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Preservative & Deodorizing Efficacy Across Broad pH Spectrum Formulations

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Presented by: Dr. Glenn Carroll/Marketing Manager
Written by: Tracey Ross/Sr. Research Scientist

Outline

1. Challenge for Preservatives

2. Strength of Cetyl Pyridinium Chloride (CPC)

3. Application Examples with CPC

4. Compatibility Considerations with CPC

Challenge for Preservatives

Necessity of Effective Preservatives

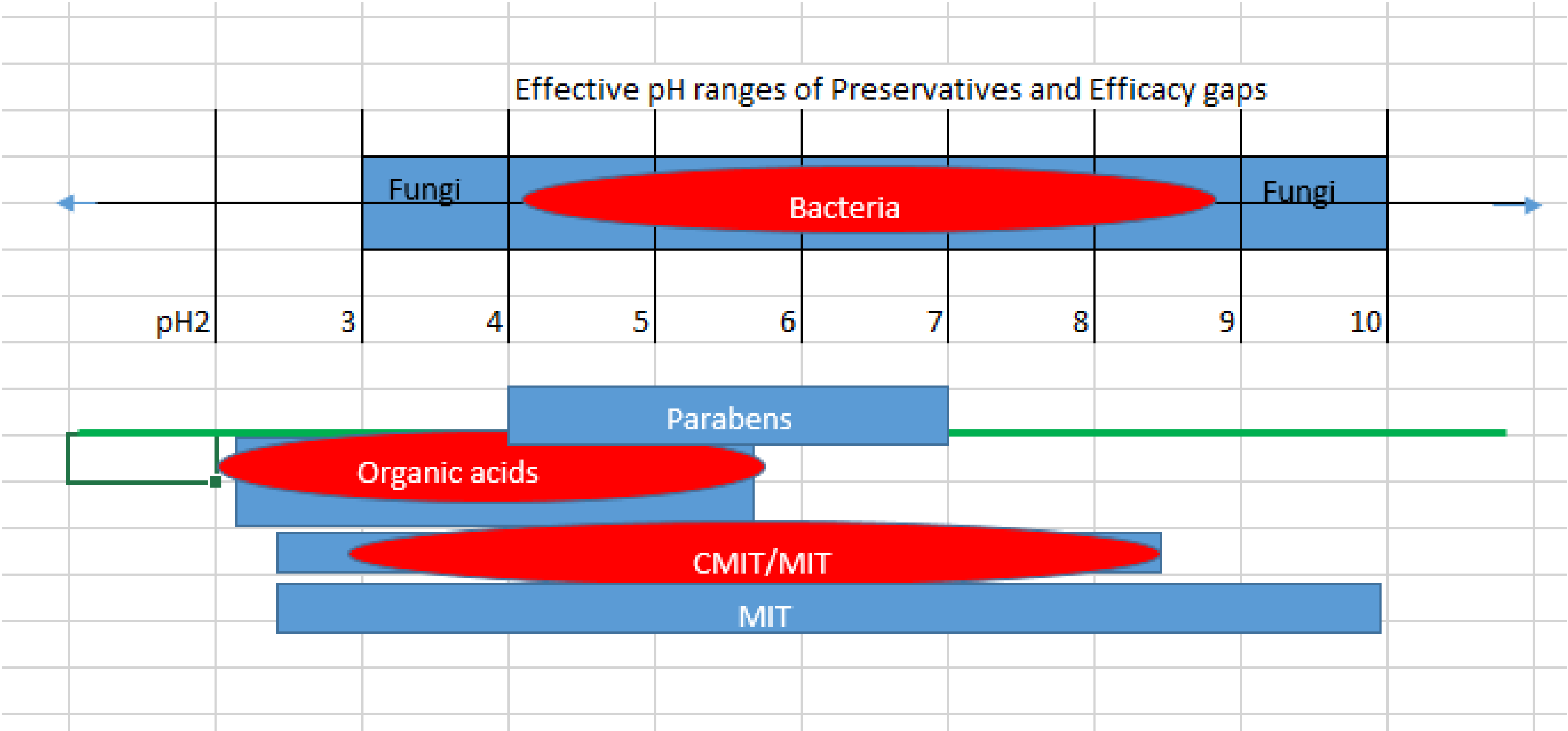
- Product preservation has become more complicated over the past decade.

- Pressure to replace conventional synthetic preservatives

- New trend of Preservative-Free or 'Free of' Claims
  - Free of Parabens
  - Free of Formaldehyde Doners
  - Free of Halogenated preservatives
  - Free of Isothiazolinones

- New trend towards more sustainable/natural materials

Challenges of Going "Green"



- Constraints on available/acceptable/robust preservatives limit the application to low pH ranges
- Increase in microbial spoilage/vulnerability of effectiveness

What Kills What?

No single preservative is equally effective against all types of microorganisms

Class	Active	Efficacy			
		Bacteria		Fungi	
		Gram +	Gram -	Yeast	Mold
Parabens	methyl,ethyl, propyl, butyl	▲	⬣	●	●
Phenolic	Phenoxyethanol	▲	●	⬣	⬣
Formaldehyde doners	DMDM Hydantoin	●	●	⬣	⬣
	Imidazolidinyl Urea	●	●	⬣	⬣
	Diazolidinyl Urea	●	●	▲	▲
Isothiazolinones	MIT	●	●	⬣	⬣
	CMIT	●	●	▲	●
Halogenated	IPBC	⬣	⬣	●	●
	Chlorphenesin	⬣	⬣	●	●
Acids	Benzoic, Sorbic, p-anisic	▲	▲	●	●
Organic alcohol	Benzyl Alcohol	●	⬣	▲	▲
Quats	BAK	●	▲	●	●
	Cetylpyridinium Chloride	●	●	●	●

● Strong Efficacy
▲ Moderate activity
⬣ Weak to None

Will replacing traditional preservatives create higher susceptibility of microbial contamination?

- Cosmetic products available on the market must be harmless to human health when applied under normal conditions of use.

- Preservatives are necessary to protect the consumer and protect the product before and during use.

What happens when bacteria and/or fungi propagate in the formula?

- Physical changes to the product (pH, viscosity, color, odor)
- Stability/Separation
- Degradation of actives
- Presence of visible microbial growth

For the Consumer:

- Possibility of eye and skin infections
- Over preservation potentially leads to more cases of cosmetic-related contact allergy.

Strength of Cetyl Pyridinium Chloride (CPC)

Cetyl Pyridinium Chloride (CPC) Product and Site Regulatory Info

FDA	CPC is on the proposed FDA Oral Care Monograph
FDA	CPC combined with Propylene Glycol approved by US FDA as a secondary direct food additive, for the treatment of poultry carcasses (21 CFR 173.375)
Drug Master File	8029
US EPA FIFRA Pesticide Registration	EPA Reg. No. 83402-1 (Technical Active Ingredient) EPA Reg. No. 83402-2 (End Use Product) EPA Est. No.: 83402-MI-001
cGMP	Yes, 21 CFR 210/211: Q7A
Food Safety system certification 22000	Zeeland, MI plant
Physical Forms	Dry powder, low-dusting, chilsonated solid, 40% in propylene glycol
Certificates	Certified Kosher, Halal
HRIPT	Up to 0.5% use level
REACH	REACH-registered
GMO Info	No genetically modified organisms used
Allergens	None allowed on site; allergen policy in place
Compendial (USP, EP, JP, BP)	USP, EP, BP
BSE Info	No animal origin materials used
Biodegradable	Will not persist in the environment

Preservative Efficacy Test Results

at various pH levels 0.1% CPC in water

pH tested: 2.85, 4.1, 4.7, 5.0, 5.5, 6.0, 7.0

Results shown as % Reduction of microorganisms

	Day 3	*Day 7*	*Day 14*	*Day 21*	*Day 28*
Staphylococcus aureus	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
Escherichia coli	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
Pseudomonas aeruginosa	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
Burkholderia cepacia	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
Candida albicans	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
Aspergillus brasiliensis	99.90%	>99.99%	>99.99%	>99.99%	>99.99%
Corynebacterium jeikeium	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%
Corynebacterium xerosis	>99.99%	>99.99%	>99.99%	>99.99%	>99.99%

0.1% CPC use level Passed Preservative Challenge Testing

***PCPC* method used in various chassis**

	.01% CPC in Water	0.1% CPC in Simple Non-ionic System	0.1% CPC in Simple Anionic System*	0.1% CPC in Simple Cationic System
PCPC Organisms				
Staphylococcus aureus	pass	pass	pass	pass
Escherichia coli	pass	pass	pass	pass
Pseudomonas aeruginosa	pass	Pass	pass	pass
Candida albicans	pass	pass	pass	pass
Aspergillus brasiliensis	pass	pass	*	pass
Other Organisms	pass	pass	pass	pass
Burkholderia cepacia	Not Tested	Not Tested	Not Tested	Not Tested
Corynebacterium jeikeium	Not Tested	Not Tested	Not Tested	Not Tested
Corynebacterium xerosis	Not Tested	Not Tested	Not Tested	Not Tested

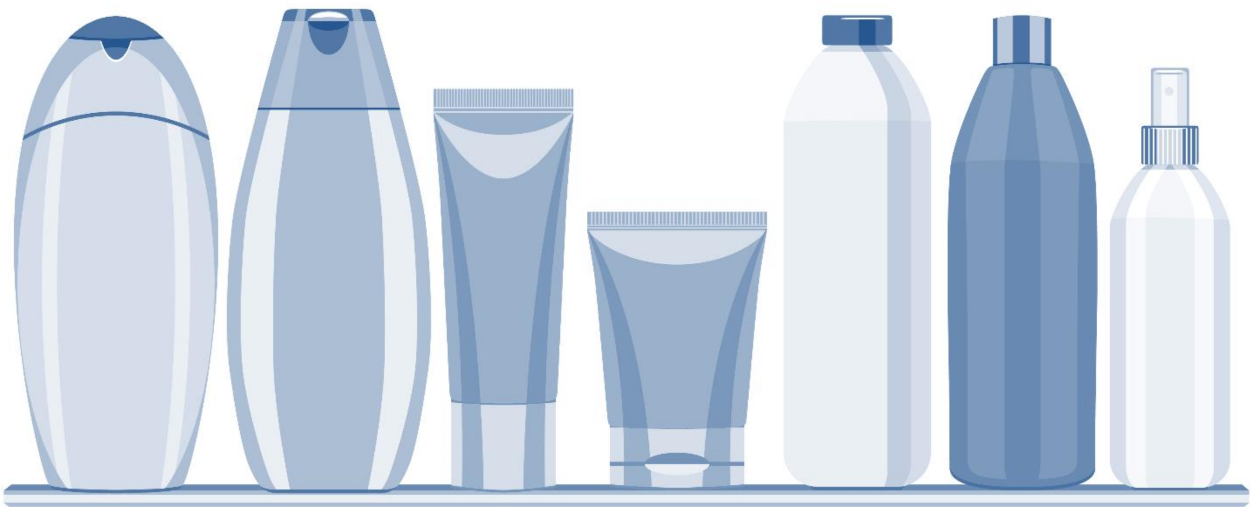
- Creams made with an ethoxylated alcohol, a fatty alcohol and esters
- Hair conditioners made with Cetyl alcohol and quats for conditioning
- Body washes made with SLES and CMPB
- * Failed for A.brasiliensis in this system

Application Examples with CPC

Common Applications

CPC might be used in systems that are mostly water with various pH's:

- Micellar Water - type cleanser
- Bi-Phase type Make-Up Removers
- Facial Toners
- Clear Hair Styling Gels
- AHA type peels and gels



CPC Is Effective

at inhibiting growth and reducing concentration of odor producing bacteria

Deodorant applications Test Results (PCPC Method)

Results represent percent reduction of bacteria at day 1, 7, 14, 21 and 28

Odor causing bacteria	0.068% CPC in 10% SLES	0.15% CPC in a Thin Emulsion Spray	0.15% CPC in a ClearGel Stick	0.2% CPC in a Roll on	
Corynebacterium jeikeium	>99.9%	>99.9%	>99.9%	>99.9%	
Corynebacterium xerosis	>99.9%	>99.9%	>99.9%	>99.9%	

3-log reduction of bacteria = >99.9% reduction

- When used in a "soap" based product, CPC enhances the effect of washing and aid in the reduction of odor
- When used in a deodorant formulation (no AP active), CPC provides additional reduction of odor

Time Kill Studies against Odor Causing Bacteria

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Hydro-Alcohol Gel with 25% Ethanol + 0.2% CPC

	% Reduction of Organisms			
	30s	**60s**	**5 min**	
Negative Control 25% ETOH	28%	46%	99.99%	
Corynebacterium jeikeium	99.97%	>99.99%	>99.99%	with CPC

Improved efficacy with CPC allows the percentage of Ethanol to be lower in the formulation. Residual CPC can improve long term bacterial inhibition for deodorancy

Make Up Remover Wipe Base

PET Comparative results with Freshstat vs PE + EHG

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Ingredients	1	2
Make Up Remover Wipe Base	99.65	98.90
Phenoxyethanol (and) Ethylhexylglycerin		1.00
CPC (and) Propylene Glycol	0.25	
Chelator	0.10	0.10
Total	100.00	100.00

CPC has Better Performance against Mold vs PE + EHG

Organism	**CPC** with Chelator				PE + EHG with Chelator				**CPC** /No Chelator			
	Day 7	Day 14	Day 21	Day 28	Day 7	Day 14	Day 21	Day 28	Day 7	Day 14	Day 21	Day 28
S. aureus	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99
E. coli	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99
P. aeruginosa	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99
C. albicans	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99	>99.99
A.brasiliensis	99.9	>99.99	>99.99	>99.99	***NR**	**60.77**	**71.54**	**66.92**	99.9	>99.99	>99.99	>99.99

Results Reported in % Reduction of Microorganisms: >99.99% kill = 3 log reduction of bacteria (PASS)
>90.0% kill = 1 log reduction of fungi (PASS)
*NR = No Reduction

Compatibility Considerations with CPC

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CPC Compatibility with PC Raw Materials

Compatible with

- ✓ **Cellulose Gums: category non-ionic**
  - Hydroxypropyl Methylcellulose
  - Hydroxyethylcellulose
  - Hydroxypropylcellulose
  - Guar Hydroxypropyltrimonium Chloride
  - Hydroxypropyl Guar

- ✓ **Polymeric Emulsifiers:**
  - Sodiumpolyacrylate
  - Polyacrylate Crosspolymer-6
  - Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer-Isohexadecane-Polysorbate-60
  - Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer-Polyisobutene-PEG-7 Trimethylpropane Coconut Ether
  - PVM/MA Decadiene Crosspolymer

- ✓ **Other Polymers:**
  - PVP
  - Corn Starch Modified

CPC Compatibility

May have incompatibilities with some anionic raw materials

✓ Anionic stabilizers used in O/W systems

- Xanthan Gum (anionic) in large amounts, small amounts ok
- Acacia Senegal Gum (anoionic) in large amounts, small amounts ok
- Acrylates/C10-30 Alkyl Acrylate Crosspolymer*****
- Carbomer*****
- Dehydroxanthan Gum

✓ Clays

- Hectorite
- Bentonite
- Magnesium Aluminum Silicate
- Smectite
- Laponite

*Homogenization is needed

**compatibility cannot be predicted based on its individual ingredients alone. It must be established by process of the complete formulation and formulation type.

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