

Glypure™

Cosmetic-Grade Glycolic Acid

Reduce Additional Preservatives in Cosmetic Formulations

Technical Information

Report Summary

Results show that the use of Glypure™ cosmetic grade glycolic acid in formulation allows the user to forego additional preservatives in formulation when Glypure™ is used at certain pH levels and concentrations. Product samples were tested by a third party per Chapter USP <51>. All samples tested successfully met the passing criteria set forth in Chapter <51> of USP NF-2009.

Objective

Evaluate the preservative efficacy of Glypure™ in formulation at concentrations of 1-8% and pH 3.5-4.2.

Samples

The following Glypure™ anti-aging serum samples were tested.

- One sample containing 1% glycolic acid at pH 3.8
- Three samples containing 4% glycolic acid at pH 3.5, 3.8, and 4.2
- One sample containing 8% glycolic acid at pH 3.8

Methodology

The USP <51> test method passing criteria for antimicrobial effectiveness for a Category 2 product is for bacteria to be no less than 2 log₁₀ reduction from the initial count at 14 days and no increase from the 14 day count at 28 days. The criteria for yeast is to have no increase from the initial count at 14 and 28 days. No increase is defined as no more than a 0.5 log₁₀ reduction higher than the previous value.

Microorganisms used for testing include:

- *Staphylococcus aureus*
- *Aspergillus brasiliensis*
- *Pseudomonas aeruginosa*
- *Candida albicans*
- *Escherichia coli*

Calculation to determine log₁₀ reduction is as follows:

$$\text{Log}_{10} \text{Reduction} = \text{Log} \frac{B}{A}$$

Where:

B = Number of viable test microorganisms in the control substances immediately after inoculation

A = Number of viable test microorganisms in the test substances after the contact time

Experimental Formulation

All samples were made using the Glypure™ anti-aging serum starting point formulation below.

Formulation: Glypure™ Skin Care: Anti-Aging Serum

Phase	Ingredient	Trade Name	Supplier	Wt%
A1	Purified Water	Purified Water		37
A2	Disodium EDTA	Dissolvine® NA2 S	AkzoNobel	0.05
A3	Polyquaternium-10	Ucare™ Polymer JF-30M	Dow	1
A4	Glycerin	Glycerin USP	Vantage Specialty Ingredients, Spectrum	3
A5	Propanediol	Zemea™ Propanediol	DuPont Tate & Lyle Bioproducts	10
B1	Purified Water	Purified Water		37
B2	Glycolic Acid (99%)	Glypure™ 99	Chemours	4
B3	Ammonium Hydroxide (40%)	Ammonium Hydroxide (40%)	Spectrum	1
C1	Polysorbate 80	Tween™ 80	Croda	3
C2	Retinyl Palmitate	Vitamin A Palmitate USP	Spectrum	0.05
C3	Tetrahexyldecyl Ascorbate	BV-OSC	Barnet	0.05
Adjust	Adjust final pH to 3.5–4.2 with Ammonium Hydroxide (40%) or Glypure™ as necessary			qs to 100%
qs	Purified Water	Purified Water		100

Concentration and pH were adjusted according to sample specifications, and water was used to acquiesce sample to 100%.

Testing Protocol: Samples were tested by a third-party testing facility following the USP <51> test method to quantitatively assess antimicrobial preservatives added to non-sterile dosage forms.

Results

For each sample, results are represented in **Figures 1–5** and **Table 1** showing initial CFU/g levels followed by the levels at day 14 and day 28. The limit of detection for this assay was 50 CFU/g. Values less than 5.0E+01 are presented as zero.

All log₁₀ reductions for all samples tested were 3 or greater for all microorganisms at day 14 and day 28, except for sample E with a glycolic acid concentration of 4% at pH 3.5, which had a 2 log₁₀ reduction at day 14 for *A. brasiliensis*. This result is still within the passing criteria for USP <51> and log₁₀ reduction for this sample was 3 at day 28 for *A. brasiliensis*.

Summary/Conclusion

Results of testing show that at the pH and concentrations tested, Glypure™ has the added benefit of acting as a preservative in cosmetic formulation, eliminating the need for additional preservatives within the matrix. Passing result for the 1% glycolic acid at pH = 3.8 points to the possibility of removing preservative substrates from Glypure™ hair care starting point formulations.

Figure 1. 1% Glypure™ pH 3.8

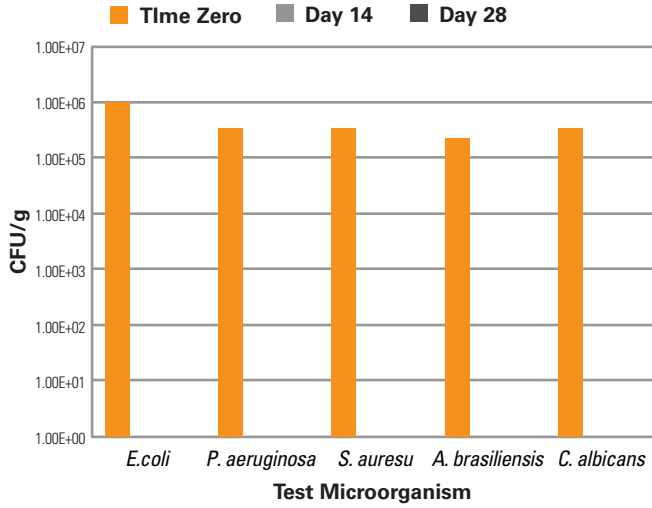


Figure 4. 4% Glypure™ pH 3.5

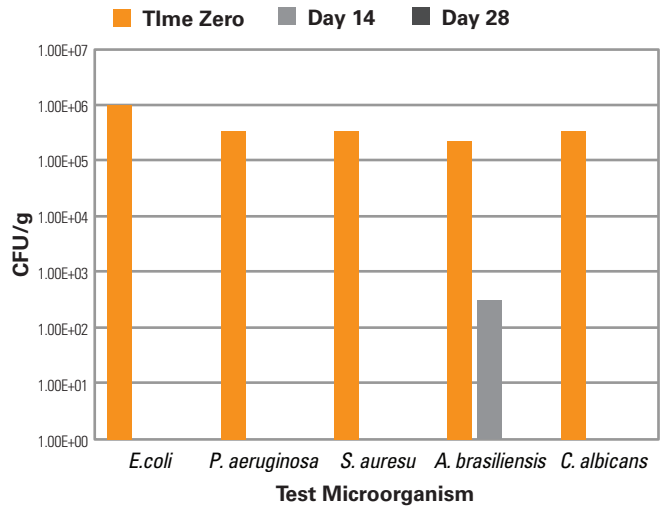


Figure 2. 4% Glypure™ pH 3.8

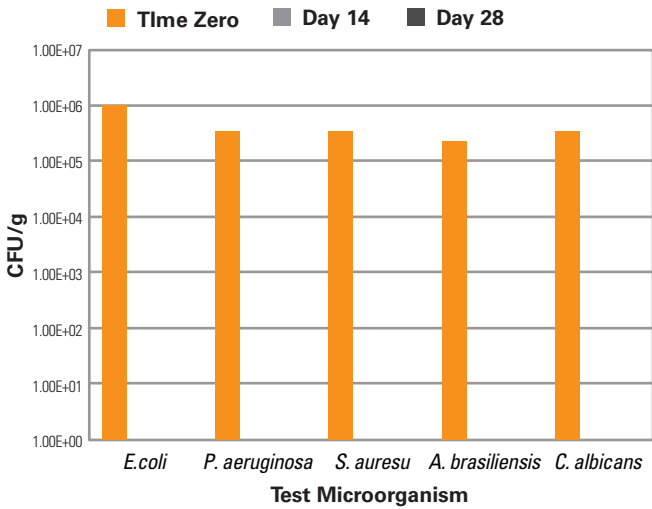


Figure 5. 4% Glypure™ pH 4.2

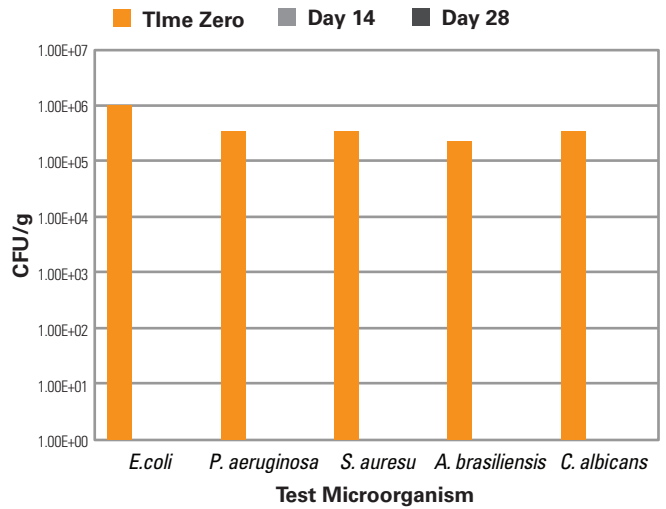


Figure 3. 8% Glypure™ pH 3.8

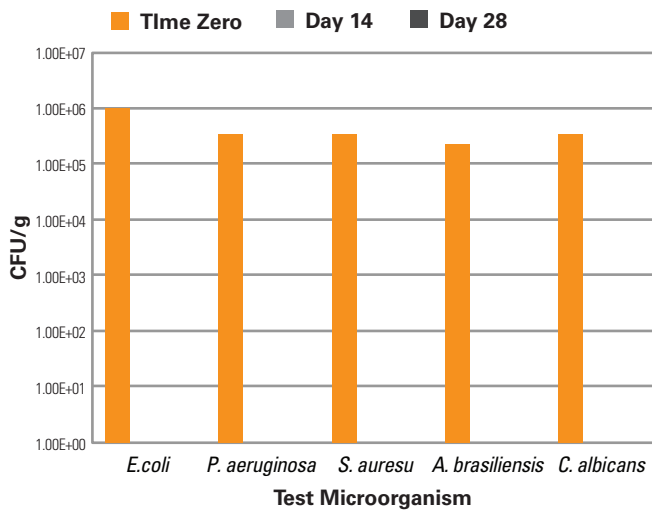


Table 1. Log Reduction Table

Data Description		<i>E. coli</i>	<i>P. aeruginosa</i>	<i>S. aureus</i>	<i>A. brasiliensis</i>	<i>C. albicans</i>
1% Glypure pH 3.8						
Time Zero	CFU/g	9.50E+05	3.45E+05	3.60E+05	2.45E+05	3.60E+05
Day 14	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
Day 28	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
4% Glypure pH 3.8						
Time Zero	CFU/g	9.50E+05	3.45E+05	3.60E+05	2.45E+05	3.60E+05
Day 14	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
Day 28	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
8% Glypure pH 3.8						
Time Zero	CFU/g	9.50E+05	3.45E+05	3.60E+05	2.45E+05	3.60E+05
Day 14	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
Day 28	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
4% Glypure pH 3.5						
Time Zero	CFU/g	9.50E+05	3.45E+05	3.60E+05	2.45E+05	3.60E+05
Day 14	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	3.5E+02	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	2.85	>3.86
Day 28	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86
4% Glypure pH 4.2						
Time Zero	CFU/g	9.50E+05	3.45E+05	3.60E+05	2.45E+05	3.60E+05
Day 14	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	3.5E+02	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	2.85	>3.86
Day 28	CFU/g	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01	<5.00E+01
	Log ₁₀ Reduction	>4.28	>3.84	>3.86	>3.69	>3.86

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