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COSMETIC LABORATORIES

# Safety assessment of leave-on emollients intended for AD skin

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## Introduction

Proper skin care plays a key role in restoring skin barrier function in children both with healthy skin and suffering for atopic dermatitis. Emollients are the basis of AD management.

## Aim of the study

To evaluate the safety of an emollient-based dermocosmetics intended for everyday usage for infants, children and adults with healthy as well as with AD skin.

## Material and Methods

Two leave-on emollients (16912 and 16914) based on natural, plant anti-inflammatory oils were assessed by in vitro tests: cytotoxicity on L929 cells according to ISO 10993-5:2009 and skin irritation on EpiDerm model according to OECD test guideline 439. Dermatological patch test was performed on 29 adult volunteers with skin prone to allergic reaction. Tolerance and efficacy of products were tested on 23 children with AD (2 - 17 yrs) and with 108 children with healthy skin (< 5yrs old). Dermatologists were evaluating skin condition using 10 point analogue scale and instrumental measurements (Corneometer and Sebumeter) before and after 2 weeks treatment were performed.

## RESULTS:

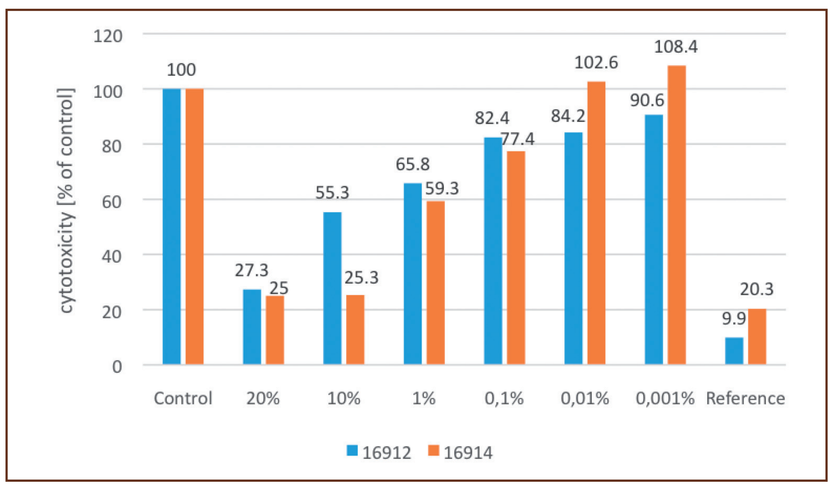


**Fig. 1.** *In vitro* cytotoxicity of two leave-on emollients performed on L929 cell line according to ISO 10993-5:2009. Viability < 70% of control is equal to cytotoxic potential. Products are non-cytotoxic in 0,1% of concentration. Reference – 0,5% SDS.

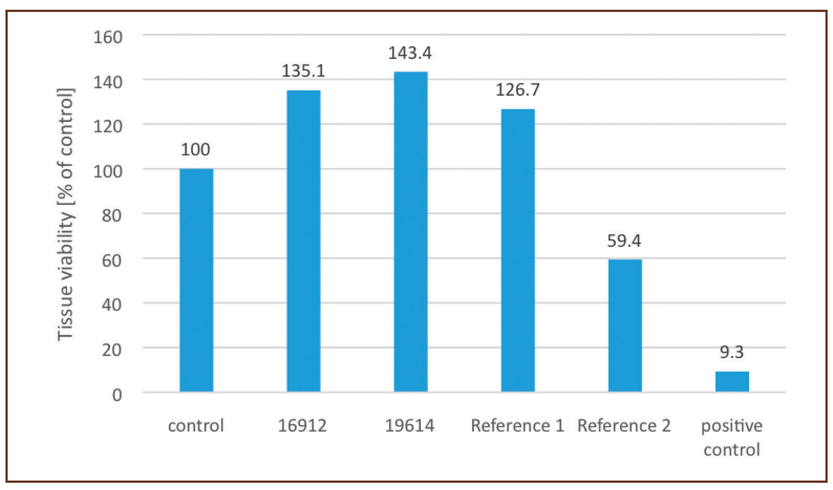


**Fig. 2.** *In vitro* skin irritation test on EpiDerm skin model performed according to OECD guideline 439. **Corre-lation of *in vitro* and *in vivo* results: tissue viability ≤ 50% - irritant, tissue viability ≥ 50% - non-irritant.** Reference 1- naphthalene acetic acid (CAS 86-87-3) – non-classified. Reference 2 - cyclamen aldehyde (CAS 103-95-7) - classified (Cat. 2, *in vivo* score 2,3 so it may give borderline results).

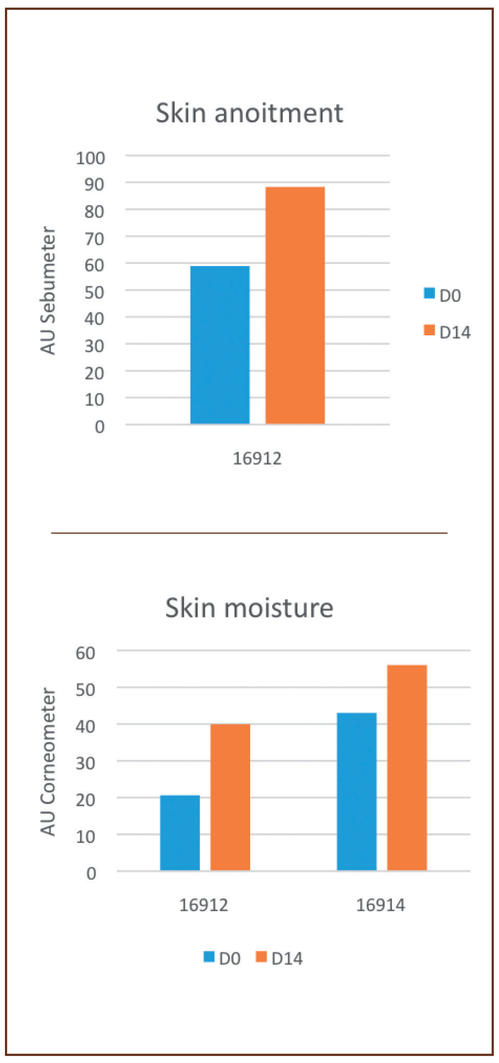


**Fig. 3.** *In vivo* measurements of skin condition of 10 children (in each emollient) with atopic skin with Sebu-meter and Corneometer (Courage-Khazakha) before and after 2 weeks of emollients treatment.

| Dermatological evaluation of the patient's facial skin condition (1 – bad/small; 10-very good/big) | 16912 | | | 16914 | | |
|---|---|---|---|---|---|---|
| | D0 | D14 | % of change | D0 | D14 | % of change |
| Skin dryness | 4,9 | 1,9 | **-61%** | 9 | 6,1 | **-32%** |
| Skin anointment | 5,6 | 9 | **+61%** | 1,6 | 4,5 | **+81%** |
| Elasticity | 8,4 | 9,7 | **+15%** | 4 | 4,5 | **+13%** |
| Smoothness | 7,1 | 9,3 | **+31%** | 2,4 | 5,2 | **+17%** |
| Dry spot visibility | 2,8 | 0,4 | **-86%** | 6,2 | 2 | **-26%** |

**Table 1.** Dermatoligical evaluation of skin condition in children with atopic skin before and after 2 weeks of emollient treatment according to 10-point analogue scale. In opinion of dermatologists products decreased visible skin dryness and dry spots as well as increased skin elasticity and smoothness.

| Effects after 2 weeks' treatment | % of patients | |
|---|---|---|
| | 16912 n=10 | 16914 n=12 |
| Moisturizes skin | 100% | 92% |
| Nourishes and anoints skin | 100% | 67% |
| Softens and smoothens | 90% | 75% |
| Regenerates and restores elasticity | 80% | 67% |
| Regenerates and increases the natural protective layer of the skin | 50% | 58% |
| Restores comfort of the skin | 100% | 75% |
| Soothes and calms skin irritation | 100% | 58% |
| Reduces the signs of skin roughness | 100% | 83% |
| Reduces itching and flaking of the skin | 100% | 50% |
| Prevents increase in skin changes (dryness and flaking) | 100% | 83% |
| Prevents micro damages of the skin | 80% | 92% |

**Table 2.** Self-evaluation of two emollients after 2 weeks of usage. In patients' opinion both products were delicate and reduced symptoms of dryness and roughness of the skin.

## CONCLUSION:

Emollients were non-cytotoxic and non-irritating according to *in vitro* tests.
Under occlusive patch no skin irritation or allergic reaction was induced. Also application demonstrated that emollients were well tolerated regardless of the subject age.
Evaluation of the product safety is crucial in the development of cosmetics intended for children. In this study 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.