Personal Care

Lonza

Consumer Care

Cosmocil CQ™

Broad Spectrum, Fast-Acting Bactericide

INCI Name: Polyaminopropyl Biguanide
SAP Code#: 137260

Key Product Benefits

- Clear, colorless, highly water-soluble
- Remains in the aqueous phase
- Broad spectrum of activity
  - High activity vs. tough Gram (negative) organisms e.g. Pseudomonas
- Chemically stable and non-volatile
  - Zero VOC
  - Greater than two year storage stability
  - Effective and stable over a broad pH range (4-10)
  - Active agent heat stable to >140°C
  - UV stable
  - Odorless, non-foaming, clear and colorless
- Has a wide range of global regulatory acceptance
- Ease of formulation
- Positive aesthetics
  - Non-sticky feel on the skin
  - No smell; no taste; non-staining

Recommended Use Level

0.2 - 1.5%

Description

Cosmocil CQ™ is a broad spectrum, fast acting bactericide. A 20% aqueous solution of poly(hexamethylenebiguanide) hydrochloride, also known as PHMB, Cosmocil CQ™ is an effective preservative for personal care formulations and offers antibacterial and deodorant properties. Cosmocil CQ™ is effective against a wide range of both Gram-positive and Gram-negative bacteria, such as *Staphylococcus aureus* and E. coli 0157, antibiotic resistant bacteria such as MRSA (methicillin resistant *Staphylococcus aureus*) and VRE (vancomycin resistant *Enterococcus*) and odor-causing bacteria.

Compositional Breakdown

Chemical Compound Breakdown	CAS No.	EINECS
Water	7732-18-5	231-791-2
Polyaminopropyl Biguanide	133029-32-0 / 27083-27-8	Not assigned

Chemical Compound Breakdown	%
Water	79.0 - 81.0%
Polyaminopropyl Biguanide	19.0 - 21.0%

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)
- Liptick/gloss
- Lotion
- Make-up remover
- Mascara
- Oil in Water
- Oral care (as preservative, not the active)
- Powder
- Shampoo
- Suncare
- Toner
- Vaginal (exterior)
- Water in Oil

Efficacy

Microbiological Challenge Studies

Studies were run on three formulas using a 1.5% concentration of Cosmocil CQ™. 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.

Make-Up Remover

pH: 6.02
% water: 88.5%; Aw: n/a

Ingredient	%
Deionized Water	q.s. to 100%
Propylene Glycol	2.00%
Glycerin	2.00%
Plantaren 4	4.00%
PEG-8	2.00%

Test Results

Colony Forming Units per Gram (CFU/g)

Test Organism	Unpreserved Control				Test-Cosmocil CQ™ (1.5%)			
	Initial Challenge			Re challenge	Initial Challenge			Re-challenge
	24 hrs	7 days	28 days	28 days	24 hrs	7 days	28 days	28 days
S. aureus	*	*	*	ND	<10	<10	<10	<10
P. aeruginosa	*	*	*	ND	<10	<10	<10	<10
K. pneumoniae	*	*	*	ND	<10	<10	<10	<10
C. albicans	*	$1.7x10^3$	$2.7x10^3$	$1.8x10^3$	<10	<10	<10	<10
A. niger + *Penicillium sp.*	$2.7x10^4$	$1.4x10^3$	$1.7x10^2$	$1.2x10^4$	$2.0x10^1$	$4.0x10^1$	<10	<10

** Unpreserved formulation highly contaminated prior to start of test (>10) so unable to count the challenge organisms, however, addition of Cosmocil CQ™ killed this contamination and the challenge organisms.*
ND = Not determined

Mascara

pH: 5.2
% water: 91.5%; Aw: n/a

Ingredient	%
Water	q.s. to 100
Jaguar	C 1.00
Glycerin	2.00
Honeyquat 50	1.00
Musol 20	1.00
Brookosome P	2.00

Test Results

Colony Forming Units per Gram (CFU/g)

Test Organism	Unpreserved Control				Test-Cosmocil CQ™ (1.5%)			
	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	7 days	28 days	28 days	24 hrs	7 days	28 days	28 days
S. aureus	$2.0x10^6$	**	$5.4x10^6$	$7.8x10^5$	<10	<10	<10	<10
P. aeruginosa	$2.7x10^5$	**	$<10^7$	$<10^8$	<10	<10	<10	<10
K. pneumoniae	$7.9x10^5$	**	$3.7x10^5$	$3.4x10^6$	<10	<10	<10	<10
C. albicans	$2.9x10^5$	$2.1x10^6$	$8.5x10^7$	$3.9x10^6$	<10	<10	<10	<10
A. niger + *Penicillium sp.*	$2.7x10^4$	**	**	$1.7x10^4$	<10	<10	<10	<10

*** Heavy yeast contamination*

Non-Ionic Emulsion

pH: 5.1
% water: 68%; Aw: n/a

Ingredient	%
Phase A	
Deionized Water	q.s. to 100%
Glycerin	5.00%
Phase B	
Brookswax D	4.50%
GMS 165	4.00%
Mineral Oil	15.00%

Test Results

Colony Forming Units per Gram (CFU/g)

Test Organism	Unpreserved Control				Test-Cosmocil CQ™ (1.5%)			
	Initial Challenge			Rechallenge	Initial Challenge			Rechallenge
	24 hrs	7 days	28 days	28 days	24 hrs	7 days	28 days	28 days
S. aureus	$5.9x10^6$	$5.5x10^4$	***	***	<10	<10	<10	<10
P. aeruginosa	$4.2x10^6$	$7.3x10^6$	$3.3x10^6$	$3.6x10^6$	<10	<10	<10	<10
K. pneumoniae	$6.3x10^6$	$5.2x10^6$	$6.3x10^5$	$3.4x10^5$	<10	<10	<10	<10
C. albicans	$1.2x10^6$	$1.3x10^6$	$1.4x10^6$	$3.1x10^5$	<10	<10	<10	<10
A. niger + *Penicillium sp.*	$1.4x10^5$	$1.9x10^5$	1.7	$1.9x10^5$	$2.4x10^4$	$1.6x10^3$	$1.2x10^2$	$1.0x10^1$

**** Heavy mold contamination*

Additional Information

Mode of Action

As a biguanide, Cosmocil CQ™ can be classified according to its mode of action as a membrane-active compound. As such, Cosmocil CQ™ is either bacteriostatic or bactericidal depending on the concentration, and unlike antiobiotics, there is no risk of organism resistance developing. The antimicrobial effect of Cosmocil CQ™ can be described by the following sequence:

1. Rapid attraction towards the bacterial surface
2. Binding to a receptive site on the surface
3. Overcoming bacterial defense/exclusion mechanisms
4. Attraction towards the cytoplasmic membrane
5. Leakage of low molecular weight cytoplasmic components and inhibition of membrane-bound enzymes
6. Extensive disruption of cytoplasmic membrane and leakage of macromolecular components
7. Precipitation of cell contents

Global Regulatory

Europe

- Polyaminopropyl biguanide is listed on the Annex V to Regulation EC/1223/2009 – formerly Annex VI to Council Directive 76/768/EEC relating to preservatives for use in cosmetic products
- Max authorized use level of 1.5% Cosmocil CQ™ (0.3% PHMB) as a preservative

Japan

- Approved by the Japanese Pharmaceutical and Food Safety Bureau and added to their positive list of preservatives (10/05). The Japanese approval covers all categories of cosmetic products (leave-on, rinse-off and mucous contact) at a maximum dosage of 0.1% (1000 ppm) active or 0.5% of Cosmocil CQ™
- Outside Japan, current users of Cosmocil CQ™ may continue to use this product at the conventional 1.5% level

United States

- Allowed for Personal Care Products (Industrial usage by EPA)

General

- PHMB is supported under the review program established by the Biocidal Products Directive 98/8/EC for use in Product Type 1 (Human Hygiene products) as well as 7 other product types. Arch Biocides (a subsidiary of Lonza)is the only participant with a complete dossier under the review program.

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Formulation Recommendations

- Cosmocil CQ™ can be formulated with certain acidic preservatives to enhance antifungal activity
  - 0.6% Sorbic Acid
  - 0.5% Benzoic Acid
  - 0.3% Salicylic Acid
  - 0.3% Anisic Acid
  - 1.0% D-gluconolactone.
  - Compatibility is formulation dependent
- Active agent (PHMB) is cationic (like QACs)
- Positive charge is delocalized (unlike QACs)
- Active agent is highly water-soluble
- pH: 3-8
- Multiple binding sites per molecule
- Compatible with non-ionic, cationic and amphoteric surfactants
- Compatibility varies with anionic surfactants

Typical Properties	
Appearance	Slightly opalescent liquid
Color (Gardner)	Colorless to slightly pale yellow
Odor	Characteristic

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