

Scientific Documentation

Sodium Bicarbonate, USP, 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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Kosher Certification



Specification for Sodium Bicarbonate, USP, FCC, bioCERTIFIED (TM) (S9100)

Item Number	S9100
Item	Sodium Bicarbonate, USP, FCC, bioCERTIFIED (TM)
CAS Number	144-55-8
Molecular Formula	NaHCO ₃
Molecular Weight	84.01
MDL Number	
Synonyms	Baking Soda ; Sodium Hydrogen Carbonate ; Carbonic Acid Monosodium Salt

Test	Specification		
	Min	Max	
ASSAY (DRIED BASIS)	99.0	100.5 %	
AMMONIA	TO PASS TEST		
Insoluble Matter/Substances	TO PASS TEST		
LEAD		2 mg/kg	
LOSS ON DRYING		0.25 %	
NORMAL CARBONATE		TO PASS TEST	
CHLORIDE (CI)		0.015 %	
SULFUR COMPOUNDS		0.015 %	
ELEMENTAL IMPURITIES		AS REPORTED	
ARSENIC		2 ppm	
IDENTIFICATION			
CERTIFIED KOSHER			
CERTIFIED HALAL			
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS		AS REPORTED	

Spectrum Chemical Mfg Corp

769 Jersey Ave. 14422 S. San Pedro St.

New Brunswick, NJ 08901 Gardena, CA 90248

732.214.1300 310.516.8000



Certificate Of Analysis

Item Number	S9100	Lot Number	4LB0014
Item	Sodium Bicarbonate, USP, FCC, bioCERTIFIED (TM)	CAS Number	144-55-8
Molecular Formula	NaHCO ₃	Molecular Weight	84.01

TECT	SPECIF	ICATION	DECLUT.
TEST	MIN	MAX	RESULT
ASSAY (DRIED BASIS)	99.0	100.5 %	99.6 %
AMMONIA	TO PASS TEST		PASSES TEST
Insoluble Matter/Substances	TO PASS TEST		PASSES TEST
LEAD		2 mg/kg	<0.05 mg/kg
LOSS ON DRYING		0.25 %	0.19 %
NORMAL CARBONATE		TO PASS TEST	PASSES TEST
CHLORIDE (CI)		0.015 %	<0.0015 %
SULFUR COMPOUNDS		0.015 %	<0.015 %
ELEMENTAL IMPURITIES		AS REPORTED	COMPLIES WITH STANDARD
ARSENIC		2 ppm	<2 ppm
IDENTIFICATION			PASSES TEST
CERTIFIED KOSHER			CERTIFIED KOSHER
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			29-SEP-2023
DATE OF MANUFACTURE			29-SEP-2021
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	PASSES TEST
ENDOTOXIN			2.5 EU/G
TOTAL PLATE COUNT			1000 CFU/G
TOTAL YEAST AND MOLD COUNT (ChP)			100 CFU/G

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 13-SEP-22 06:40:31

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 13-SEP-22 13:49:52

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 15-December-2021 Revision Number 1

1. Identification

Product identifier

Product Name SODIUM BICARBONATE, USP, FCC, bioCERTIFIED™

Other means of identification

Product Code(s) S9100

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on useNo 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

Not classified.

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

Not classified.

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Crystalline powder Physical state Solid Odor Odorless

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Sodium Bicarbonate	144-55-8	100	*

^{*}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

5. Fire-fighting measures

surrounding environment.

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

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Sodium oxides.

Explosion data

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

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.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up 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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Moisture sensitive. Protect from moisture. Keep container tightly closed in a dry and

well-ventilated place.

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 No special protective equipment required.

Skin and body protectionNo special protective equipment required.

Solid

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

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state

Appearance Crystalline powder

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 Melting point / freezing point 270 °C / 518 °F None known no data available Boiling point / boiling range 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 pressure No data available None known Vapor density no data available None known Relative density 2.159 - 2.2 None known Soluble in water None known Water solubility None known Solubility(ies) Insoluble in Ethanol None known **Partition coefficient** No data available **Autoignition temperature** no data available None known **Decomposition temperature** None known

Kinematic viscosity

no data available

None known

None known

None known

None known

Other information

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 84.01

VOC Content (%)
Liquid Density
No information available
No information available
No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

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

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
Sodium Bicarbonate 144-55-8	= 4220 mg/kg (Rat)	-	-

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. No information available.

Reproductive toxicity No information available.

STOT - single exposure STOT - repeated exposure Aspiration hazard No information available. No information available. 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	Crustacea
			microorganisms	
Sodium Bicarbonate	EC50: =650mg/L (120h,	LC50: 8250 - 9000mg/L	-	EC50: =2350mg/L (48h,
144-55-8	Nitzschia linearis)	(96h, Lepomis		Daphnia magna)
	·	macrochirus)		

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: IECSCThis 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 0 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 15-December-2021 Revision Note 15-December-2021 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
S9100	Sodium Bicarbonate, USP, FCC, 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 qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez

Quality Assurance Specialist

Order Clony



\$9100, Sodium Bicarbonate, USP, FCC, bioCERTIFIED

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.

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 - Sodium Bicarbonate, USP, FCC, bioCERTIFIED ™ (Cat# S9100)

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	< 0.2 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 0.5 ppm
Mercury	Hg	1	< 0.02 ppm
Cobalt	Со	2A	Lot specific analysis *
Vanadium	V	2A	Lot specific analysis *
Nickel	Ni	2A	Lot specific analysis *
Thallium	TI	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	Ir	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	Not tested
Barium	Ва	3	Not tested
Molybdenum	Мо	3	Not tested
Copper	Cu	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

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

^{*} Refer to CofA for lot specific analysis



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.

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.

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 - Sodium Bicarbonate, USP, FCC, bioCERTIFIED ™ (Cat# S9100)

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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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.

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. 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

S9100 SIZ SY **Sodium Bicarbonate**

(Baking Soda; Carbonic Acid Monosodium Salt; Sodium Hydrogen Carbonate)



USP, FCC, bioCERTIFIED™



CAUTION: For manufacturing, processing or repacking. Not intended for use in hemodialysis. 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

NaHCO₃

Accay (Dried Racie)

F.W. 84.01

00 0-100 5%

Not sterile.

Maday (Dilicu Dadia)	
MAXIMUM LIMITS Ammonia	
Ammonia	To pass test
Insoluble Matter/Substances	To pass test
Lead	2 mg/kg
Loss on Drying	0.25%
Normal Carbonate	To pass test
Chloride (CI)	0.015%
Sulfur Compounds	0.015%
Elemental Impurities	As reported
Arsenic	2 ppm
Residual Solvents	To pass test

MOISTURE SENSITIVE: Keep tightly closed.

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 1/K11GHS ?

Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901

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

732.214.1300

310.516.8000