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.
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,

Alan Wang, MSQA, ASQ CQA
Senior Manager, Global Supplier Quality Assurance
qualityassurance@spectrumchemical.com

5.Apr.2016
Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Allergen Statement
- Product Aflatoxins Statement
- General Label Information – Sample Label
- Product Certificate of Analysis Sample(s)
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance
**Specification for Polyvinyl Alcohol, USP (P1180)**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>P1180</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Polyvinyl Alcohol, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>9002-89-5</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>(C₂H₄O)n</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>(44.05)N</td>
</tr>
<tr>
<td>MDL Number</td>
<td></td>
</tr>
<tr>
<td>Synonyms</td>
<td>Ethenol Homopolymer, PVA ; PVA</td>
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<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
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</thead>
<tbody>
<tr>
<td>ACTUAL VISCOSITY OF 4% SOLUTION @ 20°C</td>
<td></td>
</tr>
<tr>
<td>VISCOSITY METHOD USED</td>
<td>AS REPORTED</td>
</tr>
<tr>
<td>pH OF A 4% SOLUTION</td>
<td>5.0 - 8.0</td>
</tr>
<tr>
<td>DEGREE OF HYDROLYSIS</td>
<td>85 - 89%</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>5.0%</td>
</tr>
<tr>
<td>RESIDUE ON IGNITION</td>
<td>1.0%</td>
</tr>
<tr>
<td>HEAVY METALS</td>
<td>10 µg/g</td>
</tr>
<tr>
<td>ACID VALUE</td>
<td>3.0</td>
</tr>
<tr>
<td>WATER INSOLUBLE SUBSTANCES</td>
<td>0.1 %</td>
</tr>
<tr>
<td>METHANOL AND METHYL ACETATE</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
</tr>
</tbody>
</table>

**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

1. IDENTIFICATION

Product identifier

Product code: P1180
Product Name: POLYVINYL ALCOHOL, USP

Other means of identification

Synonyms: Alkotex; Alvyl; Aracet APV; Covol; Elvanol; Enbra OV; Ethenol homopolymer; Gohsenol; Lamephil OJ; Lamicel; Lemol; Liquifilm Forte; Mowiol; PVA; Poly(1-hydroxyethylene); Polydesis; Polyethenol; Polyviol; Polyviol M 13/140; Polyviol MO 5/140; Polyviol W 25/140; Polyviol W 28/20; Polyviol W 40/140; Poval; Resistoflex; Rhodoviol; Sloviol R; Solor; Vibatex S; Vinacol DT; Vinacol MH; Vinalak; Vinarol; Vinarol DT; Vinarol ST; Vinarole; Vinyl alcohol polymer

CAS #: 9002-89-5
RTECS #: TR8100000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Resin in textile wrap sizing and finishing, in adhesives, in grease-resistant paper coating; suspension agent in polymerization of vinyl acetate and vinyl chloride; thickener in latex coatings, ingredient in pesticide sprays; binder for phosphorescent pigments in tv picture tubes, ain in photoengraving process; resin in cosmetic face masks, photographic and ether films; pigment binder in paper coatings.

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 by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Label elements
Warning

May form combustible dust concentrations in air

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Keep away from heat/sparks/open flames/hot surfaces. — No smoking
Keep container closed and grounded
Prevent dust accumulations to minimize explosion hazard

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
<th>Trade Secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>9002-89-5</td>
<td>100</td>
<td>*</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

First aid measures

General Advice: Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126).

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops. If symptoms persist, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get 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 irritation. May cause skin irritation. May cause hypermotility, diarrhea. May cause central nervous system effects. May affect the liver. May affect the blood.

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

Product code: P1180  Product name: POLYVINYL ALCOHOL, USP
### 5. FIRE-FIGHTING MEASURES

**Suitable Extinguishing Media:** Water spray. Sand.

**Unsuitable Extinguishing Media:** Dry chemical. CO2.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon oxides

**Specific hazards:**
- Combustible material
- Containers may explode when heated
- May form explosive mixtures with air
- May be ignited by heat, sparks or flames
- Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard

**Special Protective Actions for Firefighters**

**Specific Methods:** Cool closed containers with flooding quantities of water until fire is out.

**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. Remove all sources of ignition. Avoid contact with skin, eyes and clothing. Avoid dispersal of dust in the air. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Nonsparking tools should be used.

**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

**Precautions for safe handling**

**Technical Measures/Precautions:** Provide sufficient air exchange and/or exhaust in work rooms. Minimize dust generation and accumulation. Dry powders can build static electricity charges when subjected to friction of transfer and mixing operations. All equipment used when handling the product must be grounded. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Keep away from incompatible materials.

**Safe Handling Advice** Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe vapours/dust. Do not ingest. Do not smoke. 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. Store away from incompatible materials.

Incompatible Materials:

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
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</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>9002-89-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Canada

<table>
<thead>
<tr>
<th>Components</th>
<th>Alberta</th>
<th>British Columbia</th>
<th>Ontario</th>
<th>Quebec</th>
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</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>9002-89-5</td>
<td></td>
<td></td>
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</table>

Australia and Mexico

<table>
<thead>
<tr>
<th>Components</th>
<th>Australia</th>
<th>Mexico</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>9002-89-5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment) It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in the handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

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. apron. Gloves.
Respiratory protection: Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent..

Product code: P1180
Product name: POLYVINYL ALCOHOL, USP
**Hygiene measures:**
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

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>Taste</td>
<td>Formula:</td>
</tr>
<tr>
<td>Odorless</td>
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<td>(C2H4O)n</td>
</tr>
<tr>
<td>Molecular/Formula weight: (44.05)n</td>
<td>Flammability:</td>
<td>Flash point (°C):</td>
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<tr>
<td></td>
<td>Combustible dust</td>
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</tr>
<tr>
<td>Flashpoint (°C/°F):</td>
<td>Flash Point Tested according to:</td>
<td>Autoignition Temperature (°C/°F):</td>
</tr>
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<td>79°C/ 174.2°F</td>
<td>Open cup</td>
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<tr>
<td>Lower Explosion Limit (%):</td>
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<td>pH:</td>
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<td>Melting point/range(°C/°F):</td>
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<td>200°C/ 392°F</td>
<td>Boiling point/range(°C/°F):</td>
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<tr>
<td>228°C/ 442.2°F</td>
<td>Density (g/cm³):</td>
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<tr>
<td>400-670 kg/m³</td>
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<td>1.19-1.31</td>
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<tr>
<td>Vapor pressure @ 20°C (kPa):</td>
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<td>Vapor density:</td>
</tr>
<tr>
<td>No information available</td>
<td>Evaporation rate:</td>
<td>No information available</td>
</tr>
<tr>
<td>No information available</td>
<td>Odor threshold (ppm):</td>
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<tr>
<td>VOC content (g/L):</td>
<td>Partition coefficient (n-octanol/water):</td>
<td>No information available</td>
</tr>
<tr>
<td>No information available</td>
<td>No information available</td>
<td>Solubility:</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>Miscibility:</td>
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<tr>
<td>No information available</td>
<td>No information available</td>
<td>Soluble in hot water</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insoluble in diethyl ether</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insoluble in acetone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insoluble in aromatic hydrocarbons</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insoluble in esters</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Practically in soluble in animal and vegetable oils and chlorinated hydrocarbons</td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

**Reactivity**
Incompatible with oxidizing agents (perchlorates, nitrates, etc.), reactive metals (sodium, calcium, zinc. etc.), sodium or calcium hypochlorite, materials reactive with hydroxyl compounds. Reaction with peroxides may result in violent decomposition of peroxide possibly creating and explosion.

**Chemical stability**
Stable under recommended storage conditions.

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

**Conditions to avoid:**
Heat. Ignition sources. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.

**Product code:** P1180  **Product name:** POLYVINYL ALCOHOL, USP

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

Polyvinyl Alcohol - 9002-89-5
LD50/oral/rat = 23854 mg/kg Oral LD50 Rat
LD50/oral/mouse = 14700 mg/kg
LD50/dermal/rat = No information available
LD50/dermal/rabbit = 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 = 23854mg/kg
LD50/oral/mouse = Value - Acute Tox Oral = 14700mg/kg
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
LC50/inhalation/mouse = VALUE - Gas = No information available
LC50/inhalation/mouse = VALUE - Dust/Mist = No information available

Symptoms

Product code: P1180 Product name: POLYVINYL ALCOHOL, USP
Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause respiratory tract irritation.

Ingestion Causes digestive (gastrointestinal) tract irritation. May cause hypermotility, diarrhea. May affect behavior/central nervous system (symptoms may include general depressed activity, somnolence, altered sleep time, muscle weakness, ataxia).

Aspiration hazard No information available

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

Chronic Toxicity Prolonged or repeated ingestion of very large amounts may cause hypermotility and diarrhea. Prolonged or repeated ingestion may affect the blood (changes in serum composition). Prolonged or repeated ingestion may affect the liver, urinary system, and metabolism. Prolonged or repeated ingestion may cause weight loss. Prolonged or repeated ingestion may affect the spleen.

Sensitization: No information available

Mutagenic Effects: No information available

Carcinogenic effects: Not classifiable as to its carcinogenicity to humans.

<table>
<thead>
<tr>
<th>Components</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>Group 3 (Not Classifiable) - Supplement 7 [1987 Monograph 19 [1979]</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer) 
Group 3 - Not classifiable as to its carcinogenicity to humans

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

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.

Product code: P1180

Product name: POLYVINYL ALCOHOL, USP
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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: None
ERG No: No information available
Marine Pollutant: No data available
DOT RQ (lbs): 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
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
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

IMO / IMDG

UN-No: Not Regulated

Product code: P1180
Product name: POLYVINYL ALCOHOL, USP
14. TRANSPORT INFORMATION

Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available
IMDG Page: No information available
Marine Pollutant: No information available
MFAG: No information available

Maximum Quantity: 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
Classification Code: No information available
Description: 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
Description: 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
Description: No information available

15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>U.S. TSCA</th>
<th>KOREA KECL (PICCS)</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol</td>
<td>Present XU</td>
<td>Present KE-29060</td>
<td>Present</td>
<td>Present (6)-682</td>
<td>Present</td>
<td>Present</td>
<td>Not present</td>
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</tbody>
</table>

U.S. Regulations

Polyvinyl Alcohol
FDA - 21 CFR - Total Food Additives
175.105 175.300 175.320 176.170 176.180 177.1200 177.1670 177.2260 177.2800
178.3910 181.30 73.1


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 | Carcinogen | Developmental Toxicity | Male Reproductive Toxicity | Female Reproductive Toxicity:
--- | --- | --- | --- | ---
Polyvinyl Alcohol | Not Listed | Not Listed | Not Listed | Not Listed

CERCLA/SARA

| Components | 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 |
--- | --- | --- | --- | --- | ---
Polyvinyl Alcohol | None | None | None | None | None

U.S. TSCA

| Components | TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS) | TSCA 8(d) - Health and Safety Reporting |
--- | --- | ---
Polyvinyl Alcohol | Not Applicable | Not Applicable |

Canada

WHMIS hazard class:
Non-controlled

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 | Canada (DSL) | Canada (NDSL) |
--- | --- | ---
Polyvinyl Alcohol | Present | Not Listed |

| Components | CEPA Schedule I - Toxic Substances | CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting |
--- | --- | ---
Polyvinyl Alcohol | Not listed | Not listed |

EU Classification

R-phrase(s)
not determined (not applicable)

S-phrase(s)
none

| Components | Classification | Concentration Limits: | Safety Phrases |
--- | --- | --- | ---
Polyvinyl Alcohol | | No information | |

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

Indication of danger:
None.

Product code: P1180  Product name: POLYVINYL ALCOHOL, USP
16. OTHER INFORMATION

Preparation Date: 06/16/2015
Revision Date: 06/16/2015
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: P1180, Polyvinyl Alcohol, 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,

Alan Wang, MSQA, ASQ CQA
Senior Manager, Global Supplier Quality Assurance
qualityassurance@spectrumchemical.com

5.Apr.2016
Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, LLC
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 facilitates 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 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.
Certificate of Registration

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

This is to certify that the quality management system of Spectrum China Ltd. has been assessed and registered by Intertek as conforming to the requirements of ISO 9001: 2008.

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

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

Authorized Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited; 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

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 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.
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: 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 if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist
March 31, 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.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1180</td>
<td>Polyvinyl Alcohol, USP</td>
</tr>
</tbody>
</table>

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 if we may be of further assistance.

Sincerely,

Michelle Weston
Quality Assurance Specialist
March 31, 2016

Re: Polyvinyl Alcohol, USP-P1180

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 Polyvinyl Alcohol, USP-P1180

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.

Sincerely,

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

This document has been produced electronically and is valid without a signature
March 31, 2016

Re: Polyvinyl Alcohol, USP – P1180

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 (Peanuts and peanut products; Tree nuts; Sesame, Sunflower, Poppy, Cottonseed, except refined oils; Milk and its derivatives, eg whey, milk, caseninate, etc.; Eggs; Fish and fish products; Shellfish; Soy, except refined soy oil; Autolyzed yeast; Cereal proteins, including HVP;FD&C Yellow#5; Sulfites; Celery; Seeds; Lupin; Mollusks and products thereof; Gluten; Mustard; Wheat and Carmine)

Polyvinyl Alcohol, USP – P1180

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at 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
April 1, 2016

Re: Polyvinyl Alcohol, USP - P1180

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 the production. The following product does not come in contact with Aflatoxins at any stage of production.

Polyvinyl Alcohol, USP - P1180

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at 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

- May form combustible (explosive) dust-air mixtures.
- Keep away from all ignition sources including heat, sparks and flame
- Keep container closed and grounded
- Prevent dust accumulations to minimize explosion hazard.

This material has been evaluated per GHS criteria and is not classified as hazardous under GHS. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

Polyvinyl Alcohol
(Ethenol Homopolymer, PVA)
U.S.P.

CAUTION: For manufacturing, processing or repackaging.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

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

(C2H4O)n

Actual Viscosity of 4% Solution @ 20°C ........... 0.8 mPa·s
Viscosity Method Used ......................................... 22.1
pH of a 4% Solution ............................................. 5.0-8.0
Degree of Hydrolysis .......................................... 85-89%

MAXIMUM LIMITS
Loss on Drying ....................................................... 5.0%
Residue on Ignition ............................................... 1.0%
Heavy Metals ...................................................... 10 µg/g
Acid value .......................................................... 3.0
Water Insoluble Substances ............................... 0.1%
Methanol and Methyl Acetate To pass test
Residual Solvents To pass test

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

Retest Date: 03-31-2025

Expiration Information
Lot Number
Bar Code
Warning, Safety Data and Precautionary Information
Product Catalog Number
Item Name, Form, Grade
Size/Quantity
Storage Color Band

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.

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
## Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pi180</td>
<td>1EG0776</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol, USP</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Molecular Formula</th>
<th>Molecular Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>9002-89-5</td>
<td>((C_2H_4O)_n)</td>
<td>(44.05)N</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTUAL VISCOSITY OF 4 % SOLUTION @ 20 C</td>
<td>AS REPORTED (mPa·s)</td>
<td>23.1 mPa·s</td>
</tr>
<tr>
<td>VISCOSITY METHOD USED</td>
<td>AS REPORTED</td>
<td>Cannon Fenske 150</td>
</tr>
<tr>
<td>pH OF A 4% SOLUTION</td>
<td>5.0 - 8.0</td>
<td>5.81</td>
</tr>
<tr>
<td>DEGREE OF HYDROLYSIS</td>
<td>85 - 89%</td>
<td>86.45 %</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>5.0%</td>
<td>4.7 %</td>
</tr>
<tr>
<td>RESIDUE ON IGNITION</td>
<td>1.0%</td>
<td>0.33 %</td>
</tr>
<tr>
<td>HEAVY METALS</td>
<td>10 µg/g</td>
<td>&lt; 10 µg/g</td>
</tr>
<tr>
<td>ACID VALUE</td>
<td>3.0</td>
<td>&lt; 3.0</td>
</tr>
<tr>
<td>WATER INSOLUBLE SUBSTANCES</td>
<td>0.1 %</td>
<td>0.1 %</td>
</tr>
<tr>
<td>METHANOL AND METHYL ACETATE</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>RETEST DATE</td>
<td>01-JUL-2017</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
<td>NO RESIDUAL SOLVENTS USED</td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>TO PASS TEST</td>
<td>WHITE GRANULES</td>
</tr>
<tr>
<td>MANUFACTURE DATE</td>
<td>01-JUL-2015</td>
<td></td>
</tr>
</tbody>
</table>

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia. 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
# Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>P1180</th>
<th>Lot Number</th>
<th>2EJ0128</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Polyvinyl Alcohol, USP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>9002-89-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>((C_2H_4O)_n)</td>
<td>Molecular Weight</td>
<td>((44.05)N)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTUAL VISCOSITY OF 4 % SOLUTION @ 20 C</td>
<td>AS REPORTED (mPa·s)</td>
<td>24.7 cps</td>
</tr>
<tr>
<td>VISCOSITY METHOD USED</td>
<td>AS REPORTED</td>
<td>DIGITAL VISCOSITY METER</td>
</tr>
<tr>
<td>pH OF A 4% SOLUTION</td>
<td>5.0 - 8.0</td>
<td>6.01</td>
</tr>
<tr>
<td>DEGREE OF HYDROLYSIS</td>
<td>85 - 89%</td>
<td>87.53 %</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>5.0%</td>
<td>(&lt;5.0)</td>
</tr>
<tr>
<td>RESIDUE ON IGNITION</td>
<td>1.0%</td>
<td>0.31 %</td>
</tr>
<tr>
<td>HEAVY METALS</td>
<td>10 µg/g</td>
<td>(&lt;10) µg/g</td>
</tr>
<tr>
<td>ACID VALUE</td>
<td>3.0</td>
<td>(&lt;3.0)</td>
</tr>
<tr>
<td>WATER INSOLUBLE SUBSTANCES</td>
<td>0.1 %</td>
<td>(&lt;0.1) %</td>
</tr>
<tr>
<td>METHANOL AND METHYL ACETATE</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>RETEST DATE</td>
<td></td>
<td>01-OCT-2017</td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
<td>NO RESIDUAL SOLVENTS USED</td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
<td>01-OCT-2015</td>
</tr>
<tr>
<td>APPEARANCE</td>
<td></td>
<td>WHITE CRYSTALS</td>
</tr>
</tbody>
</table>

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

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:

Mulbah F. Dwanah
Laboratory Supervisor
Spectrum Chemicals & Laboratory Products
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\textsuperscript{th} 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\textsuperscript{th} 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 if we may be of further assistance.

Sincerely,

Michael Dang  
Manager, GMP Compliance
Stability – Shelf Life Guidance

Product Covered: P1180, Polyvinyl Alcohol, USP

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

The product, Polyvinyl Alcohol, USP, is assigned a 24 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

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