

PENTAPHARM

REGU[®]-SEB

The natural polyphenols in REGU[®]-SEB lead to a long-lasting reduction in sebum secretion. REGU[®]-SEB regulates sebum production especially in the T-zone area of greasy problem skin.

DESCRIPTION

REGU[®]-SEB is a clear, yellow to orange, slightly viscous solution containing polyphenol-rich fractions from the fruits of the North American saw palmetto and South American sesame seeds in a Moroccan argan oil base. Its perfectly balanced polyphenol formula, consisting mostly of lignans and phytosterols, helps to control and reduce sebum production, especially in the T-zone area of the face.

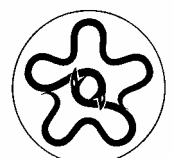
The phytosterols in argan kernels are unique in their composition. They exclusively contain rare and beneficial Δ -7 sterols. These sterols were already used as a remedy for acne vulgaris in Moroccan folk medicine. On the other hand, the fruits of the saw palmetto are rich in Δ -5 sterols, whereas valuable lignans can be found in sesame seeds.

COSMETIC BACKGROUND

Seborrheic skin is often a serious cosmetic problem: the complexion appears pale and uneven, the horny layer of the epidermis is thickened, the skin's noticeably greasy shine causes emotional stress, and the larger pores make the skin look coarse. The excessive production of sebum is also largely responsible for inflammation, pimples and blackheads. Contrary to popular notion, oily skin is thus less resistant. As most of the face's 20,000 sebaceous glands are situated on the forehead, chin and nose (the so-called T-zone), people with combination-type skin are particularly affected.

It is an undisputed fact that hormonal factors are the main cause of oily skin. Sun, stress, sweat and smog, however, are additional factors that adversely affect the skin and promote its oiliness. Oily skin is even more noticeable during the summer months and in tropical climates because of increased sweating. Moreover, dirt particles in urban areas accumulate on the skin, mix with sweat and sebum, and finally block up the pores. This in turn leads to irritation and to hormone-induced excess sebum production.

The biological action of REGU[®]-SEB helps to regulate the excess sebum and normalise its secretion on an ongoing basis.

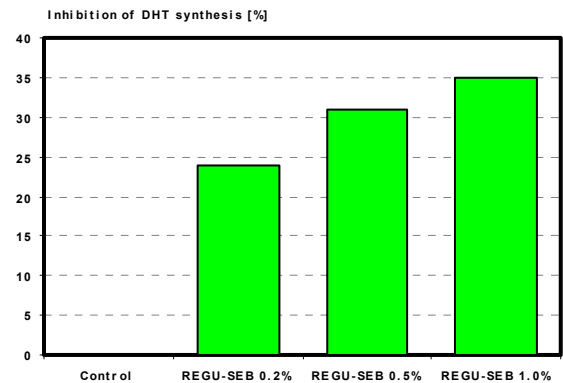


EFFICACY

IN VITRO INHIBITION OF 5 α -REDUCTASE

An overproduction of sebum is due to the hyperactivity of the skin's 5 α -reductase. This enzyme produces dihydrotestosterone (DHT), which stimulates the production of sebum. Inhibition of 5 α -reductase slows down the activity of the sebaceous glands.

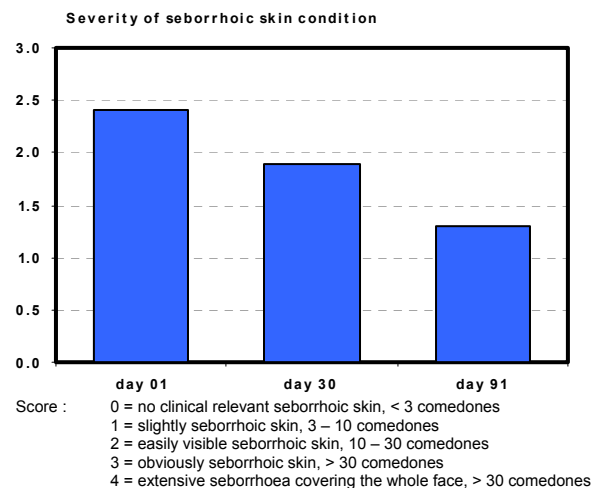
The sebum-regulating activity of REGU[®]-SEB was examined on reconstructed epidermis. REGU[®]-SEB was applied topically. A dose dependent inhibition of DHT synthesis up to 35% versus control could be shown with REGU[®]-SEB.



IN VIVO SEBUM REGULATION EFFICACY

Ten volunteers with seborrheic skin conditions applied a cream-gel containing 5% of REGU[®]-SEB to the face twice daily over a 90 day treatment period. A clinical assessment by dermatologists was performed before the first application as well as after 30 and 90 days of treatment.

A statistically significant decrease of 46% in severity of seborrheic skin condition was shown by clinical assessment after 90 days of treatment.



COMPLEMENTARY INFORMATION

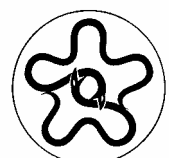
A questionnaire evaluation during the sebum regulation efficacy study revealed that REGU[®]-SEB was generally very well accepted by the subjects. Most subjects reported of very good efficacy and tolerance. 75% of the subjects would buy the product.

CONCLUSIONS

REGU[®]-SEB showed a very good efficacy in decreasing the severity of seborrheic skin condition via the inhibition of 5 α -reductase.

Although hereditary factors and hormones are the primary cause of oily and blemished skin, the 4S's (smog, sun, sweat and stress) are contributing factors that play an increasingly important role in our urban society, particularly as regards mature skin.

Due to its unique formula, REGU[®]-SEB is particularly suitable for use in special formulations designed to regulate excessively oily skin, especially in the T-zone area of the face. Thanks to its effectiveness and long-term benefits, REGU[®]-SEB is also an ideal active for use in product lines destined for the young generation.



TECHNICAL INFORMATION

PRODUCT SPECIFICATIONS

Appearance	:	Clear, yellow to orange, slightly viscous solution
Relative density (20°C)	:	0.90 – 0.95
Refractive index (25°C)	:	1.470 – 1.475
HPTLC	:	Corresponds
Microbial count	:	< 100 CFU/ml
Specified pathogens	:	Absent

PRESERVATION AND MICROBIOLOGY

As an oily solution, REGU[®]-SEB doesn't contain any preservative. REGU[®]-SEB is free of specified pathogens. The amount of non-pathogenic microorganisms with less than 100 CFU per ml of REGU[®]-SEB meets the CTFA microbiology guidelines.

SAFETY AND ECOLOGY

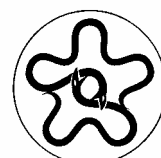
Results from safety testing have proved REGU[®]-SEB to be safe for use in cosmetic products. The data available don't indicate any environmental risk. The manufacturing process is designed to meet the criteria for the assessment of safety, health and protection of people and of the environment set out in the *Responsible Care Program*.

PROCESSING AND DOSAGE

REGU[®]-SEB can be processed either warm (< 80°C) or cold, and is incorporated into the oily phase of a cosmetic formulation. REGU[®]-SEB is compatible with ethanol at concentrations of up to 10%. For skin care preparations, we recommend the addition of 1 to 5% of REGU[®]-SEB. Basic Guide Formulations are available upon request.

STORAGE AND SHELF LIFE

REGU[®]-SEB should be stored in the original sealed containers protected from light in a clean place at a temperature between 15 and 25°C. In order to avoid secondary microbial contamination, following opening, containers should be handled with special care. If stored under the recommended conditions, REGU[®]-SEB remains stable for at least 3 years.



GENERAL PRODUCT INFORMATION

Trade name	: REGU [®] -SEB
Product Code	: 331-01
INCI Name (CTFA)	: Argania Spinosa Kernel Oil, Serenoa Serrulata Fruit Extract, Sesamum Indicum (Sesame) Seed Extract
EU-Labeling Name	: Argania Spinosa, Serenoa Serrulata, Sesamum Indicum
Chemical name	: Polyphenol-containing extracts of saw palmetto fruits and sesame seeds in an argan oil base
CAS No	: 299184-75-1, 84604-15-9, 8008-74-0
EINECS No	: 283-292-4, 232-370-6
NICNAS, listed under	: 84604-15-9, 8008-74-0
Customs Tariff No	: 1302.1900 (Harmonized System Number)
Shelf life	: 3 years

COMPOSITION

A) Ingredient(s)	INCI Name #	Amount *
Argan oil	Argania Spinosa Kernel Oil	A
Saw palmetto fruit extract	Serenoa Serrulata Fruit Extract	C
Sesame seed extract	Sesamum Indicum (Sesame) Seed Extract	C

B) Additives	INCI Name #	Amount *
Solvent	None	---
Preservative	None	---
Others (buffers, antioxidants, colorants)	None	---

CTFA Dictionary

* FDA-Code (A = > 50%, B = 25-50%, C = 10-25%, D = 5-10%, E = 1-5%, F = 0.1-1%, G = < 0.1%)

REMARK

Although these data and information have been prepared with the utmost possible care, we reserve the right to make changes due to product improvement and other considerations.

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