



Scientific Documentation

BE129, Benzethonium Chloride, USP

Not appropriate for regulatory submission.
Please visit www.spectrumchemical.com or
contact Tech Services for the most up-to-date
information contained in this information
package.

Spectrum Chemical Mfg Corp

769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300

Ver4.02 3.May.2016



Dear Customer,

Thank you for your interest in Spectrum's quality products and services.

Spectrum has been proudly serving our scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry's most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", with a large, sweeping flourish at the end.

Alan Wang, MSQA, ASQ CQA
Senior Manager of Technical Services
techservices@spectrumchemical.com

3.May.2016

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CHEMICAL MFG CORP



Specification for Benzethonium Chloride, USP (BE129)

Item Number	BE129
Item	Benzethonium Chloride, USP
CAS Number	121-54-0
Molecular Formula	$C_{27}H_{42}ClNO_2$
Molecular Weight	448.08
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	97.0 - 103.0%	
MELTING RANGE	158° - 163°C	
LOSS ON DRYING		5.0%
RESIDUE ON IGNITION		0.1%
AMMONIUM COMPOUNDS		TO PASS TEST
IDENTIFICATION		TO PASS TEST
RETEST DATE		
RESIDUAL SOLVENTS	TO PASS TEST	

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

SAFETY DATA SHEET

Preparation Date: 7/10/2014

Revision Date: 7/10/2014

Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: BE129
Product Name: BENZETHONIUM CHLORIDE, USP

Other means of identification

Synonyms: N,N-Dimethyl-N[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]benzenemethanaminium chloride;
Benzyldimethyl[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]benzenemethanaminium, N,N-dimethyl-N-[2-[2-[4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride;
Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride;
p-tert-Octylphenoxyethoxyethyl dimethylbenzylammonium chloride;
Antiseptol;
BZT;
Diapp;
Disilyn;
Hymaine;
Phemeride;
Phemerol;
Phemerol Chloride;
Phemithyn;
Polymine D;
Quatrachlor;
Solamin;
Solamine
CAS #: 121-54-0
RTECS # BO7175000
Cl#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemicals and Laboratory Products, Inc.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Regina Wachenheim (East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 1 Sub-category B
Serious eye damage/eye irritation	Category 1

Label elements

Danger

Hazard statements

Harmful if swallowed

Causes severe skin burns and eye damage



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Do not breathe dust/fume/gas/mist/vapors/spray

Wear protective gloves/protective clothing/eye protection/face protection

Precautionary Statements - Response

Immediately call a POISON CENTER or doctor/physician

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.

Immediately call a POISON CENTER or doctor/physician.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower

Wash contaminated clothing before reuse

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Rinse mouth

Do NOT induce vomiting

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Benzethonium Chloride 121-54-0	121-54-0	100	*

4. FIRST AID MEASURES**First aid measures****General Advice:**

Poison information centres in each State capital city can provide additional assistance for scheduled poisons (13 1126). Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. First aider needs to protect himself.

Skin Contact:

Wash off immediately with soap and plenty of water. Continue flushing with plenty of water for at least 15 minutes. Remove all contaminated clothes and shoes. Immediate medical attention is required. Call a physician immediately.

Eye Contact:

Flush eye with water for 15 minutes. Immediate medical attention is required. Call a physician immediately.

Inhalation:

Move to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. **WARNING!** It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Centre immediately.

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

Severe skin and eye irritation or burns. Causes digestive (gastrointestinal) tract irritation. May cause gastrointestinal (digestive) tract burns. May cause nausea and vomiting. May cause central nervous system effects. Convulsions. Somnolence.

Indication of any immediate medical attention and special treatment needed**Notes to Physician:**

Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES**Extinguishing Media****Suitable Extinguishing Media:**

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

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products:	Carbon oxides, Hydrogen chloride gas, nitrogen oxides
Specific hazards:	May be combustible at high temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Special Protective Actions for Firefighters

Specific Methods:	No information available.
Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions:	Keep people away from and upwind of spill/leak. Ensure adequate ventilation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid contact with skin, eyes and clothing.
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<u>Environmental precautions</u>	Prevent further leakage or spillage if safe to do so. Should not be released into the environment. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.
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Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.
Methods for cleaning up	Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Use only in area provided with appropriate exhaust ventilation. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not ingest. Do not breathe vapours/dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Protect from light. Sensitive to light. Store in light-resistant containers.

Incompatible Materials:

Oxidizing agents. Organic materials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Benzethonium Chloride - 121-54-0	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Benzethonium Chloride - 121-54-0	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
Benzethonium Chloride 121-54-0	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. 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: Face-shield.

Skin and body protection: Chemical resistant protective suit. Gloves. boots.

Respiratory protection: Wear respirator with dust filter..

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid.	Appearance: Crystalline powder. Powder.	Color: White. Off-white.
Odor: Mild.	Taste Bitter.	Formula: C27-H42-Cl-N-O2
Molecular/Formula weight: 448.08	Flash point (°C): No data available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Lower Explosion Limit (%): No information available	Upper Explosion Limit (%): No information available
Autoignition Temperature (°C/°F): No information available	pH: No information available	Melting point/range(°C/°F): 158-163 °C/316.4-325.4 °F
Boiling point/range(°C/°F): No information available	Decomposition temperature(°C/°F): No information available	Specific gravity: 1.1 @ 20 °C
Density (g/cm3): No information available	Bulk density: 12.4 kg/m ³	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Very soluble in water Slightly soluble in Ether Soluble in Acetone Soluble in alcohol Soluble in Chloroform	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable at normal conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.

Incompatible Materials: Oxidizing agents. Organic materials.

Hazardous decomposition products: Carbon monoxide. Carbon dioxide. Hydrogen chloride gas. Nitrogen oxides (NOx).

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

Product code: BE129

Product name: BENZETHONIUM
CHLORIDE, USP

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11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Skin. Inhalation. Ingestion.

Acute Toxicity

Component Information

Benzethonium Chloride - 121-54-0

LD50/oral/rat = 295 mg/kg Oral LD50 Rat
368 mg/kg

LD50/oral/mouse = 338 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 LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = 368mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 338mg/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: Severe skin irritation. Causes skin burns.

Eye Contact: Severe eye irritation. Causes eye burns.

Inhalation
Ingestion May cause irritation of respiratory tract.
Harmful if swallowed. May cause digestive (gastrointestinal) tract burns. May cause vomiting. May affect behavior/central nervous system (convulsions). May affect behavior/central nervous system (somnolence). May affect the kidneys. May affect respiration (respiratory depression).

Aspiration hazard No information available

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

Chronic Toxicity Chronic exposure may cause dermatitis..
Sensitization: No information available

Mutagenic Effects: May affect genetic material

Carcinogenic effects: Not considered carcinogenic

Components	ACGIH - Carcinogens	IARC	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Benzethonium Chloride	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available
STOT - repeated exposure No information available
Target Organs: Skin. Eyes. Central nervous system.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Benzethonium Chloride - 121-54-0

Freshwater Fish Species Data: 1.6 mg/l LC50 96 h Pimephales promelas
1.4 mg/l LC50 96 h Lepomis macrochirus

Persistence and degradability: No information available

Bioaccumulative potential: No information available

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	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Benzethonium Chloride	None	None	None	None

14. TRANSPORT INFORMATION**DOT**

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s. (benzethonium chloride)
Hazard Class: 8
Subsidiary Risk: Not applicable
Packing Group: III
Marine Pollutant: No data available
ERG No: 154
DOT RQ (lbs): No information available
Symbol(s): G

TDG (Canada)

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s.
Hazard Class: 8
Subsidiary Risk: No information available
Packing Group: III
Description: No information available

ADR

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s.
Hazard Class: 8
Packing Group: III
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

IMO / IMDG

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s.
Hazard Class: 8
Subsidiary Risk: No information available
Packing Group: III
Description: No information available
IMDG Page: No information available
Marine Pollutant: No information available
EMS: F-A
MFAG: No information available
Maximum Quantity: No information available

RID

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s.
Hazard Class: 8
Subsidiary Risk: 8

14. TRANSPORT INFORMATION

Packing Group: III
Classification Code: No information available
Description: No information available

ICAO

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s.
Hazard Class: 8
Subsidiary Risk: No information available
Packing Group: III
Description: No information available

IATA

UN-No: UN3261
Proper Shipping Name: Corrosive solid, acidic, organic, n.o.s.
Hazard Class: 8
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 8L
Description: No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Benzethonium Chloride</i>	Present	Present KE-11871	Present	Present (9)-849 (9)-252 (3)-2782	Present	Present	Present 204-479-9

U.S. Regulations

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	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Benzethonium Chloride	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	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 <i>de minimis</i>
<i>Benzethonium Chloride</i>	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
<i>Benzethonium Chloride</i>	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

E Corrosive material
D1B Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Benzethonium Chloride	Present	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Benzethonium Chloride	Not listed	Not listed

EU Classification

R-phrase(s)

R34 - Causes burns.
R22 - Harmful if swallowed.

S -phrase(s)

S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S46 - If swallowed, seek medical advice immediately and show this container or label.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	Classification	Concentration Limits:	Safety Phrases
Benzethonium Chloride		No information	

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

Indication of danger:

C - Corrosive.
Xn - Harmful.



16. OTHER INFORMATION

16. OTHER INFORMATION

NFPA	HMIS	Personal Protective Equipment
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Health Hazard	3
Fire Hazard	1
Reactivity	0



See Section 8.

Preparation Date: 7/10/2014
Revision Date: 7/10/2014
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 Material Safety Data Sheet



Manufacturer

Product Covered: BE129, Benzethonium Chloride, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

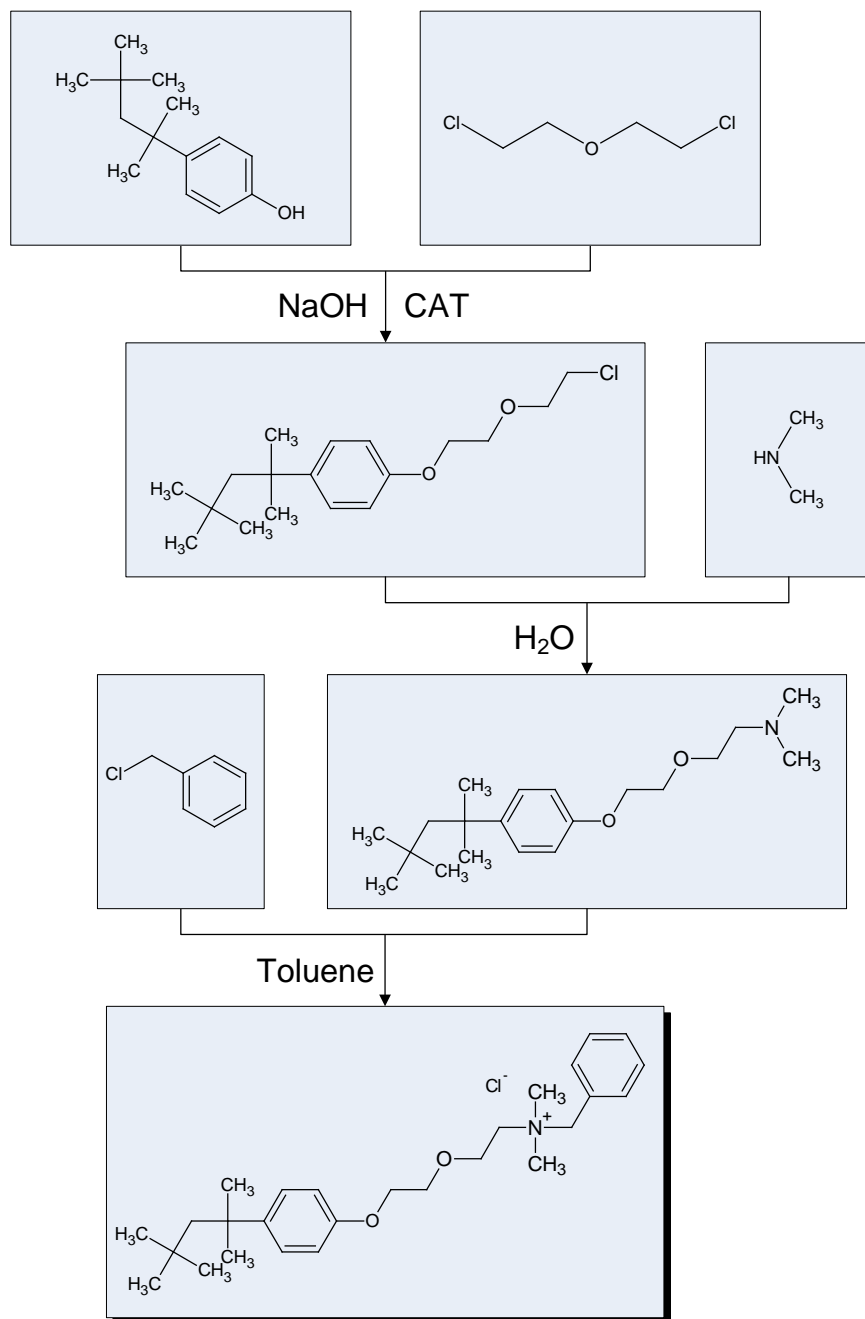
Sincerely,

A handwritten signature in black ink, appearing to read "Alan Wang", is written over a light gray rectangular background.

Alan Wang, MSQA, ASQ CQA
Senior Manager of Technical Services
techservices@spectrumchemical.com

3.May.2016

Manufacturing Process Flowchart Benzethonium Chloride, USP - BE129



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

Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum Chemicals and Laboratory Products, Inc

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA

Additional Sites: 13915 South Main Street, Los Angeles, California, 90061, USA

755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA

7400 North Oracle Road, Suite 221, Tucson, Arizona, 85704, USA

has been assessed and registered by Intertek as conforming to the requirements of

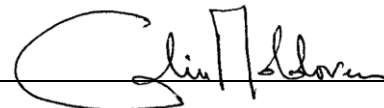
ISO 9001:2008

The quality management system is applicable to

California and New Jersey sites: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Arizona site: Supporting Spectrum's two manufacturing facilities by: selecting and qualifying distributors of Laboratory and Safety Equipment; processing bids and quotes to generate new sales opportunities; sourcing bulk chemicals in support of bulk bids and quotes; assisting production operations through order expediting and IT infrastructure support.

Certificate Number: 94-316m-01
Initial Certification Date: 27 December 1994
Certificate Issue Date: 29 January 2016
Certificate Expiry Date: 14 September 2018



Calin Moldovean, President
Intertek Testing Services NA, Inc.
900 Chelmsford Street, Suite 301-3, Lowell, MA, USA



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The certificate remains the property of Intertek, to whom it must be returned upon request.

CT-ISO 9001-2008-ANAB-EN-LT-L-26.jun.15

Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018



Authorised Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom
Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The annual validity of the certificate can also be checked through the website <http://www.cnca.gov.cn> of CNCA in China.



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The certificate remains the property of Intertek, to whom it must be returned upon request.



March 28, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify that our USP, NF, FCC, EP, BP, JP, and food grade products are 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.

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:	<u>2020632</u>
Spectrum-New Brunswick, NJ:	<u>2246824</u>
Spectrum -Shanghai, China:	<u>3006174778</u>

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

Sincerely,

A handwritten signature in cursive script that reads "Michelle Weston".

Michelle Weston
Quality Assurance Specialist



April 25, 2016

Certificate of cGMP

Dear Valued Customer:

Spectrum Chemicals and Laboratory Products certify 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
BE129	Benzethonium Chloride, 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
Spectrum-Shanghai, China: 3006174778

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

Sincerely,

Michelle Weston
Quality Assurance Specialist



April 27, 2016

Re: Benzethonium Chloride, USP-BE129

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical

Benzethonium Chloride, USP-BE129

is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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



April 27, 2016

Re: Benzethonium Chloride, USP-BE129

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO₂; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Benzethonium Chloride, USP-BE129

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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



April 27, 2016

Re: Benzethonium Chloride, USP-BE129

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Benzethonium Chloride, USP-BE129

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

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

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

A **DANGER**

C • Causes severe skin burns and eye damage • Harmful if swallowed.
• Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe dust • Wash face, hands and any exposed skin thoroughly after handling.
FIRST AID: Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue Rinsing. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting.

L Retest Date: 03-31-2025

B

SPECTRUM[®]

BE129 **D** **F** **2.5 KG**

E **Benzethonium Chloride**

H **U.S.P.**

G CAS 121-54-0

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

I DOT: UN3261, Corrosive solid, acidic, organic, n.o.s. (benzethonium chloride), 8, PG III

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

K **C**₂₇**H**₄₂**ClNO**₂ **K** **F.W. 448.08**

M **W 6/D7GHS** **A** **O** **Lot No. 062233**

www.SpectrumChemical.com

M **Assay (Dried Basis)** 97.0-103.0%
M **Melting Range** 158°-163°C

M **MAXIMUM LIMITS**

M **Loss on Drying** 5.0%
M **Residue on Ignition** 0.1%
M **Residual Solvents** To pass test

N **LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

SPECTRUM CHEMICAL MFG. CORP.

Gardena, CA 90248 • New Brunswick, NJ 08901

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

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

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

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.
New Brunswick, NJ 08901

732.214.1300

West Coast Facility:

14422 S. San Pedro St.
Gardena, CA 90248

310.516.8000

Item Number	BE129	Lot Number	2FA0304
Item	Benzethonium Chloride, USP		
CAS Number	121-54-0		
Molecular Formula	$C_{27}H_{42}ClNO_2$	Molecular Weight	448.08

Test	Specification		Result
	min	max	
ASSAY (DRIED BASIS)	97.0 - 103.0%		99.6 %
MELTING RANGE	158° - 163°C		161 C
LOSS ON DRYING		5.0%	0.6 %
RESIDUE ON IGNITION		0.1%	0.07 %
AMMONIUM COMPOUNDS		TO PASS TEST	PASSES TEST
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			31-DEC-2017
RESIDUAL SOLVENTS	TO PASS TEST		.
CLASS 2 (solvent) / XYLENE			<2170 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
APPEARANCE			WHITE CRYSTALLINE POWDER
DATE OF MANUFACTURE			03-JAN-2015

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

Certificate of Analysis Results Certified By:



Mulbah F. Dwanah
Laboratory Supervisor
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

January 26, 2016

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

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 qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,



Michael Dang
Manager, GMP Compliance



Stability – Shelf Life Guidance

Product Covered: BE129, Benzethonium Chloride, USP

Spectrum Chemical's manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, BE129, Benzethonium Chloride, USP, is assigned a 24 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

A handwritten signature in black ink, appearing to read "Adan R. Hernandez".

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605