Scientific Documentation BE140, Benzoic Acid, Crystal, USP, EP, BP, JP

Not appropriate for regulatory submission. Please visit <u>www.spectrumchemical.com</u> 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 22.June.2022

BE140, Benzoic Acid, Crystal, USP, EP, BP, JP

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

- General Lot Numbering System Guidance
- Kosher Certificate
- Halal Certificate

Spectrum®



Specification for Benzoic Acid, Crystal, USP, EP, BP, JP (BE140)

Item Number	BE140
Item	Benzoic Acid, Crystal, USP, EP, BP, JP
CAS Number	65-85-0
Molecular Formula	C ₇ H ₆ O ₂
Molecular Weight	122.12
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
ASSAY (ANHYDROUS BASIS)	99.5	100.5%	
CONGEALING RANGE	121°	123°C	
WATER DETERMINATION		0.7 %	
READILY CARBONIZABLE SUBSTANCES	LESS COLOR THAN MATCHING FLUID Q		
RESIDUE ON IGNITION (SULFATED ASH)		0.05 %	
ELEMENTAL IMPURITIES	AS REPORTED		
HEAVY METALS (JP)		20 ppm	
READILY OXIDIZABLE SUBSTANCES		0.50 ml	
POTASSIUM PERMANGANATE-REDUCING SUBSTANCES (JP)	RED COLOR PERSISTS		
CHLORINATED COMPOUNDS (JP)	NOT MORE TURBID THAN STANDARD		
PHTHALIC ACID	GREEN FLOURESCENCE NOT GREATER THAN STANDARD		
LOSS ON DRYING		0.5 %	
IDENTIFICATION A1	SALMON COLORED PRECIPITATE		
IDENTIFICATION A2	WHITE PRECIPITATE SOLUBLE IN ETHER		
IDENTIFICATION B (JP)	POSITIVE FOR BENZOATE		
•			
ASSAY (ANHYDROUS BASIS; EP)	99.0	100.5%	
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS		
CARBONISABLE SUBSTANCES (EP)	NO MORE INTENSELY COLOURED THAN REFERENCE SOLUTION		

Test	Specification		
	Min	Max	
OXIDISABLE SUBSTANCES (EP)	THE SOLUTION IS STILL COLOURED PINK		
HALOGENATED COMPOUNDS AND HALIDES (EP)	- 300 ppm		
SULFATED ASH (EP)		0.1 %	
IDENTIFICATION (A) EP	121°C	124°C	
IDENTIFICATION (B) EP	POSITIVE FOR BENZOATE		
CERTIFIED KOSHER			
CERTIFIED HALAL			
APPEARANCE			
EXPIRATION DATE			
DATE OF MANUFACTURE			
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
732.214.1300	310.516.8000



Certificate Of Analysis

Item Number	BE140	Lot Number	2LB0124
Item	Benzoic Acid, Crystal, USP, EP, BP, JP	CAS Number	65-85-0
Molecular Formula	C ₇ H ₆ O ₂	Molecular Weight	122.12

TEST	SPECIFICATION		RESULT	
	MIN	МАХ	RESULI	
ASSAY (ANHYDROUS BASIS)	99.5	100.5%	99.99%	
CONGEALING RANGE	121°	123°C	122.4°C	
WATER DETERMINATION		0.7 %	<0.1%	
READILY CARBONIZABLE SUBSTANCES	LESS COLOR THAN MATCHING FLUID Q		LESS COLOR THAN MATCHING FLUID Q	
RESIDUE ON IGNITION (SULFATED ASH)		0.05 %	<0.05%	
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD	
HEAVY METALS (JP)		20 ppm	<20 PPM	
READILY OXIDIZABLE SUBSTANCES		0.50 ml	<0.05 ML	
POTASSIUM PERMANGANATE- REDUCING SUBSTANCES (JP)	RED COLOR PERSISTS		RED COLOR PERSISTS	
CHLORINATED COMPOUNDS (JP)	NOT MORE TURBID THAN STANDARD		NO MORE TURBID THAN STANDARD	
PHTHALIC ACID	GREEN FLOURESCENCE NOT GREATER THAN STANDARD		GREEN FLOURESENCE NOT GREATER THAN STANDARD	
LOSS ON DRYING		0.5 %	0.4%	
IDENTIFICATION A1	SALMON COLORED PRECIPITATE		SALMON COLORED PRECIPITATE	
IDENTIFICATION A2	WHITE PRECIPITATE SOLUBLE IN ETHER		WHITE PRECIPITATE SOLUBLE IN ETHER	

TECT	SPECIFICATION		850117	
TEST	MIN	ΜΑΧ	RESULT	
IDENTIFICATION B (JP)	POSITIVE FOR BENZOATE		POSITIVE FOR BENZOATE	
ASSAY (ANHYDROUS BASIS; EP)	99.0	100.5%	99.99%	
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS		CLEAR AND COLORLESS	
CARBONISABLE SUBSTANCES (EP)	NO MORE INTENSELY COLOURED THAN REFERENCE SOLUTION		NO MORE INTENSELY COLORED THAN REFERENCE	
OXIDISABLE SUBSTANCES (EP)	THE SOLUTION IS STILL COLOURED PINK		THE SOLUTION IS STILL COLOURED PINK	
HALOGENATED COMPOUNDS AND HALIDES (EP)	- 300 ppm		<300 PPM	
SULFATED ASH (EP)		0.1 %	<0.05%	
IDENTIFICATION (A) EP	121°C	124°C	122.4°C	
IDENTIFICATION (B) EP	POSITIVE FOR BENZOATE		POSITIVE FOR BENZOATE	
CERTIFIED KOSHER			CERTIFIED KOSHER	
CERTIFIED HALAL			CERTIFIED HALAL	
APPEARANCE			WHITE CRYSTALLINE FLAKES	
EXPIRATION DATE			09-AUG-2023	
DATE OF MANUFACTURE			09-AUG-2021	
RESIDUAL SOLVENTS	AS REPORTED			
CLASS 1 (solvent) / BENZENE			<2 PPM	
CLASS 2 (solvent) / TOLUENE			<890 PPM	

Certificate of Analysis Results Entered By:

BPATEL Bhargavi Patel 18-FEB-22 12:11:14

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

BPATEL Bhargavi Patel 18-FEB-22 12:11:27 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 31-December-2021

1. Identification	
Product identifier	
Product Name	BENZOIC ACID, CRYSTAL, USP, EP, BP, JP
Other means of identification	
Product Code(s)	BE140
Synonyms	None
Recommended use of the chemica	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

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Not applicable

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful if swallowed Causes skin irritation Causes serious eye irritation May cause respiratory irritation



Revision Number 5



Appearance flakes or Crystals or powder

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Wear protective gloves/eye protection/face protection Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

Specific treatment (see .? on this label) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention Take off contaminated clothing and wash it before reuse IF INHALED: Remove person to fresh air and keep comfortable for breathing Call a POISON CENTER or doctor if you feel unwell IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell Rinse mouth

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
Benzoic Acid	65-85-0	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. Get medical attention immediately if symptoms occur.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. 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 impac	et 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 meas	sures	
Personal precautions, protective ec	uipment and emergency procedures	
Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. 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. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

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, suc	ch as personal protective equipment
Eye/face protection	If splashes are likely to occur, wear safety glasses with side-shields.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved 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	Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties			
Physical state	Solid		
Appearance	flakes or Crystals or powder		
Color	White		
Odor	No information available		
Odor threshold	No information available		
Property	Values	Remarks • Method	
pH	< 3	None known	
Melting point / freezing point	121 - 123 °C / 249.8 - 253.4 °F		
Boiling point / boiling range	249 - 250 °C / 480.2 - 482 °F		
Flash point	no data available	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			
Vapor pressure	No data available	None known	
Vapor density	no data available	None known	
Relative density	1.3	None known	
Water solubility	Slightly soluble in water	None known	
Solubility(ies)	Soluble in Alcohol	None known	

	Soluble in Acetone	
	Soluble in diethyl ether	
	Soluble in Benzene	
	Soluble in Chloroform	
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
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	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
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	Strong acids. Strong bases. Strong oxidizing agents.
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. Irritating to eyes. (based on components). Causes serious eye irritation.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).
Symptoms related to the physic	al, chemical and toxicological characteristics
Symptoms	Redness May cause redness and tearing of the eyes

Symptoms Redness. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Dermal LD50

Component information			
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Benzoic Acid	= 1700 mg/kg (Rat)	-	-
65-85-0			

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	Classification based on data available for ingredients. Irritating to skin. Classification based on data available for ingredients. Causes serious eye irritation. No information available. No 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

LOOLOXIONY				
Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Benzoic Acid 65-85-0	EC50: =5mg/L (3h, Anabaena inaequalis)	180 mg/L LC50 Gambusia affinis 96 h		860 mg/L EC50 Daphnia magna 48 h; 300 mg/L EC50 Daphnia magna 24 h

Persistence and degradability	No in
Bioaccumulation	Inher

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Benzoic Acid	1.9
65-85-0	

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

not regulated
not regulated

15. Regulatory information

International Inventories

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

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

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

Complies

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 Extrem	ely Hazardous Substances RQs
---	------------------------------

Benzoic Acid	5000 lb final RQ	-
65-85-0	2270 kg final RQ	

US State Regulations

<u>California Proposition 65</u> 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 chen <u>HMIS</u> Health hazards 2 Flammability 0 Physical hazards Personal protection	* 0		
Key or legend to a	bbreviations and acronyms used in the	safety data sheet	
	EXPOSURE CONTROLS/PERSONAL PI		
	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		
Agency for Toxic St U.S. Environmental European Food Saf EPA (Environmental Acute Exposure Gu U.S. Environmental U.S. Environmental Food Research Jou Hazardous Substar International Uniforn Japan GHS Classifi Australia National In NIOSH (National In National Library of I National Library of I National Library of I National Toxicology New Zealand's Che Organization for Ec	ce Database m Chemical Information Database (IUCLID) cation ndustrial Chemicals Notification and Assess stitute for Occupational Safety and Health) Medicine's ChemID Plus (NLM CIP) Medicine's PubMed database (NLM PUBMI Program (NTP) mical Classification and Information Databa onomic Co-operation and Development En- onomic Co-operation and Development Hig onomic Co-operation and Development Scr	ngicide, and Rodentic e Chemicals ment Scheme (NICN ED) ase (CCID) <i>r</i> ironment, Health, an h Production Volume	IAS) nd Safety Publications e Chemicals Program
Revision date	31-December-2021		

No information available.

Revision Note 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	
BE140	Benzoic Acid, Crystal, USP, 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: Spectrum-New Brunswick, NJ: 2020632 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 <u>gualityassurance@spectrumchemical.com</u>

Sincerely,

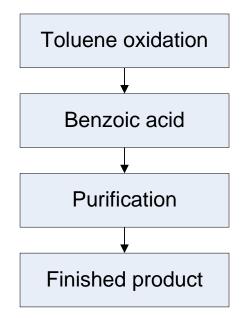
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Benzoic Acid, Crystal, USP, EP, BP, JP - BE140



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

Spectrum[®] **BE140**, Benzoic Acid, Crystal, USP, EP, BP, JP

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 24 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
- Bisphenol A (BPA)
- CMR Substances
- Parabens

- Pesticides
- Phthalates
- Preservatives

RE: Elemental Impurities - Benzoic Acid, Crystal, USP, EP, BP, JP (Cat# BE140)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 1 ppm
Lead	Pb	1	< 1 ppm
Arsenic	As	1	< 1 ppm
Mercury	Hg	1	< 1 ppm
Cobalt	Co	2A	< 1 ppm
Vanadium	V	2A	< 1 ppm
Nickel	Ni	2A	< 1 ppm
Thallium	TI	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	lr	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	< 1 ppm
Platinum	Pt	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	< 1 ppm
Barium	Ba	3	Not tested
Molybdenum	Мо	3	Not tested
Copper	Cu	3	< 1 ppm
Tin	Sn	3	< 1 ppm
Chromium	Cr	3	< 1 ppm

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These

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

AN ISO 9001:2015 REGISTERED COMPANY

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 <u>TechServices@spectrumchemical.com</u>.

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

AN ISO 9001:2015 REGISTERED COMPANY

www.spectrumchemical.com

RE: Residual Solvents - Benzoic Acid, Crystal, USP, EP, BP, JP (Cat# BE140)

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
Toluene	2	< 890 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 <u>TechServices@spectrumchemical.com.</u>

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. Below you will find a typical label example for this catalog item.



Spectrum Chemical Mfg Corp

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

732.214.1300

310.516.8000

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 <u>guality_assurance@spectrumchemical.com</u> if we may be of further assistance.

Sincerely,

Oulu Clony

Oralia Chavez, Quality Assurance Specialist

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A N IS O 9 001 : 201 5 R E GI STE R ED C O M P AN Y



בס״ד Jan 20, 2022

The following product(s) prepared by the named company are certified kosher with the stated requirements:

Spectrum Laboratory Products, Inc.

S-0032

14422 South San Pedro Street Gardena CA 90248	Product Name	BE140, Benzoic Acid, Crystal, USP, EP, BP, JP
USA	Brand	Spectrum
	UKD-ID	KSAV3-I2S3K70
	D/P/M	Р
	Symbol Required	KSA
This certificate expires on Feb 01, 2023	Special Conditions	

Rabbi Binyomin Lisbon Kashrus Administrator

Placing the KSA logo on products not listed above constitutes an un-authorized use of the KSA symbol, which is a federally registered trademark.



شهادة حلال IFANCA HALAL PRODUCT CERTIFICATE

This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America(IFANCA). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: November 02, 2021

Document #: 11205.11206.II213910

Company Name & Address: Spectrum Laboratory Products, Inc. 755-769 Jersey Ave New Brunswick, New Jersey 08901 USA				
Plant Name & Address:	Spectrum Laboratory Pr	oducts, Inc. 769-Jersey Ave New Brunsv	vick, New Jersey 08901 USA	
ProductName		Product Code	Halal-ID	Product Certificate #
1. Benzoic Acid, Crystal, USP,	EP, BP, JP	BE140	B93985	HC-21SP9V26
Huhammethlum (haw by Muhammad Munir Chaudry, Pl.D. President	NU NUTRITION COLOR PORTO COLOR FAMO SOUND STATES	This Certificate is valid until August 31	, 2022 and subject to renewal at that tim	e. MEMBER Page 1 of 1
WWW.IFANCA.ORG •	IFANCA Head Office • 77	7 Busse Highway • Park Ridge, Illinois	60068 USA • Tel: (847) 993-0034 • Fa	ax (847) 993-0038 D160135404ICP1E