

Cosmetic and Drug Preservation

PRINCIPLES AND PRACTICE

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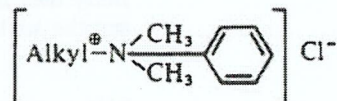
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EEC No.:	54
CAS No.:	139-07-1
Registered names:	Zephirol, Roccal, Dodigen 226, Barquat MB-50
Type of compound:	Quaternary (cationic) compound

1. Structure and Chemical Properties

Appearance:	White or yellowish white, amorphous powder, mostly in 50% solution; very bitter taste
Odor:	Aromatic odor
Solubility:	Very soluble in water (about 50%) and alcohols
Optimum pH:	4.0-10.0; 1% solution pH 6.0-8.0
Stability:	Good, stable at 121°C for 30 min
Compatibility and inactivation:	Incompatible with anionics, soap, nitrates, heavy metals, citrates, sodium tetraphosphate, sodium hexymetaphosphate, and oxidants, rubber, proteins, blood; adsorbed by plastic materials [2]

Structural formula:



Represents a mixture of the alkyls C₈H₁₇ to C₁₈H₃₇

Assay:	1. Gas chromatography [1] 2. Thin layer chromatography
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2. Antimicrobial Spectrum [3]

Test organisms (~10 ⁶ CFU/ml)	Minimal germicidal concentration (μg/ml) (suspension test)	
	24 hr	5 min
<i>Staphylococcus aureus</i>	4-10	50
<i>Escherichia coli</i>	10	80
<i>Klebsiella pneumoniae</i>	10	
<i>Pseudomonas aeruginosa</i>	10-100	200
<i>Pseudomonas fluorescens</i>	10-100	
<i>Pseudomonas cepacia</i>	10-100	

2. Antimicrobial Spectrum [3]
(Continued)

Test organisms ($\sim 10^6$ CFU/ml)	Minimal germicidal concentration ($\mu\text{g/ml}$) (suspension test)	
	24 hr	5 min
<i>Candida albicans</i>	10	160
<i>Aspergillus niger</i>	100-200	
<i>Penicillium notatum</i>	100-200	

Activation by addition of 0.1% EDTA sodium or nonionic detergents; reduced activity if pH <5.

3. Toxicity

Acute oral toxicity

Mouse: LD₅₀, 300 mg/kg
Rat: LD₅₀, 450-750 mg/kg

Subacute oral toxicity

Rat: Daily oral application of 550 ppm over 3 months without toxic effects.

Chronic toxicity

Rat: Dietary study with addition of 0.25% over 2 years showed no toxic effects.

Primary skin irritation:

0.1% solution shows no effect on the skin of animals and human volunteers; 0.5% caused irritation.

Rabbit eye irritation:

1:3000 dilution is tolerated.

Mutagenicity:

Negative Ames test

4. Cosmetic Applications

Hair conditioner with cationics; addition as preservative or antibacterial compound; eye preparations; EEC maximum, 0.5%; addition to deodorants (0.05-0.1%) and hair conditioners

5. Other Applications

Preoperative antiseptic for skin or for wounds, burns; disinfectants, technical germicide; preservative in pharmaceutical preparations; eyedrops, 0.01-0.1%

6. Suppliers

Onyx Chemical, Lonza Inc., Hoechst Corp.

7. References

1. H. Mitchner and E. C. Jennings, *J. Pharm. Sci.*, 56:1595 (1967).