Safety and Efficacy of a Gluconolactone (Poly Hydroxyacid) Containing Regimen on Sensitive Skin and Photodamage Following Controlled Consumer Use

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Introduction

The **poly hydroxyacids** (PHAs) are a new class of skin care ingredients that provide unique benefits to skin as compared to traditional **alpha hydroxyacids** (AHAs). In comparison to commonly used AHAs, PHAs do not cause sensory irritation responses that can limit conventional AHA use.[1-3] Some PHAs also possess antioxidant properties.[1-3] As part of their molecular structure, poly hydroxyacids contain a hydroxyl group on the aliphatic or alicyclic carbon in the position alpha to the terminal carboxylic acid group, thereby possessing the fundamental alpha hydroxyacid (AHA) structure and the related ability to modulate the process of keratinization.[4,5] Additionally, PHAs contain hydroxyl groups on multiple other positions (β, γ, δ, ε, etc.) throughout the molecule, leading to the designation poly hydroxyacid. Polyol compounds such as glycerol are known to impart humectant properties in skin care formulations. Likewise, PHAs are purported to provide enhanced degrees of moisturization.[1]

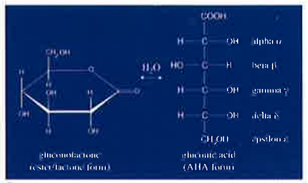


figure 1

Gluconolactone is the lactone form of gluconic acid (figure 1), a poly hydroxyacid found naturally occurring in skin.[6] In previous studies with gluconolactone, compatibility with atopic and rosacea skin conditions was demonstrated,[7] as well as, a conditioning effect to skin barrier function as evidenced by reduced damage from a surfactant challenge.[8]

The purpose of this study was to assess the efficacy of a gluconolactone containing regimen in reducing the visible symptoms of photoaging, while monitoring compatibility in self-assessed sensitive skin types.

Objective

To assess a gluconolactone containing skin care regimen with regard to:

1. Improvement in symptoms of photoaging
2. Compatibility with self-assessed sensitive skin

Method

- Pre-treatment **conditioning phase:** one week period of twice daily test cleanser use with discontinuation of all facial moisturizers three days prior to study initiation.
- Open label, **normal use regimen evaluation** with comparisons to baseline.
- **Study duration:** 12 weeks with visits at baseline, week 6 and week 12
- **N=25**, healthy women, 35-55 years, Fitzpatrick skin type I, II, III.
- Participants must have **self-assessed sensitive skin** according to a questionnaire administered during study enrollment.
- Participants must not have used topical **AHAs or retinoids** for 6 months prior to study initiation, or oral retinoids for 12 months prior to study initiation.
- Participants must have moderate (II) to advanced (III) **photodamage** according to the modified **Glogau scale**:

> II – Moderate: early actinic keratoses-slight yellow skin; discoloration; early wrinkling-parallel smile lines.
>
> III – Advanced: actinic keratoses-obvious yellow skin; discoloration with telangiectasia; wrinkling present at rest; moderate acne scarring.

- **Test Materials:** *Cleanse-Tone-Moisturize* regimen applied twice daily to face.

Product	Usage	% Gluconolactone	pH
Foaming cleansing gel	a.m. and p.m.	<1%	4.00
Toner solution, alcohol free	a.m. and p.m. after cleanser	<1%	4.70
Daytime lotion SPF 15 (Octyl Methoxycinnamate, Oxybenzone)	a.m. after toner	4%	3.70
Nighttime crème	p.m. after toner	8%	3.70

- **Efficacy Assessments:** baseline, week 6, week 12
  1. **Clinical assessments** were made by a trained evaluator using a **visual analog scale** (10 cm) to assess signs of **photoaging** including: firmness, sallowness, fine lines, wrinkles, tactile roughness, mottled hyperpigmentation, and pore size.
  2. **Clinical assessments** were made by a trained evaluator to assess **objective irritation** (erythema, edema, scaling) and inquire about **subjective irritation** (itching, stinging, burning, tightness, tingling).
  3. **D-Squame** tape disc – right cheek
  4. **Silicone replica** – left crow's feet
  5. **Self-assessment** – via questionnaire

Results

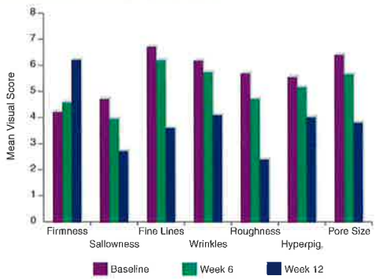
- The study was conducted over the summer months in the relatively low humidity environment of Colorado Springs, Colorado.
- Thirty-one subjects entered the study; five withdrew due to non-product related reasons. One subject presented with mild irritation after the conditioning phase, which worsened after initiating product use and resulted in discontinuation.
- Protocol deviation: one subject experienced irritation following use of the regimen, which was reduced when the subject began using the cleanser twice daily as directed, rather than three times daily. The subject did not discontinue.
- All parameters were analyzed for **statistical significance** relative to baseline scores.

Results - Clinical Assessment

Visual Signs of Photoaging

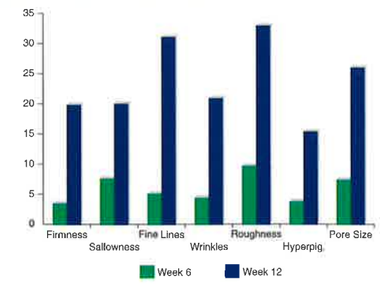
- All parameters of photoaging were significantly improved at weeks 6 and 12 ($p<0.05$).

Clinical Assessment – Photoaging Parameters



*All parameters significantly improved ($p<0.05$) at weeks 6 and 12 compared to baseline.

Clinical Assesement – Photoaging Parameters Mean Relative Percent (%) Improvement (compared to baseline)

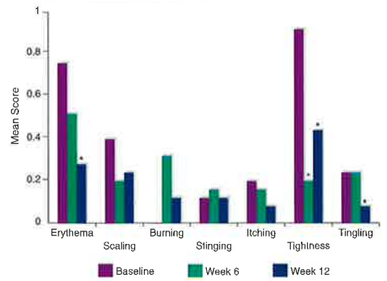


*All parameters significantly improved ($p<0.05$) at weeks 6 and 12 compared to baseline.

Visual Assessment of Irritation

- There were no significant increases in irritation as a result of using the test regimen ($p<0.05$).
- Irritation parameters present at baseline improved during regimen use ($p<0.05$):
  - Decreased erythema, week 12
  - Decreased tightness, weeks 6 and 12
  - Decreased tingling, week 12

Clinical Assessment – Irritation Parameters



*Significant improvement ($p<0.05$) compared to baseline.

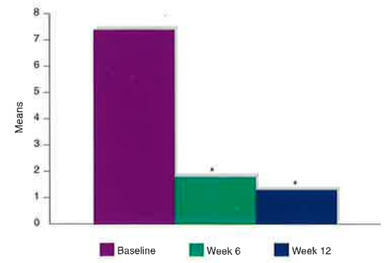
Results - Silicone Replicas

- Significant decrease in the number and depth of fine lines at weeks 6 and 12 ($p<0.05$).
- Significant decrease in crow's feet lines at week 12 ($p<0.05$).
- There was a 35% improvement in fine lines at week 12.

Results - D-Squames

- Significant reduction of fine flakes at week 12 ($p<0.001$).
- Significant reduction of course flakes at weeks 6 and 12 ($p<0.05$).
- Significant reduction in desquamation index at weeks 6 and 12 ($p<0.05$).

D-Squame Analysis – Course Flakes



*Significant improvement ($p<0.05$) compared to baseline.

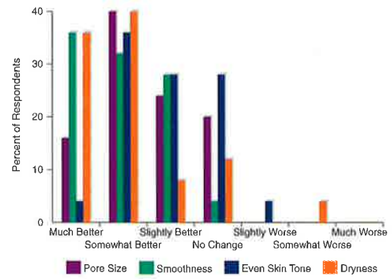
Self Assessment

Evaluation of Test Regimen at Week 12

Characteristics	%*
Compatible with sensitive skin	92
Reduces appearance of fine lines and wrinkles	84
Improves skin feel	92
Improves skin appearance	92
Is not irritating	88
Does not cause acne breakouts	84

*% of respondents scoring: Excellent + Very Good + Good

Self Assessment – Improvements in Facial Attributes at Week 12 Compared to Baseline



Self Assessment – Regimen Is Compatible with Sensitive Skin

Self Assessment – Regimen Reduces Appearance of Fine Lines and Wrinkles

Conclusion

- **Significant improvements in the signs of photoaging** were observed using the PHA (gluconolactone) test regimen at 6 weeks with more pronounced improvements after 12 weeks of product usage.
- The PHA (gluconolactone) test materials **did not cause irritation** and were well tolerated in the self-assessed sensitive skin population. Moreover, some parameters of **irritation** present at baseline were **reduced** with product usage demonstrating compatibility with this self-assessed sensitive skin population.
- The PHA (gluconolactone) containing regimen is an **alternative to traditional AHAs** to achieve skin smoothening benefits and reduced appearance of aging signs, and is **appropriate for the use on sensitive skin.**

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