



# Impatto dei nuovi sistemi conservanti sulle formulazioni

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22 Nov 2016 - MiCo - Milano Congressi  
3rd Formulating Cosmetics and Making Cosmetics  
<http://www.making-cosmetics.it>



Scopo della ricerca riguarda l'efficacia antimicrobica di sistemi di preservanti, includendo molecole multifunzionali per ottenere un giusto equilibrio e per garantire la sicurezza microbiologica di una formulazione cosmetica.

### **REGULATION (EC) No. 1223/2009**

**Annex I** Cosmetic Product Safety Report

**Annex II** List of Prohibited substances

**Annex III** List of Restricted substances

**Annex IV** List of colourants

**Annex V** List of Preservatives

**Annex VI** List of UV-filters

**Annex VII** Symbols used on packaging/container

**Annex VIII** List of validated alternative methods to animal testing

**Annex IX**

**Part A** Repealed Directive with its successive amendments

**Part B** List of time-limits for transposition into national law and application

**Annex X** Correlation table between Directive 76/768/EEC and Regulation (EC) No 1223/2009

### **THE SCCS NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 9th revision**

The SCCS adopted this guidance document at its 11th plenary meeting of 29 September 2015

1 [http://ec.europa.eu/health/scientific\\_committees/docs/rules\\_procedure\\_2013\\_en.pdf](http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2013_en.pdf)

2 [http://ec.europa.eu/health/scientific\\_committees/experts/database/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/experts/database/index_en.htm)

3 [http://ec.europa.eu/health/scientific\\_committees/open\\_consultation/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/open_consultation/index_en.htm)

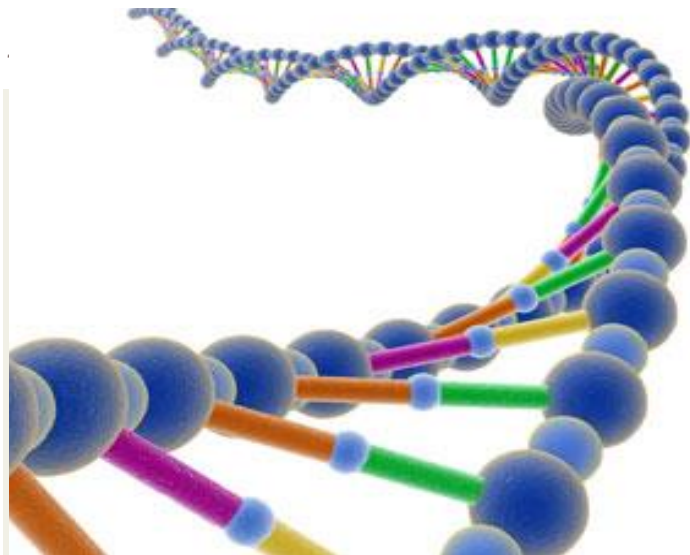
4 [http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/requests/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/requests/index_en.htm)

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## CDVtox (grado di inquinamento nell'ambiente)

Benzyl alcohol	23,15
5-bromo-5-nitro-1,3-dioxane	2083333,33
Guanidine, hexamethylene-, homopolymer	694444,44
CMI + MIT in mixture 3:1 (§)	730994,15
Methyldibromoglutaronitrile	55555,56
e-phtaloimidoperoxyhexanoic acid	1412429,38
Methyl-, Ethyl- and Propylparaben	2705,63
o-Phenylphenol	9057,97
Sodium benzoate	65,10
Sodium hydroxy methyl glycinate	22831,05
Sodium Nitrite	19157,09
Triclosan	1207729,47
Phenoxy-ethanol	4,17



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 A woman's face with elaborate gold glitter makeup around her eyes and on her cheeks. The background is dark with pink bokeh lights.

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Una forma d'inquinamento molto frequente è indotta dal consumatore, che utilizza e conserva i **cosmetici in modo improprio e senza le opportune cautele igieniche**.

È importante quindi che il cosmetico a rischio (matrici formulative complesse, alto contenuto in acqua, sostanze particolarmente inquinabili) sia opportunamente protetto con un sistema conservante controllato e sottoposto alle prove di verifica (Challenge test) che ne predicono la resistenza all'inquinamento durante l'uso.



- *Regulation (EC) No 1223/2009 (the “Cosmetic Products Regulation”), replaced the European Union (EU) Cosmetics Directive 76/768/EEC, which harmonizes and simplifies the cosmetics regulations across the EU member states by Product Information File (PIF).*
- *COLIPA Guidelines “Product Information File (PIF)”- December 15<sup>th</sup> 2011.*
- *ISO (International Organization for Standardization) 11930:2012.*



I conservanti più diffusi sono:

Fenossietanolo

Esteri dell'acido p-idrossibenzoico

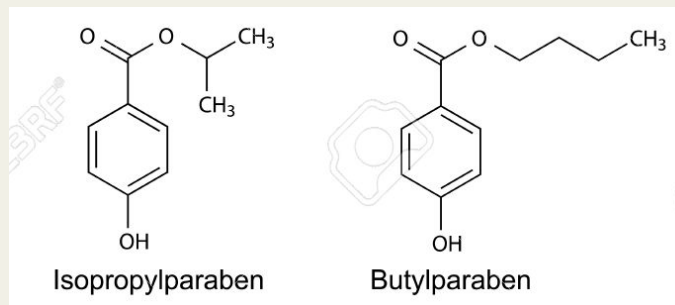
(Methylparaben, Ethylparaben, Propylparaben, **Isobutylparaben**, **Buthylparaben**)

Imidazolidinilurea

Isotiazolinone e i suoi derivati (Isothiazolinon, Methylisothiazolinon, Methylchloroisothiazolinon)

Metildibromoglutaronitrile

Acido sorbico, acido deidroacetico, acido benzoico, clorofenoli



- Dony J. "Effetto antimicrobico dei conservanti nei cosmetici" dal convegno Colloqui Biotossicologie et Observation des Produits Cosmetiques-Knokke-Heist, (19-21 Marzo 1984) 42-46.

Un altro parametro da considerare è quello legato alla quantità di acqua presente nel prodotto, tenendo conto della differenza tra contenuto di acqua totale e l'acqua a disposizione nota come attività dell'acqua ( $a_w$ ) che viene facilmente utilizzata dai microrganismi per la loro crescita.



Quantità di acqua disponibile che per la crescita dei batteri è 0,94-0,99 di  $a_w$  , per i lieviti  $>0.70 a_w$  e per le muffe  $>0.6 a_w$ .

Il valore dell' acqua disponibile necessaria per la crescita dei patogeni è: 0,77 di  $a_w$  per l'*Aspergillus niger*, 0,86 di  $a_w$  per lo *Staphylococcus aureus*, 0,95  $a_w$  per *Escherichia Coli*, 0,97  $a_w$  per lo *Pseudomonas aeruginosa* e 0,87 di  $a_w$  per la *Candida albicans*.

Una valida strategia formulativa quella di ridurre la quantità di acqua BIO-disponibile al fine di limitare l'uso di sostanze conservanti.

- D. Steinberg, Steinberg & Associates “Effective Vs Ineffective preservation using water activity” *Cosmetics & Toiletries*-January 4', 2011.

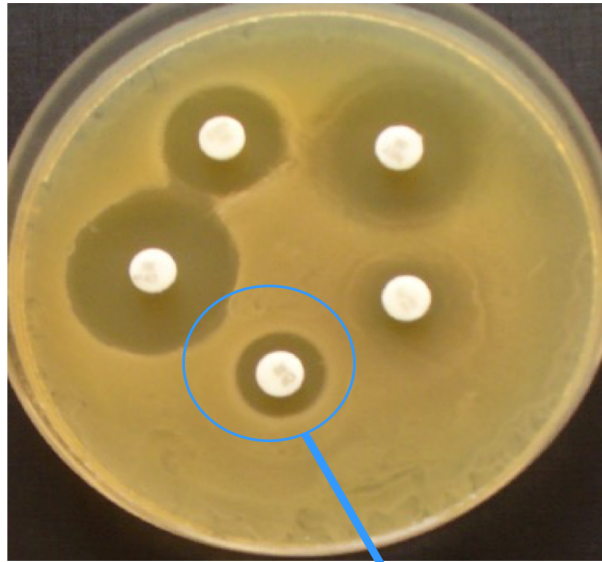


Conservante A	Ethylhexylglycerin
Sistema conservante B	Phenoxyethanol; Caprylyl Glycol
Sistema conservante C	Phenoxyethanol; Caprylyl Glycol; Decylene glycol
Sistema conservante D	Phenethyl Alcohol; Caprylyl Glycol; Propanediol in miscela di Polyglyceryl-4 e Polyglyceryl-6
Sistema conservante E	Methylpropanediol /Caprylyl Glycol / Phenylpropanol
Sistema conservante F	Caprylhydroxamic acid / Propanediol
Sistema conservante G	Triethyl Citrate / Caprylyl Glycol / Benzoic Acid
Sistema conservante H	Phenoxyethanol / Ethylhexylglycerin / Caprylyl glycol

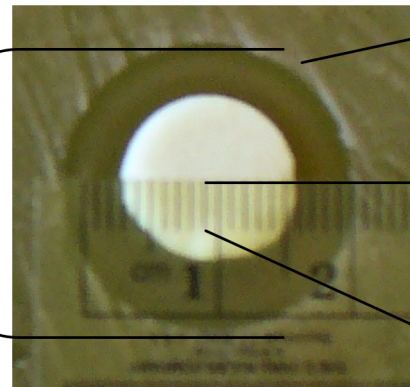
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22-23  
November 2016

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Making Cosmetics

Piastra Petri con dischetti a diverse concentrazioni di sostanza ad attività antibatterica:



Diametro dell'alone di inibizione



Prato o coltura batterica

Dischetto di carta Wathman sterile

Righello per misura alone di inibizione

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22-23  
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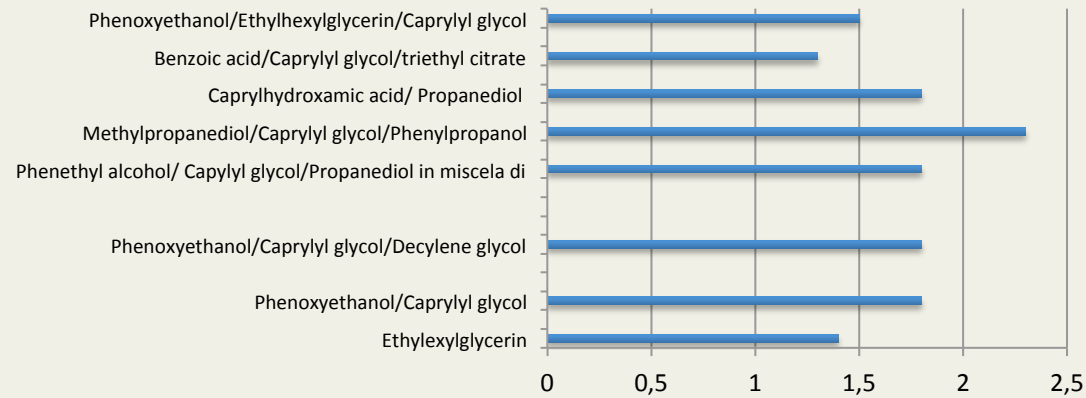
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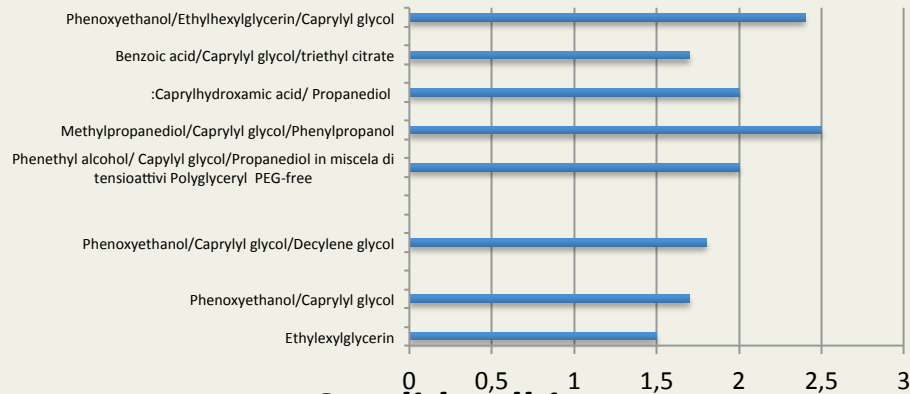
A vertical banner with a black background. At the top, it says "MiCo, Milano, Italy" and "22-23 November 2016". Below this is a photograph of a woman's face with elaborate, colorful cosmetic makeup. At the bottom, there are two logos: "Formulating Cosmetics" and "Making Cosmetics", both in pink and white text.



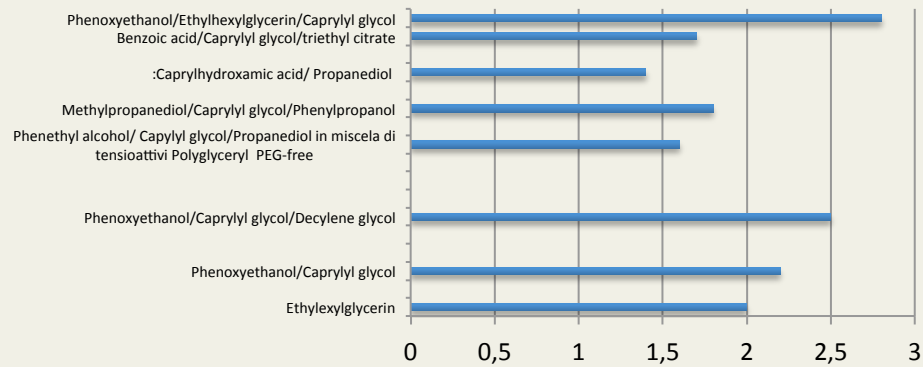
## Staphylococcus aureus



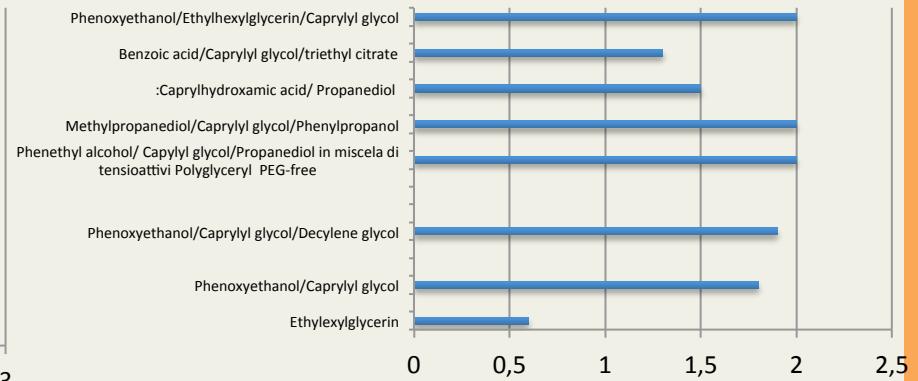
## Escherichia coli



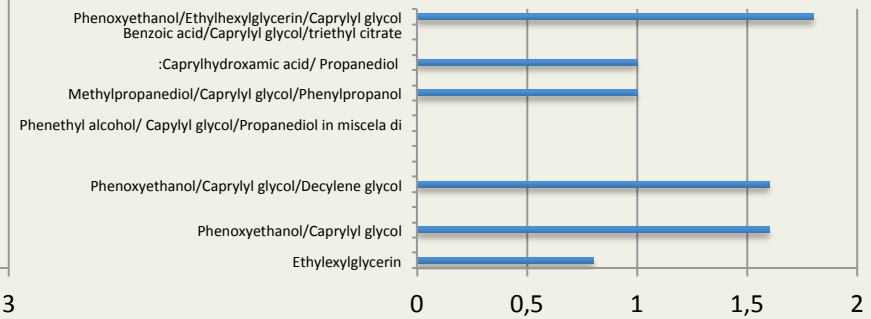
## Candida albicans



## Pseudomonas aeruginosa



## Aspergillus brasiliensis



## Latte Detergente (INCI della formulazione base senza conservanti)

### Ingredients:

Aqua, Hydrogenated Polyisobutene, C14-22 Alcohols, Caprylic/Capric Triglyceride, Triethylhexanoin, Ethylhexyl Stearate, **Glycerin, Propylene Glycol, Propanediol**, Peg-7 Glyceryl Cocoate, Poloxamer 184, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, C12-20 Alkyl Glucoside, Squalane, Parfum, Polysorbate 60, **Disodium EDTA**, Hydroxypropyl Cyclodextrin, Triethanolamine, Hydrolyzed Soy Protein, Hexyl Cinnamal, Malva Sylvestris Leaf Extract, Mel Extract, Linalool, Limonene, Sodium PCA, Salvia Officinalis Extract, Sodium Hyaluronate.



- Prova 1: *Phenoxyethanol/Caprylyl glycol/Decylene glycol 1%*
- Prova 2: *Methylpropanediol/Caprylyl glycol/Phenylpropanol 3%*
- Prova 3: *Benzoic acid/Caprylyl glycol/triethyl citrate 1%*
- Prova 4: **Caprylhydroxamic acid/ Propanediol 1%**
- Prova 5: **Caprylhydroxamic acid/ Propanediol 1,5% + Phenoxyethanol/ Caprylyl glycol 0,5%**
- Prova 6: *Caprylhydroxamic acid/ Propanediol 1,5% Ethylhexylglycerin 0,25%*
- Prova 7: *Phenethyl alcohol/ Caprylyl glycol/Propanediol / Polyglyceryl 1,5%*
- Prova 8: **Phenoxyethanol 0.8% Ethylhexylglycerin 0.5% Caprylyl Glycol 0.1%**

A vertical banner with a black background. At the top, it says 'MiCo, Milano, Italy' in white. Below that is '22-23' in large white numbers, and 'November 2016' in white. The center features a woman's face with gold and pink makeup. At the bottom, there are two logos: 'Formulating Cosmetics' and 'Making Cosmetics', both in pink and white. The banner is flanked by orange and green vertical bars.

## CHALLENGE TEST:

### METODO ISO 11930:2012 DELL'EFFICACIA PRESERVANTE

#### SCOPO

Verificare “*in vitro*” l'efficacia del sistema di conservazione e, quindi, la stabilità microbiologica di formulazioni cosmetiche entro un determinato intervallo di tempo, in base al Regolamento Europeo 1223/2009.

Il Challenge test è eseguito secondo il metodo *ISO* (International Organization for Standardization) 11930:2012.

#### CRITERI DI ACCETTABILITÀ: CRITERIO A e B METODO ISO 11930:2012

Il campione in esame deve presentare attività inibente nei confronti dei microrganismi utilizzati secondo i criteri di accettabilità secondo i criteri di accettabilità del metodo ISO come riportato nella tabella B.1:

Table B.1 — Evaluation criteria

Micro-organisms	Log reduction values ( $R_x = \lg N_0 - \lg N_x$ ) required <sup>a</sup>							
	Bacteria			<i>C. albicans</i>			<i>A. brasiliensis</i>	
Sampling time	T7	T14	T28	T7	T14	T28	T14	T28
Criteria A	≥3	≥3 and NI <sup>b</sup>	≥3 and NI	≥1	≥1 and NI	≥1 and NI	≥0 <sup>c</sup>	≥1
Criteria B	Not performed	≥3	≥3 and NI	Not performed	≥1	≥1 and NI	≥0	≥0 and NI

<sup>a</sup> In this test, an acceptable range of deviation of 0,5 log is accepted (see 5.7).  
<sup>b</sup> NI: no increase in the count from the previous contact time.  
<sup>c</sup>  $R_x = 0$  when  $\lg N_0 = \lg N_x$  (no increase from the initial count).

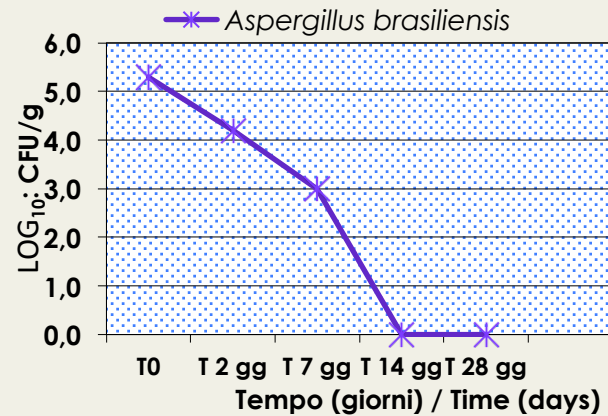
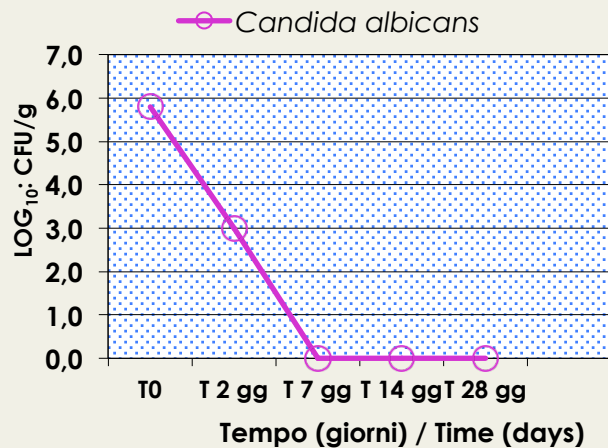
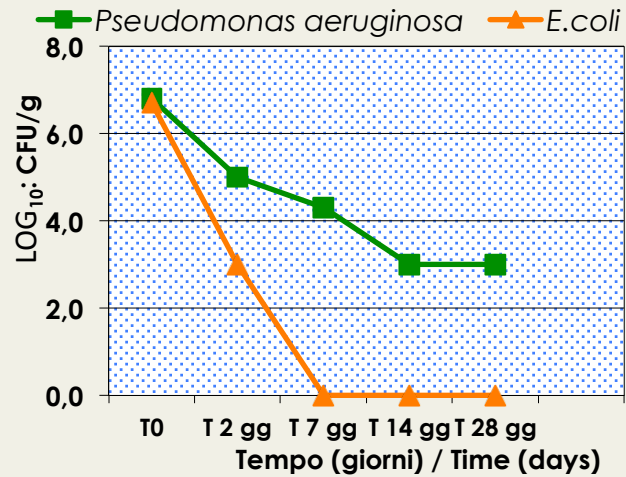
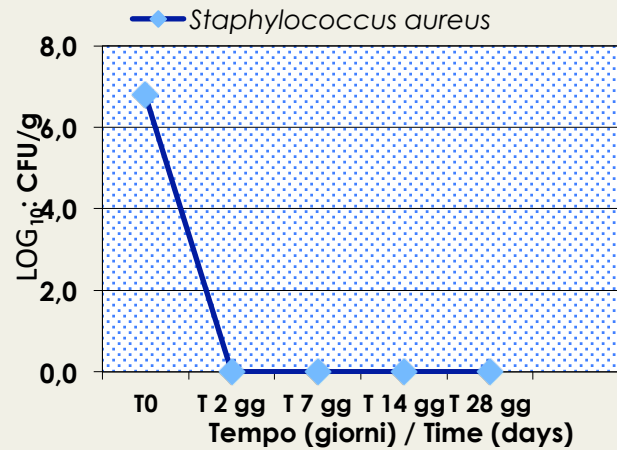


Prova 4: Latte Detergente

Caprylhydroxamic acid / Propanediol 1%

		Inoculum T0	T48 h	T7 gg.	T14 gg	T28 gg
<i>Staphylococcus aureus</i>	ATCC* 6538	6,70E+06	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Escherichia coli</i>	ATCC* 9027	5,30E+06	1,00E+03	9,00E+00	9,00E+00	9,00E+00
<i>Pseudomonas aeruginosa</i>	ATCC* 8739	6,60E+06	1,00E+05	2,00E+04	1,00E+03	1,00E+03
<i>Candida albicans</i>	ATCC* 10231	6,00E+05	1,00E+03	9,00E+00	9,00E+00	9,00E+00
<i>Aspergillus brasiliensis</i>	ATCC* 16404	2,00E+05	1,50E+04	8,00E+03	1,00E+03	9,00E+00

\*ATCC (American Type Collection Control)

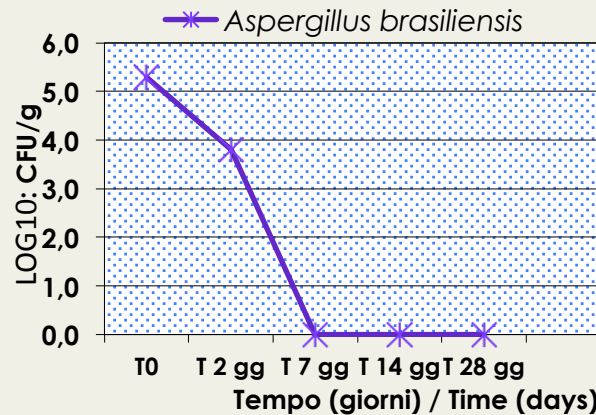
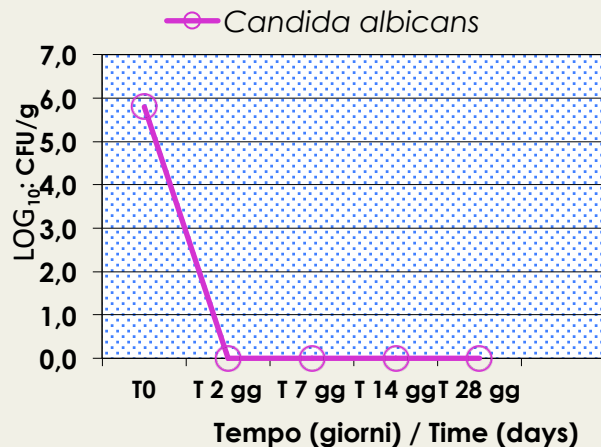
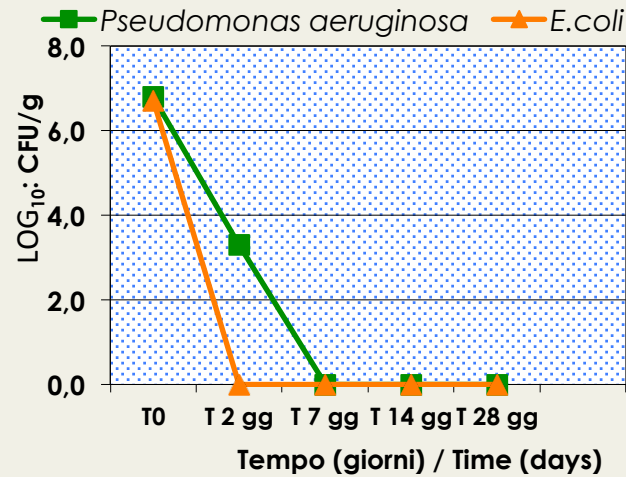
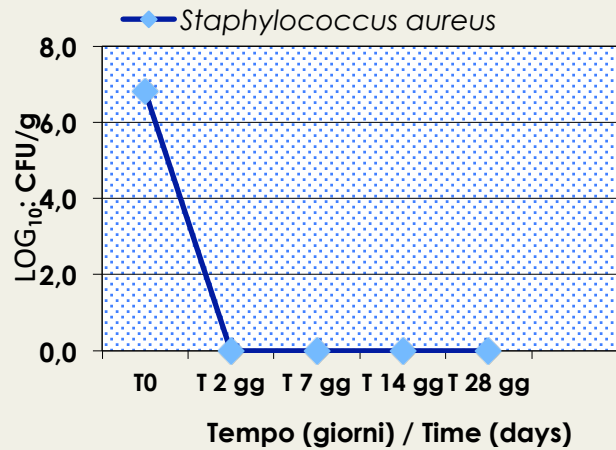


### Prova 5: Latte Detergente

Caprylhydroxamic acid/ Propanediol 1,5%+Phenoxyethanol/ Caprylyl glycol 0,5%

		Inoculum T0	T48 h	T7 gg.	T14 gg	T28 gg
<i>Staphylococcus aureus</i>	ATCC* 6538	6,70E+06	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Escherichia coli</i>	ATCC* 9027	5,30E+06	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Pseudomonas aeruginosa</i>	ATCC* 8739	6,60E+06	2,00E+03	9,00E+00	9,00E+00	9,00E+00
<i>Candida albicans</i>	ATCC*10231	6,00E+05	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Aspergillus brasiliensis</i>	ATCC*16404	2,00E+05	8,00E+03	9,00E+00	9,00E+00	9,00E+00

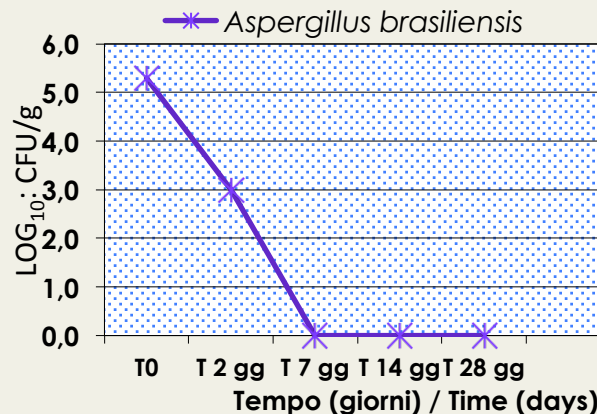
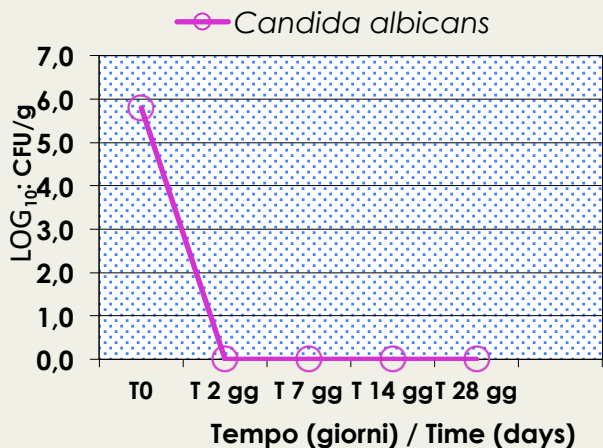
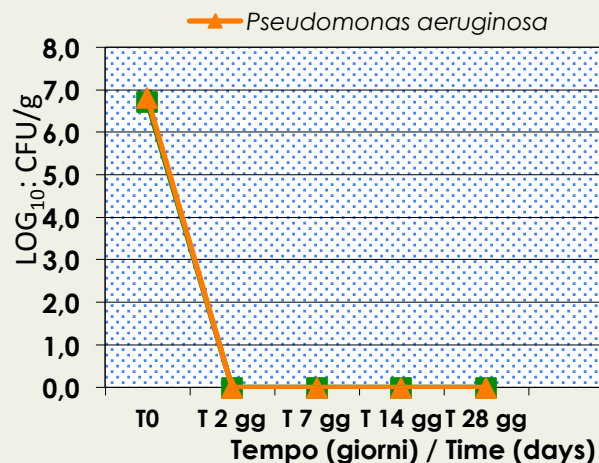
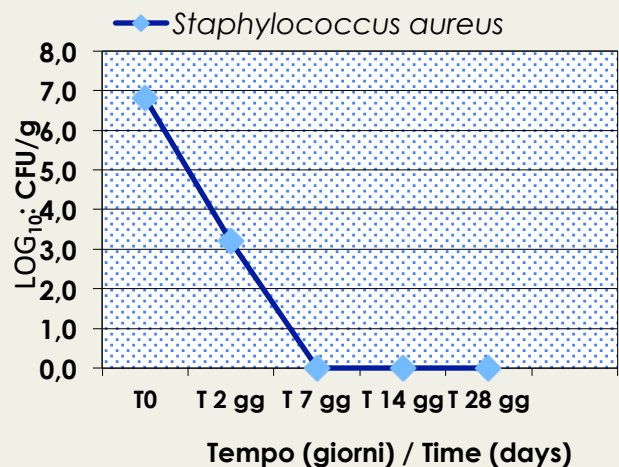
\*ATCC (American Type Collection Control)



Prova 8: Latte Detergente **Phenoxyethanol 0.8% Ethylhexylglycerin 0.5% Caprylyl Glycol 0.1%**

		Inoculum T0	T48 h	T7 gg.	T14 gg	T28 gg
<i>Staphylococcus aureus</i>	ATCC* 6538	6,70E+06	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Escherichia coli</i>	ATCC* 9027	5,30E+06	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Pseudomonas aeruginosa</i>	ATCC* 8739	6,60E+06	2,00E+03	9,00E+00	9,00E+00	9,00E+00
<i>Candida albicans</i>	ATCC*10231	6,00E+05	9,00E+00	9,00E+00	9,00E+00	9,00E+00
<i>Aspergillus brasiliensis</i>	ATCC*16404	2,00E+05	8,00E+03	9,00E+00	9,00E+00	9,00E+00

\*ATCC (American Type Collection Control)



## CONCLUSIONI

Si evince che è possibile studiare una formula cosmetica “sicura”, utilizzando più meccanismi di azione antimicrobica:

- 1- limitare l'attività dell'acqua.
- 2- ambiente con un pH “ostile” alla crescita di microorganismi.
- 3- Utilizzare attivi o eccipienti cosmetici con una potenziale funzione antimicrobica.
- 4 – Utilizzare molecole chelanti.

I risultati ottenuti dallo studio sperimentale consentono di concludere che è possibile garantire sia la stabilità microbiologica, scegliendo concentrazioni corrette e sostanze ad azione inibente e/o “autoconservante” (molecole multifunzionali), che rappresentare una buona tollerabilità cutanea per minimizzare i rischi riguardanti il profilo tossicologico e allergologico.



# Grazie per la vostra attenzione



*It is possible  
to achieve the goal*

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Cell.: 333-7285676

Attenzione le immagini e le foto riportate, provengono dal web  
Google immagini

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