

Safety assessment of bath emollients intended for children

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INTRODUCTION AND OBJECTIVE

Proper skin care plays a key role in restoring skin barrier function in children both with healthy skin and suffering from atopic dermatitis. Atopic dermatitis (AD) is a common chronic, recurrent, inflammatory dermatosis with associated pruritus, characteristic age-specific morphology and distribution of skin lesions. Emollients should form the basis of atopic dermatitis management.

The aim of our study was to evaluate the safety of a new emollient-based dermocosmetics intended for everyday hygiene of children with healthy as well as AD skin. These dermocosmetic formulations are based on Canola and Hemp oils, containing essential oils and high ratio of unsaturated fatty acids, which are the key elements in epidermal barrier formation as well as regulators of inflammation.

MATERIALS AND METHODS

IN VITRO STUDIES

The skin compatibility of bath emollients based on natural, plant anti-inflammatory oils 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.

IN VIVO STUDIES

After that emollient rinse off products were **patch tested** on 28 adult volunteers with dry, sensitive skin prone to allergic reaction. Finally, cleansers was tested in **in-use tolerance study** on 31 children with AD (16 mths-17 yrs old, home-panel study) and with 115 children with healthy skin (under 5yrs old; clinical-panel study). The patients were selected on the basis of dermatological interview and skin examination. Medical doctors were evaluating skin condition of patients using 10 point analogue scale before and after 2 weeks treatment with tested products. The patients or their legal guardians were evaluating safety and efficacy of products in the questionnaire at the end of the test.

RESULTS

SUMMARY OF IN VITRO TESTS

Bath Oil

- **non-irritant** on EpiDerm skin model (tissue viability 123%)
- **not cytotoxic** (viability >70% of the control) towards L-929 cells at the concentration of at least or equal to **10%**

Washing Gel

- **non-irritant** on EpiDerm skin model (tissue viability 96%)
- **not cytotoxic** (viability >70% of the control) towards L-929 cells at the concentration of at least or equal to 0,01%

SUMMARY OF IN VIVO TESTS

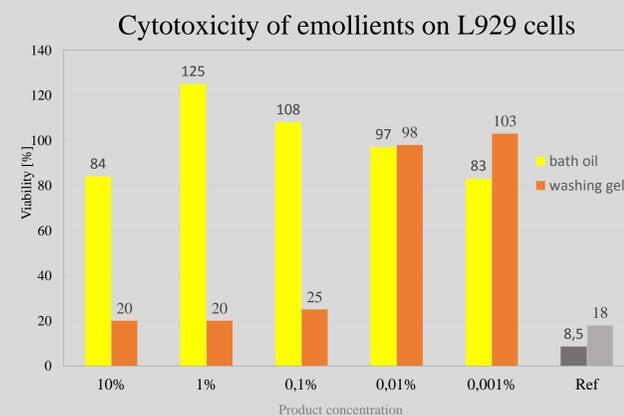
Tested cosmetics under occlusive patch on a panel of 28 adult volunteers induced **no skin irritation or allergic reaction**. Finally, rinse off application of tested cleansers, in 146 children subjects, demonstrated that emollients were **well tolerated** according to both patients' and specialists' (dermatologists or paediatricians) assessment, regardless of the age of subject. Moreover, in-use study showed that tested products induced **no skin irritation or allergic reaction in healthy subjects as well as subjects affected by AD**. In opinion of dermatologists both products **decreased visible dryness of skin** as well as **increased skin elasticity and smoothness**. In patients' opinion both products were **delicate and reduced symptoms of dryness and roughness of the skin**.

CONCLUSION

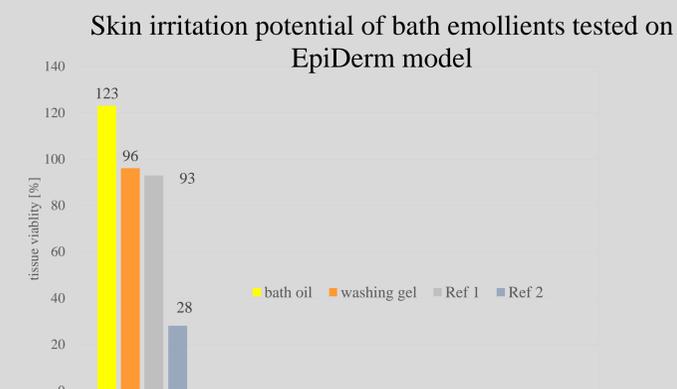
In-depth evaluation of the product safety is crucial in the development of cosmetics intended to children. In our study bath emollients were assessed as safe in either in vitro, patch tests or in-use tolerance tests. Multistage testing strategy of cosmetics presented here could be useful for minimizing the risk of adverse skin reaction.

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)

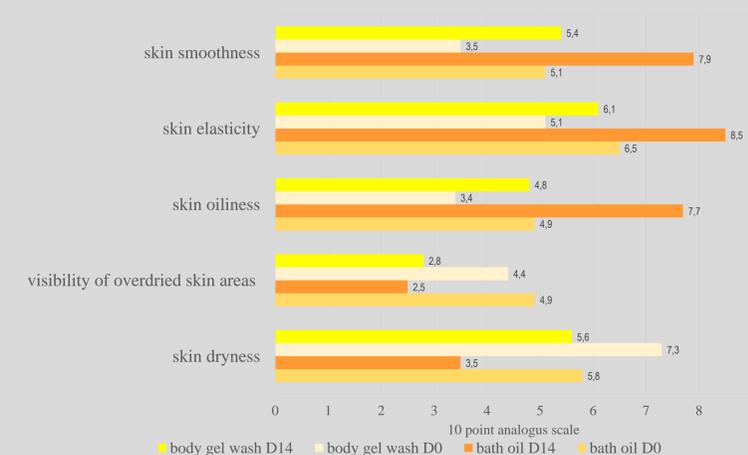
Ref 2 - cyclamen aldehyde (CAS 103-95-7) – classified (irritant, Cat. 2)

IN VIVO STUDIES

Self-evaluation of products after 2 weeks of usage

Patients self assessment	Bath oil		Washing gel	
	Yes	No	Yes	No
Effects after 2 weeks of treatment				
Is washing without overdrying the skin	100%	0%	100%	0%
Moisturized the skin	93%	7%	88%	6%
Nourishing the skin	87%	7%	50%	25%
Softens and smoothens	93%	7%	81%	6%
Sooths irritations and calms the skin	80%	0%	69%	6%
Is reducing symptoms of skin roughness	93%	7%	94%	6%
Is reducing pruritus and skin scaling	80%	0%	50%	19%
Is delicate even for sensitive skin	100%	0%	100%	0%

Clinical evaluation of skin condition in 10-point analogous scale, before and after 2 weeks of usage of bath oil and washing gel



Scale measure:
skin dryness, visibility of overdried skin areas: 1 – mild/lack of symptoms, 10 - severe symptoms; skin smoothness, elasticity, oiliness: 1 - very low, 10 - very high