

Scientific Documentation

Sodium Carbonate, Hydrous, NF

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

Specification for Sodium Carbonate, Hydrous, NF (SO150)

Item Number	SO150
Item	Sodium Carbonate, Hydrous, NF
CAS Number	5968-11-6
Molecular Formula	Na ₂ CO ₃ •H ₂ O
Molecular Weight	124.00
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (Na ₂ CO ₃)	99.5	100.5 %
WATER DETERMINATION	12.0	15.0 %
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION (A)	POSITIVE FOR SODIUM	
IDENTIFICATION (B)	POSITIVE FOR CARBONATE	
CERTIFIED HALAL		
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		

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	SO150	Lot Number	1MJ0304
Item	Sodium Carbonate, Hydrous, NF	CAS Number	5968-11-6
Molecular Formula	Na ₂ CO ₃ •H ₂ O	Molecular Weight	124.00

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (Na ₂ CO ₃)	99.5	100.5 %	99.5 %
WATER DETERMINATION	12.0	15.0 %	14.3 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION (A)	POSITIVE FOR SODIUM		POSITIVE FOR SODIUM
IDENTIFICATION (B)	POSITIVE FOR CARBONATE		POSITIVE FOR CARBONATE
CERTIFIED HALAL			CERTIFIED HALAL
APPEARANCE			WHITE CRYSTALS
EXPIRATION DATE			03-MAR-2026
DATE OF MANUFACTURE			03-MAR-2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
08-NOV-23 09:13:47

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



Certificate of Analysis Results Approved By:

SHANSEN
Selin Hansen
08-NOV-23 09:16:09

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before

handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.



SAFETY DATA SHEET

Preparation Date: 8/29/2016

Revision Date: 8/29/2016

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: SO150
Product Name: SODIUM CARBONATE, MONOHYDRATE, NF

Other means of identification

Synonyms: Disodium Carbonate, monohydrate
Carbonic acid, disodium salt, monohydrate
CAS #: 5968-11-6
RTECS # Not available
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

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

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

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

Label elements

Warning

Hazard statements

Causes serious eye irritation
May cause respiratory irritation

**Hazards not otherwise classified (HNOC)**

Not Applicable

Other hazards

Causes mild skin irritation

May be harmful if swallowed

Reacts with water to evolve heat

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Wear eye/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/physician if you feel unwell.

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Sodium Carbonate, Monohydrate	5968-11-6	100

4. FIRST AID MEASURES**First aid measures****General Advice:**

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Product code: SO150

Product name: SODIUM
CARBONATE, MONOHYDRATE, NF

2 / 11

Most important symptoms and effects, both acute and delayed

Symptoms Causes eye irritation. Eye contact may result in redness or pain. May be harmful if swallowed. Mild skin irritation. Irritating to respiratory system.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: The product is not flammable. If it is involved in a fire, extinguish the fire using an agent suitable for the type of surrounding fire.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: No information available.

Specific hazards: The product is not flammable

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Product code: SO150

Product name: SODIUM
CARBONATE, MONOHYDRATE, NF

3 / 11

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities**Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Protect from moisture. Hygroscopic.

Incompatible Materials:

Acids
Fluorine
Fluoride
Lithium
Phosphorus pentoxide
Moisture
2,4,6-trinitrotoluene
Ammonia

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Control parameters****National occupational exposure limits****United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Sodium Carbonate, Monohydrate	5968-11-6	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Sodium Carbonate, Monohydrate	5968-11-6	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Sodium Carbonate, Monohydrate	5968-11-6	None	None

Appropriate engineering controls**Engineering measures to reduce exposure:**

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles or Safety glasses with side-shields
Skin and body protection:	Long sleeved clothing. Chemical resistant apron. Gloves.
Respiratory protection:	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
Hygiene measures:	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystals. Granular. Granular powder. Crystalline powder.	Color: White.
Odor: Odorless.	Taste Alkaline.	Formula: Na ₂ CO ₃ .H ₂ O
Molecular/Formula weight: 124.00	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 100 °C/212 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm³): 2.25
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Soluble in Glycerol Insoluble in Alcohol Soluble in Water Soluble in 3 parts cold water, 1.8 parts boiling water, and 7 parts glycerol	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with acids

Decomposition by acids with effervescence (release of CO₂)
Combines/reacts with water with evolution of heat
Sodium carbonate applied to red hot aluminum can cause an explosion
Sodium carbonate can ignite and burn fiercely in contact with fluoride
Sodium carbonate can react violently with F₂, Li, 2,4,6-trinitrotoluene

Chemical stability

Stability: Stable at normal conditions. Hygroscopic.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Exposure to moisture. Exposure to moist air.
Incompatible materials. Exposure to warm, dry air. Dries out somewhat in warm dry air or above 50 deg. C.

Incompatible Materials: Acids
Fluorine
Fluoride
Lithium
Phosphorus pentoxide
Moisture
2,4,6-trinitrotoluene
Ammonia

Hazardous decomposition products: Carbon oxides. Sodium oxides.

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Eyes. Ingestion. Inhalation. Skin.

Acute Toxicity

Component Information

Sodium Carbonate, Monohydrate	
CAS-No.	5968-11-6

LD50/oral/rat = No information available
LD50/oral/mouse = No information available
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

Product code: SO150

Product name: SODIUM
CARBONATE, MONOHYDRATE, NF

6 / 11

LD50/oral/rat =
VALUE- Acute Tox Oral = 4090 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = 2300 mg/m³ (2-hr)

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = 1200 mg/m³ 2 hr

Symptoms

Skin Contact: Mild skin irritation.

Eye Contact: Causes serious eye irritation. Causes conjunctival irritation.

Inhalation Irritating to respiratory system. Symptoms may include coughing and shortness of breath.

Ingestion May be harmful if swallowed. Acute sodium carbonate ingestion may cause irritation of the digestive tract resulting in nausea, vomiting, diarrhea, thirst, abdominal pain depending on concentration and amount ingested. May also affect the cardiovascular system (circulatory collapse).

Aspiration hazard No information available.

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

Chronic Toxicity No information available.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Sodium Carbonate, Monohydrate	5968-11-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

Product code: SO150

Product name: SODIUM
CARBONATE, MONOHYDRATE, NF

7 / 11

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
STOT - repeated exposure No information available.
Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Sodium Carbonate, Monohydrate	5968-11-6	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available

Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant Description: No Information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Sodium Carbonate, Monohydrate	5968-11-6	Not Listed	Not present	Present	Present (1)-164	Present	Present	Not present

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Sodium Carbonate, Monohydrate	5968-11-6	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Sodium Carbonate, Monohydrate	5968-11-6	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Sodium Carbonate, Monohydrate	5968-11-6	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

D2B Toxic materials

E Corrosive material

Components

Sodium Carbonate, Monohydrate

WHIMHAZ

D2B E

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Sodium Carbonate, Monohydrate	5968-11-6	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Sodium Carbonate, Monohydrate	5968-11-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Sodium Carbonate, Monohydrate	5968-11-6	Not listed

EU Classification

R-phrases

R36 - Irritating to eyes.

R37 - Irritating to respiratory system.

Product code: SO150

Product name: SODIUM
CARBONATE, MONOHYDRATE, NF

10 / 11

S -phrase(s)

S 2 - Keep out of the reach of children.

S22 - Do not breathe dust.

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Sodium Carbonate, Monohydrate	5968-11-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xi - Irritant.

Xi

**16. OTHER INFORMATION**

Preparation Date: 8/29/2016
Revision Date: 8/29/2016
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

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
SO150	Sodium Carbonate, Hydrous, NF

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

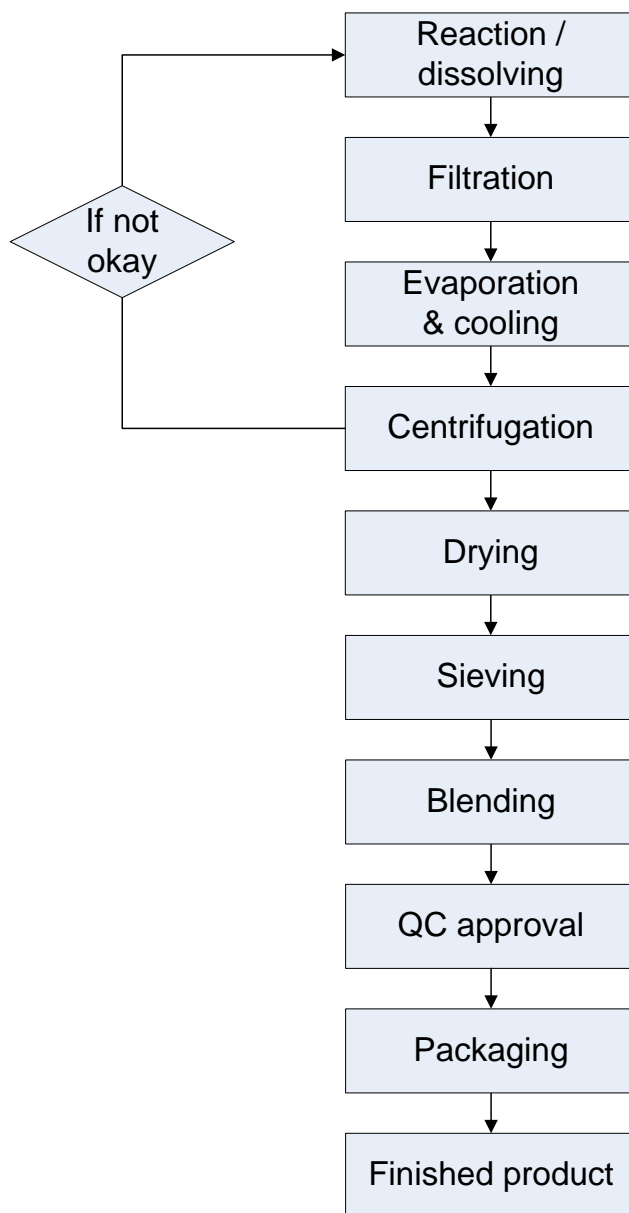
Sincerely,

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, Hydrous, NF - SO150



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

SO150, Sodium Carbonate, Hydrous, NF

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



RE: Elemental Impurities - Sodium Carbonate, Hydrous, NF (Cat# SO150)

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
Arsenic	As	1	< 5 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.

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 Carbonate, Hydrous, NF (Cat# SO150)

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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CORPORATE HEADQUARTERS


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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

- Causes serious eye irritation • May cause respiratory irritation • Causes mild skin irritation • May be harmful if swallowed • Reacts with water to evolve heat.
- Wear eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: 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 attention. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell.


KEEP FROM CHILDREN



S0150 SIZ SY

Sodium Carbonate

Hydrous
NF
CAS 5968-11-6



CAUTION: For manufacturing, processing or repackaging.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300
www.SpectrumChemical.com

$\text{Na}_2\text{CO}_3 \cdot \text{H}_2\text{O}$ F.W. 124.00

Assay (Anhydrous Basis) 99.5-100.5%
 Water Determination 12.0-15.0%
MAXIMUM LIMITS
 Elemental Impurities As reported
 Residual Solvents To pass test

HYGROSCOPIC: Keep tightly closed.

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

G 11/H11GHS ?
Lot No. XQ####

Spectrum Chemical Mfg Corp

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