

# **Scientific Documentation**

# Sodium Bicarbonate, Powder, FCC

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 General Label Information – Sample Label



# **Specification for Sodium Bicarbonate, Powder, FCC** (S1148)

Item Number	S1148
Item	Sodium Bicarbonate, Powder, FCC
CAS Number	144-55-8
Molecular Formula	NaHCO <sub>3</sub>
Molecular Weight	84.01
MDL Number	
Synonyms	Baking Soda ; Sodium Hydrogen Carbonate ; Carbonic Acid Monosodium Salt

Test	Specification		
	Min	Max	
ASSAY (NaHCO3; DRIED BASIS)	99.0	100.5 %	
AMMONIA	NO ODOR OF AMMONIA		
INSOLUBLE SUBSTANCES	CLEAR		
LEAD		2 mg/kg	
LOSS ON DRYING		0.25 %	
IDENTIFICATION (A)	POSITIVE FOR BICARBONATE		
IDENTIFICATION (B)	POSITIVE FOR SODIUM		
CERTIFIED HALAL			
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:	West Coast Facility:
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	S1148	Lot Number	1ML0105
Item	Sodium Bicarbonate, Powder, FCC	CAS Number	144-55-8
Molecular Formula	NaHCO <sub>3</sub>	Molecular Weight	84.01

тгст	SPECIFICATION		
TEST	MIN	MAX	RESULT
ASSAY (NaHCO <sub>3</sub> ; DRIED BASIS)	99.0	100.5 %	100.07 %
AMMONIA	NO ODOR OF AMMONIA		NO ODOR OF AMMONIA
INSOLUBLE SUBSTANCES	CLEAR		CLEAR
LEAD		2 mg/kg	0.05 mg/kg
LOSS ON DRYING		0.25 %	0.00 %
IDENTIFICATION (A)	POSITIVE FOR BICARBONATE		POSITIVE FOR BICARBONATE
IDENTIFICATION (B)	POSITIVE FOR SODIUM		POSITIVE FOR SODIUM
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			22-NOV-2026
DATE OF MANUFACTURE			22-NOV-2023
APPEARANCE			WHITE POWDER

Certificate of Analysis Results Entered By:

SHANSEN Selin Hansen 20-DEC-23 15:02:21

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Approved By:

HBERMUDEZ Hernan Bermudez 21-DEC-23 08:27:02

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

Revision date 04-March-2020

1. Identification	
Product identifier	
Product Name	SODIUM BICARBONATE, POWDER, FCC
Other means of identification	
Product Code(s)	S1148
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**

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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

Appearance Powder crystalline

Odor Odorless



**Revision Number** 2

#### Other information

May be harmful if swallowed.

#### 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.
Meet important symptoms and offe	eta hath aquita and delavad
Most important symptoms and effe	cts, 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	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Sodium oxides.
Explosion data Sensitivity to mechanical impac	et 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	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 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	Handle in accordance with good industrial hygiene and safety practice.		

# 9. Physical and chemical properties

Information on basic physical and chemical propertiesPhysical stateSolidAppearancePowder crystalline

Color Odor Odor threshold white Odorless No information available

Property	Values	Remarks • Method
рН	no data available	None known
Melting point / freezing point	270 °C / 518 °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	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
Water solubility	No data available	None known
Solubility(ies)	Soluble in water	None known
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	84.01	
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	Stable under normal conditions.	
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 Spontaneous polymerisation.		

## 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	May be harmful if swallowed.

#### Symptoms related to the physical, chemical and toxicological characteristics

#### Symptoms

No information available.

Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium Bicarbonate	= 4220 mg/kg (Rat)	-	-
144-55-8			

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

ECOLOXICITY	•			
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       No information available.         Bioaccumulation       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

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

#### 15. Regulatory information

#### International Inventories

#### TSCA

Complies

\*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL EINECS/ELINCS	Complies 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 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 Skin designation 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 04-March-2020

 Revision Note
 No information available.

 <u>Disclaimer</u>
 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

# spectrum

#### 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
S1148	Sodium Bicarbonate, Powder, FCC

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: Spectrum-New Brunswick, NJ: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

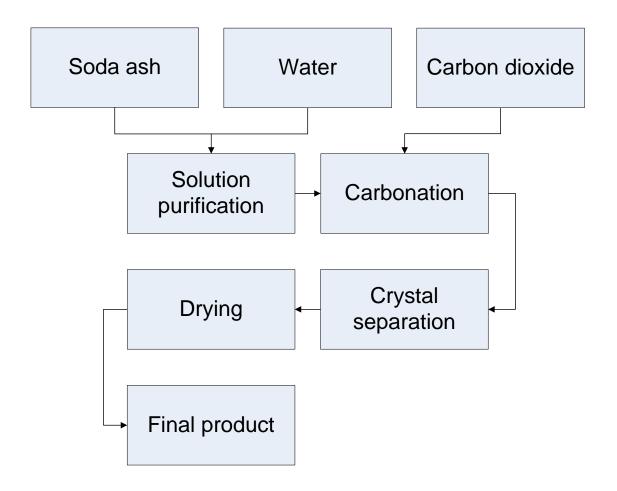
Oulu Umy

Oralia Chavez Quality Assurance Specialist



# **Manufacturing Process Flowchart**

# Sodium Bicarbonate, Powder, FCC - S1148



#### 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

# S1148, Sodium Bicarbonate, Powder, FCC

#### **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

spectrum

- 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 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

# spectrum®

# **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.

		NaHCO₃	F.W. 84.01
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	- ·	MAX Ammonia Insoluble Substa Lead Loss on Drying MOISTURE SENS	Dried Basis)

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:

732.214.1300

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

310.516.8000