

# Scientific Documentation

## Methylprednisolone Acetate, 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  
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New Brunswick, NJ 08901  
Phone 732.214.1300



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# Specification for Methylprednisolone Acetate, Micronized, USP (ME171)

Item Number	ME171
Item	Methylprednisolone Acetate, Micronized, USP
CAS Number	53-36-1
Molecular Formula	C <sub>24</sub> H <sub>32</sub> O <sub>6</sub>
Molecular Weight	416.51
MDL Number	
Synonyms	Methylprednisolone 21-Acetate ; 11Beta,17,21-Trihydroxy-6alpha-methylpregna-1,4-diene-3,20-dione 21-Acetate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0	103.0%
SPECIFIC ROTATION [α] <sub>D</sub>	+97° to +105°	
LOSS ON DRYING		1.0%
ORGANIC IMPURITIES	TO PASS TEST	
RESIDUE ON IGNITION		0.2%
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION	TO PASS TEST	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

## *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
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# Certificate Of Analysis

Item Number	ME171	Lot Number	4LJ0014
Item	Methylprednisolone Acetate, Micronized, USP	Manufacturer Lot	MPLA 001/0822
CAS Number	53-36-1	Manufacturer Code	15002
Molecular Formula	C <sub>24</sub> H <sub>32</sub> O <sub>6</sub>	Molecular Weight	416.51

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	97.0	103.0%	98.7 %
SPECIFIC ROTATION [α] <sub>D</sub>	+97° to +105°		102°
LOSS ON DRYING		1.0%	0.0 %
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
RESIDUE ON IGNITION		0.2%	0.039 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			31-JUL-2027
DATE OF MANUFACTURE			01-AUG-2022
APPEARANCE			WHITE FINE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST

Certificate of Analysis Results Entered By:

SVANGOOR  
Swetha Vangoor  
22-NOV-22 05:08:06

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS  
Allison Williams  
22-NOV-22 08:25:56

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.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

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 Symbiotica Speciality Ingredients Sdn. Bhd. at No. 518, Jalan Waja 4, Taman Industri Waja, Kulim, Kedah 09000, Malaysia (MYS). 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

Preparation Date: 6/27/2018

Revision Date: 6/27/2018

Revision Number: G1

## 1. IDENTIFICATION

### Product identifier

**Product code:** ME171  
**Product Name:** METHYLPREDNISOLONE ACETATE, MICRONIZED, USP

### Other means of identification

**Synonyms:** 11,17,21-Trihydroxy-6-methyl-1,4-pregnadiene-3,20-dione acetate  
Methylprednisolone 21-acetate  
6-Methylprednisolone acetate  
6-alpha-Methylprednisolone acetate  
Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-6-methyl-,  
(6-alpha,11-beta)-  
**CAS #:** 53-36-1  
**RTECS #** TU4154050  
**CI#:** Not available

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

**Recommended use:** No information available.  
**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)

Reproductive toxicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2

### Label elements

#### **Warning**

#### **Hazard statements**

Suspected of damaging fertility or the unborn child

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May cause damage to organs through prolonged or repeated exposure



**Hazards not otherwise classified (HNOC)**

Not Applicable

**Other hazards**

May be harmful in contact with skin

**Precautionary Statements - Prevention**

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Use personal protective equipment as required

Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response**

*IF exposed or concerned: Get medical advice/attention*

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Methylprednisolone Acetate	53-36-1	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 irritation develops. Consult a physician if necessary.

**Eye Contact:**

Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If eye irritation persists, consult a specialist.

**Inhalation:**

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

**Ingestion:**

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

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

**Symptoms**

May cause eye/skin/respiratory tract irritation

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

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

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Monoxide, Carbon Dioxide.

**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. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Remove all sources of ignition.

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**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

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### 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. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. 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. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

#### **Incompatible Materials:**

Strong oxidizing agents

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Control parameters

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

##### **United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Methylprednisolone Acetate	53-36-1	None	None	None	None

##### **Canada**

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Methylprednisolone Acetate	53-36-1	None	None	None	None

##### **Australia and Mexico**

Components	CAS-No.	Australia	Mexico
Methylprednisolone Acetate	53-36-1	None	None

### Appropriate engineering controls

#### **Engineering measures to reduce exposure:**

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**

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<b>Eye protection:</b>	Goggles or Safety glasses with side-shields
<b>Skin and body protection:</b>	Long sleeved clothing apron Gloves
<b>Respiratory protection:</b>	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.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White. Nearly White.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available.	<b>Formula:</b> C24-H32-O6
<b>Molecular/Formula weight:</b> 416.51	<b>Flammability:</b> Not Flammable	<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> 206-225 °C/402.8-437 °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> No information available	<b>Partition coefficient (n-octanol/water):</b> log Kow = 1.62	<b>Viscosity:</b> No information available
<b>Miscibility:</b> No information available	<b>Solubility:</b> Insoluble in water	

10. STABILITY AND REACTIVITY

Reactivity  
May react with strong oxidizers

Chemical stability

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

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

**Conditions to avoid:** Heat. Incompatible materials. Avoid dust formation.

**Incompatible Materials:** Strong oxidizing agents

**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:**

Inhalation. Ingestion.

### **Acute Toxicity**

#### **Component Information**

Methylprednisolone Acetate	
CAS-No.	53-36-1

**LD50/oral/rat** = > 10 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**

**LD50/oral/rat** =

**VALUE- Acute Tox Oral** = > 10000 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

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VALUE - Gas = No information available  
VALUE - Dust/Mist = No information available

### **Symptoms**

<b>Skin Contact:</b>	May cause skin irritation.
<b>Eye Contact:</b>	May cause eye irritation.
<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Ingestion</b>	May affect behavior/central nervous system (somnolence). May cause flushing or redness of skin. May cause excessive sweating. May cause diarrhea. May cause constipation. Corticosteroids(glucocorticoids): Nausea, vomiting, headache. May cause bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, increased appetite, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, increased hair growth, acne, redistribution of body fat, menstrual irregularities, impotence, increased sweating, eye pain, vision changes, mental and personality changes, swelling, lightheadedness, numbness, tremors, Fluid and electrolyte imbalance (sodium and fluid retention), suppression of calcium absorption and increased calcium excretion, potassium loss, hypokalemic alkalosis, Cushing's syndrome, immune system depression.
<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 eye contact with glucocorticoids/corticosteroids may affect vision (glaucoma, cataracts). Prolonged or repeated skin contact with corticosteroids/glucocorticoids may cause dryness, folliculitis, acne, hypopigmentation, dermatitis, thinning of skin (skin atrophy). Prolonged or repeated ingestion of corticosteroids may cause osteoporosis and bone fractures due to mobilization of calcium (reduced calcium absorption) and phosphorus, hypokalemia due to increase urinary loss of potassium, development of glaucoma and cataracts, muscle weakness/muscle wasting, swelling of the feet or lower legs due fluid and sodium retention, hip or shoulder pain, irregular heartbeat. It may affect the liver, kidneys, pancreas (pancreatitis), blood (changes in serum composition), behavior/central nervous system (anxiety, nervousness or restlessness, trouble sleeping, mental disturbances such as psychosis, euphoria, depression), protein metabolism, lipid metabolism, carbohydrate metabolism causing insulin resistance, hyperglycemia, diabetes, and the immune system (immunosuppressant) causing increased susceptibility to infections), thinning skin. Repeated ingestion of large doses of corticosteroids may also produce other symptoms typical of hyperactivity of the adrenal gland and overproduction of cortisol (Cushing's Syndrome) such moon-face, buffalo hump, increased bruising, ecchymoses, striae, and acne, menstrual irregularities, amenorrhea, sometimes hirsutism (deepening of the voice in women), and excess hair growth (in women). Corticosteroids may also have an inhibitory effect on wound healing. This may affect persons who have experienced recent nasal ulcers, nasal surgery or nasal trauma.
<b>Sensitization:</b>	No information available.
<b>Mutagenic Effects:</b>	No information available
<b>Carcinogenic effects:</b>	Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Methylprednisolone Acetate	53-36-1	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)  
Group 3 - Not classifiable as to its carcinogenicity to humans  
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:**

No information available

#### **Developmental Effects:**

May cause adverse developmental effects based on animal data

Possible risk of harm to the unborn child

Glucocorticoid medication used during pregnancy has been associated with an increased risk of cleft palate and impaired fetal growth by some studies (REPROTOX)

#### **Teratogenic Effects:**

No information available

#### **Specific Target Organ Toxicity**

#### **STOT - single exposure**

No information available.

#### **STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

#### **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
Methylprednisolone Acetate	53-36-1	None	None	None	None

## **14. TRANSPORT INFORMATION**

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**DOT**

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

**TDG (Canada)**

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

**ADR**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Subsidiary Risk:</b>	No information available

**IMO / IMDG**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>Marine Pollutant</b>	No information available

**RID**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

**ICAO**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available
<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available

**IATA**

<b>UN-No:</b>	Not Regulated
<b>Proper Shipping Name:</b>	No information available
<b>Hazard Class:</b>	No information available

**Product code:** ME171**Product name:**  
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<b>Subsidiary Risk:</b>	No information available
<b>Packing Group:</b>	No information available
<b>ERG Code:</b>	No information available
<b>Special Provisions</b>	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.
Methylprednisolone Acetate	53-36-1	Not Listed	Not present	Not present	Present (9)-488	Not present	Present	Present 200-171-3

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:**  
 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Methylprednisolone Acetate	53-36-1	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
Methylprednisolone Acetate	53-36-1	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
Methylprednisolone Acetate	53-36-1	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:
 

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation
 

This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

**WHMIS 1988 Hazard Class**  
 D2A Very 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)
Methylprednisolone Acetate	53-36-1	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Methylprednisolone Acetate	53-36-1	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Methylprednisolone Acetate	53-36-1	Not listed

**EU Classification****EU GHS - SV - CLP 1272/2008**

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Methylprednisolone Acetate	53-36-1	No information

**EU - CLP (1272/2008)****R-phrases(s)**

R63 - Possible risk of harm to the unborn child.

**S -phrase(s)**

S46 - If swallowed, seek medical advice immediately and show this container or label.

S36/37 - Wear suitable protective clothing and gloves.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Methylprednisolone Acetate	53-36-1		No information	

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

**Indication of danger:**

Xn - Harmful.

Xn

**16. OTHER INFORMATION**

**Preparation Date:** 6/27/2018  
**Revision Date:** 6/27/2018  
**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

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MICRONIZED, USP

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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**



**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
ME171	Methylprednisolone Acetate, 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

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)

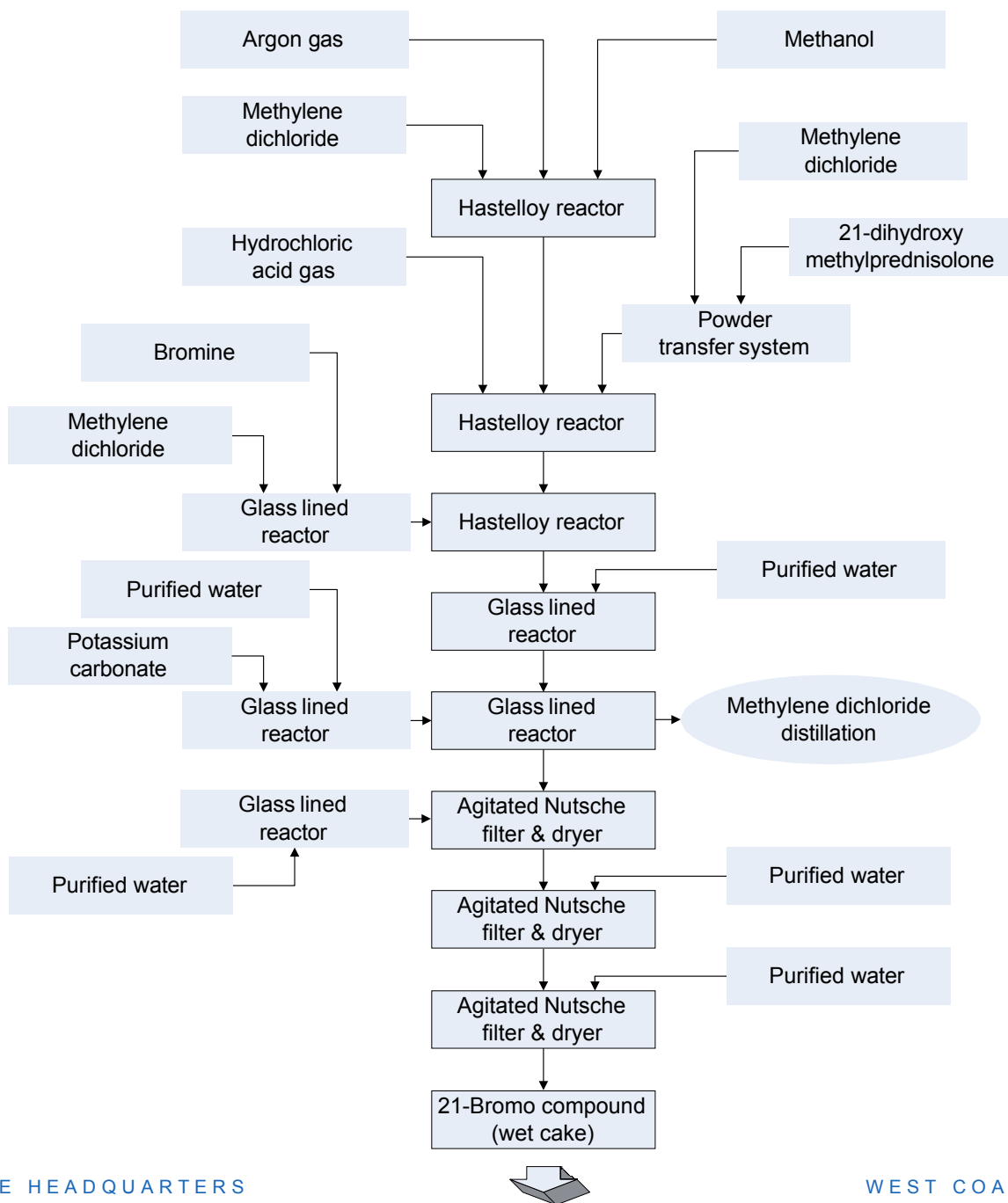
Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Methylprednisolone Acetate, Micronized, USP - ME171

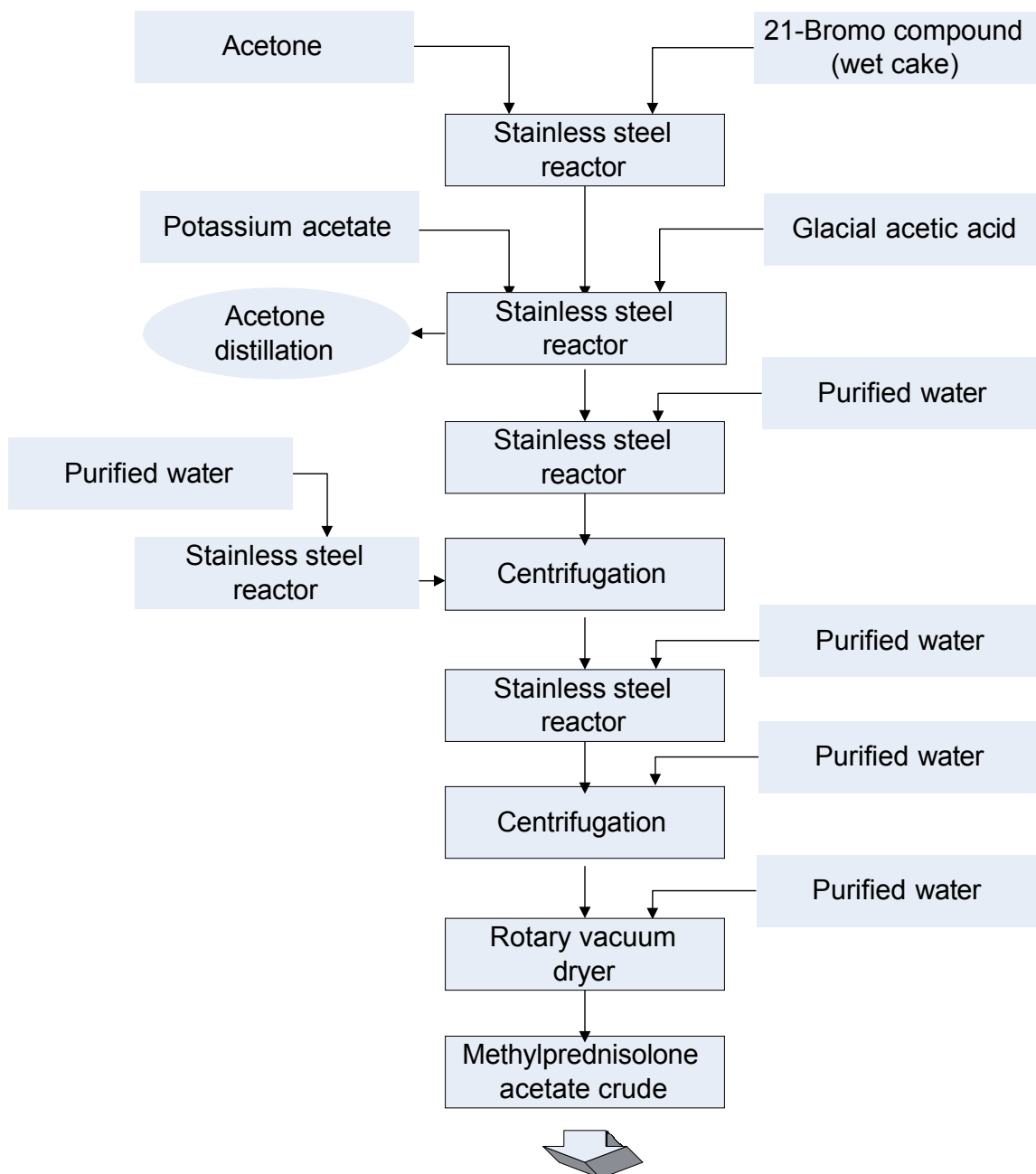


#### CORPORATE HEADQUARTERS

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New Brunswick, NJ 08901  
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FAX 732.246.7132

#### WEST COAST FACILITY

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

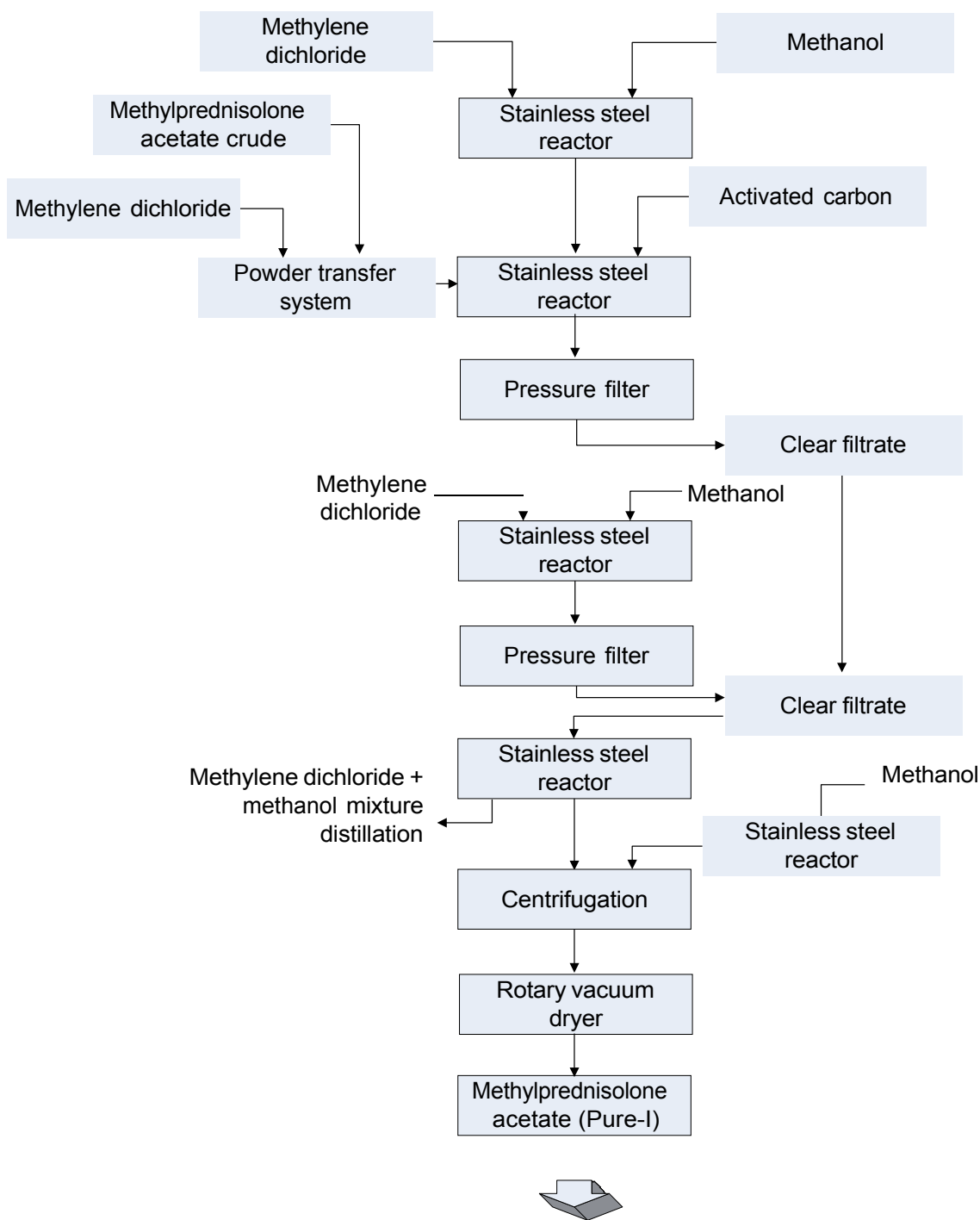


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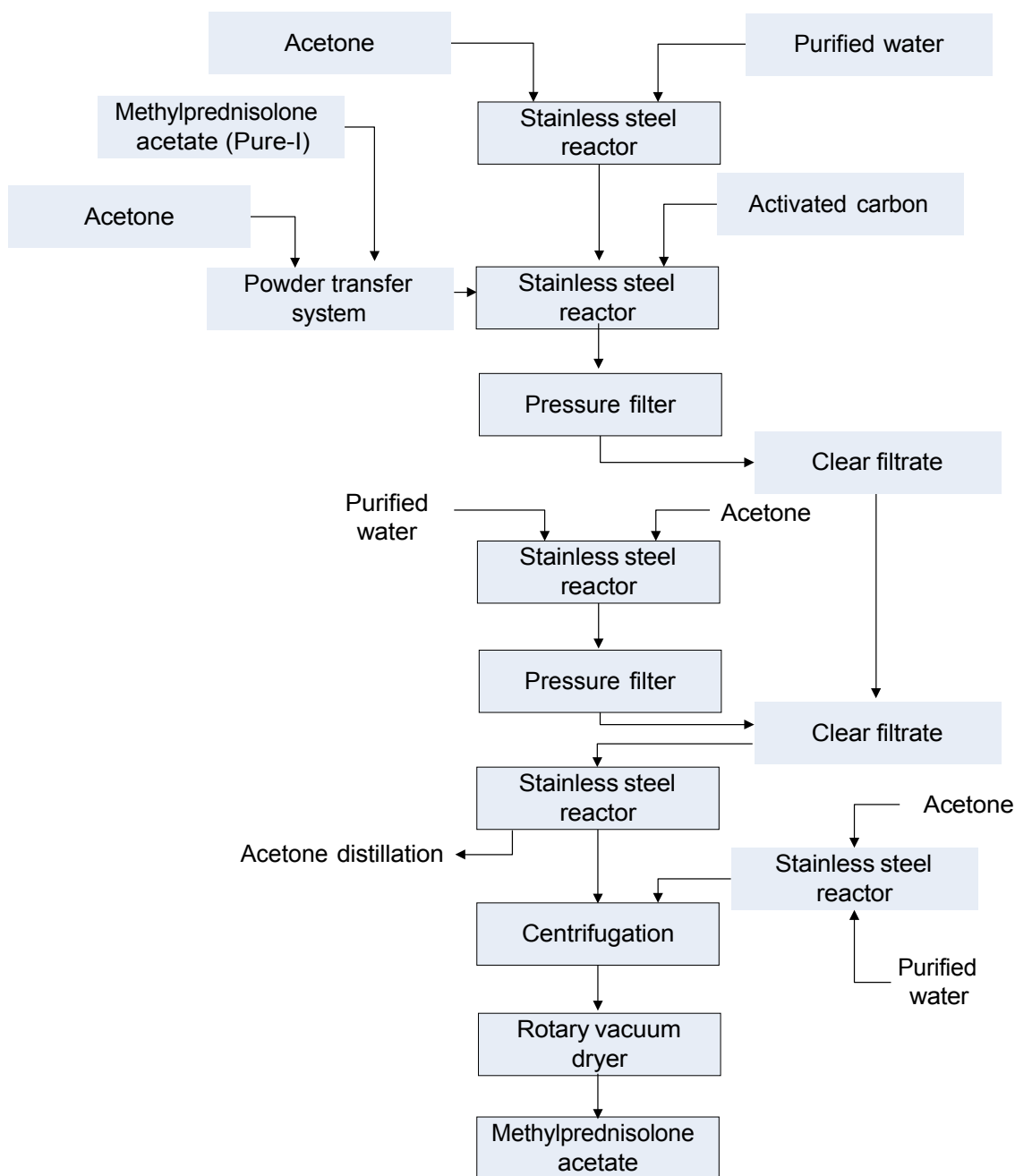


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## ME171, Methylprednisolone Acetate, Micronized, USP

### Source Statement

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

### BSE/TSE Statement

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

### Allergen Statement

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

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

### 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 - Methylprednisolone Acetate, Micronized, USP  
(Cat# ME171)**

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.

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**RE: Residual Solvents - Methylprednisolone Acetate, Micronized, USP  
(Cat# ME171)**

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
<i>N,N</i> -Dimethylformamide	2	< 880 ppm
2-Propanol	3	< 5000 ppm

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

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

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

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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## 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. Below you will find a typical label example for this catalog item.

**WARNING**

- Suspected of damaging fertility or the unborn child • May cause damage to organs through prolonged or repeated exposure.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe dust.

**FIRST AID:** If exposed or concerned: Get medical attention.

**KEEP FROM CHILDREN**



**ME171**

**SIZ SY**

**Methylprednisolone Acetate**

(11β,17,21-Trihydroxy-6α-methylpregna-1,4-diene-3,20-dione 21-Acetate)

Micronized, USP

CAS 53-36-1

**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](http://www.SpectrumChemical.com)

$C_{24}H_{32}O_6$  F.W. 416.51

Manufacturer/Supplier Code ..... ?

Manufacturer Lot Number ..... ?

Assay (Dried Basis) ..... 97.0-103.0%

Specific Rotation,  $[\alpha]_D^{25}$  ..... +97° to +105°

MAXIMUM LIMITS

Loss on Drying ..... 1.0%

Organic Impurities:

Any Individual Impurity ..... 1.0%

Total Impurities ..... 2.0%

Residue on Ignition ..... 0.2%

Elemental Impurities ..... As reported


Residual Solvents ..... To pass test

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

Lot No. XQ####

Retest Date: 00-00-0000



\* 4 9 4 5 2 M E 1 7 1 \*

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

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New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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