

Scientific Documentation

Sodium Carbonate, Anhydrous, USP, EP, BP, JP, FCC, 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



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Specification for Sodium Carbonate, Anhydrous, USP, EP, BP, JP, FCC, bioCERTIFIED (TM) (S9150)

Item Number	S9150
Item	Sodium Carbonate, Anhydrous, USP, EP, BP, JP, FCC, bioCERTIFIED (TM)
CAS Number	497-19-8
Molecular Formula	Na ₂ CO ₃
Molecular Weight	105.99
MDL Number	
Synonyms	Exsiccated Sodium Carbonate

Test	Specification	
	Min	Max
Assay (USP/NF: Anhydrous Basis)	99.5	100.5 %
Assay (FCC: Dried Basis)	99.5	100.5 %
Water Determination (USP/NF)		0.5 %
LEAD (FCC)		4 mg/kg
LOSS ON DRYING (FCC)		1 %
ELEMENTAL IMPURITIES		AS REPORTED
BACTERIAL ENDOTOXINS		6 EU/g
TAMC		1000 CFU/g
TYMC		100 CFU/g
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		AS REPORTED

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:
 769 Jersey Ave. 14422 S. San Pedro St.
 New Brunswick, NJ 08901 Gardena, CA 90248

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

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310.516.8000

Certificate Of Analysis

Item Number	S9150	Lot Number	4MJ0008
Item	Sodium Carbonate, Anhydrous, USP, EP, BP, JP, FCC, bioCERTIFIED (TM)	CAS Number	497-19-8
Molecular Formula	Na ₂ CO ₃	Molecular Weight	105.99

TEST	SPECIFICATION		RESULT
	MIN	MAX	
Assay (USP/NF: Anhydrous Basis)	99.5	100.5 %	99.9 %
Assay (FCC: Dried Basis)	99.5	100.5 %	99.5 %
Water Determination (USP/NF)		0.5 %	0.2 %
LEAD (FCC)		4 mg/kg	<0.05 mg/kg
LOSS ON DRYING (FCC)		1 %	0.6 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
BACTERIAL ENDOTOXINS		6 EU/g	<6 EU/g
TAMC		1000 CFU/g	<100 CFU/g
TYMC		100 CFU/g	<75 CFU/g
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			30-JAN-2025
DATE OF MANUFACTURE			30-JAN-2023
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	MEETS USP CHAPTER <467> REQUIREMENTS
MONOGRAPH EDITION			EP 11, BP 2023
MONOGRAPH EDITION			JP 18 FCC 13
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
29-JAN-24 06:54:41

Certificate of Analysis Results Approved By:

MCAMACHO
Matheu Camacho
29-JAN-24 06:56:48

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



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.

SAFETY DATA SHEET

spectrum®



Revision date 29-September-2021

Revision Number 1

1. Identification

Product identifier

Product Name SODIUM CARBONATE, ANHYDROUS, USP, FCC, BIOCERTIFIED(TM)

Other means of identification

Product Code(s) S9150

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

Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes serious eye irritation
May cause respiratory irritation



Appearance Crystals or powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Wear eye protection/ face protection

Avoid breathing dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention

If skin irritation occurs: Get medical advice/attention

IF INHALED: Remove person to fresh air and keep comfortable for breathing

Call a POISON CENTER or doctor if you feel unwell

Precautionary Statements - Storage

Store in a well-ventilated place

Other information

May be harmful if swallowed. May be harmful in contact with skin. Causes mild skin irritation. Reacts with water to evolve heat.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Sodium Carbonate, Anhydrous	497-19-8	100	*

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

4. First-aid measures

Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

Skin contact

Wash skin with soap and water.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider

Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms	May cause redness and tearing of the eyes. Burning sensation. Prolonged contact may cause redness and irritation.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
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Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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Specific hazards arising from the chemical	No information available.
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Explosion data

Sensitivity to mechanical impact	none.
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Sensitivity to static discharge	none.
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Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
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Other information	Refer to protective measures listed in Sections 7 and 8.
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Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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Methods for cleaning up	Pick up and transfer to properly labeled containers.
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7. Handling and storage

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
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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
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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).
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Hand protection	Wear suitable gloves.
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Skin and body protection	Wear suitable protective clothing.
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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.
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General hygiene considerations	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.
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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystals or powder
Color	White
Odor	Odorless
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	11.5	None known
Melting point / freezing point	851 °C / 1563.8 °F	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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	2.532	None known
Water solubility	Soluble in hot water	None known
	Slightly soluble in cold water	
Solubility(ies)	Soluble in Glycerol	None known
	Insoluble in Acetone	
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available

Molecular weight	105.99
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Hygroscopic.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
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. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation. Causes mild skin irritation. May be harmful in contact with skin.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	May cause redness and tearing of the eyes. Prolonged contact may cause redness and irritation.
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Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Carbonate, Anhydrous 497-19-8	>2000 mg/kg (Rat)	=2000 mg/kg (Rabbit)	3.2 mg/L (Rat)

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

Skin corrosion/irritation	May cause skin irritation. Classification based on data available for ingredients.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium Carbonate, Anhydrous 497-19-8	-	LC50: 740mg/L (96h, <i>Gambusia affinis</i>) LC50: =300mg/L (96h, <i>Lepomis macrochirus</i>)	-	EC50: = 200 - 227 mg/L (48h, <i>Ceriodaphnia dubia</i>)

Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.

Other adverse effects	No information available.
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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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

15. Regulatory information

International Inventories

TSCA	Complies
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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 3

Flammability 0

Instability 0
Physical and chemical properties W
HMIS
Health hazards 3
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 29-September-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
S9150	Sodium Carbonate, Anhydrous, USP, FCC, bioCERTIFIED (TM)

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

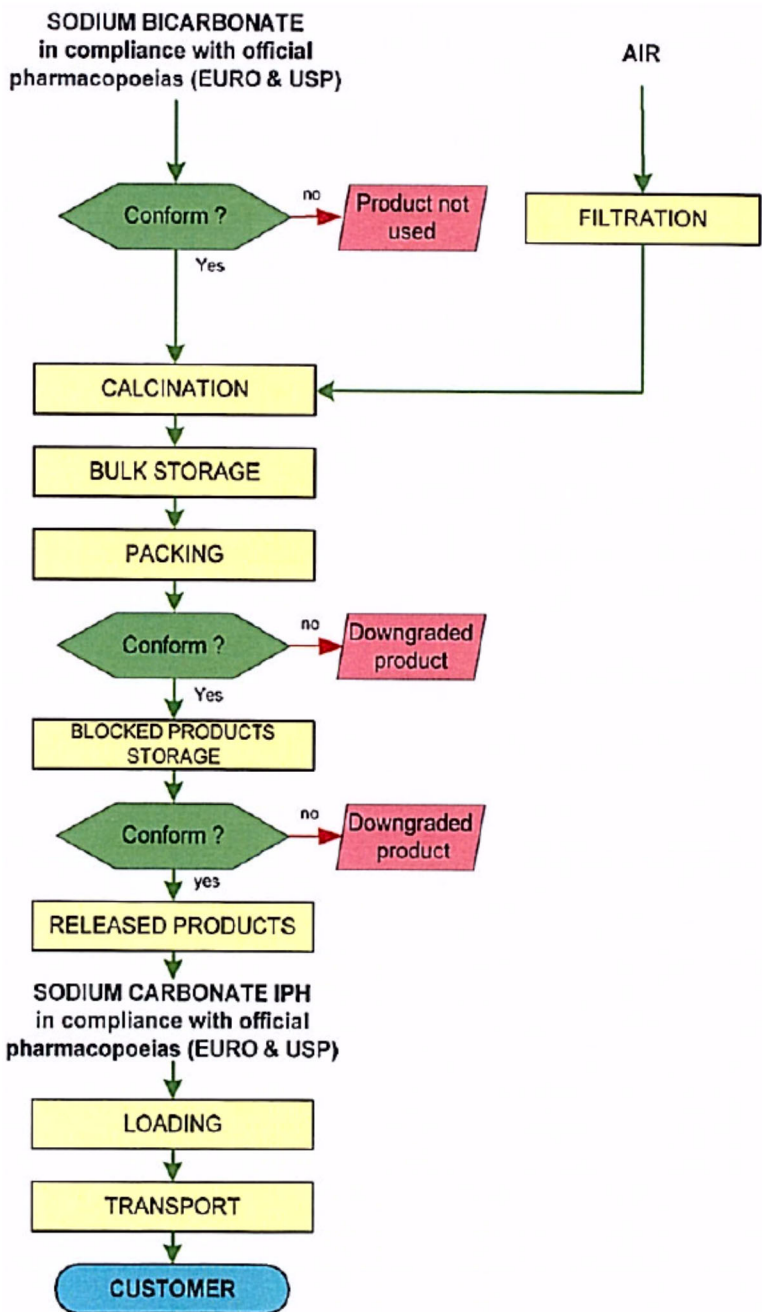
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Sodium Carbonate, Anhydrous, USP, FCC, bioCERTIFIED™ (Cat# S9150)



CORPORATE HEADQUARTERS

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Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843

S9150, Sodium Carbonate, Anhydrous, USP, FCC, bioCERTIFIED™

Source Statement

The above mentioned catalog item is manufactured from inorganic mineral origin. 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 complies with the requirements of EC Directive 123/2009.

GMO Statement

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

Melamine Statement

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

Nitrosamine Statement

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

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Other Chemicals Statement

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

- | | |
|---------------------|-----------------|
| • Aflatoxins | • Parabens |
| • Antibiotics | • Pesticides |
| • Bisphenol A (BPA) | • Phthalates |
| • CMR Substances | • Preservatives |



**RE: Elemental Impurities - Sodium Carbonate, Anhydrous, USP, FCC,
bioCERTIFIED™ - Cat# S9150**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.3 ppm
Lead	Pb	1	< 0.4 ppm
Arsenic	As	1	< 0.1 ppm
Mercury	Hg	1	< 0.02 ppm
Cobalt	Co	2A	< 0.1 ppm
Vanadium	V	2A	< 0.1 ppm
Nickel	Ni	2A	< 4 ppm
Thallium	Tl	2B	< 0.3 ppm
Selenium	Se	2B	< 1 ppm
Lithium	Li	3	< 0.4 ppm
Antimony	Sb	3	< 0.4 ppm
Barium	Ba	3	< 2 ppm
Molybdenum	Mo	3	< 2 ppm
Copper	Cu	3	< 0.4 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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.

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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.

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RE: Residual Solvents - Sodium Carbonate, Anhydrous, USP, FCC, bioCERTIFIED[™] - (Cat# S9150)

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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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