

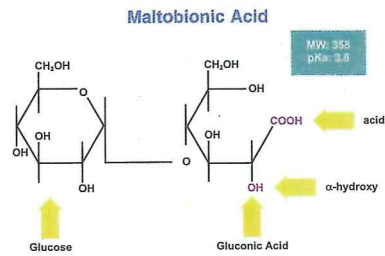
Maltobionic Acid, A Plant-Derived

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Introduction

Maltobionic acid (4-O- α -D-glucopyranosyl-D-gluconic acid, MW: 358, pKa: 3.8) is a **new polyhydroxy bionic acid** formed by oxidation of **maltose**. Maltobionic acid is comprised of one molecule of D-glucose attached via an ether-type linkage to D-gluconic acid (a polyhydroxy acid or PHA).



A chemically similar compound to the well-known lactobionic acid, this novel ingredient has the advantage of being **plant derived**, as well as, **gentle and non-irritating**. Maltobionic acid is a strong humectant and is also an antioxidant/chelator.

Previous work has documented prominent anti-aging effects for lactobionic acid including skin plumping and smoothing of surface topography with diminished appearance of fine lines and wrinkles.¹

A study was conducted to evaluate the anti-aging effects of the new polyhydroxy bionic acid, maltobionic acid.

Objective

This poster will present safety data of maltobionic acid as well as clinical study results of a topical cream formulation containing **8% maltobionic acid** to evaluate its anti-aging effects on human skin.

Safety Profile of Maltobionic Acid²

Test	Test Material	Result
1. Ames II Assay	10% maltobionic acid (aq.)	Non-mutagenic: no base pair or frame shift mutations in the presence of S9 fraction
2. Cell Viability: Epiderm (EPI-100)	8% maltobionic acid cream in contact with living skin equivalent for 1, 4, and 24 hours. Negative control: water; Positive control: Triton-X 100 (1%), a mild irritant	Test material was classified as innocuous and nonirritating
2a. PGE2 assay (EPI-100)	(above)	No inflammatory prostaglandin release; test material was equivalent to the water control
2b. Lactate Dehydrogenase (LDH) (EPI-100)	(above)	No increase in cellular lysis; test material was equivalent to the water control
2c. Interleukin-1 α (EPI-100)	(above)	No effect on cytokines; test material was equivalent to the water control

Anti-Aging Study Results

Study Conduct

- > **Design:** prospective, direct-comparison to baseline scores (for visual grading & firmness) and to untreated control skin (for skin thickness & biopsies); protocol received IRB approval and informed consent was executed
- > **Subjects:** 28 women, 35-58 years of age, Fitzpatrick types I, II and III (Caucasian), presence of mild-moderate periorcular fine lines, periorcular coarse wrinkles and mottled hyperpigmentation on the face
- > **Product Application:** maltobionic acid, 8% cream, pH 3.8 was applied twice daily to the face and 3 times daily to one forearm; one forearm remained untreated as a control for forearm measurements
- > **Clinical Evaluations:**
 - **Clinical Grading** (weeks 0, 6, 12): scores were collected visually by a trained evaluator using a 0 to 10

Parameter	Site for Grading	Low Extreme of Scale	High Extreme of Scale
Fine Lines	Eye area	0 = None	10 = Severe
Coarse Wrinkles	Eye area	0 = None	10 = Severe
Pore Size	Cheek	0 = Invisible	10 = Very Large
Laxity	Cheek	0 = Firm, unpliable	10 = Loose, pliable
Roughness	Cheek	0 = Soft, smooth	10 = Rough, coarse
Sallowness	Face	0 = Light, non-yellow	10 = Dark, matte
Clarity	Face	0 = Dull, matte	10 = Clear, radiant
Mottled Pigmentation	Face	0 = Even tone	10 = Mottled, uneven tone

- **Pinch Recoil** (weeks 0, 6, 12) measurements were taken of the under eye area to assess skin elasticity by pinching the skin and recording time with a stopwatch (in hundredths of a second) to full recovery of the skin. The measurements were performed in triplicate, and the average score was reported. Pinch recoil is a recognized indicator of skin resiliency and firmness.³

- **Total Skin Thickness (plumping) Measurements** (weeks 0, 12) were collected on the outer forearms using a hinged pinching device and digital calipers as previously described.* Duplicate measurements representing a two-fold thickness of skin were taken and averaged at baseline and endpoint for both the treated and untreated control arms
- **Irritation/Safety Grading** (weeks 0, 6, 12): global evaluation of objective irritation and safety was conducted for dryness, erythema and edema and subjective irritation scores were collected for burning, stinging, itching, tightness and tingling. Scale: 0 – 3 (none, mild, moderate, severe)
- **Digital Photography** (weeks 0, 12) was collected using standardized lighting and positioning
- **Self-Assessment** (weeks 0, 6, 12) was collected via questionnaires
- **3-millimeter Punch Biopsies** were collected at endpoint on the forearms of several study participants. Biopsies were stored in 10% formalin and subsequently processed for histological assessments

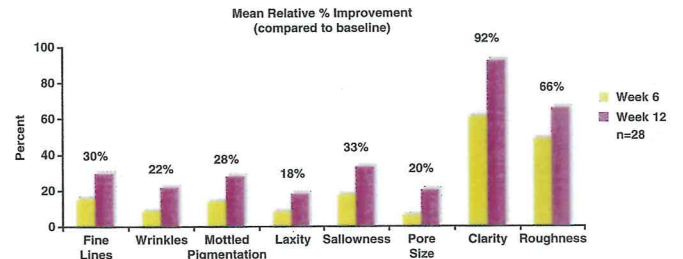
Statistics

- > Clinical grading and pinch recoil: mean values were compared to baseline scores using a paired t-test, p \leq 0.05
- > Total skin thickness: mean values were compared to baseline scores using a paired t-test, p \leq 0.05. Comparisons between treated and untreated test sites were made using ANOVA with Fishers LSD for pair-wise comparisons
- > Self-assessment questionnaires were tabulated and a top box analysis was performed

Results

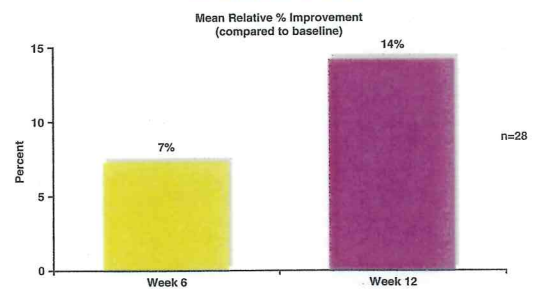
- > 28 of 33 subjects completed the study. 4 subjects discontinued for reasons unrelated to the test product and 1 subject discontinued due to a reported allergic response.

Anti-Aging Effects



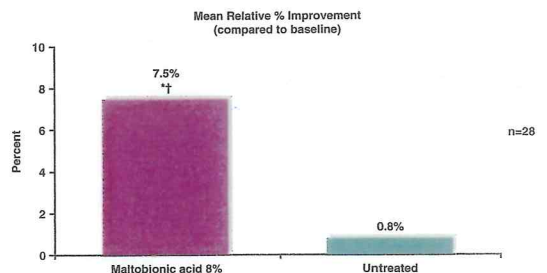
Clinical grading revealed significant improvements in all of the visually graded parameters at 6 and 12 weeks compared to baseline, p $<$ 0.05

Pinch Recoil/Firmness



Firmness/elasticity was significantly improved at 6 and 12 weeks compared to baseline, p $<$ 0.05

Skin Thickness Measurements on Forearms



*Significant increase in skin thickness (plumpness) compared to baseline, p $<$ 0.05.

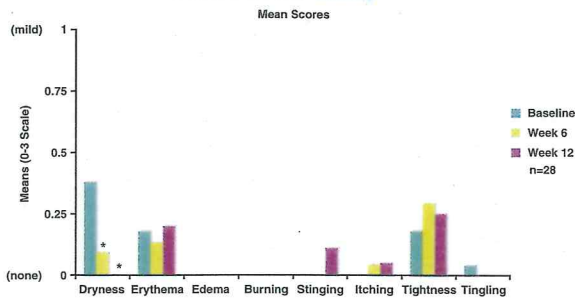
††Significantly thicker than untreated (p=0.0001).

Bionic Acid for Topical Anti-Aging

Edison B.A., Richard H. Wildnauer Ph.D.

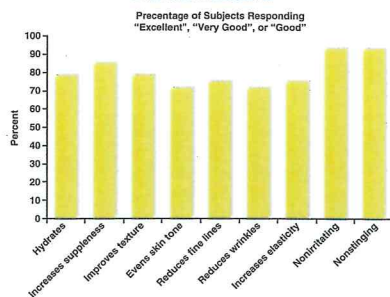
Princeton, NJ, USA

Facial Irritation Grading



The test material was well tolerated with no increases in irritation parameters. *Denotes significant improvements in preexisting symptoms compared to baseline, $p < 0.05$

Self-Assessment



Significant self-assessed skin improvements were noted. These findings support the clinical grading and efficacy measurements

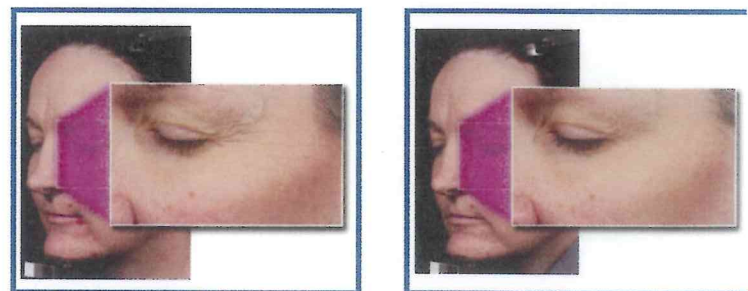
Clinical Photographs



Diminished periorcular fine lines and smoother texture at 12 weeks



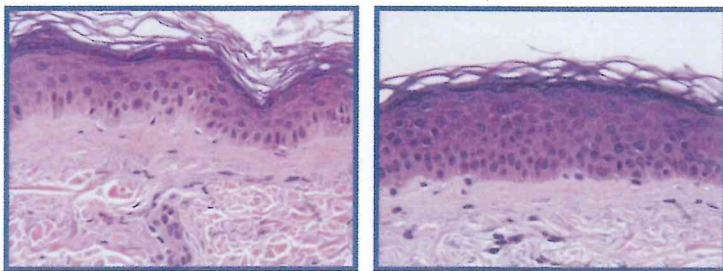
Improved texture, reduced pore size and erythema at 12 weeks



Diminished periorcular fine lines and smoother texture at 12 weeks

Histology Results

Epidermal Structure: 400x

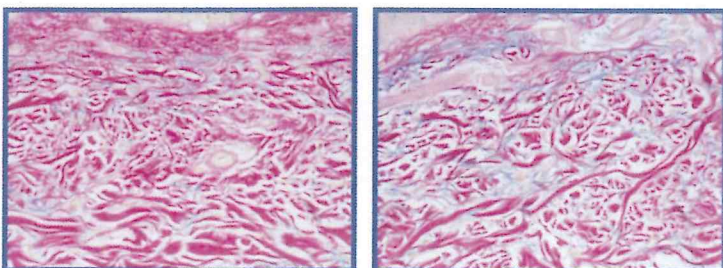


Untreated control

Maltobionic acid 8%

Increased viable epidermal thickness and a more compact stratum corneum

GAGs: 400x



Untreated control

Maltobionic acid 8%

Increased density of dermal colloidal iron staining (blue color) representing glycosaminoglycans/acid mucopolysaccharides (GAGs)

Summary

Maltobionic acid is a **new, plant-derived polyhydroxy bionic acid** for anti-aging and skin smoothing. Due to its polyhydroxy structure, it is a potent **humectant** and **antioxidant**. Safety studies indicate that this compound is **safe and nonirritating** to skin. The clinical study presented in this poster reveals **significant cutaneous anti-aging effects** of an 8% formulation. Benefits presented in this poster include:

- Increased skin thickness and plumping to provide skin smoothing effects
- Visual improvements in skin texture, clarity and roughness
- Increased skin firmness and elasticity
- Self-assessed improvements in skin texture, suppleness, degree of hydration and elasticity
- No irritation
- Histological effects

References

- Green BA, Edison BL, Wildnauer RH, Sigler ML. Lactobionic acid and Gluconolactone: PHAs for Photoaged Skin. *Cosmet Dermatol* 2001;9:24-28.
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- Ditre CM, Griffin TD, Murphy GF, Sueki H, Telegan B, Johnson WC, Yu RJ, Van Scott EJ. Effects of α -hydroxy acids on photoaged skin: A pilot clinical, histologic, and ultrastructural study. *J Am Acad Dermatol*. 1996;34:187-195.