



# Scientific Documentation

PR900, Prednisolone Sodium Phosphate,  
USP, bioCERTIFIED™

Not appropriate for regulatory submission.  
Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or  
contact Tech Services for the most up-to-date  
information contained in this information  
package.

## **Spectrum Chemical Mfg Corp**

769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300

Ver4.06 16.July.2021

**PR900**, Prednisolone Sodium Phosphate, USP, bioCERTIFIED™

## Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Source Statement
- BSE/TSE Statement
- Allergen Statement
- EU Fragrance Allergen Statement
- GMO Statement
- Melamine Statement
- Nitrosamine Statement
- Organic Compliance Statement
- Shelf Life Statement
- Other Chemicals Statement
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label
- General Lot Numbering System Guidance

spectrum®

|                   |  |
|-------------------|--|
| Item Number       | PR900  |
| Item              | Prednisolone Sodium Phosphate, USP, bioCERTIFIED (TM)            |
| CAS Number        | 125-02-0   |
| Molecular Formula | C <sub>21</sub> H <sub>27</sub> Na <sub>2</sub> O <sub>8</sub> P |
| Molecular Weight  | 484.39   |
| MDL Number        |  |
| Synonyms          | Prednisolone 21-(Disodium Orthophosphate)                        |

| Test   | Specification         |         |
|--|-----------------------|---------|
|  | Min                   | Max     |
| ASSAY (ANHYDROUS BASIS)  | 96.0                  | 102.0 % |
| IDENTIFICATION (IR)  | TO PASS TEST          |         |
| IDENTIFICATION (SODIUM, PHOSPHATE)   | TO PASS TEST          |         |
| SPECIFIC ROTATION, [α] <sub>D</sub> <sup>25</sup>                                | +95° to +102°         |         |
| pH OF A 1 IN 100 SOLUTION  | 7.5                   | 10.5    |
| WATER DETERMINATION  |                       | 6.5 %   |
| PHOSPHATE IONS (PO <sub>4</sub> <sup>3-</sup> )                                  |                       | 1.0 %   |
| SELENIUM (Se)  |                       | 0.003 % |
| RELATED COMPOUNDS:   |                       |         |
| IMPURITY A   |                       | 0.2 %   |
| IMPURITY B   |                       | 1.0 %   |
| D-HOMO A DERIVATIVE  |                       | 1.0 %   |
| PREDNISOLONE (FREE)  |                       | 1.0 %   |
| D-HOMO B DERIVATIVE  |                       | 1.0 %   |
| PREDNISONE SODIUM PHOSPHATE  |                       | 0.5 %   |
| IMPURITY C   |                       | 0.3 %   |
| IMPURITY D   |                       | 0.2 %   |
| IMPURITY E   |                       | 0.5 %   |
| IMPURITY F   |                       | 0.2 %   |
| ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY  |                       | 0.1 %   |
| TOTAL OF ALL IMPURITIES WITH RETENTION TIME GREATER THAN THE RETENTION TIME OF G |                       | 3.0 %   |
| ELEMENTAL IMPURITIES   | AS REPORTED           |         |
| BACTERIAL ENDOTOXINS   |                       | 5 EU/mg |
| MICROBIAL LIMITS:  |                       |         |
| TOTAL AEROBIC MICROBIAL COUNT  | 10 <sup>3</sup> CFU/g |         |
| TOTAL YEAST AND MOLD COUNT   | 10 <sup>2</sup> CFU/g |         |
| RESIDUAL SOLVENTS  | AS REPORTED           |         |

|                   |   |                   |            |
|-------------------|---|-------------------|------------|
| Item Number       | PR900   | Lot Number        | 4JL0005    |
| Item              | Prednisolone Sodium Phosphate, USP, bioCERTIFIED (TM) | Manufacturer Lot  | PSPUy19002 |
| CAS Number        | 125-02-0  | Manufacturer Code | 15074      |
| Molecular Formula | $C_{27}H_{27}Na_2O_8P$                                | Molecular Weight  | 484.39     |

| Test   | Specification |         | Result                 |
|--|---------------|---------|------------------------|
|  | min           | max     |                        |
| ASSAY (ANHYDROUS BASIS)  | 96.0          | 102.0 % | 98.4%                  |
| IDENTIFICATION (IR)  | TO PASS TEST  |         | PASSES TEST            |
| IDENTIFICATION (SODIUM, PHOSPHATE)   | TO PASS TEST  |         | PASSES TEST            |
| SPECIFIC ROTATION, $[\alpha]_D^{25}$   | +95° to +102° |         | +99°                   |
| pH OF A 1 IN 100 SOLUTION  | 7.5           | 10.5    | 8.3                    |
| WATER DETERMINATION  |               | 6.5 %   | 6.4%                   |
| PHOSPHATE IONS ( $PO_4$ )  |               | 1.0 %   | <1.0%                  |
| SELENIUM (Se)  |               | 0.003 % | <0.0001%               |
| RELATED COMPOUNDS:   |               |         | .                      |
| IMPURITY A   |               | 0.2 %   | 0.0%                   |
| IMPURITY B   |               | 1.0 %   | 0.1%                   |
| D-HOMO A DERIVATIVE  |               | 1.0 %   | 0.1%                   |
| PREDNISOLONE (FREE)  |               | 1.0 %   | 0.0%                   |
| D-HOMO B DERIVATIVE  |               | 1.0 %   | 0.0%                   |
| PREDNISON SODIUM PHOSPHATE   |               | 0.5 %   | 0.1%                   |
| IMPURITY C   |               | 0.3 %   | 0.1%                   |
| IMPURITY D   |               | 0.2 %   | 0.0%                   |
| IMPURITY E   |               | 0.5 %   | 0.0%                   |
| IMPURITY F   |               | 0.2 %   | 0.0%                   |
| ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY  |               | 0.1 %   | 0.0%                   |
| TOTAL OF ALL IMPURITIES WITH RETENTION TIME GREATER THAN THE RETENTION TIME OF G |               | 3.0 %   | 0.4%                   |
| ELEMENTAL IMPURITIES   | AS REPORTED   |         | COMPLIES WITH STANDARD |
| BACTERIAL ENDOTOXINS   |               | 5 EU/mg | <5 EU/mg               |
| MICROBIAL LIMITS:  |               |         | .                      |
| TOTAL AEROBIC MICROBIAL COUNT  | $10^3$ CFU/g  |         | < $10^3$ CFU/g         |
| TOTAL YEAST AND MOLD COUNT   | $10^2$ CFU/g  |         | < $10^2$ CFU/g         |
| RESIDUAL SOLVENTS  | AS REPORTED   |         | PASSES TEST            |
| CLASS 2 (solvent) / ACETONITRILE   |               |         | <400 ppm               |
| CLASS 2 (SOLVENT) / METHANOL   |               |         | <3000 ppm              |
| CLASS 3 (solvent) / ACETIC ACID  |               |         | <5000 ppm              |

|                     |  |  |  |
|---------------------|--|--|--|
| APPEARANCE          |  |  | WHITE<br>POWDER<br>ODORLESS<br>AND SLIGHTLY<br>HYGROSCOPIC |
| RETEST DATE         |  |  | 31-AUG-2023  |
| DATE OF MANUFACTURE |  |  | 01-SEP-2019  |

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

*Jigisha Patel*

Jigisha Patel  
VP Regulatory Compliance & Technical Services,  
Regulatory

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Symbiotec Pharmed Private Limited at 385 / 2, Pigdamber, Near Hotel Mashal, Off. A.B. Road Rau., Indore, M.P. 453331, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

# spectrum®



Revision date 21-October-2020

Revision Number 1

## 1. Identification

### Product identifier

**Product Name** PREDNISOLONE SODIUM PHOSPHATE, USP

### Other means of identification

**Product Code(s)** PR900

**Synonyms** None

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

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

|  |             |
|--|-------------|
| Reproductive toxicity                              | Category 1A |
| Specific target organ toxicity (repeated exposure) | Category 2  |

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

May damage fertility or the unborn child  
May cause damage to organs through prolonged or repeated exposure



**Appearance** Powder or granules

**Physical state** Solid

**Odor** No information available

**Precautionary Statements - Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

**Precautionary Statements - Storage**

Store locked up.

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

| Chemical name                 | CAS No   | Weight-% | Trade secret |
|-------------------------------|----------|----------|--------------|
| Prednisolone Sodium Phosphate | 125-02-0 | 100      | *            |

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. First-aid measures

**Description of first aid measures**

|                       |   |
|-----------------------|---|
| <b>General advice</b> | Show this safety data sheet to the doctor in attendance.  |
| <b>Inhalation</b>     | Remove to fresh air.  |
| <b>Eye contact</b>    | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.<br>Consult a physician. |
| <b>Skin contact</b>   | Wash skin with soap and water.  |
| <b>Ingestion</b>      | Clean mouth with water and drink afterwards plenty of water.  |

**Most important symptoms and effects, both acute and delayed**

**Symptoms** No information available.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

## 5. Fire-fighting measures

|   |   |
|---|---|
| <b>Suitable Extinguishing Media</b>                   | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.   |
| <b>Large Fire</b>                                     | CAUTION: Use of water spray when fighting fire may be inefficient.  |
| <b>Unsuitable extinguishing media</b>                 | Do not scatter spilled material with high pressure water streams.   |
| <b>Specific hazards arising from the chemical</b>     | No information available.   |
| <b>Hazardous combustion products</b>                  | Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Phenols. Phosphorus oxides. Sodium oxides. Produce toxic and/or corrosive substances on contact with water. |
| <b>Explosion data</b>                                 |   |
| <b>Sensitivity to mechanical impact</b>               | none.   |
| <b>Sensitivity to static discharge</b>                | none.   |
| <b>Special protective equipment for fire-fighters</b> | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.                              |

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

|                             |   |
|-----------------------------|---|
| <b>Personal precautions</b> | Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. |
| <b>Other information</b>    | Refer to protective measures listed in Sections 7 and 8.  |

### Methods and material for containment and cleaning up

|                                |   |
|--------------------------------|---|
| <b>Methods for containment</b> | Prevent further leakage or spillage if safe to do so. |
| <b>Methods for cleaning up</b> | Pick up and transfer to properly labeled containers.  |

## 7. Handling and storage

### Precautions for safe handling

|                                |  |
|--------------------------------|--|
| <b>Advice on safe handling</b> | Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation. |
|--------------------------------|--|

### Conditions for safe storage, including any incompatibilities

|                           |  |
|---------------------------|--|
| <b>Storage Conditions</b> | Very hygroscopic; protect from moisture. Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. |
|---------------------------|--|

## 8. Exposure controls/personal protection

### Control parameters

|                        |   |
|------------------------|---|
| <b>Exposure Limits</b> | The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other |
|------------------------|---|





|                         |                          |
|-------------------------|--------------------------|
| <b>Molecular weight</b> | 484.39                   |
| <b>VOC Content (%)</b>  | No information available |
| <b>Liquid Density</b>   | No information available |
| <b>Bulk density</b>     | No information available |

## 10. Stability and reactivity

|   |  |
|---|--|
| <b>Reactivity</b>                         | No information available.                    |
| <b>Chemical stability</b>                 | Stable under recommended storage conditions. |
| <b>Possibility of hazardous reactions</b> | None under normal processing.                |
| <b>Conditions to avoid</b>                | None known based on information supplied.    |
| <b>Incompatible materials</b>             | None known based on information supplied.    |
| <b>Hazardous decomposition products</b>   | None known based on information supplied.    |

## 11. Toxicological information

### Information on likely routes of exposure

#### **Product Information**

|                     |   |
|---------------------|---|
| <b>Inhalation</b>   | Specific test data for the substance or mixture is not available. |
| <b>Eye contact</b>  | Specific test data for the substance or mixture is not available. |
| <b>Skin contact</b> | Specific test data for the substance or mixture is not available. |
| <b>Ingestion</b>    | Specific test data for the substance or mixture is not available. |

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

|                 |                           |
|-----------------|---------------------------|
| <b>Symptoms</b> | No information available. |
|-----------------|---------------------------|

### Acute toxicity

|                                       |                          |
|---------------------------------------|--------------------------|
| <b>Numerical measures of toxicity</b> | No information available |
|---------------------------------------|--------------------------|

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

|  |   |
|--|---|
| <b>Skin corrosion/irritation</b>         | No information available.   |
| <b>Serious eye damage/eye irritation</b> | No information available.   |
| <b>Respiratory or skin sensitization</b> | No information available.   |
| <b>Germ cell mutagenicity</b>            | No information available.   |
| <b>Reproductive toxicity</b>             | Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child. |
| <b>STOT - single exposure</b>            | No information available.   |
| <b>STOT - repeated exposure</b>          | May cause damage to organs through prolonged or repeated exposure.  |
| <b>Aspiration hazard</b>                 | No information available.   |
| <b>Other adverse effects</b>             | No information available.   |
| <b>Interactive effects</b>               | No information available.   |

## 12. Ecological information

|  |   |
|--|---|
| <b>Ecotoxicity</b>   | The environmental impact of this product has not been fully investigated. |
| <b>Persistence and degradability</b><br><b>Bioaccumulation</b> | No information available.<br>Inherently biodegradable.                    |
| <b>Other adverse effects</b>                                   | No information available.   |

## 13. Disposal considerations

### Waste treatment methods

|  |   |
|--|---|
| <b>Waste from residues/unused products</b> | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
| <b>Contaminated packaging</b>              | Do not reuse empty containers.  |

## 14. Transport information

|                          |               |
|--------------------------|---------------|
| <b><u>DOT</u></b>        | not regulated |
| <b><u>TDG</u></b>        | not regulated |
| <b><u>MEX</u></b>        | not regulated |
| <b><u>ICAO (air)</u></b> | not regulated |
| <b><u>IATA</u></b>       | not regulated |
| <b><u>IMDG</u></b>       | not regulated |
| <b><u>RID</u></b>        | not regulated |
| <b><u>ADR</u></b>        | not regulated |
| <b><u>ADN</u></b>        | not regulated |

## 15. Regulatory information

### International Inventories

|                      |   |
|----------------------|---|
| <b>TSCA</b>          | Complies  |
| <b>DSL/NDSL</b>      | Complies  |
| <b>EINECS/ELINCS</b> | Complies  |
| <b>ENCS</b>          | This product complies with ENCS:  |
| <b>IECSC</b>         | This product does not comply with china:  |
| <b>KECL</b>          | Does not Comply   |
| <b>PICCS</b>         | Does not Comply   |
| <b>AICS</b>          | All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS). |

### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

### US Federal Regulations

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### **SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (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**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### US State Regulations

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

#### **NFPA**

**Health hazards** 0

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

#### **HMIS**

**Health hazards** 1\*

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

*Chronic Hazard Star Legend*

*\* = Chronic Health Hazard*

#### **Key or legend to abbreviations and acronyms used in the safety data sheet**

##### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### **Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision date** 21-October-2020  
**Revision Note** No information available.

**Disclaimer**

**The information provided in this Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.**

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

| Catalog Number | Product Name                                      |
|----------------|---|
| PR900          | Prednisolone Sodium Phosphate, USP, bioCERTIFIED™ |

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

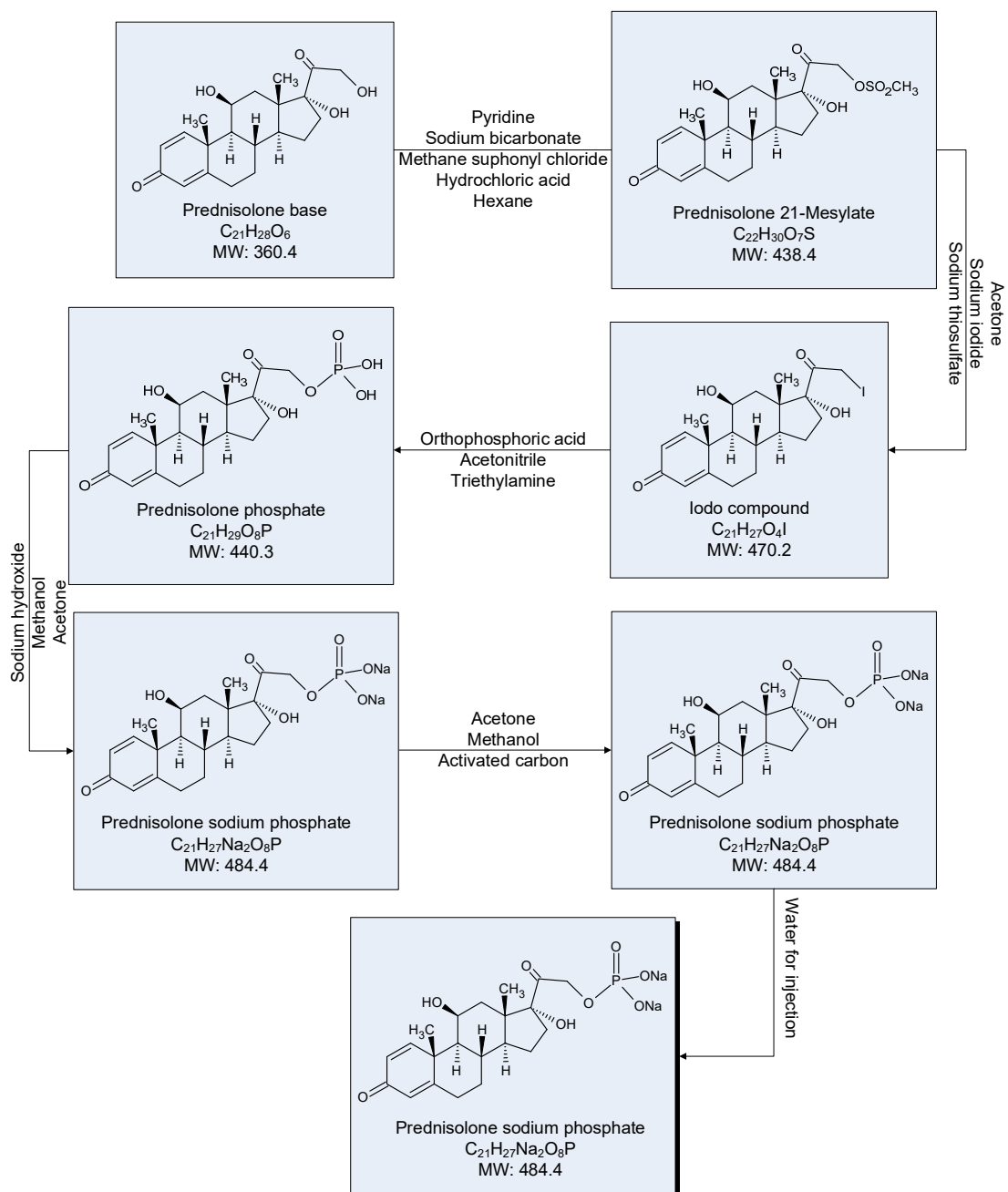
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Prednisolone Sodium Phosphate, USP, bioCERTIFIED™ – PR900



#### CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

#### WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843

## PR900, Prednisolone Sodium Phosphate, USP, bioCERTIFIED™

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.



## Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 48 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives



**RE: Elemental Impurities - Prednisolone Sodium Phosphate, USP, bioCERTIFIED™  
(Cat# PR900)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**RE: Residual Solvents - Prednisolone Sodium Phosphate, USP, bioCERTIFIED™  
(Cat# PR900)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

| Residual Solvent | Class | Expected Concentration |
|------------------|-------|------------------------|
| Acetonitrile     | 2     | < 410 ppm              |
| Methanol         | 2     | < 3000 ppm             |
| Acetone          | 3     | < 5000 ppm             |

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843

## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

**spectrum®**  
CHEMICAL MFG CORP

**PR900** **100 G**

**Prednisolone Sodium Phosphate**  
USP

CAS 125-02-0 **bio** CERTIFIED

**DANGER**  
• May damage fertility or the unborn child • May cause damage to organs through prolonged or repeated exposure.  
• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe dust.  
**FIRST AID:** If exposed or concerned: Get medical attention.  
**KEEP FROM CHILDREN**  
**WARNING:** Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

**CAUTION:** For manufacturing, processing or repackaging. Rx only. Further processing and testing required for use in parenteral applications.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**  
[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{21}H_{27}Na_2O_8P$  F.W. 484.39

Not sterile.  
Manufacturer/Supplier Code .....?  
Manufacturer Lot Number .....?  
Assay (Anhydrous Basis) ..... 96.0-102.0%  
Identification (IR) ..... To pass test  
Identification (Sodium, Phosphate) ..... To pass test  
Specific Rotation, [α]<sub>D</sub><sup>25</sup> ..... +95° to +102°  
pH of a 1 in 100 Solution ..... 7.5-10.5

| MAXIMUM LIMITS                            |                       |
|---|-----------------------|
| Water Determination                       | 6.5%                  |
| Phosphate Ions (PO <sub>4</sub> )         | 1.0%                  |
| Selenium (Se)                             | 0.003%                |
| Related Compounds:                        |                       |
| Impurity A                                | 0.2%                  |
| Impurity B                                | 1.0%                  |
| D-homo A Derivative                       | 1.0%                  |
| Prednisolone (Free)                       | 1.0%                  |
| D-homo B Derivative                       | 1.0%                  |
| Prednisone Sodium Phosphate               | 0.5%                  |
| Impurity C                                | 0.3%                  |
| Impurity D                                | 0.2%                  |
| Impurity E                                | 0.5%                  |
| Impurity F                                | 0.2%                  |
| Any Other Individual Unspecified Impurity | 0.1%                  |
| Total of all Impurities                   | 3.0%                  |
| Elemental Impurities                      | As reported           |
| Residual Solvents                         | To pass test          |
| Bacterial Endotoxins                      | 5 EU/mg               |
| Microbial Limits:                         |                       |
| Total Aerobic Microbial Count             | 10 <sup>6</sup> CFU/g |
| Total Yeast and Mold Count                | 10 <sup>6</sup> CFU/g |

HYGROSCOPIC: Keep tightly closed.  
Repackaged by Spectrum as:  
Lot No. 062233

G 2/J8GHS-A A D M

**SPECTRUM CHEMICAL MFG. CORP.** Gardena, CA 90248 • New Brunswick, NJ 08901

- A** Bar Code
- B** GHS Hazard Pictograms
- C** Warning, Safety Data and Precautionary Information
- D** Product Catalog Number
- E** Item Name, Form, Grade
- F** Size/Quantity
- G** Chemical Abstracts Service (CAS) Registry Number
- H** Caution Information
- I** DOT Shipping Information
- J** Toll-Free 24-Hour Chemical Emergency Telephone Number
- K** Empirical Formula, Formula Weight and Technical Specifications Panel
- L** Expiration Information
- M** Lot Number
- N** Kosher Certified by Kosher Supervision of America (KSA).
- O** Storage Color Band
- P** Halal Certified by IFANCA
- Q** bioCertified

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- **YELLOW:** Oxidizer
- **RED:** Flammable
- **GREEN:** General Storage
- **BLUE:** Health Hazard
- **WHITE:** Corrosive

### Spectrum Chemical Mfg Corp

**Corporate Headquarters:**  
769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**  
14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000



**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example:** ZI0928 = The 928<sup>th</sup> material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

- 1 = Gardena, CA Facility
- 2 = New Brunswick, NJ Facility
- 3 = China Facility
- 4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example:** 2AA0706 = The 706<sup>th</sup> material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at [quality\\_assurance@spectrumchemical.com](mailto:quality_assurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,

Oralia Chavez,  
Quality Assurance Specialist

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843