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Safety, efficacy and tolerability of a medical device starch-based cream-to-powder formulation: *in vitro* and observational study from a dermatologist

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Background

Sweat, inadequate hygiene, skin-to-skin friction may trigger skin chafing or intertrigo. Barrier creams and powders containing magnesium silicate (talcum powder) have been commonly used for the prevention of these conditions because of their water-absorbing and have friction decreasing properties. However, some of the patients are concerned about talcum powder's safety due to case reports of its side effects, including pulmonary complications and risk of tumors. We developed a safe medical device cream-to-powder product with a formula based on natural tapioca starch and zinc oxide for use in sensitive areas prone to chafing and irritation.

Objectives: The aim of this study was to examine the efficacy, safety and tolerability of a Medical Device (MD) **15104** starch-based cream-to-powder formulation.

Methods

In vivo – group 1: In this open-label study, we included adults of oth sexes aged 50-93. Twenty subjects were recruited from September to November 2020. They or their caregivers were asked to apply MD 15104 on the cleansed skin between skin folds or other sensitive areas prone to friction once or twice daily for 2 weeks. Satisfaction and self-reported changes in skin appearance were measured on a 100-point scale.

***In vivo – group 2*:** In this open-label study, we included adults of both sexes aged 32-89. Sixteen subjects, including recumbent, were recruited by a dermatologist from October to November 2020. They or their caregivers were instructed to use MD 15104 same as above. Changes in skin appearance were assessed by a dermatologist.

Dermatological patch test: The forearm skin of 20 healthy adults with sensitive skin was repeatedly exposed to MD 15104 with Whatman 3 assay papers. The appearance of skin irritations was assesed by a dermatologist.

In vitro: 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 15104 was biocompatible with the skin and well-tolerated. It may be considered as an effective replacement for products containing talcum powder to prevent and manage mild-to-moderate symptoms of skin chafing or intertrigo.

KEYWORDS: Medical device, intertrigo, chafing skin, tolerability

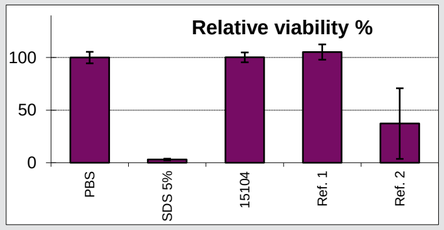
Results

In vivo: Thirty-six subjects were included and completed the study. Twenty subjects were examined in the Dr Irena Eris Centre for Science and Research. All the subjects (100%) reported decreased discomfort from skin irritation at the end of the study compared with Day 1. The mean self-reported improvement in skin condition was 36%. The next sixteen patients were included from a non-hospital-based dermatologist. The dermatologist confirmed reduced redness in irritated and that it may be used used prophylactically. Most subjects were satisfied with the product application. Overall tolerability was very good to excellent, including recumbent patients. No allergy reaction was reported. Similarly, the patch test results showed that use of MD 15104 does not irritate the skin.

Subjects' self-assessment (group I)	% subjects
The product protects the skin against damage	95
Reduces itching and burning sensation	90
The product reduces discomfort resulting from damage to the superficial layers of the skin	100
Has soothing effect on skin irritated by friction	100
Prevents irritation	85
Strengthens the protective properties of the skin	95

Table 1. Self-assessment after 2 weeks of MD 15104 application. **Study participants reported increased skin regeneration, soothing as well as restored skin comfort and reduced pruritus.**

In vitro: The tested product did not show skin irritation potential (mean tissue viability – 100,2%). It has been also confirmed that it was deemed as not cytotoxic (Figure 3) towards L-929 cells at the concentration of at least or equal to 0,01%. 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
15104	1,904	0,088	100,2	4,62	4,62
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 15104 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 100,2%.**

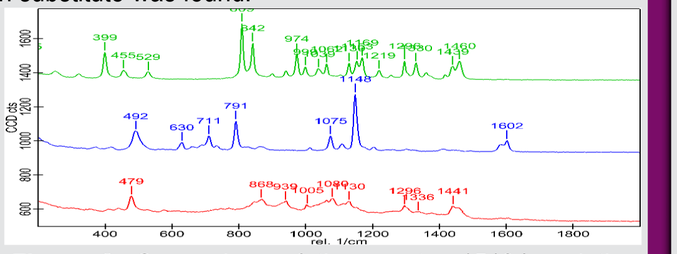


Figure 2. Comparison of the spectra 15104 and the spectra of the human skin substitute (Strat-M) layers.

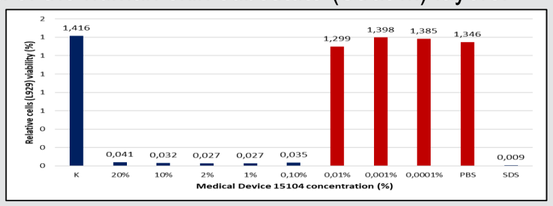


Figure 3. Cytotoxicity of MD 15104 on L929 cells. Viability <70% of the control - cytotoxic potential. Ref – 5% SDS. The tested MD emulsion was **non-cytotoxic at the concentration at the concentration of at least or equal to 0,01%** (cells viability: 91,74%).