

# Scientific Documentation

## **Dexamethasone Sodium Phosphate, USP, bioCERTIFIED (TM)**

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



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Technical Statements  
Elemental Impurities Statement  
Residual Solvents Statement  
General Label Information – Sample Label

# Specification for Dexamethasone Sodium Phosphate, USP, bioCERTIFIED (TM) (DE901)

Item Number	DE901
Item	Dexamethasone Sodium Phosphate, USP, bioCERTIFIED (TM)
CAS Number	2392-39-4
Molecular Formula	$C_{22}H_{28}FNa_2O_8P$
Molecular Weight	516.41
MDL Number	
Synonyms	9-Fluoro-11Beta,17,21-trihydroxy-16alpha-methylpregna-1,4-diene-3,20-dione(dihydrogen phosphate) Disodium Salt ; Sodium Dexamethasone Phosphate

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS, SOLVENT-FREE BASIS)	97.0	102.0 %
IDENTIFICATION (IR)	TO PASS TEST	
IDENTIFICATION (PHOSPHATE)	TO PASS TEST	
IDENTIFICATION (SODIUM)	TO PASS TEST	
Specific Rotation (Anhydrous, Solvent-free Basis)	+74° to +82°	
pH of a 1% Aqueous Solution	7.5	10.5
WATER DETERMINATION		10.0 %
ALCOHOL		1.5 %
PHOSPHATE IONS		1.0 %
ORGANIC IMPURITIES:		
16(17)a-HOMODEXAMETHASONE SODIUM PHOSPHATE		0.2 %
16(17)a-HOMOBETAMETHASONE SODIUM PHOSPHATE		0.2 %
16(17)a-17R-HOMODEXAMETHASONE SODIUM PHOSPHATE		0.2 %
13(17)a-HOMODEXAMETHASONE SODIUM PHOSPHATE		0.2 %

Test	Specification	
	Min	Max
BETAMETHASONE SODIUM PHOSPHATE		0.2 %
DEXAMETHASONE ETHYL ESTER		0.3 %
DEXAMETHASONE		0.5 %
FLUOROANDROSTADIENE CARBOXYLIC ACID		0.3 %
DEXAMETHASONE SODIUM PHOSPHATE DIESTER		0.1 %
ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %
TOTAL IMPURITIES		1.0 %
ELEMENTAL IMPURITIES		AS REPORTED
BACTERIAL ENDOTOXINS		31.3 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
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

***Spectrum Chemical Mfg Corp***

---

<b><i>Corporate Headquarters:</i></b>	<b><i>West Coast Facility:</i></b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	DE901	Lot Number	4KK0022
Item	Dexamethasone Sodium Phosphate, USP, bioCERTIFIED (TM)	Manufacturer Lot	DJ9532
CAS Number	2392-39-4	Manufacturer Code	70
Molecular Formula	C <sub>22</sub> H <sub>28</sub> FN <sub>2</sub> O <sub>8</sub> P	Molecular Weight	516.41

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS, SOLVENT-FREE BASIS)	97.0	102.0 %	100.6%
IDENTIFICATION (IR)	TO PASS TEST		PASSES TEST
IDENTIFICATION (PHOSPHATE)	TO PASS TEST		PASSES TEST
IDENTIFICATION (SODIUM)	TO PASS TEST		PASSES TEST
Specific Rotation (Anhydrous, Solvent-free Basis)	+74° to +82°		+81.37°
pH of a 1% Aqueous Solution	7.5	10.5	8.0
WATER DETERMINATION		10.0 %	6.5%
ALCOHOL		1.5 %	NONE DETECTED
PHOSPHATE IONS		1.0 %	<1.0%
ORGANIC IMPURITIES:			.
16(17)a-HOMODEXAMETHASONE SODIUM PHOSPHATE		0.2 %	0.0%
16(17)a-HOMOBETAMETHASONE SODIUM PHOSPHATE		0.2 %	0.0%
16(17)a-17R-HOMODEXAMETHASONE SODIUM PHOSPHATE		0.2 %	0.0%
13(17)a-HOMODEXAMETHASONE SODIUM PHOSPHATE		0.2 %	0.0%
BETAMETHASONE SODIUM PHOSPHATE		0.2 %	0.0%
DEXAMETHASONE ETHYL ESTER		0.3 %	0.0%
DEXAMETHASONE		0.5 %	0.0%
FLUOROANDROSTADIENE CARBOXYLIC ACID		0.3 %	0.0%
DEXAMETHASONE SODIUM PHOSPHATE DIESTER		0.1 %	0.0%

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ANY OTHER INDIVIDUAL UNSPECIFIED IMPURITY		0.10 %	0.0%
TOTAL IMPURITIES		1.0 %	0.0%
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
BACTERIAL ENDOTOXINS		31.3 EU/mg	<31.3 EU/mg
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT		10 <sup>3</sup> CFU/g	< 10 <sup>3</sup> CFU/g
TOTAL YEAST AND MOLD COUNT		10 <sup>2</sup> CFU/g	<10 <sup>2</sup> CFU/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
MANUFACTURE DATE			05-AUG-2019
EXPIRATION DATE			03-AUG-2024
CLASS 2 (SOLVENT) / METHANOL			<3000 PPM
CLASS 2 (solvent) / METHYLENE CHLORIDE			<600 PPM
CLASS 3 (solvent) / ETHANOL			<5000 PPM

Certificate of Analysis Results Entered By:

BPATEL  
Bhargavi Patel  
13-JAN-22 12:35:12

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

BPATEL  
Bhargavi Patel  
13-JAN-22 12:35:22

**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 Pharmacia & Upjohn Company LLC at 7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA). 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 25-December-2023

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** DEXAMETHASONE SODIUM PHOSPHATE, USP

### Other means of identification

**Product Code(s)** DE901

**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

Acute toxicity - Oral	Category 4
Carcinogenicity	Category 2
Reproductive toxicity	Category 2

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### **Hazard statements**

Harmful if swallowed  
Suspected of causing cancer  
Suspected of damaging fertility or the unborn child



**Appearance** Crystalline powder

**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  
Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product

**Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention  
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell  
Rinse mouth

**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-%
Dexamethasone Sodium Phosphate	2392-39-4	100

### 4. First-aid measures

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
<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. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

**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 dioxide (CO <sub>2</sub> ). Produce toxic and/or corrosive substances on contact with water. Phenols. Flammable/toxic gases may accumulate in tanks and hopper cars.
<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.
<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.
--------------------------------	---

### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up. Hygroscopic. It absorbs moisture from the air. Keep refrigerated.
---------------------------	--

## 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 recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

#### **Appropriate engineering controls**

**Engineering controls**                      Showers  
    Eyewash stations  
    Ventilation systems.

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

**Eye/face protection**                      No special protective equipment required.

**Hand protection**                              Wear suitable gloves.

**Skin and body protection**                      Wear suitable protective clothing.

**Respiratory protection**                      No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations**                      Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

### **9. Physical and chemical properties**

#### **Information on basic physical and chemical properties**

**Physical state**                                      Solid  
**Appearance**                                      Crystalline powder  
**Color**    White to yellowish  
**Odor**    No information available  
**Odor threshold**                                      No information available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks • Method</u></b>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	233 - 235 °C / 451.4 - 455 °F	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	no data available	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	no data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

#### **Other information**

**Explosive properties**                              No information available  
**Oxidizing properties**                              No information available  
**Softening point**                                      No information available  
**Molecular weight**                                      516.41

VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

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

Symptoms	No information available.
----------	---------------------------

### Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Dexamethasone Sodium Phosphate 2392-39-4	1800 mg/kg (mouse)	-	-

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

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	Contains a known or suspected carcinogen. Classification based on data available for ingredients. Suspected of causing cancer.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<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>	No information available.
<b>Bioaccumulation</b>	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>	Complies
<b>PICCS</b>	Complies
<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** 2

**Flammability** 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards \* 2

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

25-December-2023

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
DE904	Dexamethasone Sodium Phosphate, USP

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,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## DE901, Dexamethasone Sodium Phosphate, USP

### Source Statement

The above mentioned catalog item is derived from plant-based starting material. No animal 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
- 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.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## 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 60 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Dexamethasone Sodium Phosphate, USP (Cat# DE901)**

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 - Dexamethasone Sodium Phosphate, USP (Cat# DE901)**

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
Methanol	2	< 3000 ppm
Methylene Chloride	2	< 600 ppm
Ethanol	3	< 1.5%*

\*Per USP monograph requirement under *Limit of Alcohol*

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.

**Exp. Date: 03-31-2025**

**WARNING**

- Harmful if swallowed • Suspected of causing cancer • Suspected of damaging fertility or the unborn child.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** Call a POISON CENTER or physician if you feel unwell. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**

**spectrum®**  
CHEMICAL MFG CORP

**DE901-25 G**

**Dexamethasone Sodium Phosphate**  
[9-Fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione (Dihydrogen Phosphate) Disodium Salt]

USP  
CAS 2392-39-4

**CAUTION:** For manufacturing, processing or repacking. 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

**REFRIGERATE**  
 $C_{22}H_{28}FNa_2O_8P$  F.W. 516.41

Not sterile.

MAXIMUM LIMITS	
Water Determination	10.0%
Alcohol	1.5%
Phosphate Ions	1.0%
Organic Impurities:	
16(17)α-Homodexamethasone Sodium Phosphate	0.2%
16(17)α-Homobetamethasone Sodium Phosphate	0.2%
16(17)α-17R-Homodexamethasone Sodium Phosphate	0.2%
13(17)α-Homodexamethasone Sodium Phosphate	0.2%
Betamethasone Sodium Phosphate	0.2%
Dexamethasone Ethyl Ester	0.3%
Dexamethasone	0.5%
Fluorandrostadiene Carboxylic Acid	0.3%
Dexamethasone Sodium Phosphate Diester	0.1%
Any Other Individual Unspecified Impurity	0.10%
Total Impurities	1.0%
Elemental Impurities	As reported
Residual Solvents	To pass test
Bacterial Endotoxins	31.3 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

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

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