

Scientific Documentation

Dexamethasone Sodium Phosphate, USP, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
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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 ₂ O ₈ P
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 %
BETAMETHASONE SODIUM PHOSPHATE		0.2 %
DEXAMETHASONE ETHYL ESTER		0.3 %

Test	Specification	
	Min	Max
DEXAMETHASONE		0.5 %
FLUROANDROSTADIENE 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 ³ CFU/g
TOTAL YEAST AND MOLD COUNT		10 ² CFU/g
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

Spectrum Chemical Mfg Corp

Corporate Headquarters: **West Coast Facility:**
769 Jersey Ave. 14422 S. San Pedro St.
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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 ₂₂ H ₂₈ FNa ₂ O ₈ 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%
FLUROANDROSTADIENE CARBOXYLIC ACID		0.3 %	0.0%

TEST	SPECIFICATION		RESULT
	MIN	MAX	
DEXAMETHASONE SODIUM PHOSPHATE DIESTER		0.1 %	0.0%
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 ³ CFU/g	< 10 ³ CFU/g
TOTAL YEAST AND MOLD COUNT		10 ² CFU/g	<10 ² 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 21-October-2020

Revision Number 1

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

Unknown acute toxicity

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Dexamethasone Sodium Phosphate	2392-39-4	100	*

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

4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	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

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the chemical No information available.

Hazardous combustion products Carbon dioxide (CO₂). Produce toxic and/or corrosive substances on contact with water. Phenols. Flammable/toxic gases may accumulate in tanks and hopper cars.

Explosion data
Sensitivity to mechanical impact none.
Sensitivity to static discharge none.

Special protective equipment for fire-fighters 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

Personal precautions Ensure adequate ventilation.
Other information Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling 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

Storage Conditions Keep refrigerated. Very hygroscopic; protect from moisture. Keep container tightly closed. Keep out of the reach of children. Store locked up.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

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
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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

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

Numerical measures of toxicity

Unknown acute 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.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.
STOT - single exposure	No information available.

STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

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

14. Transport information

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

15. Regulatory information

International Inventories

TSCA	Complies
DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product does not comply with china:
KECL	Complies

PICCS
AICS

Complies
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

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) (AELG(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
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

Sincerely,

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