

# Scientific Documentation

## Hydrous Benzoyl Peroxide, 75 Percent, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://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  
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# 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 <sub>14</sub> H <sub>10</sub> O <sub>4</sub> (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*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
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	BE156	Lot Number	4ML0002
Item	Hydrous Benzoyl Peroxide, 75 Percent, USP	Manufacturer Lot	2623214305
CAS Number	94-36-0	Manufacturer Code	258
Molecular Formula	C <sub>14</sub> H <sub>10</sub> O <sub>4</sub> (Anhydrous)	Molecular Weight	242.23

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (BENZOYL PEROXIDE)	70.0	80.0 %	73.5 %
ORGANIC IMPURITIES:			.
INDIVIDUAL PEAK		1.5 %	0.6 %
TOTAL PEAK		2.0 %	0.6 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT (M)
IDENTIFICATION (A)	Rf VLUE MTCHS ST		Rf VALUE MATCHES STANDARD
IDENTIFICATION (B)	RET TM CORS 2STD		RETENTION CORRESPONDS TO STANDARD
RETEST DATE			23-MAY-2024
DATE OF MANUFACTURE			23-MAY-2023
APPEARANCE			WHITE GRANULAR POWDER
RESIDUAL SOLVENTS		AS REPORTED	NO RESIDUAL SOLVENT PRESENT (M)
NOTE:All results reported with (M) are from manufacturer certificate of analysis			.
MONOGRAPH EDITION			USP 2023

Certificate of Analysis Results Entered By:

GHERRERA  
Genaro Herrera  
29-DEC-23 12:00:45

Certificate of Analysis Results Approved By:

MCAMACHO  
Matheu Camacho  
02-JAN-24 07:45:04

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



**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, repackaging 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 No. 49 Carr. México - Texcoco Km. 20.700, Tecamachalco, La Paz, 56500, Mexico (MEX). 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.

# SAFETY DATA SHEET

# spectrum®



Revision date 23-November-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** HYDROUS BENZOYL PEROXIDE, USP

### Other means of identification

**Product Code(s)** BE156

**UN/ID no** UN3104

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

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

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Danger**

#### Hazard statements

Causes skin irritation  
Causes serious eye irritation  
May cause an allergic skin reaction

May cause respiratory irritation  
Heating may cause a fire  
May mass explode in fire



**Appearance** Wetted solid Granular

**Physical state** slurry in water

**Odor** No information available

#### Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Contaminated work clothing must not be allowed out of the workplace  
Use only outdoors or in a well-ventilated area  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking  
Keep/Store away from clothing/ combustible materials  
Keep only in original container  
Wear protective gloves/eye protection/face protection

#### 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  
Take off contaminated clothing and wash it before reuse  
If skin irritation or rash occurs: Get medical advice/attention  
IF INHALED: Remove person to fresh air and keep comfortable for breathing  
Call a POISON CENTER or doctor if you feel unwell

#### Precautionary Statements - Storage

Store in a well-ventilated place. Keep container tightly closed  
Store locked up.  
Store at temperatures not exceeding .?1 °C/ .?2 °F. Keep cool  
Protect from sunlight  
Store away from other materials

#### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

#### Other information

Very toxic to aquatic life with long lasting effects.

### 3. Composition/information on ingredients

#### Substance

Not applicable.

#### Mixture

Chemical name	CAS No	Weight-%
Benzoyl Peroxide, Hydrous	94-36-0	60 - 80
Water	7732-18-5	20 - 40

### 4. First-aid measures

### **Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	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.
<b>Skin contact</b>	May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician. Wash off immediately with soap and plenty of water for at least 15 minutes.
<b>Ingestion</b>	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.
<b>Self-protection of the first aider</b>	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

### **Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning sensation.
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### **Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	May cause sensitization in susceptible persons. Treat symptomatically.
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## **5. Fire-fighting measures**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray or fog is preferred; if water not available use dry chemical, CO <sub>2</sub> or regular foam. Flood fire area with water from a distance. Use water spray or fog; do not use straight streams. Move containers from fire area if you can do it without risk. Cool containers with flooding quantities of water until well after fire is out. CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Large Fire</b>	
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	These substances will accelerate burning when involved in a fire. Some may burn rapidly with flare burning effect. Some may decompose explosively when heated or involved in a fire. May ignite combustibles (wood, paper, oil, clothing, etc.). Runoff may create fire or explosion hazard. Keep product and empty container away from heat and sources of ignition. Product is or contains a sensitizer. May cause sensitization by skin contact.
<b>Hazardous combustion products</b>	Carbon Monoxide, Carbon Dioxide, Benzene, Benzoic acid. Decomposition of benzoyl peroxide releases dense white smoke, toxic and irritating fumes and gases containing benzoic acid, phenyl benzoate, terphenyls, biphenyls, benzene, and carbon dioxide.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	yes.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. oxidizer. May ignite combustibles (wood, paper, oil, clothing, etc.). Some may burn rapidly with flare burning effect. Do not move cargo or vehicle if cargo has been exposed to heat. Move containers from fire area if you can do it without risk. Fight fire from maximum distance or use unmanned hose holders or monitor nozzles. ALWAYS stay away from tanks engulfed in fire. For massive fire, use unmanned hose holders or monitor nozzles; if this is impossible withdraw from area and let fire burn.



## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. See section 8 for more information. Stop leak if you can do it without risk. DO NOT CLEAN-UP OR DISPOSE OF, EXCEPT UNDER SUPERVISION OF A SPECIALIST. Use personal protective equipment as required.
<b>Other information</b>	Keep combustibles (wood, paper, oil, etc) away from spilled material. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

### Methods and material for containment and cleaning up

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Cover liquid spill with sand, earth or other noncombustible absorbent material. Cover powder spill with plastic sheet or tarp to minimize spreading. Take up with inert, damp, non-combustible material using clean non-sparking tools and place into loosely covered plastic containers for later disposal. Flush area with flooding quantities of water. Prevent product from entering drains.

## 7. Handling and storage

### Precautions for safe handling

<b>Advice on safe handling</b>	Use personal protection equipment. Avoid contact with skin, eyes or clothing. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Use only with adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Take off contaminated clothing and wash before reuse. Avoid breathing vapors or mists.
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### Conditions for safe storage, including any incompatibilities

<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Store in accordance with the particular national regulations. Store in accordance with local regulations. Store locked up. Keep out of the reach of children. Keep wetted with water.
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## 8. Exposure controls/personal protection

### Control parameters

<b>Exposure Limits</b>	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.
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Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Benzoyl Peroxide, Hydrous 94-36-0	No data available	5 mg/m <sup>3</sup> TWA	-

### Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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### Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
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	Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or clothing.
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## **9. Physical and chemical properties**

### Information on basic physical and chemical properties

Physical state	slurry in water
Appearance	Wetted solid Granular
Color	White
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	105 °C / 221 °F	None known
Boiling point / boiling range	no data available	None known
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 limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.3	None known
Water solubility	Practically insoluble in water	None known
Solubility(ies)	Soluble in Acetone Soluble in diethyl ether Soluble in Chloroform Soluble in Benzene Slightly soluble in alcohol	None known
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

<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	Oxidizer.
<b>Chemical stability</b>	May cause fire or explosion; strong oxidizer.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	Heat, flames and sparks. Incompatible materials.
<b>Incompatible materials</b>	Organic material. Combustible material. Hydrocarbons. Strong acids. Strong bases. Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	.
<b>Inhalation</b>	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Irritating to eyes. (based on components). Causes serious eye irritation.
<b>Skin contact</b>	May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). Causes skin irritation.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	Itching. Rashes. Hives. Redness. May cause redness and tearing of the eyes.
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### Acute toxicity

### **Numerical measures of toxicity**

### **Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Benzoyl Peroxide, Hydrous 94-36-0	= 6400 mg/kg ( Rat )	-	-
Water 7732-18-5	90 mL/kg ( Rat )	-	-

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

<b>Skin corrosion/irritation</b>	Classification based on data available for ingredients. Irritating to skin.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	May cause sensitization by skin contact.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Benzoyl Peroxide, Hydrous 94-36-0	-	Group 3- Not classifiable - Monograph 71 [1999] Supplement 7 [1987] Monograph 36 [1985]	-	-

#### Legend

**Reproductive toxicity** No information available.

**STOT - single exposure** May cause respiratory irritation.

**STOT - repeated exposure** No information available.

**Target organ effects** respiratory system, Eyes, Skin.

**Aspiration hazard** No information available.

**Other adverse effects** No information available.

**Interactive effects** No information available.

## 12. Ecological information

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Benzoyl Peroxide, Hydrous 94-36-0	72 h EC50: 0.06 mg/l	96 h LC50 0.06 mg/l	-	48 h EC50: 0.11 mg/l (Daphnia Magna)

**Persistence and degradability** No information available.

**Bioaccumulation** Inherently biodegradable.

**Other adverse effects** No information available.

## 13. Disposal considerations

#### Waste treatment methods

**Waste from residues/unused products** Should not be released into the environment. 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

**UN/ID no** UN3104  
**Proper Shipping Name:** Organic peroxide type C, solid  
**Hazard class** 5.2  
**Marine pollutant** Benzoyl Peroxide, Hydrous  
**Description:** UN3104, Organic peroxide type C, solid, 5.2  
**Emergency Response Guide Number** 146

#### TDG

**UN-No:** UN3104

<b>Proper Shipping Name:</b>	Organic peroxide type C, solid
<b>Hazard class</b>	5.2
<b>Packing Group:</b>	II
<b>Special Provisions</b>	16, 38
<b>Marine pollutant</b>	Benzoyl Peroxide, Hydrous.
<b>Description:</b>	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2, II

#### MEX

<b>UN-No</b>	UN3104
<b>Proper Shipping Name</b>	Organic peroxide type C, solid
<b>Hazard class</b>	5.2
<b>Special Provisions</b>	122, 195, 274, 323
<b>Description</b>	UN3104, Organic peroxide type C, solid, 5.2

#### ICAO (air)

<b>UN-No:</b>	UN3104
<b>Proper Shipping Name:</b>	Organic peroxide type C, solid
<b>Hazard class</b>	5.2
<b>Special Provisions</b>	A150, A20
<b>Description:</b>	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2

#### IATA

<b>UN number</b>	UN3104
<b>Proper Shipping Name:</b>	Organic peroxide type C, solid
<b>Transport hazard class(es)</b>	5.2
<b>ERG Code</b>	5L
<b>Special Provisions</b>	A20, A150, A802
<b>Description:</b>	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2

#### IMDG

<b>UN number</b>	UN3104
<b>Proper shipping name</b>	Organic peroxide type C, solid
<b>Transport hazard class(es)</b>	5.2
<b>EmS-No</b>	F-J, S-R
<b>Special Provisions</b>	122, 195, 274
<b>Marine pollutant</b>	P
<b>Description</b>	UN3104, Organic peroxide type C, solid, 5.2, Marine pollutant

#### RID

<b>UN number</b>	UN3104
<b>Proper Shipping Name:</b>	ORGANIC PEROXIDE TYPE C, SOLID
<b>Transport hazard class(es)</b>	5.2
<b>Classification code</b>	P1
<b>Special Provisions</b>	122, 274
<b>Description:</b>	UN3104, ORGANIC PEROXIDE TYPE C, SOLID (Benzoyl Peroxide, Hydrous), 5.2, ENVIRONMENTALLY HAZARDOUS
<b>Labels</b>	5.2

#### ADR

<b>UN number</b>	UN3104
<b>Proper Shipping Name:</b>	Organic peroxide type C, solid
<b>Transport hazard class(es)</b>	5.2
<b>Classification code</b>	P1
<b>Tunnel restriction code</b>	(D)
<b>Special Provisions</b>	122, 274
<b>Description:</b>	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2, (D), ENVIRONMENTALLY HAZARDOUS
<b>Labels</b>	5.2

#### ADN

<b>UN/ID No</b>	UN3104
<b>Proper shipping name</b>	Organic peroxide type C, solid
<b>Transport hazard class(es)</b>	5.2
<b>Classification code</b>	P1
<b>Special Provisions</b>	122, 274
<b>Description</b>	UN3104, Organic peroxide type C, solid (Benzoyl Peroxide, Hydrous), 5.2,

	ENVIRONMENTALLY HAZARDOUS
Hazard label(s)	5.2
Limited quantity (LQ)	100 g
ventilation	VE01
Equipment Requirements	PP, EX, A

## 15. Regulatory information

### International Inventories

**TSCA** Complies

<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product complies with China:
<b>KECL</b>	Complies
<b>PICCS</b>	Complies
<b>AICS</b>	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 contains a chemical or chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

Chemical name	SARA 313 - Threshold Values %
Benzoyl Peroxide, Hydrous - 94-36-0	1.0

#### **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**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Benzoyl Peroxide, Hydrous 94-36-0	0215	Present	Environmental hazard

## **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

### **NFPA**

**Health hazards** 2

**Flammability** 0

**Instability** 1

**Physical and chemical properties** OX

### **HMIS**

**Health hazards** 2

**Flammability** 0

**Physical hazards** 1

**Personal protection** X

### **Key or legend to abbreviations and acronyms used in the safety data sheet**

#### **Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

### **Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

**Revision date** 23-November-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
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: 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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

Oralia Chavez  
Quality Assurance Specialist

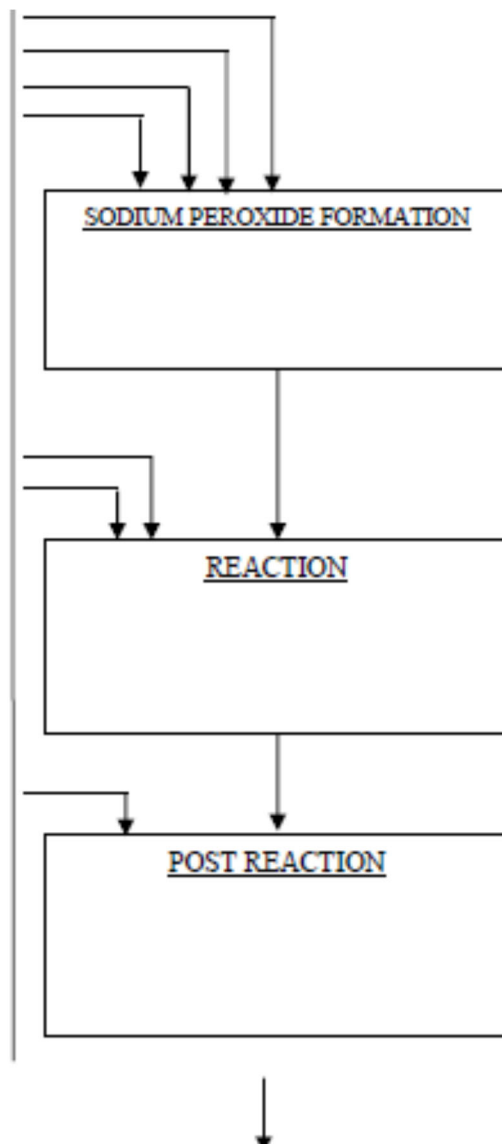


## Manufacturing Process Flowchart Hydrous Benzoyl Peroxide, 75 Percent, USP (Cat# BE156)

Water  
Surfactant  
Sodium Hydroxide 50%  
Hydrogen Peroxide 50%

Benzoyl Chloride  
Sodium Hydroxide 50%

Sodium Hydroxide 50%



### 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

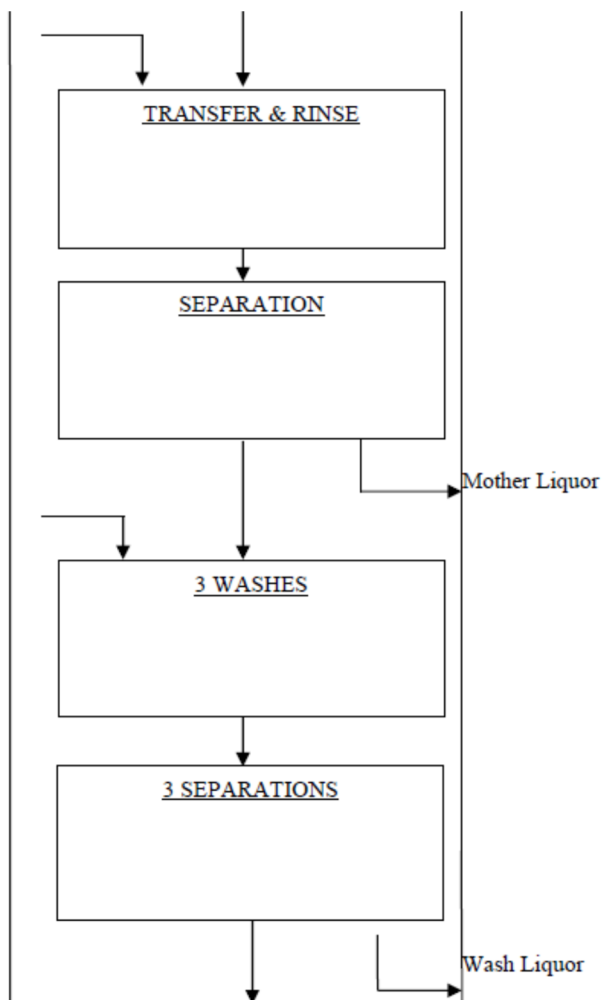
Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

Water

Water



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WEST COAST FACILITY

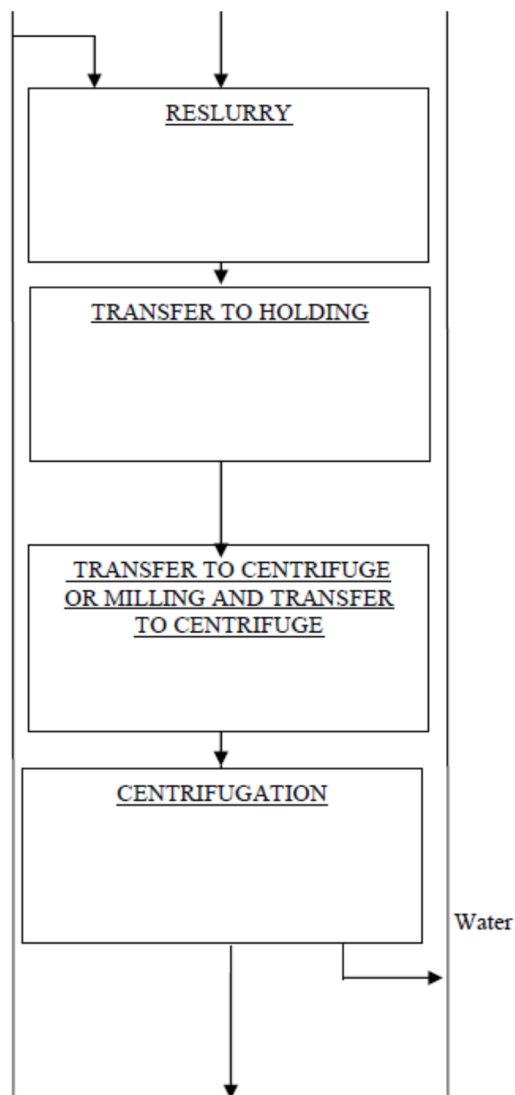
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Water



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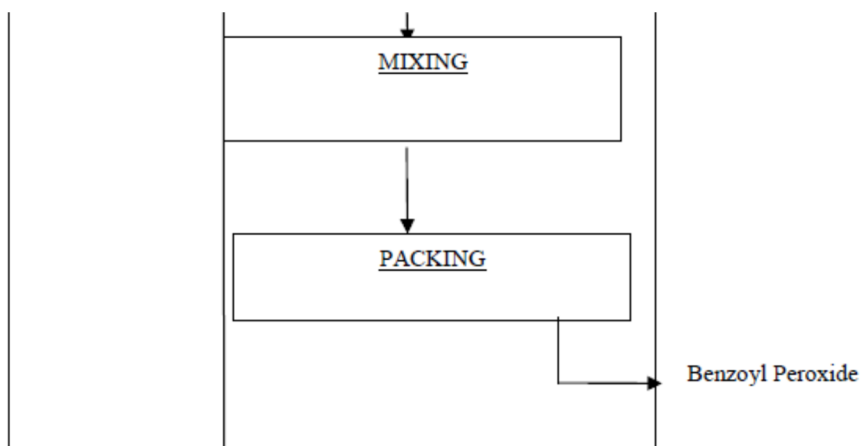
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## **BE156, Hydrous Benzoyl Peroxide, 75 Percent, USP**

### **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
- 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**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 [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

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PHONE 310.516.8000

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**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 [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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## 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.

**Retest Date: 00-00-0000**

**DANGER**

• Heating may cause a fire • May intensify fire • Oxidizer • May mass explode in fire • Causes serious eye irritation • Causes skin irritation • May cause respiratory irritation.

• Keep away from heat, sparks, open flames, hot surfaces • No smoking • Keep away from clothing and other combustible materials • Take any precaution to avoid mixing with combustibles • Keep wetted with water • Ground container and receiving equipment • Do not subject to grinding, shock or 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 Iodide results in no release of free Iodine • Wear protective gloves, eye protection, face protection • Avoid breathing dust, mist or vapors • 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.

**FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IN CASE OF FIRE: Flood with water to extinguish. FOR LARGE FIRES: Evacuate area. Explosion risk in case of fire. DO NOT fight fire when fire reaches explosives.

**KEEP FROM CHILDREN**

BE156

SIZ SY

### Hydrous Benzoyl Peroxide

75%

USP

CAS 94-36-0

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

DOT: UN3104, Organic peroxide type C, solid  
(benzoyl peroxide), 5.2, PG II

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{14}H_{10}O_4$  (Anhydrous) F.W. 242.23

This product contains a minimum of 20% water for the purpose of reducing flammability and shock sensitivity. Care must be taken to prevent drying. Assay conforms to USP limits of 90.0-110.0% of labeled value.

Manufacturer/Supplier Code ..... ?  
Manufacturer Lot Number..... ?

Components:  
Benzoyl Peroxide (Anhydrous) .....CAS 94-36-0  
Water (Min. 20%).....CAS 7732-18-5

Assay (Benzoyl Peroxide)..... 70.0-80.0%  
MAXIMUM LIMITS

Organic Impurities:  
Individual Impurities .....1.5%  
Total Impurities .....2.0%  
Elemental Impurities .....As reported  
Residual Solvents .....To pass test

Repackaged by Spectrum as:

Y 14/J2GHS-A ? Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

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