Dermocosmetic emulsions enriched with physiological lipids: Formulation end efficacy study

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INTRODUCTION

Nowadays, local application of stratum corneum lipids, i.e. physiological lipids (PL) is held in high esteem by both formulators and consumers. Among them, ceramides (CERs) are recognized as essential components which enable satisfactory skin barrier function. Thus, they may be incorporated into personal care/cosmetic products in order to either postpone certain physiological skin alterations, or overcome negative effects of numerous extrinsic factors our skin is constantly exposed to. Further, they are a part of the dermocosmetic treatment of different skin disorders associated with abnormal CER composition and/or structure, or merely reduced CER levels (1). Therefore, the aim of our study was to explore the potential of alkyl polyglucoside (APG) emulsifiers to stabilize creams with PL and to estimate the efficacy of such formulations.

MATERIALS AND METHODS

In the first part of our study six samples were prepared (Table 1). Samples MLc and MLsk were stabilized with C_{14-22}Alcohols & C_{12-20}Alkyl Glucoside (Montanov™L, Seppic, France) APG emulsifier and contained Ceramide 3 and skin-like lipid mixture (SK® Influx V, Evonik, Germany). respectively. M202c and M202sk samples were formulated correspondingly, but stabilized with Arachidyl Alcohol & Behenyl Alcohol & Arachidyl Glucoside (Montanov™202, Seppic, France) APG emulsifier. For each tested emulsifier placebo sample was also prepared and labeled ML and M202. Subsequently, prepared samples were characterized via polarization microscopy, rheology, pH and conductivity. In the second part of the study, *in vivo* efficacy two-part study was performed by the means of relevant bioengineering techniques, in order to determine the potential of the samples for improvement/maintenance of skin barrier function, along with their moisturizing effect in both normal and experimentally induced dry skin (IDS). Two phase *in vivo* study was performed on 16 healthy volunteers, in accordance to Declaration of Helsinki and relevant guidelines, after obtaining approval from local Ethical Committee. In the first phase, on the right hand, dry skin was experimentally induced (IDS) and left hand was left normal and for 4 weeks samples stabilized with Montanov ™ 202 were applied. Afterward, the second phase of the study was performed only on left hands. In this phase dry skin induction experiment was conducted on sites treated with investigated creams for 4 weeks. Investigated biophysical parameters were: transepidermal water loss (TEWL), stratum corneum hydration (SCH) and eritema index (EI).

Figure 1. Polarization micrographs a) M202, b) M202c and c) M202sk

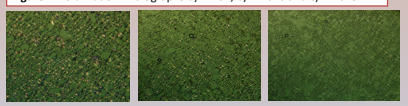


Figure 2. Polarization micrographs a) ML, b) MLc and c) MLsk

Table 1. Samples composition	Sample % (m/m)		
Ingredients	**M202/ML**	**M202c/MLc**	**M202sk/MLsk**
Montanov™202/ Montanov ™ L	4	4	4
Montanov ™ 14	1	1	1
Glyceryl Stearatet	2	2	2
Cetyl alcohol	1	1	1
Stearyl alcohol	1	1	1
Decyl Oleat	5	5	5
Caprylic/Capric Triglyceride	8	8	8
Avocadovo Oil	3	3	3
Ceramide 3	/	0.1	/
Glycerin	3	3	3
SK-Influx V ™	/	/	3
Aqua	to 100.0	to 100.0	to 100.0

RESULTS AND DISCUSSION

Physicochemical characterization confirmed that both emulsifiers enable: (i) lamellar structures formation (Fig 1a and Fig 2a), which is not disturbed with the addition of cosmetic actives (Fig 1b, 1c, 2b and 2c), (ii) formulation of creams with satisfying stability (Table 2). Polarization microscopy revealed more pronounced lamellar structures in samples stabilized with emulsifier M202 (Fig 1 and 2). Comparing the rheological curves (Fig 3) of samples it could be expected that samples stabilized with Montanov™ 202 have slightly better application properties. Based on obtained results samples with Montanov™ 202 were used in further *in vivo* investigation.

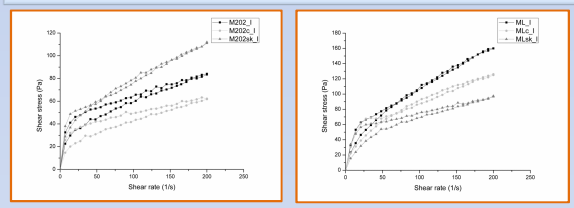


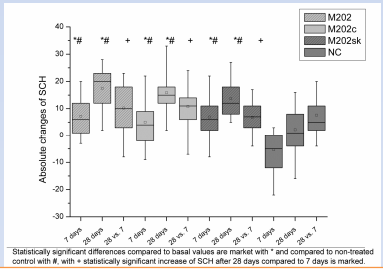
Figure 3. Rheological curves of investigated samples

Table 2. pH and conductivity results Sample	pH initial (t=20°C)	pH after 3 months (t=20°C)	Conductivity initial µS/cm (t=20°C)	Conductivity after 3 months µS/cm (t=20°C)
ML	4.2	4.1	14.1	12.6
MLc	4.3	4.3	11.9	12.4
MLsk	5.8	5.7	49.2	62.8
M202	3.6	3.5	14.6	18.8
M202c	3.7	3.6	14.7	15.5
M202sk	5.9	5.7	57.3	61.8

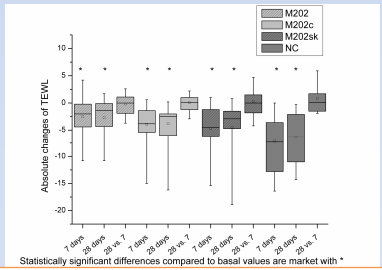
RESULTS AND DISCUSSION

SCH values were significantly increased after 7- and 28-days application on IDS for all investigated samples compared to initial values and non-treated control (NC) - Figure 4a. As for TEWL, it was decreased at all investigated sites, including NC. Nevertheless, the decrease was faster and more profound after application of samples with Ceramide III and skin-like lipid mixture (M202c and M202sk) as seen in Figure 4b.

SCH in normal skin was significantly increased after 7-days application of active samples (M202c and M202sk), and the same effect on hydration was observed after 28-days application of all creams. After 4-weeks application of investigated creams experimental induction of dry skin was not successful - SCH remained unchanged compared to basal values, and for sample M202sk treated site SCH was statistically higher compared to basal values. TEWL was significantly decreased after 4-weeks application of active samples, and for those sites experimental induction of dry skin was not effective, while induction experiment was successful at sites treated with placebo cream (M202) and NC, since TEWL was significantly increased after the induction.

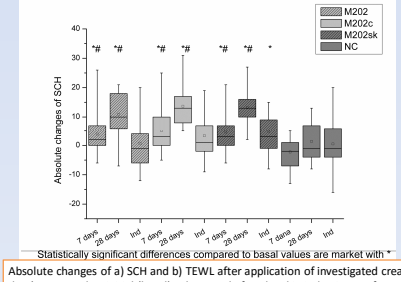


Statistically significant differences compared to basal values are market with * and compared to non-treated control with #. with + statistically significant increase of SCH after 28 days compared to 7 days is marked.



Statistically significant differences compared to basal values are market with *

Absolute changes of a) SCH and b) TEWL after application of investigated creams on induced dry skin in different time points; after 7- (7 days) and 28-days (28 days) compared to initial values (after IDS), 28 vs. 7 are absolute changes of TEWL between 28- and 7-days



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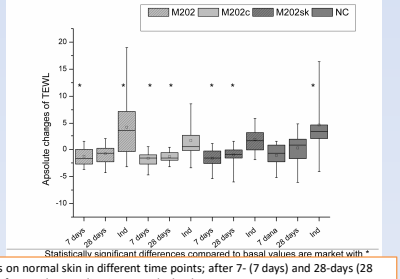

Statistically significant differences compared to basal values are market with *

Absolute changes of a) SCH and b) TEWL after application of investigated creams on normal skin in different time points; after 7- (7 days) and 28-days (28 days) compared to initial (basal) values, and after dry skin induction preformed after 28-days application – marked Ind.

CONCLUSION

Overall results signify that investigated creams have pronounced moisturizing effect which is mainly contributed to the specific structure of used vehicles stabilised with APG emulsifier. Additionally, based on obtained results formulated creams with physiological lipids could be recommended for the treatment of dry and impaired skin care, as well as for dry and normal skin care.

ACKNOWLEDGEMENT

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