

Scientific Documentation

Benzalkonium Chloride Solution, 50 Percent, NF

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
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Specification for Benzalkonium Chloride Solution, 50 Percent, NF (B1068)

Item Number	B1068
Item	Benzalkonium Chloride Solution, 50 Percent, NF
CAS Number	
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (w/v)	47.5	52.5 %
AVERAGE MOLECULAR WEIGHT		AS REPORTED
RATIO OF ALKYL COMPONENTS:		
C12	40.0 %	
C14	20.0 %	
C12 + C14	70.0 %	
C16	AS REPORTED	
LIMITS OF AMINES AND AMINE SALTS		0.1 mmol/g
ACIDITY OR ALKALINITY		0.5 ml
ALCOHOL CONTENT (v/v)		AS REPORTED
BENZYL ALCOHOL		0.5 %
BENZALDEHYDE		0.15 %
(CHLOROMETHYL)BENZENE		0.05 %
ELEMENTAL IMPURITIES		AS REPORTED
IDENTIFICATION A	WHITE PRECIPITATE FORMS DISSOLVES	
IDENTIFICATION B	POSITIVE FOR CHLORIDE	
IDENTIFICATION C	ORANGE-RED COLOR PRODUCED	

Test	Specification	
	Min	Max
IDENTIFICATION D	RETENTION TIME CORRESPONDS TO STANDARD	
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS		AS REPORTED
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

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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	B1068	Lot Number	2NB0050
Item	Benzalkonium Chloride Solution, 50 Percent, NF		

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (w/v)	47.5	52.5 %	52.0 %
AVERAGE MOLECULAR WEIGHT		AS REPORTED	350.92
RATIO OF ALKYL COMPONENTS:			.
C12	40.0 %		68.0 %
C14	20.0 %		25.0 %
C12 + C14	70.0 %		93.0 %
C16	AS REPORTED		7.0 %
LIMITS OF AMINES AND AMINE SALTS		0.1 mmol/g	0.0 mmol/g
ACIDITY OR ALKALINITY		0.5 ml	<0.5 ml
ALCOHOL CONTENT (v/v)		AS REPORTED	5.6 %
BENZYL ALCOHOL		0.5 %	<0.5 %
BENZALDEHYDE		0.15 %	<0.15 %
(CHLOROMETHYL)BENZENE		0.05 %	<0.05 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES REPORTED
IDENTIFICATION A	WHITE PRECIPITATE FORMS DISSOLVES		WHITE PRECIPITATE FORMS DISSOLVES
IDENTIFICATION B	POSITIVE FOR CHLORIDE		POSITIVE FOR CHLORIDE
IDENTIFICATION C	ORANGE-RED COLOR PRODUCED		ORANGE-RED COLOR PRODUCED
IDENTIFICATION D	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			CLEAR COLORLESS LIQUID
RETEST DATE			26-JAN-2026
DATE OF MANUFACTURE			27-JAN-2023
RESIDUAL SOLVENTS		AS REPORTED	MEETS USP CHAPTER <467> REQUIREMENTS
MONOGRAPH EDITION			NF 2023

Certificate of Analysis Results Entered By:

CACEVEDO
Charmian Acevedo
05-APR-24 08:22:32

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
05-APR-24 08:52:51

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

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

SAFETY DATA SHEET

spectrum®



Revision date 09-March-2022

Revision Number 2

1. Identification

Product identifier

Product Name BENZALKONIUM CHLORIDE, 50 PERCENT SOLUTION, NF

Other means of identification

Product Code(s) B1068

UN/ID no UN2920

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

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 1 Sub-category A
Serious eye damage/eye irritation	Category 1
Respiratory sensitization	Category 1A
Skin sensitization	Category 1A
Reproductive toxicity	Category 1A
Specific target organ toxicity (repeated exposure)	Category 1
Flammable liquids	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Harmful if swallowed
Causes severe skin burns and eye damage
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
May damage fertility or the unborn child
Causes damage to organs through prolonged or repeated exposure
Flammable liquid and vapor



Appearance Clear

Physical state Liquid

Odor Aromatic

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Do not breathe dust/fume/gas/mist/vapors/spray
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 container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof electrical/ ventilating / lighting/ .? / equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Keep cool

Precautionary Statements - Response

Immediately call a POISON CENTER or doctor
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
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower
Wash contaminated clothing before reuse
If skin irritation or rash occurs: Get medical advice/attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth
Do NOT induce vomiting
In case of fire: Use CO₂, dry chemical, or foam to extinguish

Precautionary Statements - Storage

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

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful in contact with skin. Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Trade secret
Benzalkonium Chloride	8001-54-5	40 - 60	*
Water	7732-18-5	40 - 60	*
Ethyl Alcohol 200 proof	64-17-5	3 - <5	*
Benzyl Chloride	100-44-7	<0.1	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required. IF exposed or concerned: Get medical advice/attention.
Inhalation	Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. Delayed pulmonary edema may occur. Get immediate medical advice/attention. May cause allergic respiratory reaction. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get immediate medical advice/attention. May cause an allergic skin reaction.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention. May produce an allergic reaction.
Self-protection of the first aider	Remove all sources of ignition. 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. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Most important symptoms and effects, both acute and delayed

Symptoms	Burning sensation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Product is a corrosive material. Use of gastric lavage or emesis is contraindicated. Possible perforation of stomach or esophagus should be investigated. Do not give chemical antidotes. Asphyxia from glottal edema may occur. Marked decrease in blood pressure may occur with moist rales, frothy sputum, and high pulse pressure. May cause sensitization in susceptible persons. Treat symptomatically.
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5. Fire-fighting measures

Suitable Extinguishing Media Large Fire	Dry chemical. Carbon dioxide (CO ₂). water spray. Alcohol resistant foam. CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. The product causes burns of eyes, skin and mucous membranes. Thermal decomposition can lead to release of irritating gases and vapors. Product is or contains a sensitizer. May cause sensitization by inhalation and skin contact. May cause sensitization by skin contact.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	yes.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Attention! Corrosive material.
Other information	Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.
Methods for cleaning up	Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when
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using this product. Take off contaminated clothing and wash before reuse. Provide extract ventilation to points where emissions occur. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions

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. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children. Protect from moisture. Store locked up. Store away from other materials.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethyl Alcohol 200 proof 64-17-5	No data available	1000 ppm TWA 1900 mg/m ³ TWA	-
Benzyl Chloride 100-44-7	No data available	1 ppm TWA 5 mg/m ³ TWA	-

Appropriate engineering controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection

Tight sealing safety goggles. Face protection shield.

Hand protection

Wear suitable gloves. Impervious gloves.

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Antistatic boots.

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. 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. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear
Color	Colorless
Odor	Aromatic
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	no data available	None known
Boiling point / boiling range	no data available	None known
Flash point	52 °C / 125.6 °F	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	0.97	None known
Water solubility	Miscible in water	None known
Solubility(ies)	Soluble in Alcohol Soluble in Acetone Partially soluble in diethyl ether	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
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Heat, flames and sparks. Exposure to air or moisture over prolonged periods.
Incompatible materials	Acids. Bases. Oxidizing agent.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation

Specific test data for the substance or mixture is not available. Corrosive by inhalation. (based on components). Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate. Inhaled corrosive substances can lead to a toxic edema of the lungs. Pulmonary edema can be fatal. May cause sensitization in susceptible persons. May cause drowsiness or dizziness. May cause irritation of respiratory tract.

Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye damage. (based on components). Corrosive to the eyes and may cause severe damage including blindness. May cause irreversible damage to eyes.
Skin contact	Specific test data for the substance or mixture is not available. Corrosive. (based on components). Causes burns. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. May cause sensitization by skin contact. May be harmful in contact with skin.
Ingestion	Specific test data for the substance or mixture is not available. Causes burns. (based on components). Ingestion causes burns of the upper digestive and respiratory tracts. May cause severe burning pain in the mouth and stomach with vomiting and diarrhea of dark blood. Blood pressure may decrease. Brownish or yellowish stains may be seen around the mouth. Swelling of the throat may cause shortness of breath and choking. May cause lung damage if swallowed. May be fatal if swallowed and enters airways. May cause additional affects as listed under "Inhalation".

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Redness. Burning. May cause blindness. Coughing and/ or wheezing. Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Itching. Rashes. Hives. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.
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Acute toxicity

Numerical measures of toxicity

Component Information			
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Benzalkonium Chloride 8001-54-5	= 240 mg/kg (Rat)	= 1420 mg/kg (rat)	-
Water 7732-18-5	90 mL/kg (Rat)	-	-
Ethyl Alcohol 200 proof 64-17-5	= 7060 mg/kg (Rat)	-	124.7 mg/L (Rat) 4 h
Benzyl Chloride 100-44-7	= 625 mg/kg (Rat)	-	= 0.74 mg/L (Rat) 2 h

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

Skin corrosion/irritation	Classification based on data available for ingredients. Causes burns.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Risk of serious damage to eyes. Causes burns.
Respiratory or skin sensitization	May cause sensitization by inhalation. May cause sensitization by skin contact.
Germ cell mutagenicity	No information available.
Carcinogenicity	Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.
The table below indicates whether each agency has listed any ingredient as a carcinogen.	

Chemical name	ACGIH	IARC	NTP	OSHA
Ethyl Alcohol 200 proof 64-17-5	-	Group 1 - Monograph 100E [2012] in alcoholic beverages Monograph 96 [2010] in alcoholic beverages	-	-
Benzyl Chloride 100-44-7	-	Group 2A - Probably Carcinogenic to Humans - Monograph 71 [1999] combined exposures to .alpha.-Chlorinated	-	-

		toluenes and Benzoyl chloride		
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Legend

Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child.
STOT - single exposure	May cause respiratory irritation. May cause drowsiness or dizziness.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Target organ effects	liver, respiratory system, Eyes, Skin, central nervous system, blood, Reproductive System.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Benzalkonium Chloride 8001-54-5	-	LC50: 0.223 - 0.46mg/L (96h, Lepomis macrochirus) LC50: 0.823 - 1.61mg/L (96h, Oncorhynchus mykiss) LC50: =1.3mg/L (96h, Poecilia reticulata) LC50: =2.4mg/L (96h, Oryzias latipes)	-	-
Ethyl Alcohol 200 proof 64-17-5	-	LC50: 12.0 - 16.0mL/L (96h, Oncorhynchus mykiss) LC50: 13400 - 15100mg/L (96h, Pimephales promelas) LC50: >100mg/L (96h, Pimephales promelas)	-	LC50: 9268 - 14221mg/L (48h, Daphnia magna) EC50: =10800mg/L (24h, Daphnia magna) EC50: =2mg/L (48h, Daphnia magna)
Benzyl Chloride 100-44-7	-	LC50: 4.4 - 5.6mg/L (96h, Pimephales promelas) LC50: =4mg/L (96h, Brachydanio rerio)	-	EC50: =1.3mg/L (24h, Daphnia magna)

Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Ethyl Alcohol 200 proof 64-17-5	-0.32
Benzyl Chloride 100-44-7	2.3

Other adverse effects	No information available.
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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.
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Contaminated packaging

Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

14. Transport information**DOT**

UN/ID no	UN2920
Proper Shipping Name:	Corrosive liquids, flammable, n.o.s.
Hazard class	8
Subsidiary Class	3
Packing group:	II
Special Provisions	B2, IB2, T11, TP2, TP27
Marine Pollutant	Severe Marine Pollutant
Description:	UN2920, Corrosive liquids, flammable, n.o.s. (Benzalkonium Chloride), 8 (3), II
Emergency Response Guide Number	132

TDG

UN-No:	UN2920
Proper Shipping Name:	Corrosive liquid, flammable, n.o.s.
Hazard class	8
Subsidiary Class	3
Packing Group:	II
Description:	UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride, Ethyl Alcohol 200 proof), 8 (3), II

MEX

UN-No	UN2920
Proper Shipping Name	Corrosive liquid, flammable, n.o.s.
Hazard class	8
Subsidiary Class	3
Special Provisions	274
Packing Group	II
Description	UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride), 8 (3), II

ICAO (air)

UN-No:	UN2920
Proper Shipping Name:	Corrosive liquid, flammable, n.o.s.
Hazard class	8
Subsidiary hazard class	3
Packing Group:	II
Description:	UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride, Ethyl Alcohol 200 proof), 8 (3), II

IATA

UN number	UN2920
Proper Shipping Name:	Corrosive liquid, flammable, n.o.s.
Transport hazard class(es)	8
Subsidiary hazard class	3
Packing group	II
Description:	UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride, Ethyl Alcohol 200 proof), 8 (3), II

IMDG

UN number	UN2920
Proper shipping name	Corrosive liquid, flammable, n.o.s.
Transport hazard class(es)	8
Subsidiary hazard class	3
Packing group	II
EmS-No	F-E, S-C
Special Provisions	274
Marine pollutant	P

Description UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride), 8 (3), II, (52°C c.c.), Marine pollutant

RID

UN number UN2920
Proper Shipping Name: Corrosive liquid, flammable, n.o.s.
Transport hazard class(es) 8
Packing group II
Classification code CF1
Special Provisions 274
Description: UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride, Ethyl Alcohol 200 proof), 8 (3), II, ENVIRONMENTALLY HAZARDOUS
Labels 8 + 3

ADR

UN number 2920
Proper Shipping Name: Corrosive liquid, flammable, n.o.s.
Transport hazard class(es) 8
Subsidiary hazard class 3
Packing group II
Classification code CF1
Tunnel restriction code (D/E)
Special Provisions 274
Description: 2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride, Ethyl Alcohol 200 proof), 8 (3), II, (D/E), ENVIRONMENTALLY HAZARDOUS
Labels 8 + 3

ADN

UN/ID No UN2920
Proper shipping name Corrosive liquid, flammable, n.o.s.
Transport hazard class(es) 8
Packing Group II
Classification code CF1
Special Provisions 274
Description UN2920, Corrosive liquid, flammable, n.o.s. (Benzalkonium Chloride, Ethyl Alcohol 200 proof), 8 (+ 3), II, ENVIRONMENTALLY HAZARDOUS
Hazard label(s) 8 + 3
Limited quantity (LQ) 1 L
ventilation VE01
Equipment Requirements PP, EP, EX, A

15. Regulatory information

International Inventories

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL Complies
EINECS/ELINCS Does not Comply
ENCS This product complies with ENCS:
IECSC This product complies with China:
KECL Complies
PICCS Complies
AICS All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

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

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

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

ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

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

Chemical name	SARA 313 - Threshold Values %
Benzyl Chloride - 100-44-7	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.

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Benzyl Chloride 100-44-7	100 lb final RQ 45.4 kg final RQ	-

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Ethyl Alcohol 200 proof - 64-17-5	developmental toxicity carcinogen
Benzyl Chloride - 100-44-7	carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethyl Alcohol 200 proof 64-17-5	0844	Present	Present
Benzyl Chloride 100-44-7	0217	Present	Environmental hazard

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 3

Flammability 2

Instability 0

Physical and chemical properties -

HMIS

Health hazards * 2

Flammability 2

Physical hazards 0

Personal protection X

Chronic Hazard Star Legend

* = Chronic Health Hazard

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

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

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

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

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

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

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

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

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

National Toxicology Program (NTP)

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

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

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

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

World Health Organization

Revision date

09-March-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
B1068	Benzalkonium Chloride Solution, 50 Percent, NF

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632

Spectrum-New Brunswick, NJ: 2246824

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

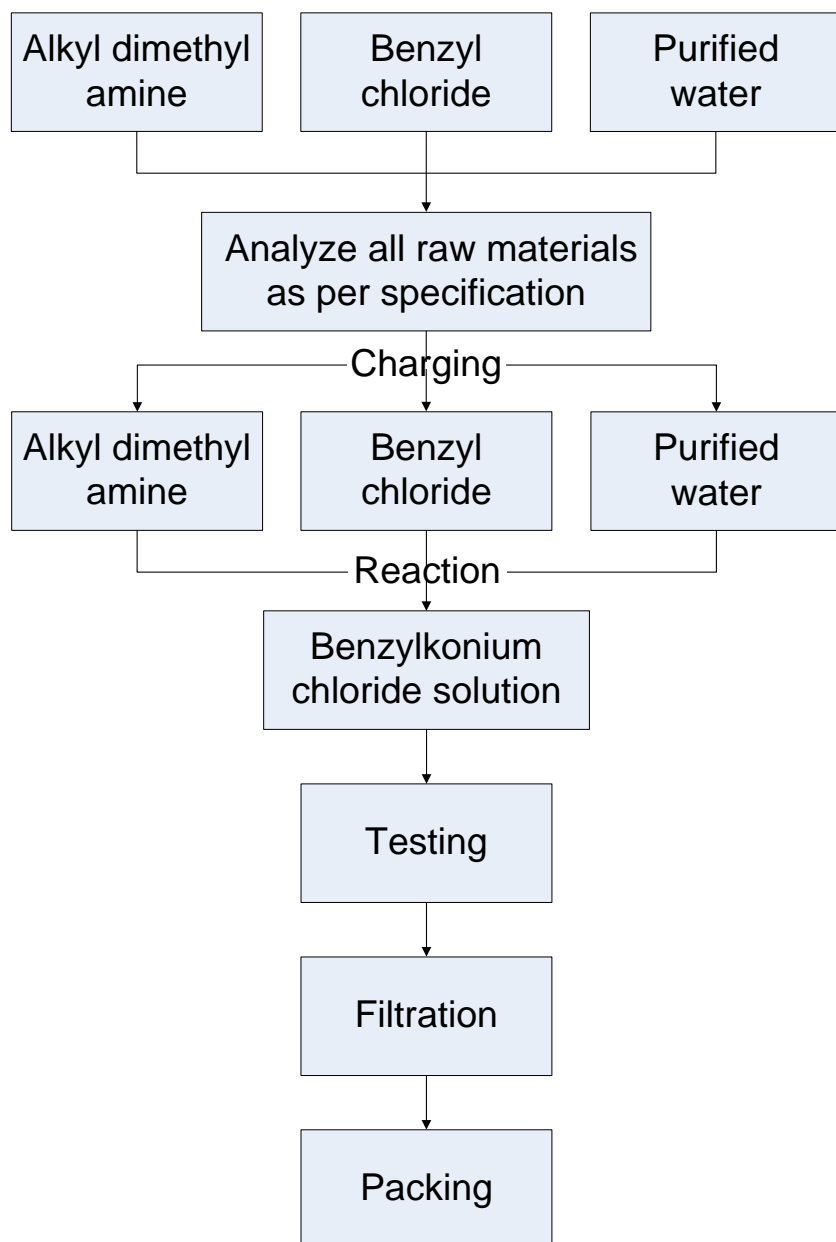
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart

Benzalkonium Chloride Solution, 50 Percent, NF - B1068



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

B1068, Benzalkonium Chloride Solution, 50 Percent, NF

Source Statement

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

BSE/TSE Statement

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

Allergen Statement

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

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

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

GMO Statement

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

Melamine Statement

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

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

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

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



RE: Elemental Impurities - Benzalkonium Chloride Solution, 50 Percent, NF (Cat# B1068)

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.

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



RE: Residual Solvents - Benzalkonium Chloride Solution, 50 Percent, NF (Cat# B1068)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Ethanol	3	< 10%*

*NF monograph requirement

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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Gardena, California 90248

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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.

A Retest Date: 03-31-2025

B **DANGER**

• Causes severe skin burns and eye damage • Flammable liquid and vapor • Harmful if swallowed • May cause an allergic skin reaction • May cause allergy or asthma symptoms or breathing difficulties if inhaled • Causes damage to organs through prolonged or repeated exposure • May damage fertility or the unborn child • May be harmful in contact with skin.

• Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Keep away from heat, sparks, open flames, hot surfaces • No smoking • Ground container and receiving equipment • Use explosion-proof equipment • Use only non-sparking tools • Take precautionary measures against static discharge • Do not eat, drink or smoke when using this product • Wear respiratory protection, eye protection, face protection, protective gloves, protective clothing • Do not breathe mist or vapors • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.

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 skin irritation or rash occurs: Get medical attention. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CENTER or physician. IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO₂ to extinguish.

L **KEEP FROM CHILDREN**

spectrum®
CHEMICAL MFG CORP

B1068 **D** **F** **4 L**

E **Benzalkonium Chloride Solution**

50%
NF

H **CAUTION:** For manufacturing, processing or repacking. Not for pesticide use.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2920, Corrosive liquid, flammable, n.o.s. (benzalkonium chloride solution), 8 (3), PG II

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

Components:

Benzalkonium Chloride..... CAS 8001-54-5
Water..... CAS 7732-18-5
Ethanol..... CAS 64-17-5

Assay 47.5-52.5%
Ratio of Alkyl Components..... To pass test
Limit of Amines and Amine Salts To pass test
Alcohol Content (v/v) ?%
Identification D..... To pass test
Acidity or Alkalinity To pass test

MAXIMUM LIMITS

Benzyl Alcohol..... 0.5%
Benzaldehyde..... 0.15%
(Chloromethyl)benzene..... 0.05%
Elemental Impurities As reported
Residual Solvents To pass test

WARNING: Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

W 17/J3GHS **A** **O** **M** Lot No. 062233

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

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