

Product Information

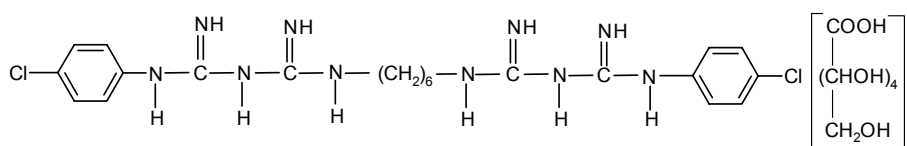
Spectradyne-G

The effective and mild antimicrobial.

Especially suited for use in preoperative scrubs, wound disinfection and wound protectants. Large body of literature existing to attest Chlorhexidine Gluconate's low toxicity. Clinical studies have shown low irritancy and low allergic reactions in humans.

1. Active matter

1,1'-Hexamethylene bis(5- (4-chlorophenyl)biguanide)digluconate



1.1	CAS No.:	18472-51-0
1.2	EINECS No.:	2423540
1.3	UN No.:	not applicable
1.4	INCI-Name:	Chlorhexidine Digluconate

2. Specifications

2.1	Description	almost colourless or pale-yellowish clear liquid,
2.2	Identification	
2.2.1	a) Test B	TLC
2.2.2	b) Test C	Mp of CHD
2.2.3	c) Test D	Cetrimide Test
2.2.2	b) TCL	TCL chromatogram conforms
2.3	pH	5.5 - 7.0
2.4	Relative density at 20°C	1.06 - 1.07
2.5	4-Chloroaniline	< 500 ppm
2.6	Related substances (HPLC)	< 3 %
2.7	Assay	19.0 - 21.0 % w/v of C ₂₂ H ₃₀ Cl ₂ N ₁₀ ·2C ₆ H ₁₂ O ₇
2.8	Declaration	PH EUR 3.97

3. Properties

3.1	Appearance	clear, water white to amber liquid
3.2	Odour	mild
3.3	Density (20°C)	1.06 - 1.07 g/cm ³
3.4	Water	80.0 % approx.
3.5	Ionogenicity	cationic
3.6	Solubility	soluble in water and in polar solvents, such as lower alcohols, glycols and other polyols

4. Registrations

4.1	Europe	European Inventory of Existing Chemical Substances (EINECS) Listed as a preservative for cosmetics on the EEC positive list (0.3 %, reference no. 42)
4.2	USA	Toxic Substances Control Act (TSCA) Inventory
4.3	Australia	Australian Inventory of Chemical Substances (AICS)
4.4	Japan	Approved by the MHW as a preservative for cosmetic uses.

5. Antimicrobial efficacy

5.1 BACTERIA

MIC values	ppm Spectradyne-G
GRAM POSITIVE	
Bacillus subtilis	1.4 – 3.0
Bacillus cereus	3.0
Bacillus megatherium	1.0
Clostridium welchii	70.0
Clostridium novyi	1.8
Clostridium tetani	7.0
Clostridium botulinum	3.5
Clostridium perfringens	14.0
Streptococcus pyogenes	0.6 5.0
Streptococcus faecalis	1.4 - 3.0
Streptococcus mutans	0.1
Streptococcus lactis	1.4
Streptococcus pneumoniae	7.0
Staphylococcus aureus	1.0 - 2.0
Staphylococcus albus	1.0
Staphylococcus epidermidis	5.0
Corynebacterium diphtheriae	5.0
Corynebacterium acne	10.0
Micrococcus luteus (Sarcina lutea)	2.0
Mycobacterium tuberculosis	0.7 - 6.0
GRAM-NEGATIVE	
Escherichia coli	1.0 - 5.0
Salmonella dublin	2.5 - 15.0
Salmonella typhi	1.6
Salmonella typhosa	2.5
Salmonella pullorum	7.0
Salmonella typhimurium	14.0
Shigella flexneri	1.5
Shigella sonnei	1.6
Klebsiella aerogenes	1.5 - 12.5
Klebsiella pneumoniae	6.2
Enterobacter cloacae	2.5 - 3.2
Proteus mirabilis	25.0 - 100.0
Proteus morgani	25.0 - 43.0
Proteus vulgaris	7.0 - 25.0
Proteus rettgeri	3.0 - 100.0
Pseudomonas fluorescens	10.0
Pseudomonas aeruginosa	3.0 - 60.0
Aeromonas aerogenes	12.5
Vibrio cholerae	7.0

5.2 YEASTS

MIC values	ppm Spectradyne-G
Candida albicans	7.0 - 15.0
Trichophyton mentagrophytes	2.5
Trychophyton tonsurans	14.0
Microsporum audouini	14.0
Microsporum gypseum	14.0
Microsporum canis	18.5
Saccharomyces ellipsoideus	< 50
Saccharomyces cerevisiae	< 50
Schizosaccharomyces octosporus	125
Schizosaccharomyces pombe	< 50

5.3 MOULDS

MIC values	ppm Spectradyne-G
Aspergillus versicolor	75
Aspergillus niger	< 200
Rhizopus nigricans	175
Trichoderma viride	125
Mucor plubeus	125
Penicillium notatum	200
Penicillium roqueforti	150
Sporendonemna spp.	< 50

6. Other investigations

Information available upon request.

7. Use areas

Preservative for cosmetics

Hospital Application

- Preoperative scrubs

- Wound disinfectants

- Wound protectants

- Disinfecting ointments in obstetrics

- Solution for bladder irrigation, catheter lubrication

- Sterile instrument storage

OTC Applications

- Toothpaste

- Gargle solutions

- Throat sprays

- Lozenges for treating mouth and throat infections

Veterinary Applications

- Teat Dip formulations

8. Recommendations to formulate

Incompatible with anionic surfactants.

9. Analytical procedure

TLC, IR

10. Packaging / Storage

Product is supplied in polyethylene drums holding 200 kgs net.

Spectradyne and its formulated products should be packaged in opaque containers and stored away from heat. If Spectradyne freezes, thaw material at room temperature and mix thoroughly to insure uniformity of the solution.

11. Regulatory information

refer to MSDS

12. Toxicological information

refer to MSDS

13. Ecological and ecotoxicological information

refer to MSDS

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