



# Scientific Documentation

DE121, Dexamethasone, Micronized, USP

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

Ver4.03 26.August.2016



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", with a large, sweeping flourish at the end.

Alan Wang, MSQA, ASQ CQA  
Director of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

**DE121, Dexamethasone, Micronized, USP**

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CHEMICAL MFG CORP



## Specification for Dexamethasone, Micronized, USP (DE121)

Item Number	DE121
Item	Dexamethasone, Micronized, USP
CAS Number	50-02-2
Molecular Formula	C <sub>22</sub> H <sub>29</sub> FO <sub>5</sub>
Molecular Weight	392.47
MDL Number	
Synonyms	9-Fluoro-16-methylprednisolone ; Hexadecadrol

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0 - 102.0 %	
SPECIFIC ROTATION [α] <sub>D</sub>	+72 to +80	
CHROMATOGRAPHIC PURITY		TO PASS TEST
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.2 %
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
RESIDUAL SOLVENTS		TO PASS TEST

### *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

## SAFETY DATA SHEET

Preparation Date: 8/23/2016

Revision Date: 8/23/2016

Revision Number: G1

### 1. IDENTIFICATION

**Product identifier**

**Product code:** DE121  
**Product Name:** DEXAMETHASONE, MICRONIZED, USP

**Other means of identification**

**Synonyms:** 1-Dehydro-16-alpha-methyl-9-alpha-fluorohydrocortisone  
 16-alpha-Methyl-9-alpha-fluoro-1,4-pregnadiene-11-beta,17-alpha,21-triol-3,20-dione  
 16-alpha-Methyl-9-alpha-fluoro-1-dehydrocortisol  
 16-alpha-Methyl-9-alpha-fluoro-11-beta,17-alpha,21-trihydroxypregna-1,4-diene-3,20-dione  
 16-alpha-Methyl-9-alpha-fluoro-delta(sup 1)-hydrocortisone  
 16-alpha-Methyl-9-alpha-fluoroprednisolone  
 4-alpha-Fluoro-16-alpha-methyl-11-beta,17,21-trihydroxypregna-1,4-diene-3,20-dione  
 9-Fluoro-11-beta,17,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione  
 9-alpha-Fluoro-11-beta,17-alpha,21-trihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione  
 9-alpha-Fluoro-16-alpha-methyl-1,4-pregnadiene-11-beta,17-alpha,21-triol-3,20-dione  
 9-alpha-Fluoro-16-alpha-methylprednisolone

**CAS #:** 50-02-2  
**RTECS #** TU3980000  
**CI#:** Not available

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

**Recommended use:** Medication.  
**Uses advised against** No information available

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

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

### 2. HAZARDS IDENTIFICATION

**Classification**

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)


Serious eye damage/eye irritation	Category 2A
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Reproductive toxicity	Category 2
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**Label elements**

**Warning**

**Hazard statements**  
 Causes serious eye irritation  
 Suspected of damaging fertility or the unborn child



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

Not 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

**Precautionary Statements - Response**

*IF exposed or concerned: Get medical advice/attention*  
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Components	CAS-No.	Weight %
Dexamethasone	50-02-2	100

**4. FIRST AID MEASURES**

**First aid measures**

**General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Immediate medical attention is required.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

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

**Symptoms** Causes serious eye irritation. May cause skin irritation. May cause irritation of respiratory tract. Central nervous system effects. May affect the cardiovascular system. May cause hyperglycemia. It may affect the kidneys. Muscle weakness. Causes digestive (gastrointestinal) tract irritation. Ingestion may cause vomiting and nausea. It may cause abdominal (stomach) distention. Hiccups. Headache. Glucocorticoids (Corticosteroids) may cause osteoporosis and bone fractures, back pain, joint pain/stiffness, numbness, weakness, infection, delayed wound healing, thinning skin, bruising, acne, menstrual irregularities, headache, sweating, eye pain, vision changes, mental and behavior changes, fever, muscle pain, immune system depression, purple lines on skin, tremors, Cushing's syndrome, electrolyte imbalance (sodium and fluid retention, potassium loss (hypokalemia).

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

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

**5. FIRE-FIGHTING MEASURES**

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO<sub>2</sub>). Water spray mist or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, and possibly, but unlikely, hydrogen fluoride gas

**Hazardous Combustion Products:** No information available.

**Specific hazards:** May be combustible at high temperatures

**Special Protective Actions for Firefighters**

**Specific Methods:** No information available.

**Special Protective Equipment for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal Precautions:** Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

### Methods and material for containment and cleaning up

**Methods for containment** Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up** Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

#### **Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

#### **Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

#### **Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

#### **Incompatible Materials:**

Oxidizing agents  
Acids

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **National occupational exposure limits**

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Dexamethasone	50-02-2	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Dexamethasone	50-02-2	None	None	None	None



## Australia and Mexico

Components	CAS-No.	Australia	Mexico
Dexamethasone	50-02-2	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

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

#### Personal Protective Equipment

- Eye protection:** Goggles or Safety glasses with side-shields
- Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- Respiratory protection:** Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White. Practically white.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available.	<b>Formula:</b> C22H29FO5
<b>Molecular/Formula weight:</b> 392.47	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 260-264 °C/500-507.2 °F	<b>Decomposition temperature(°C/°F):</b> No information available
<b>Boiling point/range(°C/°F):</b> No information available	<b>Bulk density:</b> No information available	<b>Density (g/cm3):</b> No information available
<b>Specific gravity:</b> No information available	<b>pH:</b> No information available	<b>Vapor pressure @ 20°C (kPa):</b> No information available
<b>Evaporation rate:</b> No information available	<b>Vapor density:</b> No information available	<b>VOC content (g/L):</b> No information available
<b>Odor threshold (ppm):</b>	<b>Partition coefficient</b>	
<b>Product code:</b> DE121	<b>Product name:</b> DEXAMETHASONE, MICRONIZED, USP	<b>5 / 12</b>

No information available

**(n-octanol/water):**  
1.83

**Viscosity:**  
No information available

**Miscibility:**  
No information available

**Solubility:**  
Practically insoluble in water  
Soluble in Acetone  
Soluble in Ethanol  
Chloroform

## 10. STABILITY AND REACTIVITY

### Reactivity

Reactive with oxidizing agents

### Chemical stability

**Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur

**Conditions to avoid:** Heat. Incompatible materials.

**Incompatible Materials:** Oxidizing agents  
Acids

**Hazardous decomposition products:** Carbon oxides.

### Other Information

**Corrosivity:** No information available

**Special Remarks on Corrosivity:** No information available

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

**Principal Routes of Exposure:**  
Ingestion. Inhalation.

### Acute Toxicity

### Component Information

Dexamethasone

CAS-No. 50-02-2

**LD50/oral/rat =** > 3 g/kg Oral LD50 Rat  
**LD50/oral/mouse =** No information available  
**LD50/dermal/rabbit =** No information available  
**LD50/dermal/rat =** No information available  
**LC50/inhalation/rat =** No information available  
**LC50/inhalation/mouse =** No information available  
**Other LD50 or LC50 information =** No information available

### Product Information

**Product code:** DE121

**Product name:** DEXAMETHASONE,  
MICRONIZED, USP

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**LD50/oral/rat =**  
**VALUE- Acute Tox Oral = > 3000 mg/kg**

**LD50/oral/mouse =**  
**Value - Acute Tox Oral = No information available**

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal = No information available**

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal = No information available**

**LC50/inhalation/rat**  
**VALUE-Vapor = No information available**  
**VALUE-Gas = No information available**  
**VALUE-Dust/Mist = No information available**

**LC50/Inhalation/mouse**  
**VALUE-Vapor = No information available**  
**VALUE - Gas = No information available**  
**VALUE - Dust/Mist = No information available**

### Symptoms

<b>Skin Contact:</b>	May cause skin irritation.
<b>Eye Contact:</b>	Causes serious eye irritation.
<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Ingestion</b>	May cause hyperglycemia. May cause gastrointestinal tract irritation. May cause upset stomach. May cause constipation. May cause abdominal distension. May cause headache, nausea, vomiting. May cause central nervous system effects (affect behavior).
<b>Aspiration hazard</b>	No information available.

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

<b>Chronic Toxicity</b>	Prolonged or repeated ingestion: May cause gastrointestinal tract irritation with nausea, constipation, malaise, abdominal distention, peritonitis, hiccups. May cause ulcerative esophagitis, peptic ulcer with possible subsequent perforation and hemorrhage. May affect behavior/central nervous system(convulsions, vertigo, dizziness, headache, psychic disturbances, anxiety, nervousness, irritability, insomnia), cardiovascular system, brain, endocrine system (menstrual irregularities, suppression of growth in children, Cushing's syndrome, adrenocortical and pituitary unresponsiveness, decreased carbohydrate tolerance, hyperglycemia, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics), eyes (posterior subcapsular cataracts, increased intraocular pressure, glaucoma), metabolism (weight gain, increased appetite, electrolyte imbalance, water retention), musculoskeletal system (muscle weakness, loss of muscle mass, steroid myopathy, Osteoporosis, vertebral compression fractures, pathologic fractures of long bones, tendon rupture), skin (impaired wound healing, thin fragile skin or skin atrophy, easy bruising, petechiae and ecchymoses, erythema, burning or itching, urticaria, acneform eruptions, hypopigmentation), blood (thromboembolism), kidneys. It may also cause increased hair growth. May cause anaphylactoid or hypersensitivity reactions.
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Prolonged or repeated administration onto the skin may cause skin irritation with redness, burning itching, dryness, folliculitis, increased hair growth, acneform eruptions, hypopigmentation, hives, petechiae and ecchymosis, skin atrophy and allergic contact dermatitis.

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Dexamethasone is a glucocorticoid. Glucocorticoid therapy has been linked to an increased risk of development of Kaposi's sarcoma.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Dexamethasone	50-02-2	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** Suspected of damaging fertility or the unborn child

**Reproductive Effects:** May cause adverse reproductive effects based on animal data  
**Developmental Effects:** May cause adverse developmental effects based on animal data  
**Teratogenic Effects:** May cause birth defects (teratogenic effects) based on animal test data

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.  
**STOT - repeated exposure** No information available.  
**Target Organs:** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Ecotoxicity effects:** No data available.  
**Persistence and degradability:** No information available  
**Bioaccumulative potential:** No information available.  
**Mobility:** No information available.

**13. DISPOSAL CONSIDERATIONS**

**Disposal Methods**

**Waste from residues / unused products:**  
Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Dexamethasone	50-02-2	None	None	None	None

**14. TRANSPORT INFORMATION****DOT**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Class:** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number:** No information available  
**Marine Pollutant:** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions:** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

**TDG (Canada)**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant:** No Information available  
**Description:** No information available

**ADR**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

**IMO / IMDG**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant:** No information available

**RID**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**ICAO**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available

**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

**15. REGULATORY INFORMATION**

**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Dexamethasone	50-02-2	Present	Present KE-17063	Present	Not present	Present	Present	Present 200-003-9

**U.S. Regulations**

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Dexamethasone	50-02-2	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Dexamethasone	50-02-2	None	None	None	None	None

**U.S. TSCA**

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Dexamethasone	50-02-2	Not Applicable	Not Applicable

**Canada**

**WHMIS hazard class:**

D2A Very toxic materials  
D2B Toxic materials

**Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS

contains all of the information required by the CPR.

## Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Dexamethasone	50-02-2	Not Listed	Present

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Dexamethasone	50-02-2	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Dexamethasone	50-02-2	Not listed

## EU Classification

### R-phrases

R36 - Irritating to eyes.

R63 - Possible risk of harm to the unborn child.

### S -phrase(s)

S37 - Wear suitable gloves.

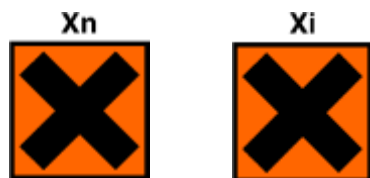
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Dexamethasone	50-02-2		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

## Indication of danger:

Xn - Harmful.



## 16. OTHER INFORMATION

**Preparation Date:** 8/23/2016  
**Revision Date:** 8/23/2016  
**Prepared by:** Sonia Owen

### Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the

completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**





## **Manufacturer**

Product Covered: DE121, Dexamethasone, Micronized, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang". The signature is stylized with overlapping loops and a long horizontal stroke at the end.

Alan Wang, MSQA, ASQ CQA  
Director of Technical Services  
[techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com)

26.August.2016

# Certificate of Registration



This is to certify that the quality management system of

## Spectrum Chemicals and Laboratory Products, Inc

**Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA**

*Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA*

*755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA*

*769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA*

*7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA*

has been assessed and registered by Intertek as conforming to the requirements of

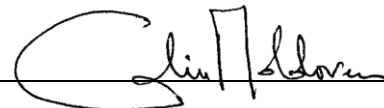
### ISO 9001:2008

The quality management system is applicable to

**California and New Jersey sites:** The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

**Arizona site:** Supporting Spectrum's two manufacturing facilities by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01  
Initial Certification Date: 27 December 1994  
Certificate Issue Date: 29 January 2016  
Certificate Expiry Date: 14 September 2018



*Calin Moldovean, President*  
Intertek Testing Services NA, Inc.  
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 9001-2008-ANAB-EN-LT-L-26.jun.15

# Certificate of Registration

# Intertek

This is to certify that the quality management system of

## Spectrum China Ltd.

**Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China**

has been assessed and registered by Intertek as conforming to the requirements of

## ISO 9001: 2008

The quality management system is applicable to:

*Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.*

Organization Code: 77762704-8  
Certificate Number: 111310001-01  
Certificate Issue Date: 17 November 2015  
Certificate Expiry Date: 14 September 2018



Authorised Signature: Calin Moldovean – President, Business Assurance  
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom  
Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.  
The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



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The certificate remains the property of Intertek, to whom it must be returned upon request.



March 28, 2016

**Certificate of cGMP**

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are 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.

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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum -Shanghai, China:	<u>3006174778</u>

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

Sincerely,

A handwritten signature in cursive script that reads "Michelle Weston".

Michelle Weston  
Quality Assurance Specialist

August 26, 2016

**Certificate of cGMP**

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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
DE121	Dexamethasone, Micronized, 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  
Spectrum-Shanghai, China: 3006174778

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

Sincerely,



Oralia Chavez  
Quality Assurance Specialist



May 13, 2016

Re: Dexamethasone, Micronized, USP- DE121

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Dexamethasone, Micronized, USP- DE121

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

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



May 13, 2016

Re: Dexamethasone, Micronized, USP- DE121

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO<sub>2</sub>; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Dexamethasone, Micronized, USP- DE121

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

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



May 17, 2016

Re: Dexamethasone, Micronized, USP-DE121

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Dexamethasone, Micronized, USP-DE121

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at [techservices@spectrumchemical.com](mailto:techservices@spectrumchemical.com).

Sincerely,

Darlene Dagdag-Lyudmirskiy  
Technical Services  
Spectrum Chemical Mfr. Corp.

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



## 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.

**WARNING**

- Causes eye irritation • 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 • Wear protective gloves, protective clothing, eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.

**FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. If exposed or concerned: Get medical attention.

**KEEP FROM CHILDREN**

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only. **Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**  
www.SpectrumChemical.com

**Assay (Dried Basis) ..... 97.0-102.0%**  
**Specific Rotation,  $[\alpha]_D^{25}$  ..... +72° to +80°**  
**Chromatographic Purity ..... To pass test**  
**MAXIMUM LIMITS**  
**Loss on Drying ..... 0.5%**  
**Residue on Ignition ..... 0.2%**  
**Residual Solvents ..... To pass test**

**Lot No. 062233**

- A** Bar Code
- B** GHS Hazard Pictograms
- C** Warning, Safety Data and Precautionary Information
- D** Product Catalog Number
- E** Item Name, Form, Grade
- O** Storage Color Band
- 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).

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

Item Number	DE121	Lot Number	1EE0343
Item	Dexamethasone, Micronized, USP		
CAS Number	50-02-2		
Molecular Formula	C <sub>22</sub> H <sub>29</sub> FO <sub>5</sub>	Molecular Weight	392.47

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	97.0 - 102.0 %		99.9 %
SPECIFIC ROTATION [α] <sub>D</sub>	+72 to +80		+77
CHROMATOGRAPHIC PURITY		TO PASS TEST	PASSES TEST
LOSS ON DRYING		0.5 %	0.3 %
RESIDUE ON IGNITION		0.2 %	<0.1%
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			08-SEP-2017
RESIDUAL SOLVENTS		TO PASS TEST	.
CLASS 2 (solvent) / METHYLENE CHLORIDE			< 600 ppm
CLASS 2 (solvent) / TETRAHYDROFURAN			< 720 ppm
CLASS 3 (solvent) / ETHYL ACETATE			< 5000 ppm
DATE OF MANUFACTURE			09-SEP-2014
APPEARANCE			WHITE CRYSTALLINE POWDER

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA



Certificate of Analysis Results Certified By:



Adan Hernandez  
Quality Control Manager  
Spectrum Chemicals & Laboratory Products

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

January 26, 2016

**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

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 [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com) if we may be of further assistance.

Sincerely,



Michael Dang  
Manager, GMP Compliance



## Stability – Shelf Life Guidance

Product Covered: DE121, Dexamethasone, Micronized, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, DE121, Dexamethasone, Micronized, USP, is assigned a 36 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez  
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters  
769 Jersey Avenue  
New Brunswick, NJ 08901-3605