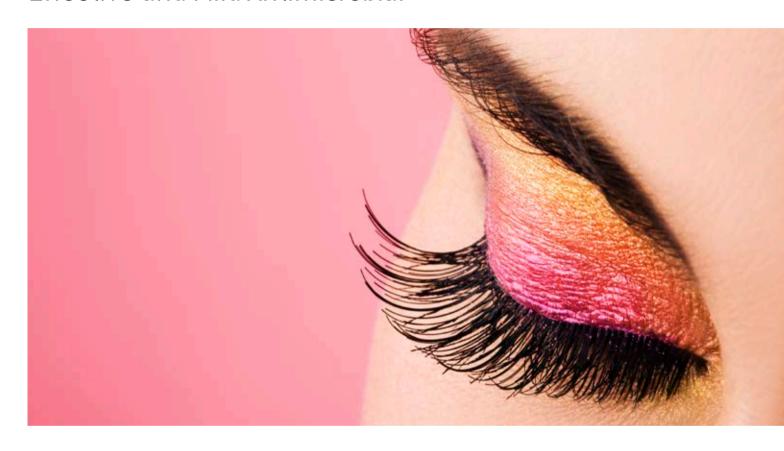




Spectradyne™

Effective and Mild Antimicrobial



INCI Name: Chlorhexidine Digluconate

Key Product Attributes

- In compliance with USP requirements
- Strong bactericide
- Not sensitizing
- Mild to skin
- Can be used in a variety of personal care applications

Recommended Use Level

0.25-1.50%

Chemical Compound Breakdown	CAS No.	EINECS No.
Chlorhexidine Digluconate	18472-51-0	242-354-0
Water	7732-18-5	231-791-2

Description

Spectradyne™ is a strong bactericide that can be used in a variety of personal care applications. It is extremely mild to skin and is non-sensitizing. Low use levels are required for an excellent effect in finished formulations.

Compositional Breakdown

Chemical Compound Breakdown	%
Chlorhexidine Digluconate	19-21%
Water	79–81%

Applications

- Baby care
- Baby wipes
- Body wash
- Conditioner
- Cream
- Deo/Anti-Perspirant
- Eye creams/gels
- Eye shadow
- Face lotion
- Face wipes
- Facial cream
- Foundation
- Hair gel
- Hand soap (non anti-bac)
- Lipstick/Gloss
- Lotion
- Makeup remover
- Mascara
- Oil in Water
- Oral Care
- Powder
- Shampoo
- Sun Care
- Toner
- Water in Oil

Efficacy

MICs were conducted on Spectradyne™ against bacteria, yeasts and molds with results displayed below

Gram-Negative	ppm Spectradyne™		
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		

Yeasts	ppm Spectradyne™		
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		

Gram Positive	ppm Spectradyne™		
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		

Molds	ppm Spectradyne™
Aspergillus versicolor	75
Aspergillus niger	< 200
Rhizopus nigricans	175
Trichoderma viride	125
Mucor plubeus	125
Penicillium notatum	200
Penicillium roqueforti	150
Sporendonemma spp.	< 50

Microbiological Challenge Studies

A study was run on a formula using a 0.4% concentration of Spectradyne™. The protocol used was a CTFA challenge test. All samples were inoculated at the beginning of the study, sampled at 24 hours, 7, 14, 21 and 28 days. The samples were diluted in neutralizer and plated quantitatively for viable organisms at all sampling times. After 28 days, all samples were re-inoculated and subjected to a second challenge.

Lotion

pH: 5-5.5

Phase (A)	%	Phase (B)	%
Water	qs	Hydroxyethylcellulose	1.5
Urea	5.00	_	_
Sorbitan Monostearate	2.00	_	
Caprylic/ Capric Triglyceride	20.00	_	
PEG 1750 Monostearate	1.50	_	
Glyceryl Monostearate	2.00	_	
Decaglycerol Decaoleate	5.00	_	_

Test Organism	Unpreserved Control			Test — Spectradyne™ (0.4%)				
	Initial Challe	enge		Rechallenge	Initial Chall	enge		Rechallenge
	24 Hrs	1 Week	28 Days	28 Days	24 Hrs	1 Week	28 Days	28 Days
S. aureus	1.4 x 10 ⁶	1.1 x 10 ⁶	< 10	8.0x 10 ¹	1.9x10²	<10	< 10	<10
K. pneumoniae + E. gergoviae	6.4 x 10 ⁵	7.1 x 10 ⁴	< 10	<10	5.3x10 ⁴	<10	< 10	<10
P. aeruginosa + B. cepacia	5.1 x 10 ⁵	1.2 x 10 ⁵	< 10	<10	<10	<10	< 10	<10
C. albicans	9.7 x 10 ⁴	5.0 x 10 ¹	< 10	<10	9.4 x 10 ⁴	1.4 x10 ²	<10	<10
Mixed Molds	9.0 x 10 ⁴	8.3 x 10 ⁴	2.3 x 10 ⁴	1.3 x 10 ³	1.4 x 10 ³	2.8 x 10 ²	7.0 x 10 ³	7.0 x 10 ¹

Formulation Recommendations

- Not for use at temperature > 70°C
- Effective at pH 5–8 (optimum between 5.5–6.5)
- Typically compatible with cationic and nonionic surfactants,
 although recommend to confirm compatibility in each specific
- Incompatible with anionic surfactants
- Not compatible with anionics including soaps, gums, carbomers
- Sensitive to inorganic substances (borate, carbonate, chloride, citrate, phosphate and sulfate)
- Can be affected by UV light
- Storage in a refrigerator is recommended

Global Regulatory

Europe

- Approved under Annex V to Regulation EC/1223/2009
- Max concentration of 0.3 % as expressed as chlorhexidine

Japan

- No limit for rinse-off products not coming into contact with mucous membranes
- 0.05 % maximum for leave-on products not coming into contact with mucous membranes
- 0.05 % maximum for products coming into contact with mucous membranes

US

- U.S. (CIR opinion) and Canada, max concentration of 0.2 %
- In compliance with USP requirements

Typical Properties	
Appearance	Liquid
Color	Clear, water white to amber
Odor	Mild

USA

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Switzerland

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