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Topical formulation containing prebiotic and hyaluronic spheres for patients with xerosis and skin hypersensitivity

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Introduction

Chronic skin xerosis is commonly observed in patients with hyper-reactive skin prone to irritation and allergy and those with atopic skin. Finding an effective hydrating treatment for such patients is often challenging.

This study is an assessment of a dermocosmetic formulation as hydrating and alleviating agent for patients with xerosis and skin hypersensitivity. The tested light emulsion (no. 16005) contained hyaluronic acid in two molecule sizes, a prebiotic oligosaccharide and anti-inflammatory agent.

Hyaluronic acid (HA) is a major component of the skin, where it is involved in tissue repair and ensures proper skin hydration by binding water molecules. The tested formula **contained high and low molecular weight HA** that penetrates to varying depths of the epidermis providing multi-level hydration. HA spheres can also **fill fine lines on the skin** making them less visible.

Alterations in skin microflora are commonly observed in patients with sensitive, hyperreactive and atopic skin. Applying topical prebiotics like inulin from chicory root contained in tested emulsion supports growth of symbiotic bacteria preventing the expansion of harmful species like *S. aureus*. The addition of *Laminaria ochroleuca* algae extract provides **immediate soothing and anti-inflammatory effects** by reducing the expression of TNFα, LTB4, COX-2 & IL10 inflammatory mediators (*Mekideche N., Personal Care, 2002: 63-73*).

Methods

Safety *in vitro* tests included: cytotoxicity on L929 cells according to ISO 10993-5:2009, 10993-12:2012, and skin irritation on EpiDerm skin model according to OECD test guideline 439 and ISO 10993-10:2013.

Safety *in vivo* tests included: skin patch test with 30 human subjects with allergy-prone skin and multiple day at-home application by 40 subjects (details of patients skin type showed below).

Efficacy *in vivo* tests were performed in two groups of volunteers.

Group I: 19 patients (aged 17-58) with dry and sensitive skin and history of atopic dermatitis. Dermatologist's assessment (before and after 14 days of product use) included skin dryness and level of pruritus using 1-10 analogue scale (10 – very severe symptom, 0 – no symptom). Patients also completed a satisfaction survey.

Group II: 21 volunteers (aged 19-65) all of whom had history of allergic reactions. Thirteen participants were subject to instrumental skin analysis after 14 days of product use with Courage-Khazaka Mexameter® and Visioscan ® camera (melanin and erythema levels, skin texture parameters). Additionally, 4 subjects measured skin hydration on the forearm with Corneometer® 5 hours after applying the tested emulsion. All subjects took satisfaction survey.

Conclusion

Results of this study indicate that the 16005 emulsion is very well tolerated and highly assessed by the patients who used it, as well as by physicians. It significantly decreases pruritus and skin dryness, alleviates irritations and accelerates skin regeneration. The formula notably improves skin hydration and the effect is long lasting – even after a single application. Biometric measurements showed improve skin tone and texture.

Results

In vivo safety tests of the emulsion proved high tolerance – no irritant potential after at-home multiply application and no delayed-type allergic reaction in patch test.

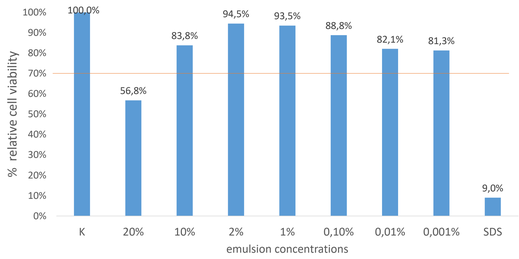

Figure 1. Cytotoxicity of 16005 emulsion on L929 cells. Viability <70% of the control - cytotoxic potential (marked by orange line). K – untreated control; SDS (5%) – positive control.
The tested emulsion was non-cytotoxic at the concentration less than or equal to 10%.

Dermatologist's assessment (group I)	% patients
The product accelerated regeneration and renewal of sensitive and allergy-prone skin	89%
The product protects skin from drying	89%
The product had soothing and alleviating effect	94%
The product forms a protective film on the skin	39%
The product immediately hydrates and alleviates skin irritated due to seasonal contact allergies	78%

Dermatologist's assessment (1-10 analogue scale)	before	after	% change
Skin dryness	8,3	4,9	-41%
Pruritus	2,7	0,5	-81%

Figure 3. Results of the clinical trial with 19 participants. Dermatologist's assessment of skin condition at baseline and after 14 days of use.
Tested emulsion was well tolerated by patients prone to skin allergies. It improved skin regeneration, soothed and hydrated irritated skin. Moreover it reduced skin dryness and pruritus.

Subjects' self-assessment (group I)	% subjects
The product intensively moisturizes the skin	90%
The cosmetic nourishes and regenerates the skin	81%
Has soothing effect on irritated skin	95%
It improves the elasticity and firmness of the skin	81%
Smoothes the skin	90%
Reduces pruritus	71%
Restores skin comfort	95%
Protects the skin from drying out	86%
Prevents irritation	71%
Restores healthy skin tone	71%
Restores skin radiance	81%
Skin is silky for the touch	95%

Figure 5. Self-assessment after 3 weeks of emulsion 16005 application.
Study participants reported increased skin hydration, regeneration, smoothnes as well as restored skin comfort and reduced pruritus.

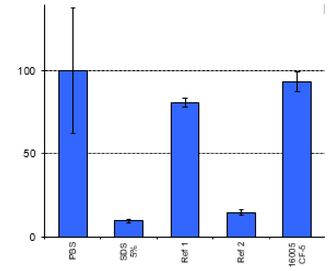

Figure 2. Skin irritation potential emulsion 16005 tested on EpiDerm model. Ref 1- naphthalene acetic acid (CAS 86-87-3) – non classified (non irritant). Ref 2 - cyclamen aldehyde (CAS 103-95-7) – classified (irritant, Cat. 2). Correlation of in vitro and in vivo results: Tissue viability ≤ 50% of the control (PBS) — irritant. Tissue viability ≥ 50% of the control — non-irritant.
Emulsion 16005 was confirmed as non-irritant on EpiDerm skin model, resulting in the mean tissue viability of 93,1%.

Skin tone parameters, n=13	change in group	% of change
melanin level	- 4%	- 20% in 54% subjects
erythema level	- 8%	- 15% in 69% subjects
Skin texture parameters, n=13	**% of change in group**	
Skin smoothness (Sesm)	+18%	
Volume, depth and number of wrinkles	-13%	

Figure 4. Biometric measurements after 3 weeks of application of emulsion 16005 (group II). **Skin measurements showed improvement in skin tone and smoothness along with decreased visibility of wrinkles.**

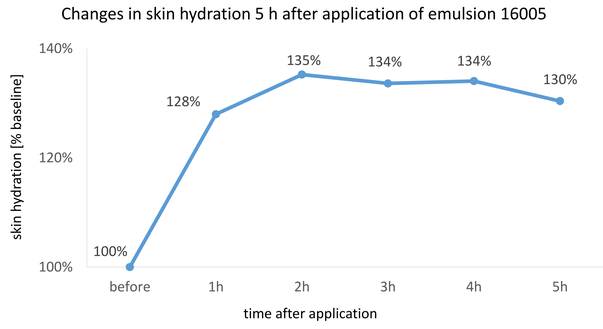

Figure 6. Skin hydration measured at baseline (before application) and 5 consecutive hours after usage of emulsion 16005, n=4.
Skin hydration peaks at 35% increase relative to baseline 2h after application and stays on a similar level up to 5 hours after use. This result indicates that tested emulsion provides long lasting skin hydration.

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