose of waste in accordance with all federal, state and local regulations.

**Contaminated packaging**

Dispose of waste in accordance with all federal, state and local regulations.

## 14. Transport information

**Notes:**

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

## 15. Regulatory information

**International inventories**

**EINECS:**

Prednisolone Sodium Phosphate, Methylparaben, Edetate Disodium, Hydroxyethylcellulose, Glycerin, Sodium Saccharin, Potassium Phosphate Dibasic, and Potassium Phosphate Monobasic are listed on the EINECS.

# Safety Data Sheet

Issuing date: 02/08/2017

Revision date: 02/20/2017

Revision number: 01

**TSCA:**

United States Toxic Substances Control Act 8(b) inventory not applicable for product. The following components are included on the inventory: Prednisolone Sodium Phosphate, Methylparaben, Hydroxyethylcellulose, Glycerin, Sodium Saccharin, Potassium Phosphate Dibasic, and Potassium Phosphate Monobasic

**U.S. Federal regulations**

**OSHA Label:** Not applicable

**US DEA:** Not applicable

**SARA 311/312 Hazard categories:**

Not Applicable

**Clean Water Act:**

This product **does not** contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA:**

No components are listed under CERCLA.

**California Proposition 65:**

This product contains Sodium Saccharin and Prednisolone Sodium Phosphate which are listed on California Proposition 65 list of chemicals as a chemical which has been found to cause cancer, birth defects or reproductive harm.

**U.S. state Right-to-Know regulations**

"X" designates that the ingredients are listed on the state Right-to-Know list

| Chemical name                 | New Jersey | Massachusetts | Pennsylvania | Illinois | Rhode Island |
|-------------------------------|------------|---------------|--------------|----------|--------------|
| Prednisolone Sodium Phosphate |            |               | X            |          |              |
| Methylparaben                 | X          |               | X            |          |              |
| Edetate Disodium              | X          |               | X            |          |              |
| Hydroxyethylcellulose         | X          |               | X            |          |              |
| Glycerin                      | X          | X             | X            | X        | X            |
| Sodium Saccharin              | X          | X             | X            |          |              |
| Potassium Phosphate Dibasic   | X          |               | X            |          |              |
| Potassium Phosphate Monobasic | X          |               | X            |          |              |
| High Fructose Corn Syrup      |            |               |              |          |              |
| Grape Flavor                  |            |               |              |          |              |

**U.S. EPA label information:**

Not applicable



# Safety Data Sheet

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## 16. Other information

Prepared by: Pharmaceutical Associates Regulatory Affairs Department  
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Revision note:

- Added "NDC 0121-0773-16" to section 1

### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**