spectrum®

Scientific Documentation

BE156, Hydrous Benzoyl Peroxide, 75 Percent, USP

> 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 18.August.2022

BE156, Hydrous Benzoyl Peroxide, 75 Percent, USP

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

Spectrum[®]



Specification for Hydrous Benzoyl Peroxide, 75 Percent, USP (BE156)

Item Number	BE156
Item	Hydrous Benzoyl Peroxide, 75 Percent, USP
CAS Number	94-36-0
Molecular Formula	C ₁₄ H ₁₀ O ₄ (Anhydrous)
Molecular Weight	242.23
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
ASSAY (BENZOYL PEROXIDE)	70.0	80.0 %	
ORGANIC IMPURITIES:			
INDIVIDUAL PEAK		1.5 %	
TOTAL PEAK		2.0 %	
ELEMENTAL IMPURITIES		AS REPORTED	
IDENTIFICATION (A)	Rf VLUE MTCHS ST		
IDENTIFICATION (B)	RET TM CORS 2STD		
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
732.214.1300	310.516.8000

Spectrum® CHEMICAL MFG CORP

Certificate Of Analysis

Item Number	BE156	Lot Number	2KL0146
Item	Hydrous Benzoyl Peroxide, 75 Percent, USP	Manufacturer Lot	2621223901
CAS Number	94-36-0	Manufacturer Code	258
Molecular Formula	$C_{14}H_{10}O_4$ (Anhydrous)	Molecular Weight	242.23

TECT	SPECIFICATION			
TEST	MIN	MAX	RESULT	
ASSAY (BENZOYL PEROXIDE)	70.0	80.0 %	76.04%	
ORGANIC IMPURITIES:				
INDIVIDUAL PEAK		1.5 %	0.62%	
TOTAL PEAK		2.0 %	0.62%	
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT	
IDENTIFICATION (A)	Rf VLUE MTCHS ST		RF VALUE MATCHES STANDARD	
IDENTIFICATION (B)	RET TM CORS 2STD		TETENTION TIME CORRESPONDS TO STANDARD	
RETEST DATE			27-AUG-2022	
DATE OF MANUFACTURE			27-AUG-2021	
APPEARANCE			WHITE GRANULAR POWDER	
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENTS USED	

Spectrum Chemical Mfg Corp 755 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Certified By:

isha.

Jigisha Patel VP Regulatory Compliance & Technical Services, Regulatory

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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Nouryon Chemicals, S.A. de C.V at Av. Morelos 49, Col. Tecamachalco, Los Reyes La Paz, Edo. Mex. 56500, Mexico. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

spectrum®



SAFETY DATA SHEET

Preparation Date: 08/11/2015

Revision Date: 10/26/2018

Revision Number: G2

1. IDENTIFICATION Product identifier Product code: **BE156** Product Name: HYDROUS BENZOYL PEROXIDE, USP Other means of identification Dibenzoyl peroxide Synonyms: Benzoic acid, peroxide Benzol peroxide Benzoperoxide Benzoyl peroxide Benzoyl superoxide Benzoylperoxid [German] BDibenzoyl peroxide Dibenzoylperoxid [German] Diphenylglyoxal peroxide Perossido di benzoile [Italian] Peroxide, dibenzoyl Peroxyde de benzoyle [French] CAS #: 94-36-0 DM8575000 **RTECS #** CI#: Not available Recommended use of the chemical and restrictions on use **Recommended use:** Catalyst in making plastics. Bleaching agent. No information available Uses advised against Supplier: Spectrum Chemical Mfg. Corp 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000 Order Online At: https://www.spectrumchemical.com Chemtrec 1-800-424-9300 Emergency telephone number Martin LaBenz (West Coast) Contact Person: Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements Causes skin irritation Causes serious eye irritation May cause respiratory irritation May intensify fire; oxidizer Heating may cause a fire May mass explode in fire



Hazards not otherwise classified (HNOC) Not Applicable

Other hazards Not available

Precautionary Statements - Prevention

Keep away from heat/sparks/open flames/hot surfaces. — No smoking Keep/Store away from clothing and other combustible materials Take any precaution to avoid mixing with combustibles Keep wetted with water Ground/bond container and receiving equipment Do not subject to grinding/shock/ .? /friction Keep only in original container Do not return unused material to its original container, but destroy it by treatment with Sodium Hydroxide solution (1 to 10) until addition of a crystal of Potassium lodide results in no release of free lodine Wear protective gloves Wear eye/face protection Avoid breathing dust/fume/gas/mist/vapors/spray Use only outdoors or in a well-ventilated area Wash face, hands and any exposed skin thoroughly after handling Contaminated work clothing must not be allowed out of the workplace

Precautionary Statements - Response

IN CASE OF FIRE: Flood with water to extinguish. FOR LARGE FIRES: Evacuate area. Explosion rish in case of fire. DO NOT fight fire when fire reaches explosives.

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

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/physician if you feel unwell.

Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Product code: BE156

Product name: HYDROUS BENZOYL PEROXIDE, USP

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components		CAS-No.	Weight %
		94-36-0	75-70
Water	7	732-18-5	20-25
	4. FIRST A	ID MEASURES	
First aid measures			
General Advice:	•		d States can provide assistance if you to a poison specialist. Call
Skin Contact:	Wash off immediately w shoes. Get medical atte		ater removing all contaminated clothing and rsists, call a physician.
Eye Contact:	Flush eyes with water fo	or 15 minutes. Get medie	cal attention.
Inhalation:	Move to fresh air. If not oxygen. Get medical att		respiration. If breathing is difficult, give
Ingestion:	Do not induce vomiting unconscious person. Ob		Never give anything by mouth to an
Most important symptoms and effec	s, both acute and dela	yed	
Symptoms Causes skin irritation Causes serious eye irritation May cause respiratory irritation			
Indication of any immediate medical	attention and special t	reatment needed	
Notes to Physician:	Treat symptomatically.		
Protection of first-aiders First-Aid Providers: Avoid exposure to contaminated clothing and equipment a		ear gloves and other ne	cessary protective clothing. Dispose of
	5. FIRE-FIGH	TING MEASURES	
Extinguishing Media Suitable Extinguishing Media:			e of no value in extinguishing fires and may only provide limited control.
Unsuitable Extinguishing Media:		Dry chemical. Halo	ns. Foam.
Specific hazards arising from	the chemical		
Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Benzene. Benzoid acid. Decomposition of benzoyl peroxide releases den white smoke, toxic and irritating fumes and gases containing benzoic acid, phenyl benzoate, terphenyls, biphenyls, benzene, and carbon dioxide.			
Specific hazards:			ay from combustible materials (wood, etc.). The product is not flammable, bu
Product code: BE156		HYDROUS BENZOYL XIDE, USP	3/1/

	it may cause fire when in contact with other material. Contact with combustible or organic materials may cause fire. Will accelerate burning when involved in a fire. Container explosion may occur under fire conditions or when heated. Shock and Friction Sensitive. Risk of explosive decomposition exists with friction, shock, or concussion. Do not allow material to dry out. Dry benzoyl peroxide may spontaneously explode and may explode when overheated under confinement or when heated over its melting point. There is explosive decomposition above its melting point (103 degrees C).
Special Protective Actions for Firefighters	
Specific Methods:	For large fires, flood fire area with water from a distance. Cool affected containers with flooding quantities of water. Do not get water inside containers. DO NOT use combustible materials such as sawdust.
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. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition. Keep combustibles (wood, paper, oil, clothing, etc.) away from spilled material. Use spark-proof tools and explosion-proof equipment.				
Environmental precautions	Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.				
Methods and material for conta	Methods and material for containment and cleaning up				
Methods for containment	Stop leak if you can do it without risk.				
Methods for cleaning up	Never allow spilled material to dry. Dampen with water without stirring. Never attempt to sweep up dry material. Use a spill response pad or pillow that is dampened with water to absorbed the spilled material. Place the pads/pillows in an appropriate impervious container with water added. Wash area with soap and water. 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. All equipment used when handling the product must be grounded. Avoid dust formation. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Avoid shock and friction. Do not ingest. Do not breathe dust. Do not smoke. Avoid letting the product become dry. Dry residue is explosive. Keep away from combustible material. Keep away from heat and sources of ignition. Re-hydrate as needed. The water content should be at least 20% water by volume. Do not use metal spatulas with removing or weighing out material. Handle in accordance with good industrial hygiene and safety practice.

Product code: BE156

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep wetted with a minimum of 20% water for the purpose of reducing flammability and shock sensitivity. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Do not store near combustible materials. Store in a segregated and approved area. Store away from incompatible materials.

Incompatible Materials:

Combustible materials Lithium Aluminum hydride Amines Metallic Naphthenates Alcohols Organic materials Strong bases Reducing agents Metals Rubber

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Benzoyl Peroxide,	94-36-0	5 mg/m³ TWA	5 mg/m³ TWA	5 mg/m³ TWA	None
Hydrous					
Water	7732-18-5	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Benzoyl Peroxide, Hydrous	94-36-0	5 mg/m³ TWA	5 mg/m³ TWA	None	None
Water	7732-18-5	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Benzoyl Peroxide, Hydrous	94-36-0	5 mg/m³ TWA	5 mg/m³ TWA
Water	7732-18-5	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

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.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection:	Goggles
Skin and body protection:	Chemical resistant apron Long sleeved clothing Gloves
Respiratory protection:	Wear respirator with dust filter. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Appearance:	Color:
Solid	Granular. Wetted solid.	White.
Odor: Faint. Benzaldehyde-like. Bitter almond.	Taste Tasteless.	Formula: C14H10O4
Molecular/Formula weight (g/mole)	: Flammability:	Flashpoint (°C/°F):
242.23	Oxidizer	No information available.
Flash Point Tested according to:	Autoignition Temperature (°C/°F):	Lower Explosion Limit (%):
Not available	No information available	No information available
Upper Explosion Limit (%):	Melting point/range(°C/°F):	Decomposition temperature(°C/°F):
No information available	103-106°C/ 217-223°F	No information available
Boiling point/range(°C/°F):	Bulk density:	Density (g/cm3):
No information available	No information available	No information available
Specific gravity:	pH:	Vapor pressure @ 20°C (kPa):
1.334	No information available	0.009 Pa (25°C)
Evaporation rate:	Vapor density:	VOC content (g/L):
No information available	No information available	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 diethyl ether Soluble in Acetone Soluble in Benzene Soluble in Chloroform Very slightly soluble in cold water Slightly soluble in oil Slightly soluble in alcohol Practically insoluble in water Solubility in water: 9.10 mg/l @ 25°C	

10. STABILITY AND REACTIVITY

Reactivity

Product code: BE156

Product name: HYDROUS BENZOYL PEROXIDE, USP Reactive with reducing agents, combustible materials, organic materials, metals, acids, alkalis. The product may undergo hazardous decomposition, condensation or polymerization, it may become self-reactive under conditions of shock or increase in temperature or pressureBenzoyl peroxide is a strong oxidant, reacting violently with reducing materials/easily oxidizable materials (such as ethers) and combustibles (such as paper, wood, oil, etc.). Violent reactions take place when this compound comes into contact with alcohols, amines, alkalies, methyl methacrylate, many inorganic and organic acids, and polymerization accelerators (such as dimethylaniline). Benzoyl peroxide will attack some forms of rubber, plastics, and coatings, presenting potential for fire and explosion. When heated to over 50 degrees C, the reaction of benzoyl peroxide and charcoal is violent. Do not mix unless approximately 33% water is present. Do not let material dry out.

Reactions resulting in flashing or explosion take place between benzoyl peroxide and organic materials(such as resins and oils), active carbon, metallic powders, and iron rust. Explosive or violent reactions result from benzoyl peroxide's contact with N,N-dimethylaniline, aniline, dimethylsulfide, lithium tetrahydroaluminate, lithium aluminum hydride, and N-bromosuccinimide + 4-toluic acid. Polymerization of vinyl acetate with benzoyl peroxide in ethyl acetate can result in discharge of a large volume of vapor which ignites and explodes.

Chemical stability

Stability:	Do not let material dry out. Dry material can be explosive. Must be kept wetted with a minimum of 20% water. Stable under recommended storage conditions.
Possibility of Hazardous Reactions	- Hazardous polymerization does not occur
Conditions to avoid:	Heat. Ignition sources. Incompatible materials. When dry, the substance is very sensitive to shock and heat (explosion hazard).
Incompatible Materials:	Combustible materials Lithium Aluminum hydride Amines Metallic Naphthenates Alcohols Organic materials Strong bases Reducing agents Metals Rubber
Hazardous decomposition products:	Carbon oxides. Biphenyls.
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: Skin. Inhalation. Ingestion.

Acute Toxicity

Component Information

Benzoyl Peroxide, Hydrous	
CAS-No.	94-36-0

LD50/oral/rat = 7710 mg/kg Oral LD50 Rat; 6400 mg/kg Oral LD50 Rat LD50/oral/mouse = 1200 mg/kg 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 LC50information = No information available

Water CAS-No.

7732-18-5

LD50/oral/rat = > 90 mL/kg Oral LD50 Rat LD50/oral/mouse = No information available **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 LC50information = No information available

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = 7710 mg/kg

LD50/oral/mouse = Value - Acute Tox Oral = 1200 mg/kg

LD50/dermal/rabbit VALUE-Acute Tox Dermal = 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:	Causes mild to moderate skin irritation with moderate erythema (redness), inflammation, swelling, stinging sensation, and itching. Skin dryness and pee may occur. It can be absorbed through intact skin where it is converted to Be acid.	
Eye Contact:	Causes eye irritation. Eye contact can cause conjunctivitis, and superficial co opacity. No permanent eye injury has been noted.	orneal
Inhalation	Inhalation of airborne concentrations greater than 12 mg/m ³ can cause respi tract (nose, throat) with sore throat, coughing, wheezing, dyspnea.	ratory
Ingestion	May cause digestive tract/gastrointestinal tract irritation with abdominal pain, nausea, vomiting. It may affect the liver, kidneys and bladder, behavior/central nervous system (stupor, hallucinations, distorted perceptions), respiration (dyspena).	
Product code: BE156	Product name: HYDROUS BENZOYL	8 / 14

Aspiration hazard	No information available.
Delayed and immediate effects	as well as chronic effects from short and long-term exposure
Chronic Toxicity	Skin: Prolonged or repeated skin contact may cause allergic contact dermatitis. Skin dryness and peeling may also occur.Inhalation: Prolonged or repeated inhalation may cause lung irritation. It may also cause bronchitis to develop with cough, phlegm, and/or shortness of breath.
Sensitization:	No information available.
Mutagenic Effects:	May affect genetic material Mutagenic effects in mammalian somatic cells

Carcinogenic effects: May cause cancer based on animal test data.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Benzoyl Peroxide, Hydrous	94-36-0	classifiable - Monograph 71	A4 Not Classifiable as a Human Carcinogen	Not listed	Not listed	Not listed	Not listed
Water	7732-18-5	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: Developmental Effects:	No information available 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:

Very toxic to aquatic organisms.

Benzoyl Peroxide, Hydrous - 94-36-0				
Freshwater Algae Data:	72 h EC50: 0.06 mg/l			
Freshwater Fish Species Data:	96 h LC50 0.06 mg/l			
Water Flea Data:	48 h EC50: 0.11 mg/ll (Daphnia Magna)			

Product code: BE156

Product name: HYDROUS BENZOYL PEROXIDE, USP

Persistence and degradability:	No information available
Bioaccumulative potential:	An estimated Biocentration Factor (BCF) value of 66.6.
Mobility:	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

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Benzoyl Peroxide, Hydrous	94-36-0	None	None	None	None
Water	7732-18-5	None	None	None	None

14. TRANSPORT INFORMATION

DOT		
UN-No:	UN3104	
Proper Shipping Name:	Organic peroxide type C, solid (benzoyl peroxide)	
Hazard Class:	5.2	
Subsidiary Class	No information available	
Packing group:	No information available	
Emergency Response Guide	146	
Number		
Marine Pollutant	No data available	
DOT RQ (lbs):	No information available	
Special Provisions	No Information available	
Symbol(s):	[DOT]: (G) - Identifies proper shipping names for which one or more technica	al
	names of the hazardous material must be entered in parentheses, in associa	ation
	with the basic description.	
Description:	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2	
TDG (Canada)		
UN-No:	UN3104	
Proper Shipping Name:	Organic peroxide type C, solid (benzoyl peroxide)	
Hazard Class:	5.2	
Subsidiary Risk:	No information available	
Packing Group:		
Marine Pollutant	No Information available	
Description:	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2, I	
Description.	UNST04, Organic peroxide type C, solid (Benzoyi Peroxide, Hydrous), 5.2, 1	I
ADR		
UN-No:	UN3104	
Proper Shipping Name:	Organic peroxide type C, solid (benzoyl peroxide)	
Hazard Class:	5.2	
Packing Group:	No information available	
Subsidiary Risk:	No information available	
Special Provisions	122, 274	
Description:	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2	
Product code: BE156		10/14
	PEROXIDE, USP	

Proper Shipping Name:OHazard Class:5.Subsidiary Risk:NPacking Group:NMarine PollutantNEMS:FSpecial Provisions12	IN3104 Organic peroxide type C, solid (benzoyl peroxide) .2 Io information available Io information available Io information available -J 22, 195, 274 IN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2
Proper Shipping Name:OHazard Class:5.Subsidiary Risk:NPacking Group:NSpecial Provisions12	N3104 Organic peroxide type C, solid (benzoyl peroxide) .2 Io information available Io information available 22, 274 IN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2
Proper Shipping Name:OHazard Class:5.Subsidiary Risk:NPacking Group:NDescription:U	IN3104 Organic peroxide type C, solid (benzoyl peroxide) .2 Io information available Io information available IN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2 150, A20
Proper Shipping Name:OHazard Class:5.Subsidiary Risk:NPacking Group:NERG Code:5.Special ProvisionsN	IN3104 Drganic peroxide type C, solid (benzoyl peroxide) .2 Io information available Io information available L Io information available IN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Benzoyl Peroxide, Hydrous	94-36-0	PresentACTIV E	Present KE-09889	Present	Present (3)-1349	Present	Present	Present 202-327-6
Water	7732-18-5	PresentACTIV E	Present KE-35400	Present	Not present	Present	Present	Present 231-791-2

U.S. Regulations

Benzoyl Peroxide, Hydrous Massachusetts RTK: Present New Jersey RTK Hazardous Substance List: 0215 New Jersey (EHS) List: 0215 500 lb TPQ New Jersey - Discharge Prevention - List of Hazardous Substances: Present New Jersey TCPA - EHS: 2500lbTQ

Pennsylvania RTK: Environmental hazard Pennsylvania RTK - Environmental Hazard List Present Minnesota - Hazardous Substance List: Present California Directors List of Hazardous Substances: Present FDA - Food Additives Generally Recognized as Safe (GRAS): 21 CFR 184.1157

FDA - 21 CFR - Total Food Additives 133.102, 133.106, 133.111, 133.141, 133.165, 133.181, 133.183, 133.195, 137.105,

- List Sourced from EAFUS 172.814, 175.105, 176.170, 177.2420, 177.2600, 184.1157

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)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male	Female
		-		Reproductive	Reproductive
				Toxicity	Toxicity:
Benzoyl Peroxide, Hydrous	94-36-0	Not Listed	Not Listed	Not Listed	Not Listed
Water	7732-18-5	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	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
Benzoyl Peroxide, Hydrous	94-36-0	None	None	None		1.0 % de minimis concentration
Water	7732-18-5	None	None	None	None	None

U.S. TSCA

Components		TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Benzoyl Peroxide, Hydrous	94-36-0	Not Applicable	Not Applicable
Water	7732-18-5	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

 WHMIS 2015 Hazard Classification
 The WHMIS 2015 classification of this product has not been validated or reviewed yet.

 Information:
 WHMIS 2015 Hazard Classification

Component Water 7732-18-5 (20-25) WHMIS 2015 Hazard Classification 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

Components	WHMIS Ingredient Disclosure List -
Benzoyl Peroxide, Hydrous	1 %

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Benzoyl Peroxide, Hydrous	94-36-0	Present	Not Listed

Product code: BE156

Water	7732-18-5	Present	Not Listed
Components		CAS-No.	CEPA Schedule I - Toxic Substances
Benzoyl Peroxide, Hydro	bus	94-36-0	Not listed
Water		7732-18-5	Not listed
Components		CAS-No.	CEPA - 2010 Greenhouse Gases Subject
-			to Mandatory Reporting
Benzoyl Peroxide, Hydro	bus	94-36-0	Not listed
Water		7732-18-5 Not listed	

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Benzoyl Peroxide, Hydrous	94-36-0	Organic Peroxides - Org. Perox. B: H241 Heating may cause a fire or explosion.; Serious Eye Damage/Eye Irritation - Eye Irrit. 2: H319 Causes serious eye irritation.; Skin sensitizers - Skin Sens. 1: H317 May cause allergic skin reaction.617-008-00-0
Water	7732-18-5	

EU - CLP (1272/2008)

R-phrase(s)

R 3 - Extreme risk of explosion by shock, friction, fire or other sources of ignition.

R 7 - May cause fire.

R36 - Irritating to eyes.

R43 - May cause sensitization by skin contact.

S -phrase(s)

S 2 - Keep out of the reach of children.

S14 - Keep away from easily oxidizable materials.

S 3/7 - Keep container tightly closed in a cool place.

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Benzoyl Peroxide, Hydrous	94-36-0	E; R3 Xi; R36 R43 O; R7	No information	S2 S3/7 S14 S36/37/39
Water	7732-18-5		No information	

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

Indication of danger:

E - Explosive.

Xi - Irritant.

O - Oxidising.



Product code: BE156

Product name: HYDROUS BENZOYL PEROXIDE, USP

16. OTHER INFORMATION

Preparation Date:	08/11/2015
Revision Date:	10/26/2018
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

spectrum

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
BE156	Hydrous Benzoyl Peroxide, 75 Percent, USP

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>qualityassurance@spectrumchemical.com</u>

Sincerely,

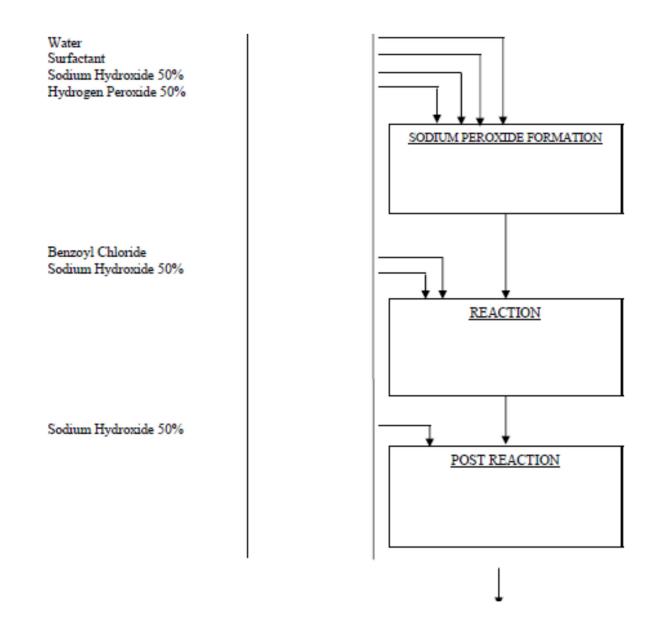
Oulu Clamy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Hydrous Benzoyl Peroxide, 75 Percent, USP (Cat# BE156)



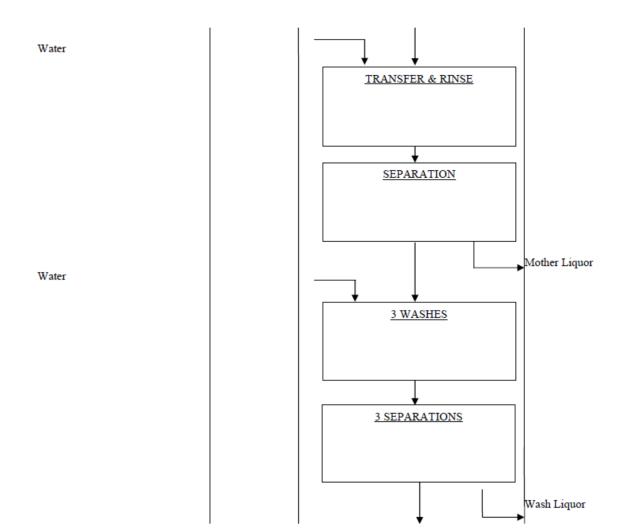
WEST COAST FACILITY

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

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132





CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

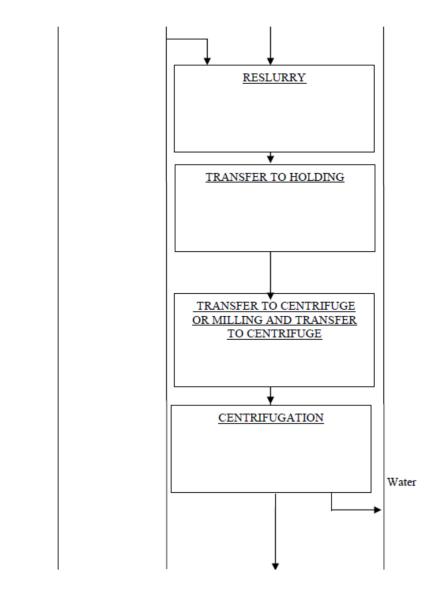
WEST COAST FACILITY

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

AN ISO 9001:2015 REGISTERED COMPANY



Water



CORPORATE HEADQUARTERS

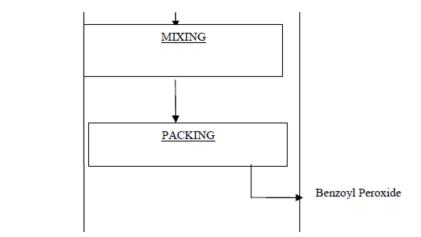
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132

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





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

BE156, Hydrous Benzoyl Peroxide, 75 Percent, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts

Cereals containing Gluten

spectrum

- Celery
- Mustard
- Sesame Seed
- Corn
- Soy
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



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 or ethylene oxide (EtO).

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 12 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances

- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum®

RE: Elemental Impurities - Hydrous Benzoyl Peroxide, 75 Percent, USP (Cat# BE156)

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 <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

spectrum

RE: Residual Solvents - Hydrous Benzoyl Peroxide, 75 Percent, USP (Cat# BE156)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <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

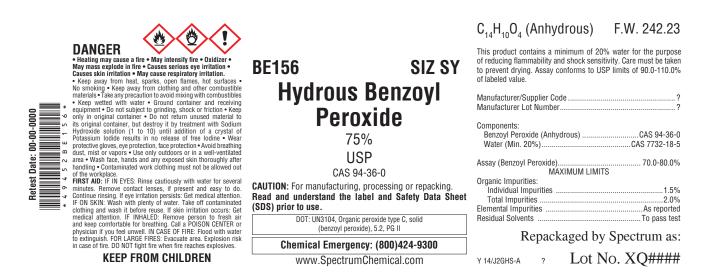
14422 South San Pedro Street Gardena, California 90248 PHONE 310.516.8000 FAX 310.516.9843

AN ISO 9001:2015 REGISTERED COMPANY

spectrum®

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

spectrum

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

CORPORATEHEADQUARTERS

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

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