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Safety, efficacy and tolerability of a medical device emollient cream containing 30% of urea for xerosis cutis

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Background

Emollients and high concentrations of urea are recommended for managing severely dry skin, especially on elbows, knees and heels. Emollients are needed to improve skin hydration and restore skin's barrier function. Urea is suitable for treating symptoms like scaling or cracking. It is also well known for its ability to increase the water content of the skin's top layers by decreasing transepidermal water loss (TEWL).

The aim of this study was to examine the efficacy, safety, and tolerability of a Medical Device (MD) **15102** containing 30% of urea in older patients with xerosis cutis.

Methods

The studied MD 15102 contained 30% of urea and emollients: argan oil, avocado oil, and glycerin.

In vivo: was an open-label study, in which adults aged 40-73 years with mild-to-moderate symptoms of xerosis cutis were instructed to apply the MD 15102 on dry skin once or twice daily for 2 weeks.

In vitro: study skin irritation (EpiDerm, MatTek) and MTT cytotoxicity (L 929 cells) assays were performed. Raman fingerprint test was perfomed on a human skin substitute Strat-M membrane (Merck-Millipore, USA), to estimate product's permeability throught the skin layers.

Conclusions

The Medical Device 15102 was biocompatible with the skin and well-tolerated. It may represent a valid therapeutic option for xerosis cutis.

KEYWORDS: Medical device, xerosis cutis, urea, emollients, tolerability

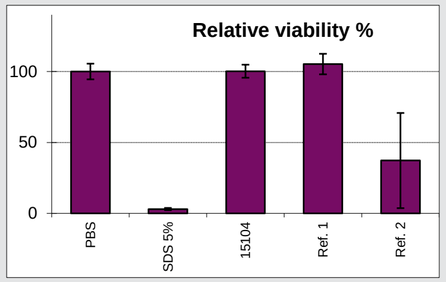
Results

In vivo: Twenty subjects were included. One patient stopped the treatment due to an acute allergy reaction. Overall tolerability was good to excellent for all 19 subjects that completed the study. Subjects reported decreased severity of xerosis cutis at the end of the study compared with Day 1, claiming long-lasting skin hydration (80%) and reduction in skin roughness (90%). The average improvness in skin condition (measured by level of moisturization) was 33%. Most subjects were satisfied with the product application and expressed a wish to continue using the product in the future (89% and 75%, respectively).

Subjects' self-assessment	% subjects
The product keeps the skin hydrated	80
Protects the skin from dryness	95
The product regenerates the skin – reduces roughness and makes it smoother to the touch	90
Reduces existing corns and calluses	85
Prevents corns and calluses	80

Table 1. Self-assessment after 2 weeks of MD 15102 application. **Study participants reported increased skin regeneration, hydration, softness, as well as restored skin comfort.**

In vitro: The tested product did not show skin irritation potential (mean tissue viability – 101,9%). It has been also confirmed that it was deemed as not cytotoxic (viability >70% of the control) towards L-929 cells at the concentration of at least or equal to 0,1%. No penetration of the product through the human skin substitute was found.



Classification		
PBS	NI	qualified
SDS 5%	I	qualified
15104	NI	qualified
Ref. 1	NI	qualified
Ref. 2	I	SD>18

NI – non-irritant
I – irritant

	mean of OD	SD of OD	mean of viabilities [%]	SD of viabilities	CV % [%]
PBS	1,901	0,104	100,0	5,49	5,49
SDS 5%	0,058	0,015	3,1	0,77	25,40
15102	1,937	0,040	101,9	2,09	2,05
Ref 1	2,001	0,138	105,3	7,25	6,89
Ref 2	0,708	0,638	37,3	33,58	90,11

Figure 1. Skin irritation potential of MD 15102 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 (R38). Tissue viability ≥ 50% of the control — non-irritant.
The tested MD 15104 was confirmed as **non-irritant** on EpiDerm skin model, resulting in the **mean tissue viability of 101,9%.**

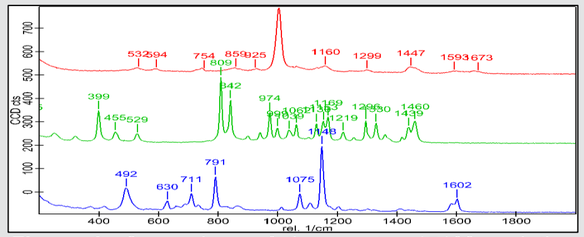


Figure 2. Comparison of the spectra 15102 and the spectra of the human skin substitute (Strat-M) layers.

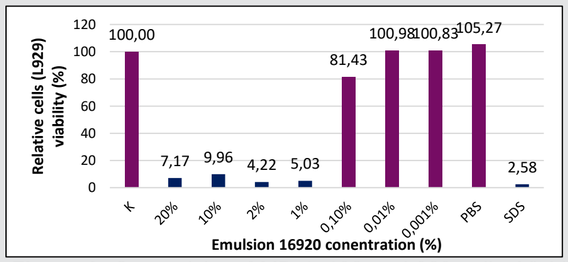


Figure 3. Cytotoxicity of MD 15102 on L929 cells. Viability <70% of the control - cytotoxic potential. Ref – 5% SDS. The tested MD emulsion was **non-cytotoxic at the concentration at the concentration of at least or equal to 0,1%** (cells viability: 81,43%).