

Scientific Documentation

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





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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	2-Butenedioic Acid ; trans-1,2-Ethylenedicarboxylic Acid ; trans-Butenedioic Acid ; Boletic Acid ; Allomalenic Acid

Test	Specification		
	Min	Max	
APPEARANCE			
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	
WATER DETERMINATION		0.5 %	
RESIDUE ON IGNITION		0.1 %	
ELEMENTAL IMPURITIES		AS REPORTED	
MALEIC ACID		0.1 %	
MALIC ACID		1.5 %	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		
EXPIRATION DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			
RESIDUAL SOLVENTS	AS REPORTED		

Spectrum Chemical Mfg Corp

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

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300 310.516.8000



Certificate Of Analysis

Item Number	F1096	Lot Number	4MJ0002
Item	Fumaric Acid, NF	CAS Number	110-17-8
Molecular Formula	$C_4H_4O_4$	Molecular Weight	116.07

TECT	SPECIFICATION		DECLILT	
TEST	MIN	MAX	RESULT	
APPEARANCE			WHITE GRANULAR POWDER	
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	99.8 %	
WATER DETERMINATION		0.5 %	0.01 %	
RESIDUE ON IGNITION		0.1 %	0.08 %	
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT	
MALEIC ACID		0.1 %	<0.1 %	
MALIC ACID		1.5 %	<1.5 %	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE			16-AUG-2024	
DATE OF MANUFACTURE			16-AUG-2023	
MONOGRAPH EDITION			(USP-NF) 2023	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 01-MAR-24 16:46:44

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 04-MAR-24 15:05:00

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 SPECTRUM®



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 Physical state Solid Odor Odorless

granules

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

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.

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

no data available None known pН Melting point / freezing point 287 °C / 548.6 °F None known 290 °C / 554 °F Boiling point / boiling range 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 No data available

limits

Lower flammability or explosive No data available

limits

No data available None known Vapor pressure Vapor density no data available None known 1.635 None known Relative density Water solubility No data available None known Solubility(ies) Soluble in Ethanol None known

Slightly soluble in Ether Insoluble in Chloroform Insoluble in Benzene

0.33 - 0.46

Partition coefficient None known 740 °C / 1364 °F **Autoignition temperature** None known 287 - °C 548.6 °F **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 No information available **Oxidizing properties** 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 avoidNone 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

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	= 9300 mg/kg (Rat)	> 20000 mg/kg (Rabbit)	-
110-17-8			

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
Germ cell mutagenicity
No information available.
No information available.

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

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

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

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 not regulated TDG not regulated MEX ICAO (air) not regulated not regulated <u>IATA</u> **IMDG** not regulated not regulated <u>RID</u> 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	5000 lb final RQ	-
110-17-8	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	0949	Present	Environmental hazard
110-17-8			

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 10-January-2022 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
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

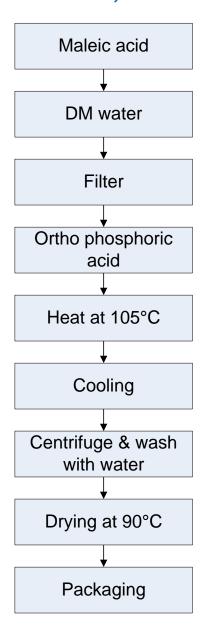
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Fumaric Acid, NF - F1096



Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

New Brunswick, NJ 08901

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



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.

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 - 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
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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.



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

C₄H₄O₄ 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 Harmwww.P65Warnings.ca.gov

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

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