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Psoriatic skin care – *in vitro* and *in vivo* safety and efficacy study of products based on pale ichthyol

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INTRODUCTION

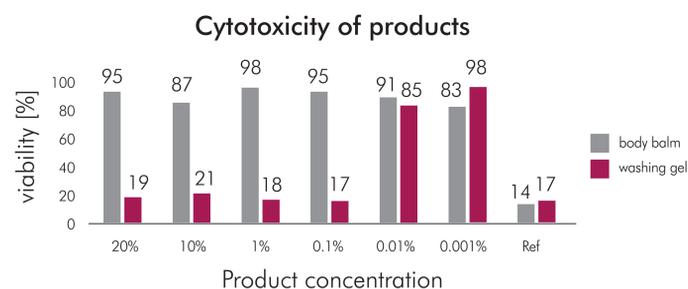
In vitro safety testing is necessary in order to fulfil regulatory procedures for medical devices or cosmetic products and is crucial for patients suffering for inflammatory skin disorders. Moreover, *in vitro* skin compatibility tests can be utilized as a valuable tool in evaluating dermal irritation potential prior to dermatological tests. Here we demonstrated both *in vitro* and *in vivo* safety and efficacy evaluation of the set of products containing pale ichthyol (body balm, body/scalp spray and scalp and body wash gel) intended for people with psoriasis.

MATERIALS AND METHODS

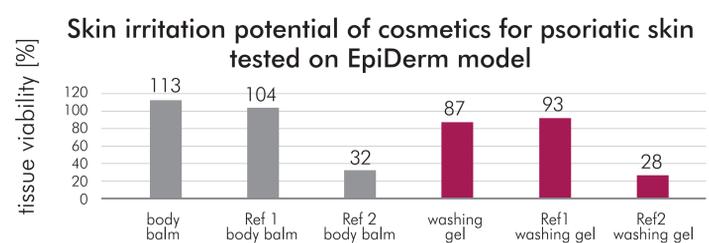
The skin compatibility of cosmetics based on pale ichthyol (body/scalp washing gel 1462A, body balm 1461A, scalp spray 1463) was assessed by two independent *in vitro* tests: MTT cytotoxicity on L929 cells according to ISO 10993-5:2009 and skin irritation on EpiDerm skin model according to OECD test guideline 439. Clinical trial was conducted on 35 patients, average age – 39 years old (17-62) and with PASI score 12,99. Patients were using body cream 1461A, shower gel 1462A and body/scalp spray 1463 based on pale ichthyol. PASI, DLQI, skin condition in 10-point analogue scale were assessed, as well as patients' self-evaluation.

RESULTS

In vitro studies



Viability <70% of the control - cytotoxic potential
Ref – 0,5% SDS



Correlation of *in vitro* and *in vivo* results:
Tissue viability ≤ 50% - irritant (R38) Tissue viability ≥ 50% - non-irritant
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)

SUMMARY OF IN VITRO TESTS Body Balm; non-irritant on EpiDerm skin model (tissue viability 113%), not cytotoxic (viability >70% of the control) towards L-929 cells at the concentration of at least or equal to 20%. Washing Gel; non-irritant on EpiDerm skin model (tissue viability 87%), not cytotoxic (viability >70% of the control) towards L-929 cells at the concentration of at least or equal to 0,01%.

In vivo studies

Clinical evaluation

Clinical evaluation in 10-point analogue scale (n=35)	Change (%)
Skin pruritus	- 60%
Scale visibility	- 43%
Nutrition	+ 54%
Skin elasticity	+ 41%
Smoothness	+ 53%
Visibility of dandruff	- 65%
Skin scaling level on the scalp	-45%

PASI vs. DLQI

PASI vs. DLQI	D0	D21	% of change	Additional observations at the end of trials
PASI (Psoriasis area and severity index)	12,99	8,76	-33%	<ul style="list-style-type: none"> 3 cases with complete recovery 5 cases with reduction of PASI score over 60%
DLQI (Dermatological Life quality index)	10	7	-30%	<ul style="list-style-type: none"> 15 cases of improvement in the score levels 11 cases claimed, no effect' or, small effect' on life quality

DLQI scale:
0-1 no effect on life
2-5 small effect on life
6-10 moderate effect on life
11-20 very large effect on life
21-30 extremely large effect on life

Self evaluation

Body balm		Body and scalp spray		Body and scalp washing gel	
% of subjects	Statements	% of subjects	Statements	% of subjects	Statements
82%	minimizes the appearance of psoriatic lesions	74%	relieves itching and burning	88%	effectively cleanses the scalp and hair
92%	moisturizes	76%	moisturizes the scalp	76%	minimizes the appearance of psoriatic lesions on the body and scalp
88%	soothes and relieves irritations	74%	minimizes the appearance of psoriatic lesions on the scalp	72%	promotes skin regeneration on the body and scalp
83%	relieves itching and burning	74%	promotes skin regeneration on the scalp	83%	soothes and relieves irritations
73%	exfoliates scales	67%	minimizes the appearance of dandruff	86%	relieves the itching and burning of the body and scalp

In vitro assays showed that tested products were safe and display no-irritation potential. *In vivo* tests after 3 weeks of products usage, the PASI score decreased by 33% as well as DLQI was improved by 30%. Clinical evaluation in 10-point analogue scale revealed that pruritus decreased by 60%, skin smoothness increased by 53% and visibility of scalp desquamation decreased by 45%. Patients' self-evaluation showed that skin care e.g. decreased the visibility of psoriatic lesions (82%, body balm treatment), relieved itching and burning (83%, body balm) and minimized the appearance of dandruff (67%, scalp treatment).

CONCLUSION

We have demonstrated that products containing pale ichthyol provide safe and effective skin care for patients suffering for psoriasis. Proper skin care can support psoriasis medical treatment extending the periods of remission, and preventing flare-ups.