

## APPENDIX A

### SUMMARY OF APPLICATION TEST ON PSORIASIS LOTION

#### Formula analysis

The product does not contain ingredients with well-known allergenic or irritating properties. The product contains cannabis oil, vegetable complexes that intensely and deeply moisturize the skin, vitamins, solvents, and a preservative – all of them permitted to be used in cosmetic products. The product is manufactured OCEANIC S.A. in Sopot.

#### Test objectives

The application test was performed to evaluate functional properties, effectiveness and tolerance of the **product marked 20003214 (Psoriasis lotion)** in the period of 10.05.2021 – 16.07.2021.

#### Material and methods

The sample consisted of 60 people of both sexes:

- 21 people had psoriasis
- 20 people had symptoms of atopic/dry/sensitive skin
- 10 people had skin showing signs of excessive exfoliation/keratosis
- 9 people had type I and II diabetes

aged from 22 to 72 with various types of skin. The subjects were qualified for the sample based on personal medical examinations performed by a dermatologist-allergologist. The subjects were instructed to use the product in accordance with manufacturer's recommendations (i.e., applied x 2 daily on clean skin). People with dermatoses (any skin defect or lesion on the skin) used it as a conditioning/supplementary cosmetic during the dermatological treatment. Each time the application cycle lasted for 4 weeks.

The skin condition was assessed 2 times a week and after the test completion by dermatologists/allergologists.

#### Results

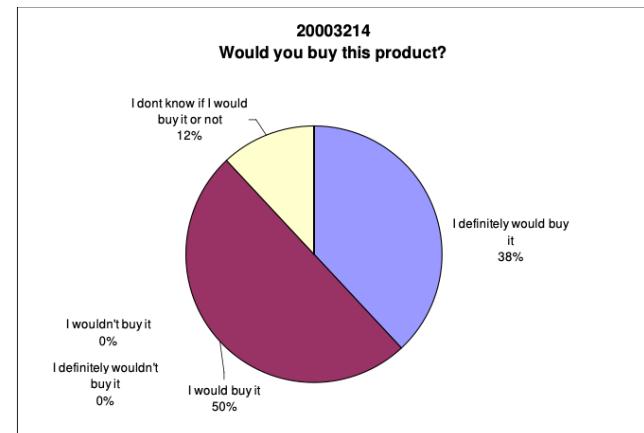
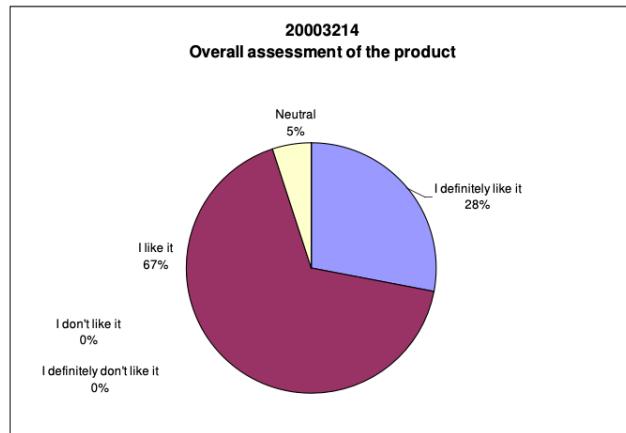
Based on application test results, the analysis of the outcomes of the questionnaire filled in by all test participants, additional observations of test participants, and the observations of the dermatologists/allergologists supervising the tests, the following comments can be formulated on product properties:

Conditioning properties	Evaluation of product by participants (%)
soothes skin irritations/reddening	75%
eliminates skin itching	70%
oils and moisturizes the skin	92%
protects the skin against excessive dryness	90%
improves skin looks and condition	87%
eliminates skin dryness and tightness	91%
offers an effect of nourished/regenerated skin	87%
offers an effect of smoothed/softer skin	81%
makes scale less visible	66%

In addition, the product can be easily applied and spread on the skin surface, can be quickly absorbed, and leaves a delicate protective layer on the skin with no effect of excessive stickiness. No irritation/allergy symptoms were observed in any test participant in places of cosmetic application or any other place of the skin.

As far as overall cosmetic assessment is concerned, **95%** of participants gave the tested cosmetic a very good or good rating.

**88%** of participants declared they would like to buy the tested product.



## Conclusion

The test results are the basis for formulating a positive opinion about the product:

- **It is a comfort cosmetic to condition** the skin of people **with various dermatoses or dry, sensitive, or exfoliating** (i.e., removal of dead skin cells from the skin surface) skin.
- **It can be used as a cosmetic conditioning the skin or supplementing dermatological treatment.**
- **It intensely moisturizes and oils the skin;** when used systematically, it **eliminates symptoms of exfoliated and tightened skin.**
- **It is safe for the skin** – no symptoms of irritation or allergy were observed during the application program.

The product should not be used by people with diagnosed allergy to any component of the tested cosmetic.

## APPENDIX B

### SUMMARY OF DERMATOLOGICAL TEST ON PSORIASIS LOTION

#### Test objectives

The objective of the dermatological test was to evaluate irritating and allergenic properties of the **product marked as: 20003214 (Psoriasis lotion)** performed on the skin of adults with the use of a patch test.

## Test methodology

The tests were carried out in two stages, on the group of 50 people of Caucasian race, with I-IV Fitzpatrick (classification of the skin by its reaction to exposure to sunlight) skin types.

The first stage took place at the „Kogotest” Dermatology Treatment Room in Gdańsk which involved 30 participants (19 women and 11 men) aged from 20–70. Out of the 30 patients, 23 were healthy and 7 reported having dermatoses. From among 5 patients with dermatoses 4 had diagnosed psoriasis, 2 – juvenile acne, and 1 – atopic dermatitis.

The second stage of the test was performed at the Allergology Laboratory, Dermatology Clinic of the Medical University of Gdańsk, with the participation of 20 patients with reported allergic dermatoses. The group consisted of 11 women and 9 men aged 19–57. On the strength of dermatologic examinations/interviews 11 patients had various types of contact dermatitis and the remaining 9 patients were diagnosed with atopic dermatitis.

In all cases patch tests were performed according to the guidelines of the Allergology Section, Polish Dermatological Association.

The results were read and interpreted according to the principles of the International Contact Dermatitis Research Group (ICDRG). The product is manufactured by **OCEANIC S.A. in Sopot**.

## Results

In all tested participants, both from the group of patients with allergic or non-allergic dermatoses, and healthy ones, epidermal tests of the said medical product brought negative results, i.e., **no pathologic changes were observed either in places of patch adhesion or in any distant place**. It must also be emphasized that in 8 patients tested at the Allergology Laboratory who had shown positive results of patch tests with European Baseline Series standard allergens (such as nickel sulphate, fragrance composition I, methylisothiazolinone) tests with the said **medical product also brought negative results**.

Aggregate assessment of test results in both tested groups (assessment of the irritation/allergy index –**W<sub>PA</sub>**):

Tested samples/WPA	Results after 48 hours	Results after 96 hours	Result interpretation
Phase I: 30 participants	0.00	0.00	No irritating/allergenic properties
Phase II: 20 participants	0.00	0.00	
<b>W<sub>PA</sub></b>	0.00		

## Conclusion

The product (Psoriasis lotion) fulfils the requirements of the Skin Compatibility Test and **thus can be categorized as nonirritating/non-allergenic**.

- Negative patch test results in patients who showed positive results of tests with standard allergens confirm that the product has no allergenic properties.
- Obtained test results cannot rule out individual hypersensitivity to the product in people with allergy to any of its ingredients.