



Scientific Documentation

A1378, Aspartame, Powder, 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

A1378, Aspartame, Powder, NF

Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Source Statement
- BSE/TSE Statement
- Allergen Statement
- EU Fragrance Allergen Statement
- GMO Statement
- Melamine Statement
- Nitrosamine Statement
- Animal Testing Statement
- Organic Compliance Statement
- Shelf Life Statement
- Other Chemicals Statement
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label

spectrum®

- General Lot Numbering System Guidance

spectrum®

Item Number	A1378
Item	Aspartame, Powder, NF
CAS Number	22839-47-0
Molecular Formula	C ₁₄ H ₁₈ N ₂ O ₅
Molecular Weight	294.31
MDL Number	
Synonyms	APM ; N-L-alpha-Aspartyl-L-phenylalanine 1-Methyl Ester

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
TRANSMITTANCE @430 nm	0.95	
SPECIFIC ROTATION [α] _D	+14.5 to +16.5°	
LOSS ON DRYING		4.5 %
RESIDUE ON IGNITION		0.2 %
ELEMENTAL IMPURITIES:		
LEAD		AS REPORTED
CADMIUM (Cd)		AS REPORTED
ARSENIC (As)		AS REPORTED
MERCURY (Hg)		AS REPORTED
5-BENZY-3,6-DIOXO-2-PIPERAZINEACETIC ACID		1.5 %
CHROMATOGRAPHIC PURITY		2.0 %
IDENTIFICATION	SPECTRUM MATCHES REFERENCE	
CERTIFIED HALAL		
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		AS REPORTED

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

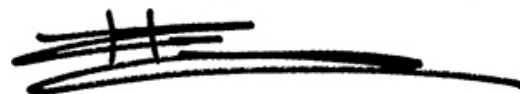
Item Number	A1378	Lot Number	2IJ0036
Item	Aspartame, Powder, NF		
CAS Number	22839-47-0		
Molecular Formula	C ₁₄ H ₁₈ N ₂ O ₅	Molecular Weight	294.31

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	98.0	102.0 %	98.3 %
TRANSMITTANCE @430 nm	0.95		0.99
SPECIFIC ROTATION [α] _D	+14.5 to+16.5°		+15.6°
LOSS ON DRYING		4.5 %	3.6 %
RESIDUE ON IGNITION		0.2 %	0.1 %
ELEMENTAL IMPURITIES:			.
LEAD		AS REPORTED	NONE DETECTED
CADMIUM (Cd)		AS REPORTED	NONE DETECTED
ARSENIC (As)		AS REPORTED	NONE DETECTED
MERCURY (Hg)		AS REPORTED	NONE DETECTED
5-BENZY-3,6-DIOXO-2-PIPERAZINEACETIC ACID		1.5 %	<0.1 %
CHROMATOGRAPHIC IMPURITIES		2.0 %	0.0 %
IDENTIFICATION	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
EXPIRATION DATE			06-FEB-2022
DATE OF MANUFACTURE			06-FEB-2019
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		AS REPORTED	.
CLASS 1 (solvent) / BENZENE			<2 ppm
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Certified by:



Himanshu Patel
Quality Control Manager
Spectrum Chemicals & Laboratory Products

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: 7/27/2015

Revision date 5/7/2019

Revision Number: G3

1. IDENTIFICATION

Product identifier

Product code: A1378
Product Name: ASPARTAME, POWDER, NF

Other means of identification

Synonyms: Succinamic acid, 3-amino-N-(alpha-carboxyphenethyl)-, N-methyl ester, stereoisomer
 3-Amino-N-(alpha-carboxyphenethyl) succinamic acid N-methyl ester, stereoisomer
 Aspartylphenylalanine methyl ester
 N-L-alpha Aspartyl-L-phenlalanine 1-methyl ester
 Nutrasweet
 L-Phenylalanine, N-L-alpha-aspartyl, 1-methyl ester
 Equal
 Methyl aspartylphenylalanate
 1-Methyl N-L-alpha-aspartyl-L-phenylalanine

CAS #: 22839-47-0
RTECS # WM3407000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Sweetener. Laboratory chemicals. Research and Development.
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: Tom Tyner (USA - West Coast)

Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Aspartame	22839-47-0	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 irritation develops. Consult a physician if necessary.
- Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
- 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.

Most important symptoms and effects, both acute and delayed

- Symptoms**
- May cause gastrointestinal disturbances
 - May cause digestive (gastrointestinal) tract irritation
 - Abdominal pain
 - May cause nausea and headache
 - May cause diarrhea
 - It may affect the brain
 - Central nervous system effects
 - Central nervous system depression
 - May cause drowsiness or dizziness
 - Headache
 - Confusion
 - Anxiety
 - Irritability
 - Insomnia
 - May affect behavior/central nervous system (convulsions, tremors, aggression)
 - Slurred speech
 - May cause personality and mood changes
 - May affect the cardiovascular system
 - May affect the liver
 - It may affect the kidneys
 - May cause tinnitus
 - Hearing impairment

May affect eyes/vision
Paresthesia (numbness and tingling of the extremities)
May cause hyperactivity and restless legs

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: Dry chemical. Carbon dioxide (CO₂). Water spray mist, or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous combustion products Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NO_x).

Specific hazards May be combustible at high temperatures. Fire may produce irritating and/or toxic gases.

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. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage. Prevent product from entering drains.

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

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when

handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice

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

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep in a dry, well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Aspartame	22839-47-0	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Aspartame	22839-47-0	None	None	None	None

Australia and Mexico

Component	CAS No	Australia	Mexico
Aspartame	22839-47-0	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. 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. In case of insufficient ventilation, wear suitable respiratory equipment.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Safety glasses with side-shields. or Goggles

Skin and body protection: apron
Long sleeved clothing

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. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product
Wear suitable gloves and eye/face protection

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder.	Color: White.
Odor: Odorless.	Taste Sweet.	Formula C14H18N2O5
Molecular/Formula weight (g/mole): 294.31 g/mol	Flammability (solid, gas) no data 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): 246-250 °C/474.8-482 °F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): >300°C/572°F at 760 mmHg (1013.25 hPa) (with decomposition)	Bulk density: 150-500 kg/m ³	Density (g/cm3): No information available
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 hot water Partially soluble in cold water Slightly soluble in alcohol Very slightly soluble in chloroform	

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx).

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:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Aspartame	
CAS No	22839-47-0

- LD50/oral/rat = > 10 g/kg Oral LD50 Rat
- LD50/oral/mouse = >10 g/kg oral LD50 mouse
- 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

LD50/oral/rat =
Value - Acute Tox = > 10000 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = >10000 mg/kg

LD50/dermal/rabbit
Value - Acute Tox = 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 = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available

VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause respiratory tract irritation.

Ingestion Ingestion of large amounts may cause gastrointestinal tract irritation. May cause gastrointestinal disturbances. May cause abdominal pain. May cause nausea. May cause diarrhea. May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (tremor, insomnia, drowsiness). May affect behavior/central nervous system (confusion, irritability, tremor). May cause migraine headaches. May also cause anxiety and stress. May affect behavior/central nervous system (convulsions, seizures). May affect the cardiovascular system (palpitations). May affect the cardiovascular system (tachycardia). May affect the cardiovascular system (cardiac arrhythmias). May cause tinnitus. May cause decreased hearing or hearing loss. May cause vision disturbances. May cause blurred or foggy vision.

Ingestion: May cause allergic dermatitis with angioedema (skin swelling), hives. Single ingestions of less than 10 grams are unlikely to produce symptoms unless the person has Phenylketonuria.

Aspiration hazard No information available.

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

Chronic Toxicity Prolonged or repeated ingestion may affect the liver, and kidneys. Prolonged or repeated ingestion may affect the brain. Prolonged or repeated ingestion may cause paresthesia - a tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities)).

Sensitization: No information available.

Mutagenic Effects: Cytogenic Analysis: human lymphocyte
Experiments with human lymphocytes have shown mutagenic effects

Carcinogenic effects: Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Aspartame	22839-47-0	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)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

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 No information available.
STOT - repeated exposure No information available.
Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.
Aspartame - 22839-47-0
Fish 23 mg/kg oral LDLo zebra fish
Persistence and degradability: No information available
Bioaccumulative potential: No information available.
Mobility in soil No information available
Other adverse effects 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Aspartame	22839-47-0	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 No Information available
Description: No information available

ADR
UN Number Not regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Packing group No information available
Subsidiary Risk: No information available

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 Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available

ICAO (air)
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 Number Not Regulated
Proper Shipping Name: No information available
Transport hazard class(es) No information available
Subsidiary Risk: No information available
Packing group No information available
Precautionary Statements - Response No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
<i>Aspartame</i>	22839-47-0	PresentACTIVE	Not present	Present	Present (9)-1616	Present	Present	Present 245-261-3

U.S. Regulations

Product code: A1378

Product name: ASPARTAME,
POWDER, NF

Aspartame

FDA - Direct Food Additives 21 CFR 172.804

FDA - 21 CFR - Total Food Additives 172.804

- List Sourced from EAFUS

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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Aspartame	22839-47-0	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	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
Aspartame	22839-47-0	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Aspartame	22839-47-0	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: Not a dangerous product according to HPR classification criteria.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)
Aspartame	22839-47-0	Present	Not Listed

Component	CAS No	CEPA Schedule I - Toxic Substances
Aspartame	22839-47-0	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Aspartame	22839-47-0	Not listed

EU Classification

Product code: A1378

Product name: ASPARTAME, POWDER, NF

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Aspartame	22839-47-0	

EU - CLP (1272/2008)

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Aspartame	22839-47-0		No information	

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

Indication of danger:

None

16. OTHER INFORMATION

Preparation Date: 7/27/2015
Revision date 5/7/2019
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



October 29, 2020

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
A1378	Aspartame, Powder, 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

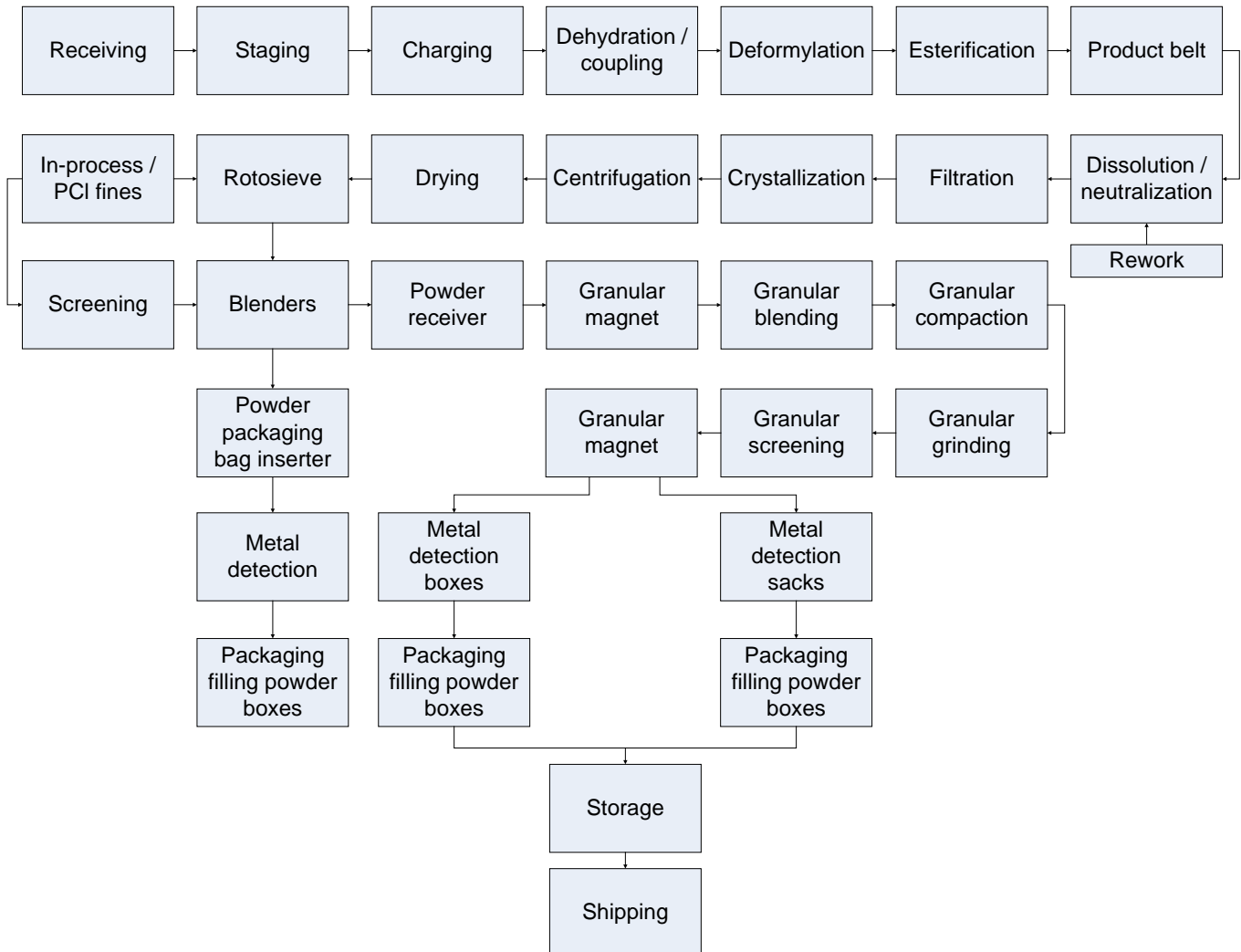
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Aspartame, Powder, NF - A1378



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

A1378, Aspartame, Powder, 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
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives



RE: Elemental Impurities - Aspartame, Powder, NF (Cat# A1378)

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 - Aspartame, Powder, NF (Cat# A1378)

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 USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Benzene	1	< 2 ppm
Methanol	2	< 3000 ppm

No Class 3 or other solvents are used or produced in the manufacturing process of this material.

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

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.

A  **L**

Exp. Date: 03-31-2025

C **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

SPECTRUM[®]

A1378 **D** **F** **12 KG**

E **Aspartame**
(APM; N-L- α -Aspartyl-L-phenylalanine 1-Methyl Ester)
Powder
N.F.

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

G CAS 22839-47-0

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

K $C_{14}H_{18}N_2O_5$ **F.W. 294.31**

Assay (Dried Basis)98.0-102.0%
Transmittance @ 430 nm Min. 0.95
Specific Rotation, $[\alpha]_D^{25}$ +14.5° to +16.5°

MAXIMUM LIMITS

Loss on Drying 4.5%
Residue on Ignition 0.2%
Heavy Metals 0.001%
5-Benzyl-3,6-dioxo-2-piperazineacetic Acid 1.5%
Chromatographic Impurities 2.0%
Residual Solvents To pass test

WARNING: This product contains a chemical known to the State of California to cause cancer.

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

M **Lot No. 062233**

G 9/E4GHS A **O**

SPECTRUM CHEMICAL MFG. CORP.
Gardena, CA 90248 • New Brunswick, NJ 08901

- | | | |
|--|---|---|
| <p>A Bar Code</p> <p>B GHS Hazard Pictograms</p> <p>C Warning, Safety Data and Precautionary Information</p> <p>D Product Catalog Number</p> <p>E Item Name, Form, Grade</p> <p>O Storage Color Band</p> | <p>F Size/Quantity</p> <p>G Chemical Abstracts Service (CAS) Registry Number</p> <p>H Caution Information</p> <p>I DOT Shipping Information</p> <p>J Toll-Free 24-Hour Chemical Emergency Telephone Number</p> | <p>K Empirical Formula, Formula Weight and Technical Specifications Panel</p> <p>L Expiration Information</p> <p>M Lot Number</p> <p>N Kosher Certified by Kosher Supervision of America (KSA).</p> |
|--|---|---|

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

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



May 28, 2020

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

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