

Scientific Documentation

Boric Acid, Granular, NF, EP, BP, JP

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 Boric Acid, Granular, NF, EP, BP, JP (BO120)

Item Number	BO120
Item	Boric Acid, Granular, NF, EP, BP, JP
CAS Number	10043-35-3
Molecular Formula	H_3BO_3
Molecular Weight	61.83
MDL Number	
Synonyms	

Test Specification		on
	Min	Max
ASSAY (H ₃ BO ₃)	99.5	100.5%
pH of a 3.3 % Solution	3.8	4.8
SOLUBILITY IN ALCOHOL	DISSOLVES COMPLETELY	
COMPLETENESS OF SOLUTION	CLEAR SOLUTION	
APPEARANCE OF SOLUTION	CLEAR AND COLORLESS	
LOSS ON DRYING		0.5%
HEAVY METALS (JP)		10 ppm
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
MOLYBDENUM (Mo)	AS REPORTED	
ARSENIC (As)		5 ppm
ORGANIC MATTER	DOES NOT DARKEN	
SULFATES (SO ₄)		450 ppm
IDENTIFICATION	POSITIVE FOR BORATE	
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
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

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Certificate Of Analysis

Item Number	BO120	Lot Number	2NC0238
Item	Boric Acid, Granular, NF, EP, BP, JP	CAS Number	10043-35-3
Molecular Formula	H_3BO_3	Molecular Weight	61.83

TEST	SPECIFICATION		DECLU T	
TEST	MIN	MAX	RESULT	
ASSAY (H ₃ BO ₃)	99.5	100.5%	100.2 %	
pH of a 3.3 % Solution	3.8	4.8	3.98	
SOLUBILITY IN ALCOHOL	DISSOLVES COMPLETELY		DISSOLVES COMPLETELY	
COMPLETENESS OF SOLUTION	CLEAR SOLUTION		CLEAR SOLUTION	
APPEARANCE OF SOLUTION	CLEAR AND COLORLESS		CLEAR COLORLESS	
LOSS ON DRYING		0.5%	<0.1 %	
HEAVY METALS (JP)		10 ppm	<10 ppm	
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD	
ORGANIC MATTER	DOES NOT DARKEN		DOES NOT DARKEN	
SULFATES (SO ₄)		450 ppm	<450 ppm	
IDENTIFICATION	POSITIVE FOR BORATE		POSITIVE FOR BORATE	
RETEST DATE			02-MAY-2026	
DATE OF MANUFACTURE			02-MAY-2023	
APPEARANCE			WHITE CRYSTALLINE POWDER	
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT	
MONOGRAPH EDITION			BP 2024, JP 18	
MONOGRAPH EDITION			NF 2023, EP 11	

Certificate of Analysis Results Entered By:

CACEVEDO Charmian Acevedo 15-APR-24 13:13:10

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 15-APR-24 13:13:12

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 25-August-2022

Revision Number 2

1. Identification

Product identifier

Product Name BORIC ACID, GRANULAR, NF, EP, BP, JP

Other means of identification

Product Code(s) BO120

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on useNo 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 2B
Carcinogenicity	Not applicable
Reproductive toxicity	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Causes eye irritation

Suspected of damaging fertility or the unborn child



Appearance Granular or Crystalline powder or powder

Physical state Solid

Odor Odorless

Precautionary Statements - Prevention

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

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

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Boric Acid	10043-35-3	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. Keep

eye wide open while rinsing. Get medical attention if irritation develops and persists.

Remove contact lenses, if present and easy to do. Continue rinsing.

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.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

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.

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. Remove

contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure LimitsThe 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

infinit 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. None required for

consumer use.

Hand protection Wear suitable gloves.

Skin and body protectionWear 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 Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product. Avoid contact with skin, eyes or clothing.

None known None known

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Granular or Crystalline powder or powder

Color White Odor Odorless

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH5.2
None known **Melting point / freezing point**169 - 171 °C / 336.2 - 339.8
None known

°F

Boiling point / boiling range300 °C / 572 °FNone knownFlash pointno data availableNone knownEvaporation rateno data availableNone knownFlammability (solid, gas)no data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive

limits

No data available

Lower flammability or explosive

limits

Vapor pressure

Vapor density

No data available None known no data available None known

Relative density 1.435 - 1.5
Water solubility Soluble in hot water

Partially soluble in cold water

Solubility(ies) Soluble in Methanol None known

Slightly soluble in Acetone

Partition coefficient No data available None known
Autoignition temperature no data available None known

Autoignition temperature no data available

Decomposition temperature

Kinematic viscosity no data available

no data available
None known
No data available
None known

Other information

Dynamic viscosity

Explosive propertiesNo information availableOxidizing propertiesNo information availableSoftening pointNo information available

Molecular weight 61.83

VOC Content (%)
Liquid Density
No information available
No information available
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 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.

Eye contact Specific test data for the substance or mixture is not available. Causes eye irritation. May

cause redness, itching, and pain.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Boric Acid	= 2660 mg/kg (Rat)	>2000 mg/kg (Rabbit)	>0.16 mg/L (Rat) 4 h
10043-35-3			

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. Irritating to eyes.

Respiratory or skin sensitization
Germ cell mutagenicity

No information available.
No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard
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	
Boric Acid	-	LC50: =1020mg/L (72h,	-	EC50: 115 - 153mg/L
10043-35-3		Carassius auratus)		(48h, Daphnia magna)

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Boric Acid	-0.757
10043-35-3	

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

15. Regulatory information

International Inventories

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

ENCS IECSCThis product complies with ENCS:
This product complies with China:

KECL Complies PICCS Complies

AICS All the constituents of this material are listed on the Australian Inventory of Chemical

Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2 Flammability 0

Instability 0

Physical and chemical properties -

HMIS
Health hazards 2 *
Flammability 0
Physical hazards 0
Personal protection X

Chronic Hazard Star Legend *=

* = Chronic Health Hazard

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 25-August-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



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
BO120	Boric Acid, Granular, NF, EP, BP, JP

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,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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



Manufacturing Process Flowchart - Boric Acid, Granular, NF, EP, BP, JP (Catalog No. BO120)

The main stages of the purification process are:

- Dissolution
- -Filtration
- Crystallization
- -Drying and packing

Then granular products can be milled to obtain powder EP/NF grade.



BO120, Boric Acid, Granular, NF, EP, BP, JP

Source Statement

The above-mentioned catalog item is manufactured by purification from natural inorganic material (mineral ore). 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 the above-mentioned 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:

- Bisphenol A (BPA)
- CMR Substances
- Parabens

- Pesticides
- Phthalates
- Preservatives



Residual Solvents - Boric Acid, Granular, NF, EP, BP, JP (Catalog No. BO120)

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. 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.



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

0000-00-00

Causes eye irritation
 Suspected of damaging fertility or the unborn child.

Obtain special instructions before use • Do
 not handle until all safety precautions have
 been read and understood • Wear protective
 gloves, protective clothing, eye protection, face
 protection • Wash face, hands and any exposed
 skin thoroughly after handling.

NET RID: 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 exposed or concerned: Get medical attention.

KEEP FROM CHILDREN

B0120

SIZ SY

Boric Acid

Granular

NF, EP, BP, JP

CAS 10043-35-3

CAUTION: For manufacturing, processing or repacking. Not for internal use.

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

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

 H_3BO_3

F.W. 61.83

Assay (H₃BO₃; Dried Basis) 99.5-100.5% pH of a 3.3% Solution 3.8-4.8 Solubility in Alcohol To pass test Completeness of Solution To pass test Appearance of Solution To pass test MAXIMUM LIMITS

Loss on Drying 0.5% Heavy Metals (JP) 10 ppm Elemental Impurities As reported Arsenic 5 ppm

 Elemental Impurities
 As reported

 Arsenic
 5 ppm

 Organic Matter
 To pass test

 Sulfates
 450 ppm

 Residual Solvents
 To pass test

HYGROSCOPIC: Keep tightly closed.

WARNING:

Cancer and Reproductive Harmwww.P65Warnings.ca.gov

G 13/K1GHS ?

Lot No. XQ####

Spectrum Chemical Mfg Corp

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