

PENTAPHARM

ELHIBIN®

The elastase inhibitor ELHIBIN® helps the skin to defend against the symptoms of accelerated aging. ELHIBIN® provides a complete solution for moisturizers, sun protection and after-sun products.

PRODUCT DESCRIPTION

ELHIBIN® is a biological, plant-based proteinase inhibitor system which represents a revolutionary active principle and amply meets the demanding criteria for protective skin care cosmetics.

The source of ELHIBIN® is *Soya hispida (Glycine max)*. ELHIBIN® is isolated and purified as a highly active yellowish aqueous solution by means of a worldwide patented and controlled multistep down-stream procedure performed in accordance with GMP. ELHIBIN® inhibits human leukocyte elastase, a proteinase that plays an essential role in irritation processes and accelerated skin aging.

BACKGROUND

Various biochemical and biophysical systems help to maintain the integrity of the skin via complex physiological processes with well-defined interactions between cells and proteolytic reaction cascades. Proteinases are involved in practically every aspect of life. Disturbance of the sensitive balance between proteinase and proteinase inhibitors, however, may lead to uncontrolled reactions. Proteinase activity is therefore carefully regulated by specific inhibitors.

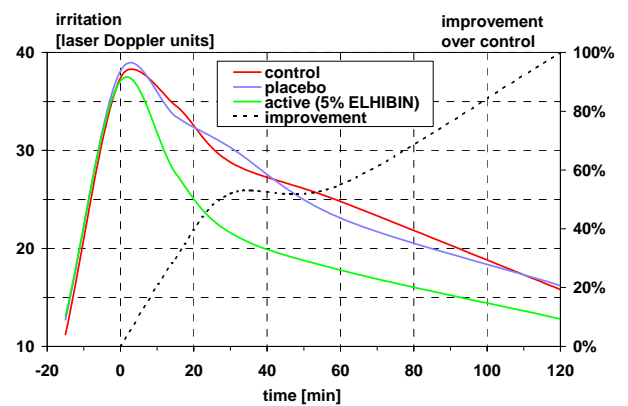
Any irritation caused by either UV-exposure or by environmental stress directly leads to the accumulation and stimulation of white blood cells, the so-called leukocytes. Stimulated leukocytes release large amounts of the proteinase elastase to their membrane surface and into their surrounding area. When uncontrolled, elastase is potentially the most destructive proteinase present in the body; it can attack all major connective tissue proteins. All uncontrolled elastase activity may thus endanger the integrity of the skin. Massively increased elastase activity is found in skin lesions due to allergic contact dermatitis, atopic dermatitis and psoriasis. However, elevated levels of elastase can also be found on the surface of dry skin and on skin irritated by UV-exposure and environmental stress. For this reason ELHIBIN® should be considered in the creation of new concepts for moisturizers, sun protection and after-sun products.



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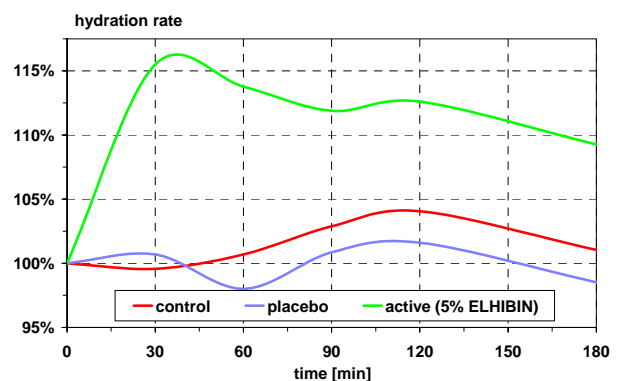
ANTI-IRRITANT PROPERTIES

The anti-irritant properties of ELHIBIN[®] incorporated at 5% into a gel formulation were evaluated on the inner forearm of ten human volunteers previously treated with Peru Balsam under semi-occlusive conditions. Skin irritation was assessed using laser Doppler technique. ELHIBIN[®] reduced irritation by more than 30% shortly after application and by more than 50% throughout the study. The results demonstrate that ELHIBIN[®] is a highly effective anti-irritant.



SKIN HYDRATION

The moisturizing efficacy of a single application of ELHIBIN[®] was determined using a corneometer. A gel containing 5% ELHIBIN[®] and the corresponding placebo were applied to the inner forearm of twelve human volunteers. It was conclusively demonstrated that the ELHIBIN[®] containing formulation led to an increase in skin hydration of more than 10%, which persisted for at least three hours after the application.

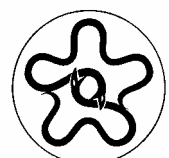


ADDITIONAL INFORMATION

Besides leukocyte elastase ELHIBIN[®] inhibits fibroblast elastase and mast cell tryptase. Tryptase, like elastase, is a non-specific proteinase that plays an extracellular role in inflammation and allergic reactions involving mast cell degranulation. Tryptase is unique, in that it is not inhibited by any endogenous proteinase inhibitors. Interestingly, ELHIBIN[®] does not inhibit pancreatic elastase. This enzyme, however, is of no interest in cosmetology as it is found exclusively in the digestive tract.

CONCLUSION

ELHIBIN[®] is a very interesting cosmetic ingredient in two respects. First, it is highly effective in inhibiting elastase released to the skin surface after skin irritation caused by UV-exposure or environmental stress as well as under dry skin conditions. Second, it acts as an extremely efficient moisturizer. ELHIBIN[®] thus exhibits both protective and preventive activity.



TECHNICAL INFORMATION

PRODUCT SPECIFICATIONS

Appearance	: clear to slightly opalescent, yellowish liquid
pH	: 5.2 - 6.0
Relative density (20°C)	: 1.052 - 1.062
Refractive index (25°C)	: 1.358 - 1.362
Total nitrogen	: 0.17 – 0.27% m/m
Inhibitory activity	: > 15 EIU/ml (Elastase Inhibitor Units)
Preservative (Parabens and phenoxyethanol)	: 0.65 – 0.85% m/m
Microbial count	: < 100 CFU/ml
Specified pathogens	: absent, not detectable

PRESERVATION AND MICROBIOLOGY

ELHIBIN[®] is preserved using parabens and phenoxyethanol. ELHIBIN[®] is free of specified pathogens. The amount of non-pathogenic microorganisms with less than 100 CFU per ml of ELHIBIN[®] meets the CTFA microbiology guidelines. ELHIBIN[®] fulfills the criteria of the repetitive germ loading test described by Shyam B. Singh-Verma (Parfümerie und Kosmetik 68(7), 414-421, 1987).

SAFETY AND ECOLOGY

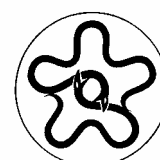
Standard and well-defined safety testing has been performed on ELHIBIN[®] which has proved the product to be safe for cosmetic use. The data available do not indicate any environmental risks. The manufacturing process is designed to meet the criteria for the assessment of safety, health and protection of people and of the environment set out in the *Responsible Care Program*.

PROCESSING AND DOSAGE

ELHIBIN[®] can be processed either warm (< 60°C) or cold, and is incorporated into the aqueous phase of a cosmetic formulation. ELHIBIN[®] is stable in the pH-range of 5.5 to 8. In formulations, ELHIBIN[®] is compatible with ethanol at concentrations of up to 20%. For skin care preparations, we recommend the addition of 3 to 7% ELHIBIN[®]. Basic Guide Formulations are available upon request.

STORAGE AND SHELF LIFE

ELHIBIN[®] 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, ELHIBIN[®] remains stable for at least three years.



GENERAL PRODUCT INFORMATION

Trade Name	:	ELHIBIN®
Product Code	:	301-02
INCI Name (CTFA)	:	Glycine Soja (Soybean) Protein
EU-Labeling Name	:	Glycine Soja Protein
Chemical Name	:	Aqueous solution of soja peptides
CAS No	:	9010-10-0
EINECS No	:	232-720-8
JCID Approval No	:	20900CZZ00511000
NICNAS	:	Listed
Customs Tariff No	:	3504.00 (Harmonized System Number)
Shelf life	:	3 years

COMPOSITION

A) Ingredient	INCI Name #	Amount *
As listed in the CTFA Dictionary	Glycine Soja (Soybean) Protein	E

B) Additives	INCI Name #	Amount *
Solvents	Water	A
	Glycerin	C
Preservative	Phenoxyethanol, Methylparaben, Ethylparaben	F
Solubilizer	Disodium Cocoamphodiacetate	F
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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