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**THE REPORT FROM
DERMATOLOGICAL RESEARCH
DETERMINING THE DEGREE OF PROTECTION
AGAINST UV RADIATION
WATER RESISTANCE
Xtrem Sun FPS 15**

Basis for the conducted research:

Order of 15.03.2011 made by Dr Piotr Koziej Centrum Kosmetyków Sp. j. and research material delivered in original packaging.

Manufacturer:

Laboratorios Diet Esthetic S.A.

Time frame of the conducted research:

18.03.2011r. – 01.04.2011r.

Product's qualitative composition:

Glycine Soja Oil (Soybean Oil), Ethylhexyl Methoxycinnamate (Octinoxate), Benzophenone-3 (Oxybenzone), C₁₂₋₂₀ Alkyl Benzoate, Polyisobutene, Cyclopentasiloxane, Butyl Methoxydibenzoylmethane (Avobenzone), Helianthus Annuus (Sunflower Seed Oil), Daucus Carota Sativa (Carrot Oil), Beta-Carotene (Carrot Extract), Tocopherol, B.H.T., Parfum (Fragrance); Geraniol, Benzyl Benzoate, Limonene, Linalool, C.I. 47000, C.I. 26100, C.I. 61565

The customer is responsible for conformity with declared qualitative and quantitative composition and microbiological purity of the delivered research samples.

Method of the research:

- All research of the preparation „Xtrem Sun FPS 15” was conducted under supervision of doctors-specialists of dermatology.
- The research was done in accordance with Act of 30 March 2001 about cosmetics No. 42, pos. 473 Art. 11 sec. 1 p. 4: evaluation of cosmetics influence on human health safety – including research regarding skin tolerance to a tested cosmetic product done by path test – half – open – European Cosmetic Directive 76/768/EEC (with amendments)
- The apparatus tests were performed using the TH-1 Skintest –Kit.

Selection of subjects - human volunteers:

- The selection of subjects, human volunteers, was conducted by a dermatologist in accordance with the Declaration of Helsinki from 1964, as amended, Polish and EU regulations, and COLIPA guidance using inclusion and exclusion criteria.

A. THE DERMATOLOGIC RESEARCH /Patch Test/

In order to execute a diagnostic test regarding harmlessness of the influence on human skin and showing a possible toxic-irritant or sensitizing characteristic of the delivered „ Xtrem Sun FPS 15”, a diagnostic test with 30 persons was conducted: 22 women and 8 men of the age between 24 – 56 years old. The participants were informed, not to use any anti – histamine pharmacological medicine in this time, which could affect the outcome of the research. The skin of the participants and their subjective impressions were evaluated before the preparation's application, during and after the doctors-specialists of dermatology finished the research. With the above mentioned preparation epidermal patch tests were conducted. Exposition of the tests lasted 48 hours. The results of the patch tests were read after 48 and 72 hours from the application time.

The results:

All results of the patch tests were **negative.**

B. UV PROTECTIVE FACTOR STUDY

The UV protective factor study was performed in accordance with the Recommendation of the Commission of the European Communities of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (*document number C(2006) 4089, 2006/647/EC*).

Sunscreen products should be sufficiently effective against UVB and UVA radiation to provide a high level of health protection. For this purpose, a sunscreen product should provide the minimum UVB and UVA protection. Protection against UVA and UVB radiation should be interconnected. Scientific findings show that some of the biological damage to the skin can be prevented or reduced if the level of SPF measured in the persistent pigment darkening test (i.e. fighting mainly UVA radiation) is at least 1/3 of the factor measured by the sunscreen test (i.e. fighting mainly UVB radiation). Additionally, in order to provide comprehensive protection, dermatologists recommend a critical wavelength of at least 370 nm.

For the determination of MED, SPF, PPD the UV TH – 1 lamp was used containing UVA radiant with a spectrum of 320 - 400 nm with a peak emission of 370 nm and UVB spectrum of 280 - 320 nm. MED indicates the minimal erythema dose which causes a distinct erythema after 24 hours.

DETERMINATION OF MED: MED (minimal erythema dose) was measured in each of the 15 subjects prior to the determination of the protective factor of the

sunscreen product. One cm² skin areas that are usually not irradiated (the back) were irradiated with a UV lamp with doses of UVB 0.01J/cm², 0.02J/cm², etc. up to 0.1 J/cm². MED was read as the lowest dose of UVB radiation which caused a erythematous reaction, usually after 2 hours, which remained after 24 hours and produced melanosis after 48 hours. The average MED determined in the Laboratory in the aforementioned manner was 0.07 - 0.11J/cm² for persons with skin types 1 – 3. In an analogous appropriate manner, the MED UVA was determined, which amounted to 7 - 10J/cm²

DETERMINATION OF SPF, PPD: In order to determine the SPF, PPD against UVB/UVA rays, studies were performed on 15 subjects of different skin types ranging in age between 26 to 54 years, after a prior assessment of the subject's skin by a dermatologist in order to exclude possible lesions, which would prevent the proper conduct of the study or its correct interpretation. The determination was consistent with the principles of Colipa. The tested product – "Xtrem Sun FPS 15" was applied onto 1 cm² skin areas of the back (2 mg/cm²), and next to it the control Colipa – P2 sample. And then after 10 minutes, the skin areas were irradiated with increasing doses of UVB UVA, which were the multiple of MED for each volunteer. The increase in dose was 1 MED. The standard range of radiation doses ranged from 1 – 10, 11 – 20 MED. Erythema was read after 2, 24, 48 and 72 hours.

Results:

In the 15 studied persons, the UVB (SPF) photo protection factor of the "Xtrem Sun FPS 15" ranged from 14 - for those with the first phototype of skin sensitive to sunlight - to 18 in patients with the third phototype and dark complexion, and the mean was 16.

The protection factor in the control Colipa P2 sample similarly varied from 15 to 19, and the mean was 16,9.

The conducted studies also showed that the UVA protection factor /PPD measurement of skin turning brown after irradiation – after the stabilization of color – permanent pigmentation/, in particular persons included in the study, was more than 1/3 of the factor measured by the sunscreen test (i.e. fighting mainly UVB radiation)

C. WATER RESISTANCE STUDY

For the determination of MED and water resistance /SPF after water immersion/, a UV TH - 1 lamp was used, containing UV lamps of the 280 - 320 nm spectrum.

MED indicates the minimal erythema dose which causes a distinct erythema after 24 hours.

In order to determine the MED and the rate of water resistance, studies were performed on 10 subjects of different skin types ranging in age between 27 to 47 years, after a prior assessment of the subject's skin by a dermatologist in order to exclude possible lesions, which would prevent the proper conduct of the study or its correct interpretation.

DETERMINATION OF MED: MED (minimal erythema dose) was measured in each of the 10 subjects. For this purpose, 1 cm² skin areas of the back were irradiated with a UV lamp with doses of UVB 0.01J/cm², 0.02J/cm², etc. up to 0.1 J/cm². MED was read as the lowest dose of UVB radiation which caused a erythematous reaction, usually after 2 hours, which remained after 24 hours and produced melanosis after 48 hours. The average MED determined in the Laboratory in the aforementioned manner was 0.07 - 0.11J/cm² for persons with skin types 1 – 3.

WATER RESISTANCE: 10 persons, who had MED determined previously, took part in a study of the „Xtrem Sun FPS 15” product. The tested product was applied onto the skin of the back – 2 mg/cm². Fifteen minutes after application, these persons bathed in water for 20 minutes. After the bath, the skin of the subjects dried naturally for 15 minutes (without using a towel), and afterwards the tested persons took a bath for another 20 minutes. After the last water immersion, the skin of the subjects was radiated after 15 minutes or after complete drying with a UV light, which was a multiple of the MED for the particular subject, in order to once again determine the protection factor. The increase in dose was 1 MED. The range of doses of radiation ranged from 1 – 10, 11 – 20. Erythema was read after 2, 24, 48 and 72 hours.

Results:

It was shown that in the studied persons the protection factor after a bath was reduced less than 50% in relation to the initial factor, thus confirming that the „Xtrem Sun FPS 15” product is water-resistant.

CONCLUSIONS

- Based on the entirety of the conducted research there were no findings for symptoms, which would implicate a harmful, i.e. allergic or toxic-irritant influence of the tested „Xtrem Sun FPS 15” on skin – path tests negative.
- The issued opinion does not apply to anybody with an allergy to any of the ingredients of the tested preparation.
- The tested preparation fulfills requirements for cosmetic products of declared specifications, i.e. hypo – allergic in regards to human health safety /Act of 30th March 2001 about cosmetics in terms of article 11, act 1, point 4/.
- The UV protective factor study was performed in accordance with the Recommendation of the Commission of the European Communities of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (document number C(2006) 4089, 2006/647/EC).
- The „Xtrem Sun FPS 15” product has SPF 15 according to the Colipa classification. It can be qualified as a preparation with a medium protective factor.
- The level of protection factor measured in the persistent pigment darkening (UVA) test is greater than 1/3 of that measured by the sunscreen protection test (i.e. fighting UVB radiation)

- Keep in mind that sunscreen products do not provide complete protection and require additional precautions. Thus, even when using a sunscreen product, prolonged exposure to the sun is not recommended, because excessive exposure to UV radiation poses a serious threat to health. This particularly applies to children and infants, who should be protected from direct sunlight.
- The study has shown that the „Xtrem Sun FPS 15” product has water-resistant properties.
- It has been shown that the protection factor after a water bath was reduced in relation to the initial factor by less than 50%.

DIAGNOSTIC-TEST

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