Scientific Documentation

F1096, Fumaric Acid, 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

Ver4.06 29.September.2022

F1096, Fumaric Acid, NF

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Specification for Fumaric Acid, NF (F1096)

Item Number	F1096
Item	Fumaric Acid, NF
CAS Number	110-17-8
Molecular Formula	$C_4H_4O_4$
Molecular Weight	116.07
MDL Number	
Synonyms	Allomalenic Acid ; Boletic Acid ; 2-Butenedioic Acid ; trans-Butenedioic Acid ; trans-1,2-Ethylenedicarboxylic Acid

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	99.5	100.5 %
WATER DETERMINATION		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES		AS REPORTED
MALEIC ACID		0.1 %
IDENTIFICATION		TO PASS TEST
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

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	F1096	Lot Number	2LF0293
Item	Fumaric Acid, NF	CAS Number	110-17-8
Molecular Formula	$C_4H_4O_4$	Molecular Weight	116.07

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	99.5	100.5 %	99.7 %
WATER DETERMINATION		0.5 %	<0.5 %
RESIDUE ON IGNITION		0.1 %	<0.1 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
MALEIC ACID		0.1 %	<=0.1 %
IDENTIFICATION		TO PASS TEST	PASSES TEST
EXPIRATION DATE			19-MAY-2023
DATE OF MANUFACTURE			19-MAY-2022
APPEARANCE			WHITE GRANULES
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST

Certificate of Analysis Results Entered By:

SVANGOOR
Swetha Vangoor
21-JUN-22 10:40:11

Certificate of Analysis Results Approved By:

BPATEL
Bhargavi Patel
21-JUN-22 10:41:01

Spectrum Chemical Mfg Corp
755 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.

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

Revision date 10-January-2022 **Revision Number** 2

1. Identification

Product identifier

Product Name FUMARIC ACID, NF

Other means of identification

Product Code(s) F1096

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

Hazards not otherwise classified (HNOC)
Not applicable

Label elements

Warning

Hazard statements
Causes serious eye irritation

Appearance Crystalline powder or granules **Physical state** Solid **Odor** Odorless

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Wear eye protection/ face protection

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

Other information
No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Fumaric Acid	110-17-8	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.

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.
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	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
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. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool 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	If splashes are likely to occur, wear safety glasses with side-shields.
Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing.
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	Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

9. Physical and chemical properties

Information on basic physical and chemical properties

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

Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	287 °C / 548.6 °F	None known
Boiling point / boiling range	290 °C / 554 °F	None known
Flash point	273 °C / 523.4 °F	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	1.635	None known
Water solubility	No data available	None known
Solubility(ies)	Soluble in Ethanol Slightly soluble in Ether Insoluble in Chloroform Insoluble in Benzene	None known
Partition coefficient	0.33 - 0.46	None known
Autoignition temperature	740 °C / 1364 °F	None known
Decomposition temperature	287 - °C 548.6 °F	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	116.07
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 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.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Fumaric Acid 110-17-8	= 9300 mg/kg (Rat)	> 20000 mg/kg (Rabbit)	-

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

Skin corrosion/irritation May cause skin irritation.
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
Fumaric Acid 110-17-8	EC50: =41mg/L (72h, Desmodesmus subspicatus)	LC50: =245mg/L (48h, Brachydanio rerio) LC50: >100mg/L (96h, Danio rerio)	-	EC50: 204 - 220mg/L (48h, Daphnia magna) EC50: =73.6mg/L (24h, Daphnia magna)

Persistence and degradability No information available.
Bioaccumulation Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Fumaric Acid 110-17-8	0.33

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

DOT not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

IATA not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL	Complies
EINECS/ELINCS	Complies
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

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

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

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

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Fumaric Acid 110-17-8	5000 lb final RQ 2270 kg final RQ	-

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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Fumaric Acid 110-17-8	0949	Present	Environmental hazard

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA
Health hazards 2
Flammability 1
Instability 0
Physical and chemical properties -
HMIS
Health hazards 2
Flammability 1
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	10-January-2022
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

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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
F1096	Fumaric Acid, 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

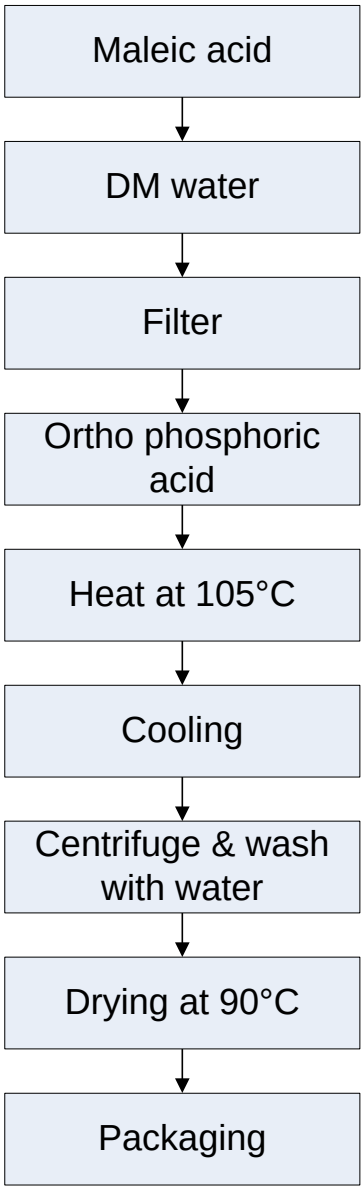
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Fumaric Acid, NF - F1096



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

F1096, Fumaric Acid, 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
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Soy
- 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.

Animal Testing Statement

The above mentioned catalog item has not been subject to animal testing.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 12 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:

- Preservatives

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RE: Elemental Impurities - Fumaric Acid, NF (Cat# F1096)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at 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 - Fumaric Acid, NF (Cat# F1096)

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.

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

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FAX 732.246.7132

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

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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.

Exp. Date: 00-00-0000

4945 2F1096

WARNING

- **Causes serious eye irritation.**
- Wear eye protection, face protection • 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.

KEEP FROM CHILDREN

F1096 **SIZ SY**

Fumaric Acid

(2-Butenedioic Acid)

NF

CAS 110-17-8

CAUTION: For manufacturing, processing or repacking.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_4H_4O_4$ F.W. 116.07

Assay (Anhydrous Basis) 99.5-100.5%

MAXIMUM LIMITS

Water Determination 0.5%
Residue on Ignition 0.1%
Elemental Impurities ..... As reported
Maleic Acid 0.1%
Residual Solvents .....To pass test

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

G 8/H3GHS ? Lot No. XQ####

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RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility
4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

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