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  - EU Fragrance Allergen Statement
  - GMO Statement
  - Melamine Statement
    - Nitrosamine Statement
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- Other Chemicals Statement
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- Residual Solvents Statement
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- General Lot Numbering System Guidance
• Halal Certificate
**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>(C$_2$H$_4$O)$_n$</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>(44.05)N</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Ethenol Homopolymer ; PVA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTUAL VISCOSITY OF 4 % SOLUTION @ 20 C</td>
<td>AS REPORTED (mPa·s)</td>
</tr>
<tr>
<td>VISCOSITY METHOD USED</td>
<td>AS REPORTED</td>
</tr>
<tr>
<td>pH OF A 4% SOLUTION</td>
<td>5.0</td>
</tr>
<tr>
<td>DEGREE OF HYDROLYSIS</td>
<td>85</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>ELEMENTAL IMPURITIES</td>
<td>AS REPORTED</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></td>
</tr>
<tr>
<td>METHANOL</td>
<td>1.0%</td>
</tr>
<tr>
<td>METHYL ACETATE</td>
<td>1.0%</td>
</tr>
<tr>
<td>IDENTIFICATION (A)</td>
<td>SPECTRUM MATCHES REFERENCE</td>
</tr>
<tr>
<td>IDENTIFICATION (B)</td>
<td>85</td>
</tr>
<tr>
<td>IDENTIFICATION (C1)</td>
<td>DARK RED TO BLUE COLOR</td>
</tr>
<tr>
<td>IDENTIFICATION (C2)</td>
<td>WHITE TURBID OR FLOCCULENT PRECIPITATE</td>
</tr>
<tr>
<td>CERTIFIED HALAL</td>
<td></td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td></td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>AS REPORTED</td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>AS REPORTED</td>
</tr>
</tbody>
</table>
# Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>P1180</th>
<th>Lot Number</th>
<th>1KK0613</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Polyvinyl Alcohol, USP</td>
<td>CAS Number</td>
<td>9002-89-5</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>$\text{(C}_2\text{H}_4\text{O)}_n$</td>
<td>Molecular Weight</td>
<td>$(44.05)N$</td>
</tr>
</tbody>
</table>

## TEST |

<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>24.1 mPa·s</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</td>
<td>8.0</td>
</tr>
<tr>
<td>DEGREE OF HYDROLYSIS</td>
<td>85</td>
<td>89%</td>
</tr>
<tr>
<td>LOSS ON DRYING</td>
<td>5.0%</td>
<td>3.4 %</td>
</tr>
<tr>
<td>RESIDUE ON IGNITION</td>
<td>1.0%</td>
<td>0.26 %</td>
</tr>
<tr>
<td>ELEMENTAL IMPURITIES</td>
<td>AS REPORTED</td>
<td>NO ELEMENTAL IMPURITIES PRESENT</td>
</tr>
<tr>
<td>ACID VALUE</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>WATER INSOLUBLE SUBSTANCES</td>
<td>0.1 %</td>
<td>0.02 %</td>
</tr>
<tr>
<td>METHANOL AND METHYL ACETATE:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>METHANOL</td>
<td>1.0%</td>
<td>0.2 %</td>
</tr>
<tr>
<td>METHYL ACETATE</td>
<td>1.0%</td>
<td>0.4 %</td>
</tr>
<tr>
<td>IDENTIFICATION (A)</td>
<td>SPECTRUM MATCHES REFERENCE</td>
<td>SPECTRUM MATCHES REFERENCE</td>
</tr>
<tr>
<td>IDENTIFICATION (B)</td>
<td>85</td>
<td>115 %</td>
</tr>
<tr>
<td>IDENTIFICATION (C1)</td>
<td>DARK RED TO BLUE COLOR</td>
<td>DARK RED TO BLUE COLOR</td>
</tr>
<tr>
<td>IDENTIFICATION (C2)</td>
<td>WHITE TURBID OR FLOCCULENT PRECIPITATE</td>
<td>WHITE TURBID OR FLOCCULENT PRECIPITATE</td>
</tr>
<tr>
<td>CERTIFIED HALAL</td>
<td>CERTIFIED HALAL</td>
<td></td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td>01-NOV-2023</td>
<td></td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td>01-NOV-2021</td>
<td></td>
</tr>
<tr>
<td>APPEARANCE</td>
<td>WHITE GRANULES</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>AS REPORTED</td>
<td>NO RESIDUAL SOLVENTS USED</td>
</tr>
<tr>
<td>MONOGRAPH EDITION</td>
<td>USP 2021</td>
<td></td>
</tr>
</tbody>
</table>
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.
# 1. Identification

**Product identifier**

- **Product Name**: POLYVINYL ALCOHOL, USP
- **Other means of identification**
  - **Product Code(s)**: P1180
  - **Synonyms**: None

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

- **Recommended use**: No information available
- **Restrictions on use**: No information available

**Details of the supplier of the safety data sheet**

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

**Emergency telephone number**

- **Emergency Telephone**: Chemtrec 1-800-424-9300

# 2. Hazard(s) identification

**Classification**

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combustible dust</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Hazards not otherwise classified (HNOC)**

- Not applicable

**Label elements**

- **Warning**

**Hazard statements**

- May form combustible dust concentrations in air

**Appearance**  Prills or amorphous powder  | **Physical state**  Solid  | **Odor**  Odorless

**Precautionary Statements - Prevention**
Keep away from all ignition sources including heat, sparks, and flame.
Keep container closed and grounded.
Prevent dust accumulations to minimize explosion hazard.

**Other information**
No information available.

### 3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical name</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>
<td></td>
</tr>
</tbody>
</table>

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

### 4. First-aid measures

**Description of first aid measures**

**Inhalation**
Remove to fresh air.

**Eye contact**
Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

**Skin contact**
Wash skin with soap and water.

**Ingestion**
Clean mouth with water and drink afterwards plenty of water.

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

**Symptoms**
No information available.

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

**Note to physicians**
Treat symptomatically.

### 5. Fire-fighting measures

**Suitable Extinguishing Media**
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire**
CAUTION: Use of water spray when fighting fire may be inefficient.

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

**Specific hazards arising from the chemical**
Avoid generation of dust. Fine dust dispersed in air may ignite.

**Hazardous combustion products**
Carbon dioxide (CO2). Carbon monoxide.

**Explosion data**
- **Sensitivity to mechanical impact**: none.
- **Sensitivity to static discharge**: yes.

**Special protective equipment for**
Firefighters should wear self-contained breathing apparatus and full firefighting turnout.
6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions

Ensure adequate ventilation. Avoid generation of dust. Avoid contact with eyes. Use personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary measures against static discharges.

Other information

Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so. Prevent dust cloud.

Methods for cleaning up

Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields (or goggles).
Skin and body protection
No special protective equipment required.

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

General hygiene considerations
Do not breathe dust.

9. Physical and chemical properties

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks • Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Prills or amorphous powder</td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>White to Off-White; Colorless</td>
<td></td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
<td></td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks • Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>4.5-7.0</td>
<td>None known</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>200 °C / 392 °F</td>
<td>None known</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>no data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flash point</td>
<td>79 °C / 174.2 °F</td>
<td>None known</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>no data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>no data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper flammability or explosive</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>limits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower flammability or explosive</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>limits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor density</td>
<td>no data available</td>
<td>None known</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.19 - 1.31</td>
<td>None known</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in cold water</td>
<td>None known</td>
</tr>
<tr>
<td></td>
<td>Soluble in hot water</td>
<td></td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Insoluble in diethyl ether</td>
<td>None known</td>
</tr>
<tr>
<td></td>
<td>Insoluble in Acetone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Insoluble in aromatic hydrocarbons</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Insoluble in esters</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Practically insoluble in animal and vegetable oils and chlorinated hydrocarbons</td>
<td></td>
</tr>
<tr>
<td>Partition coefficient</td>
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<td>None known</td>
</tr>
<tr>
<td>Autoignition temperature</td>
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<td>None known</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>228 - °C 442.4 °F</td>
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<tr>
<td>Kinematic viscosity</td>
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<tr>
<td>Dynamic viscosity</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>Softening point</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>Molecular weight</td>
<td>(44.05)n</td>
<td></td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>Liquid Density</td>
<td>No information available</td>
<td></td>
</tr>
<tr>
<td>Bulk density</td>
<td>400 - 670 kg/m³</td>
<td></td>
</tr>
</tbody>
</table>

10. Stability and reactivity

Reactivity
No information available.

Chemical stability
Stable under normal conditions.

Possibility of hazardous reactions
None under normal processing.
Conditions to avoid

Incompatible materials
None known based on information supplied.

Hazardous decomposition products
None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation
Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

Eye contact
Specific test data for the substance or mixture is not available.

Skin contact
Specific test data for the substance or mixture is not available.

Ingestion
Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms
No information available.

Acute toxicity

Numerical measures of toxicity

Component Information

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyvinyl Alcohol 9002-89-5</td>
<td>23854 mg/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

Skin corrosion/irritation
No information available.

Serious eye damage/eye irritation
No information available.

Respiratory or skin sensitization
No information available.

Germ cell mutagenicity
No information available.

Carcinogenicity
No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
</table>

Legend

Reproductive toxicity
No information available.

STOT - single exposure
No information available.

STOT - repeated exposure
No information available.

Aspiration hazard
No information available.

Other adverse effects
No information available.

Interactive effects
No information available.

12. Ecological information
Ecotoxicity
The environmental impact of this product has not been fully investigated.

Persistence and degradability
Bioaccumulation
No information available.
Inherently biodegradable.

Other adverse effects
No information available.

13. Disposal considerations

Waste treatment methods
Waste from residues/unused products
Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging
Do not reuse empty containers.

14. Transport information

DOT
not regulated

TDG
not regulated

MEX
not regulated

ICAO (air)
not regulated

IATA
not regulated

IMDG
not regulated

RID
not regulated

ADR
not regulated

ADN
not regulated

15. Regulatory information

International Inventories

TSCA
Complies

DSL/NDSL
Complies

EINECS/ELINCS
Does not Comply

ENCS
This product complies with ENCS:

IECSC
This product complies with China:

KECL
Complies

PICCS
Complies

AICS
All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations
This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA
Health hazards 0
Flammability 2 1
Instability 0
Physical and chemical properties -
HMIS
Health hazards 0
Flammability 2
Physical hazards 0
Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet
Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)
Ceiling Maximum limit value

Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 29-November-2021
Revision Note No information available.

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet
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.

<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

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist
**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

**EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

**GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

**Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.
Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals prior to or after June 20th 2002.

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 24 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives
RE: Elemental Impurities - Polyvinyl Alcohol, USP (Cat# P1180)

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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.
RE: Residual Solvents - Polyvinyl Alcohol, USP (Cat# P1180)

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:

<table>
<thead>
<tr>
<th>Residual Solvent</th>
<th>Class</th>
<th>Expected Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methanol</td>
<td>2</td>
<td>&lt; 1.0%*</td>
</tr>
<tr>
<td>Methyl Acetate</td>
<td>3</td>
<td>&lt; 1.0%*</td>
</tr>
</tbody>
</table>

*Methanol and Methyl Acetate are present below the limit of 1.0% each under the specification *Limit of Methanol (Methyl Alcohol) and Methyl Acetate* as required by the USP monograph.

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.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.
## Polyvinyl Alcohol (Ethenol Homopolymer, PVA)

### P1180

#### SIZ SY

**Actual Viscosity of 4% Solution @ 20°C**: ....... mPa·s

**Viscosity Method Used**: .................?

**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%
- **Elemental Impurities**: .......... As reported
- **Acid Value**: ..................... 3.0
- **Water Insoluble Substances**: .... 0.1%
- **Methanol and Methyl Acetate**: ... To pass test
- **Residual Solvents**: ............... To pass test

### WARNING:

- May form combustible dust concentrations in air.
- 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

### CAUTION:

For manufacturing, processing or repacking.

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)
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 928th 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
4 = Pharmacy, NJ 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 706th 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 quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist
This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America (IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: November 02, 2021  
Document #: 11205.11206.II214239

<table>
<thead>
<tr>
<th>Product Name &amp; Address:</th>
<th>Spectrum Laboratory Products, Inc. 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Name &amp; Address:</td>
<td>Spectrum Laboratory Products, Inc. 769-Jersey Ave New Brunswick, New Jersey 08901 USA</td>
</tr>
<tr>
<td>Plant Name &amp; Address:</td>
<td>Spectrum Laboratory Products, Inc. 769-Jersey Ave New Brunswick, New Jersey 08901 USA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Code</th>
<th>Halal-ID</th>
<th>Product Certificate #</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Polyvinyl Alcohol, USP</td>
<td>P1180</td>
<td>B94020</td>
<td>HC-21SP4Q08</td>
</tr>
</tbody>
</table>

Muhammad Munir Chaudry, Ph.D.  
President

This Certificate is valid until **August 31, 2022** and subject to renewal at that time.