

# **Scientific Documentation**

# Chlorhexidine Gluconate Solution, BP

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





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# **Specification for Chlorhexidine Gluconate Solution, BP (CH126)**

Item Number	CH126		
Item	Chlorhexidine Gluconate Solution, BP		
CAS Number	18472-51-0		
Molecular Formula	$C_{22}H_{30}Cl_2N_{10}$ •2 $C_6H_{12}O_7$		
Molecular Weight			
MDL Number			
Synonyms			

Test	Specification		
	Min	Max	
ASSAY(C <sub>22</sub> H <sub>30</sub> Cl <sub>2</sub> N <sub>10</sub> .2C <sub>6</sub> H <sub>12</sub> O7; w/v)	19.0	21.0 %	
pH of a 20-fold dilution	5.5	7.0	
RELATIVE DENSITY	1.06	1.07 g/ml	
RELATED SUBSTANCES	TO PASS TEST		
CHLOROANILINE	TO PASS TEST		
ELEMENTAL IMPURITIES:			
LEAD (Pb)	AS REPORTED		
IDENTIFICATION	TO PASS TEST		
EXPIRATION DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS	TO PASS TEST		

## Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



# **Certificate Of Analysis**

Item Number	CH126	Lot Number	1NC0104
Item	Chlorhexidine Gluconate Solution, BP	Manufacturer Lot	401-100-166
CAS Number	18472-51-0	Manufacturer Code	3039
Molecular Formula	$C_{22}H_{30}Cl_2N_{10} \cdot 2C_6H_{12}O_7$		

TEST	SPECIF	ICATION	RESULT
IEST	MIN	MAX	RESULI
ASSAY(C <sub>22</sub> H <sub>30</sub> Cl <sub>2</sub> N <sub>10</sub> .2C <sub>6</sub> H <sub>12</sub> O7; w/v)	19.0	21.0 %	20.3 %
pH of a 20-fold dilution	5.5	7.0	6.7
RELATIVE DENSITY	1.06	1.07 g/ml	1.07 g/ml
RELATED SUBSTANCES	TO PASS TEST		PASSES TEST (M)
CHLOROANILINE	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES:			
LEAD (Pb)	AS REPORTED		<0.05 μg/g
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			01-JUN-2025
DATE OF MANUFACTURE			17-JAN-2024
APPEARANCE			CLEAR COLORLESS LIQUID
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm (M)
CLASS 3 (solvent) / 1-BUTANOL			<5000 ppm (M)
MONOGRAPH EDITION			(BP) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 08-APR-24 09:11:40

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 15-APR-24 09:17:14 All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

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

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

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Xttrium Laboratories, Inc. at 1200 E. Business Center Drive, Mount Prospect, Illinois (IL) 60056(USA). 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.





Revision date 27-May-2022 Revision Number 4

#### 1. Identification

**Product identifier** 

Product Name CHLORHEXIDINE GLUCONATE SOLUTION, BP

Other means of identification

Product Code(s) CH126

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

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

#### Hazards not otherwise classified (HNOC)

Not applicable

#### **Label elements**

#### Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Clear Physical state Liquid Odor Odorless

#### Other information

No information available.

## 3. Composition/information on ingredients

#### **Substance**

Not applicable.

#### Mixture

Chemical name	CAS No	Weight-%	Trade secret
Water	7732-18-5	79 - 81	*
Chlorhexidine Gluconate	18472-51-0	19 - 21	*

<sup>\*</sup>The exact percentage (concentration) of composition has been withheld as a trade secret.

## 4. First-aid measures

#### Description of first aid measures

**Inhalation** Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash skin with soap and water.

**Ingestion** Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

**Note to physicians** Treat symptomatically.

#### 5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media**Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge none.

Special protective equipment for Firefighters should wear self-contained breathing apparatus and full firefighting turnout

## 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

**Personal precautions** Ensure adequate ventilation.

Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**Pick up and transfer to properly labeled containers.

## 7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Sensitive to light. Store in light-resistant containers. Air sensitive. Keep container tightly

closed in a dry and well-ventilated place.

## 8. Exposure controls/personal protection

Control parameters

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or

level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other

recommended limit. At this time, the other relevant constituents have no known exposure

limits from the sources listed here.

**Appropriate engineering controls** 

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

**Eye/face protection** No special protective equipment required.

**Skin and body protection**No special protective equipment required.

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** Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid **Appearance** Clear

Color Colorless to pale yellow

Odor Odorless

**Odor threshold** No information available

**Property** Values\_ Remarks • Method

no data available None known pН None known Melting point / freezing point no data available Boiling point / boiling range 97 °C / 206.6 °F 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

No data available

None known

Upper flammability or explosive

limits

No data available

Lower flammability or explosive limits

No data available Vapor pressure Vapor density no data available 1.06 - 1.07 Relative density Soluble in water Water solubility Solubility(ies) no data available **Partition coefficient** No data available **Autoignition temperature** no data available **Decomposition temperature** 

None known None known no data available None known No data available None known

Other information

Kinematic viscosity

Dynamic viscosity

**Explosive properties** No information available **Oxidizing properties** No information available No information available Softening point No information available Molecular weight **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 recommended storage conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied. None known based on information supplied. Incompatible materials

Hazardous decomposition products None known based on information supplied.

## 11. Toxicological information

Information on likely routes of exposure

Inhalation Specific test data for the substance or mixture is not available.

Specific test data for the substance or mixture is not available. Eye contact

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

**Acute toxicity** 

**Numerical measures of toxicity** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	90 mL/kg (Rat)	-	-
7732-18-5	-		
Chlorhexidine Gluconate	= 2 g/kg (Rat)	-	-
18472-51-0			

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization

Germ cell mutagenicity

No information available. No information available. No information available.

No information available.

No information available. Reproductive toxicity

STOT - single exposure STOT - repeated exposure **Aspiration hazard** 

No information available. No information available. No information available.

Other adverse effects No information available.

Interactive effects No information available.

## 12. Ecological information

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

Persistence and degradability

**Bioaccumulation** 

No information available. Inherently biodegradable.

Other adverse effects No information available.

## 13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

## 14. Transport information

DOT

TDG not regulated

MEX not regulated

ICAO (air) not regulated

**IATA** not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

## 15. Regulatory information

#### **International Inventories**

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

**ENCS** This product complies with ENCS: **IECSC** This product complies with China:

KECL Complies

PICCS Does not Comply

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.

#### 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

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

## 16. Other information

NFPA

Health hazards 1 Flammability 0 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 1 Flammability 0 Physical hazards 0 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 27-May-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
CH126	Chlorhexidine Gluconate Solution, BP

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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

Quality Assurance Specialist

Order Clony



# CH126, Chlorhexidine Gluconate Solution, BP

## **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 18 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

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

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

- Parabens
- Pesticides
- Phthalates
- Preservatives



## RE: Elemental Impurities - Chlorhexidine Gluconate Solution, BP (Cat# CH126)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

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

<b>Elemental Impurity</b>		Class	Expected Concentration
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Vanadium	V	2A	< 10 ppm
Nickel	Ni	2A	< 20 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These 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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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 - Chlorhexidine Gluconate Solution, BP (Cat# CH126)

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
Methanol	2	< 3000 ppm
1-Butanol	3	< 5000 ppm

No Class 1 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.

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
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FAX 310.516.9843



## **Label Information**

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

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

**KEEP FROM CHILDREN** 

## **CH126** SIZ SY **Chlorhexidine Gluconate Solution**

BP

CAS 18472-51-0

CAUTION: For manufacturing, processing or repacking. Not for use as a preoperative skin preparation.

Read and understand the label and Safety Data Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

Repackaged by Spectrum as: Lot No. XO#### G 9/I6GHS-A

## Spectrum Chemical Mfg Corp

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