

# **Scientific Documentation**

# Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

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

Spectrum Chemical Mfg Corp 769 Jersey Avenue New Brunswick, NJ 08901 Phone 732.214.1300





# **Table of Contents**

Product Specification
Certificate of Analysis
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Manufacturing Process Flowchart
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label
Kosher Certification



# Specification for Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED (TM) (D9300)

Item Number	D9300
Item	Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED (TM)
CAS Number	50-99-7
Molecular Formula	$C_6H_{12}O_6$
Molecular Weight	180.20
MDL Number	
Synonyms	D-Glucose ; Glucose ; Corn Sugar

Test	Specification		
	Min	Max	
APPEARANCE			
ASSAY (JP)	99.5	101.0 %	
ASSAY (ANHYDROUS BASIS; EP, BP, USP)	97.5	102.0%	
Acidity (JP)	RED COLOR DEVELOPS		
LOSS ON DRYING (JP)		1.0 %	
Water (USP, EP, BP)		1.0 %	
COLOR AND CLARITY OF SOLUTION	CLEAR NO MORE COLOR THAN STANDARD		
RESIDUE ON IGNITION (JP)		0.1 %	
CONDUCTIVITY (USP, EP, BP)		20 μS/cm	
RELATED SUBSTANCES (USP, EP, BP):			
MALTOSE AND ISOMALTOSE		0.4 %	
MALTOTRIOSE		0.2 %	
FRUCTOSE		0.15 %	
UNSPECIFIED IMPURITY		0.10 %	
TOTAL IMPURITIES		0.5 %	
Chloride (Cl, JP)		0.018 %	
Sulfate (SO4, JP)		0.024 %	
Arsenic (As, JP)		1.3 ppm	
ELEMENTAL IMPURITIES		AS REPORTED	

Test	Specification	
	Min	Max
HEAVY METALS (JP)		4 ppm
DEXTRIN	SAMPLE DISOLVES COMPLETELY	
SOLUBLE STARCH, SULFITES (USP, EP, BP)		15 ppm
SOLUBLE STARCH AND SULFITE (JP)	SOLUTION IS YELLOW	
MICROBIAL LIMITS:		
BACTERIAL ENDOTOXINS		2.5 EU/g
TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g
TOTAL YEASTS AND MOLDS COUNT		100 CFU/g
IDENTIFICATION (A) USP	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B) USP	RETENTION TIME MATCH STANDARD	
IDENTIFICATION (C) USP		1.0 %
IDENTIFICATION (A) EP	+52.5 to +53.3°	
IDENTIFICATION (C) EP	CHROMATOGRAM MATCHES STANDARD	
IDENTIFICATION (D) EP	RED PRECIPITATE	
CERTIFIED KOSHER		
CERTIFIED HALAL		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		AS REPORTED
MONOGRAPH EDITION		
MONOGRAPH EDITION.		
MONOGRAPH EDITION		

## Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



# **Certificate Of Analysis**

Item Number	D9300	Lot Number	4MF0041
Item	Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED (TM)	CAS Number	50-99-7
Molecular Formula	$C_6H_{12}O_6$	Molecular Weight	180.20

TECT	SPECIFICATION		RECULT	
TEST	MIN	MAX	RESULT	
APPEARANCE			WHITE POWDERY GRANULES	
ASSAY (JP)	99.5	101.0 %	101.0 %	
ASSAY (ANHYDROUS BASIS; EP, BP, USP)	97.5	102.0%	99.6 %	
Acidity (JP)	RED COLOR DEVELOPS		RED COLOR DEVELOPS	
LOSS ON DRYING (JP)		1.0 %	0.1 %	
Water (USP, EP, BP)		1.0 %	0.1 %	
COLOR AND CLARITY OF SOLUTION	CLEAR NO MORE COLOR THAN STANDARD		CLEAR NO MORE COLOR THAN STANDARD	
RESIDUE ON IGNITION (JP)		0.1 %	0.01 %	
CONDUCTIVITY (USP, EP, BP)		20 μS/cm	1.01 μS/cm	
RELATED SUBSTANCES (USP, EP, BP):				
MALTOSE AND ISOMALTOSE		0.4 %	<0.4 %	
MALTOTRIOSE		0.2 %	0.0 %	
FRUCTOSE		0.15 %	0.0 %	
UNSPECIFIED IMPURITY		0.10 %	0.0 %	
TOTAL IMPURITIES		0.5 %	0.0 %	
Chloride (Cl, JP)		0.018 %	<0.018 %	
Sulfate (SO4, JP)		0.024 %	<0.024 %	
Arsenic (As, JP)		1.3 ppm	<0.05 ppm	
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD	
HEAVY METALS (JP)		4 ppm	<4 ppm	

TECT	SPECIFICATION		DECLUT.	
TEST	MIN	MAX	RESULT	
DEXTRIN	SAMPLE DISOLVES COMPLETELY		SAMPLE DISSOLVES COMPLETELY	
SOLUBLE STARCH, SULFITES (USP, EP, BP)		15 ppm	<15 ppm	
SOLUBLE STARCH AND SULFITE (JP)	SOLUTION IS YELLOW		SOLUTION IS YELLOW	
MICROBIAL LIMITS:				
BACTERIAL ENDOTOXINS		2.5 EU/g	<2.4 EU/g	
TOTAL AEROBIC MICROBIAL COUNT		1000 CFU/g	<10 CFU/g	
TOTAL YEASTS AND MOLDS COUNT		100 CFU/g	<10 CFU/g	
IDENTIFICATION (A) USP	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B) USP	RETENTION TIME MATCH STANDARD		RETENTION TIME MATCHES STANDARD	
IDENTIFICATION (C) USP		1.0 %	0.0 %	
IDENTIFICATION (A) EP	+52.5 to +53.3°		+53.17°	
IDENTIFICATION (C) EP	CHROMATOGRAM MATCHES STANDARD		CHROMATOGRAM MATCHES STANDARD	
IDENTIFICATION (D) EP	RED PRECIPITATE		NO RED PRECIPITATE	
CERTIFIED KOSHER			CERTIFIED KOSHER	
CERTIFIED HALAL			CERTIFIED HALAL	
EXPIRATION DATE			17-DEC-2025	
DATE OF MANUFACTURE			18-DEC-2022	
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS PRESENT	
MONOGRAPH EDITION			USP 2023	
MONOGRAPH EDITION.			BP 2023,EP 11	
MONOGRAPH EDITION			JP 18th	

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 11-AUG-23 07:36:03

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

DAMILLER Davinn Miller 14-AUG-23 16:23:13 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.





Revision date 27-May-2021

Revision Number 1

#### 1. Identification

**Product identifier** 

Product Name DEXTROSE, ANHYDROUS, USP, EP, BP, JP, BIOCERTIFIED(TM)

Other means of identification

Product Code(s) D9300

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

Combustible dust Yes

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

#### Hazard statements

May form combustible dust concentrations in air

Appearance Powder or Crystalline Physical state Solid Odor Odorless

powder or granules

#### **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

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Glucose (Dextrose), Anhydrous	50-99-7	100	*

<sup>\*</sup>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

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 Monoxide, Carbon Dioxide.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

Special protective equipment for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. 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.

exceeded or irritation is experienced, ventilation and evacuation may be required.

None known

None known

None known

None known

None known

General hygiene considerations Do not breathe dust.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Powder or Crystalline powder or granules

Color White Odor Odorless

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

рΗ no data available None known 146 °C / 294.8 °F Melting point / freezing point None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityno data availableNone knownRelative density1.544None knownWater solubilityFreely soluble in waterNone knownSolubility(ies)Very slightly soluble in MethanolNone known

Slightly soluble in Acetone Slightly soluble in alcohol Soluble in pyridine

None under normal processing.

Partition coefficient

Autoignition temperature

No data available
no data available

Decomposition temperature
Kinematic viscosity

Kinematic viscosity no data available

Dynamic viscosity No data available

Other information

Explosive properties

Oxidizing properties

No information available
No information available
No information available

Molecular weight 180.16

VOC Content (%)

Liquid Density

Bulk density

No information available
No information available
No information available

#### 10. Stability and reactivity

Possibility of hazardous reactions

**Reactivity** No information available.

Chemical stability Stable under normal conditions.

**Conditions to avoid** Excessive heat. Heating in air. dust formation.

**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** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Glucose (Dextrose), Anhydrous	= 25800 mg/kg (Rat)	-	-
50-99-7			

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

Skin corrosion/irritation
Serious eye damage/eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity

No information available.
No information available.
No information available.

Reproductive toxicity No information available.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

No information available.
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 Complies

**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

**KECL** - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

#### **US Federal Regulations**

#### **SARA 313**

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

#### SARA 311/312 Hazard Categories

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

#### **CWA (Clean Water Act)**

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

#### **CERCLA**

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

#### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

#### 16. Other information

#### NFPA

Health hazards 0 Flammability 1

Instability 0

Physical and chemical properties -

HMIS

Health hazards 0
Flammability 0
Physical hazards 0
Personal protection X

#### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (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 Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 27-May-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** 



#### 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	
D9300	Dextrose, Anhydrous, USP, EP, BP, JP,	
	bioCERTIFIED ™	

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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

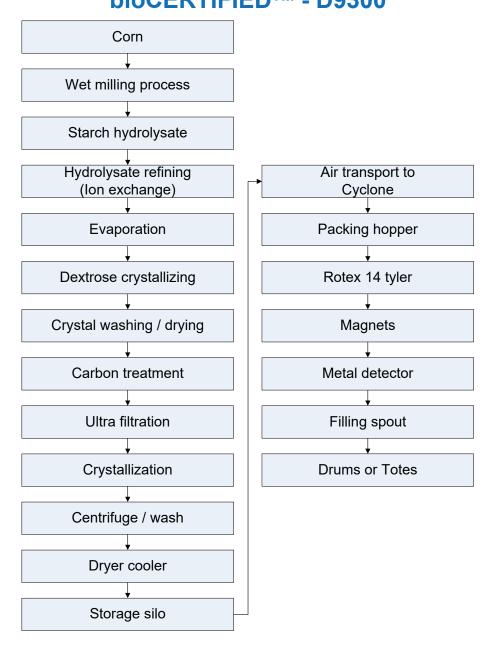
**Quality Assurance Specialist** 

Order Clony



# **Manufacturing Process Flowchart**

Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED™ - D9300



#### 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



# **D9300**, Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED™

#### **Source Statement**

The above mentioned catalog item is manufactured by using plant derived material (Corn). No animal derived products are used in the manufacturing process.

#### **BSE/TSE Statement**

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

# **Allergen Statement**

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

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Sov
- Latex
- Sulfites > 10 ppm

#### **GMO Statement**

The above mentioned catalog item is manufactured with the use of genetically modified organisms and might contain GMO's, but no detectable levels of GMO's are expected to be present.

#### **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 irradiation, ethylene oxide (EtO) or sewage sludge.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 36 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 - Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED™ (Cat# D9300)

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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



# RE: Residual Solvents - Dextrose, Anhydrous, USP, EP, BP, JP, bioCERTIFIED™ (Cat# D9300)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

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



## **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

00-00-00

• May form combustible dust concentrations

· 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** WARNING:

Cancer and Reproductive Harmwww.P65Warnings.ca.gov

D9300

SIZ SY

# Dextrose

(Glucose; Corn Sugar)

KSA KOSHER

Anhydrous USP, EP, BP, JP, bioCERTIFIED™ CAS 50-99-7



CAUTION: For manufacturing, processing or repacking. Further processing and testing required for use in parenteral applications Read and understand the label and Safety Data Sheet (SDS

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

	$C_6H_{12}O_6$	F.W. 180.20
	Not sterile.	
	Assay (JP)	
	Loss on Drying (JP)	1.00/
	Water (USP, EP, BP)	
TM	Color and Clarity of Solution	To nass test
	Residue on Ignition (JP)	0.1%
וע	Conductivity (USP, EP, BP)	20 uS/cm
ED	Related Substances (USP, EP, BP):	
	Maltose and Isomaltose	
	Maltotriose	
	Fructose	0.15%
2	Unspecified Impurity	
E	Total Impurities	
	Sulfate (SO,, JP)	
	Arsenic (As, JP)	
	Elemental Impurities	
•	Heavy Metals (JP)	
	Dextrin	To pass test
	Soluble Starch, Sulfites (USP, EP, BP)	15 ppm
er	Soluble Starch and Sulfite (JP)	
٠.	Residual Solvents	
S.	Bacterial Endotoxins	2.5 EU/g
S)	Total Aerobic Microbial Count	1000 CELI/a
′	Total Yeasts and Molds Count	
_	Total Total and more coult	100 01 0/g
	Keep tightly closed.	
_	G 2/L10GHS ? Lot No	). XQ####

# Spectrum Chemical Mfg Corp

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West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248

732.214.1300

310.516.8000





The following product(s) prepared by the named company are certified kosher with the stated requirements:

## **Spectrum Laboratory Products, Inc.**

S-0032

14422 South San Pedro Street, Gardena, CA 90248 755-769 Jersey Ave. New Brunswick NJ 08901 USA

Product Name D9300, Dextrose, Anhydrous, USP, EP, BP, JP

**Brand** Spectrum

UKD-ID KSAV3-I3V4T33

D/P/M P

Symbol Required KSA

**Special Conditions** 

This certificate expires on **Feb 01, 2025** 

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.