

### **STIMUCAP**

# A NEW AND POTENT METABOLIC AGENT, REGULATOR OF PHYSIOLOGICAL HAIR LOSS PROCESSES

#### >> THE PRODUCT

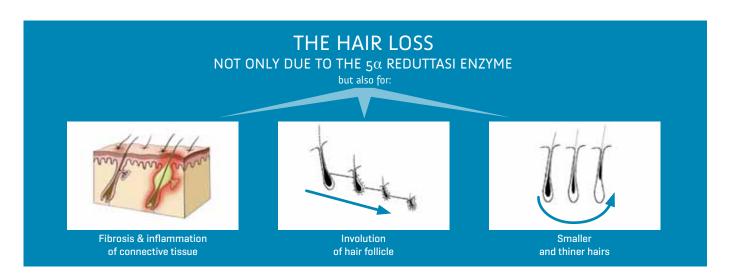
Stimucap is an innovative cosmetic ingredient, formed by the balanced association of two functional compounds: **CLA Glutathione** and **Sodium DNA**. The uniqueness of this blend is based on the complementary actions of two active substances.

1) The molecule of **CLA Glutathione**, which derives from the coupling of one molecule of Conjugated Linoleic Acid (CLA), a substance already showing an intrinsic biologic activity, with the tri-peptide Glutathione in its reduced form (GSH), partially neutralised with potassium ion that is similarly provided with an intrinsic biochemical activity (Fig.1).

2) **Sodium DNA**: is the INCI name of an active solution of nucleotide fragments which have been purified, depolymerised and finally neutralized with sodium ions.

#### >> HAIR LOSS AND BALDNESS

The time-evolution of alopecia, the scalp affection generally known as baldness, is characterized by a cascade of irreversible phenomena. Firstly, a progressive involution and miniaturization of the hair follicle is observed. Then, the follicle shifts from the subcutaneous layer to the dermal superficial layers, giving rise to smaller and thinner hair shafts. Successively, a fibrosis of the connective tissue around the bulb takes place. This is frequently accompanied by inflammatory process. After the onset of these modifications to the hair follicle and the surrounding tissue, hair loss and an irreversible atrophy of the bulb occur. Stimucap has demonstrated to be highly effective in the prevention and reduction of premature hair loss, according to the reported experimental protocol.



## >> TRANSPORT INTO CELLS AND ACTIVITY MECHANISM

In CLA Glutathione, the bipolar nature given by association of the linoleic chain, which is highly lipophile, with the very hydrophilic amino-acidic moiety, is responsible for the peculiar characteristics of biologic mobility of the compound. A very high bio-availability is thus derived, which is far superior to those of CLA and glutathione when considered individually. One can logically surmise that CLA Glutathione performs its maximum activity well before the biological breakdown into its two components takes place.

At the scalp level, the anti free-radicals activity of GSH may counteract the degeneration of connective tissue around the bulbs, while linoleic acid acts on the inflammatory process. Indeed, the input of CLA into the cells activates the arachidonic acid cycle, thus leading to the prostaglandins' synthesis. These are extremely powerful molecules that act as mediators of the local inflammatory process. Arachidonic acid, of which CLA is a precursor, requires oxygen and an electron donor in order to transform into prostaglandins. The latter activity may be guaranteed by GSH. In this case, it is readily available at the same action site as CLA, to which it is chemically bound, while it does not cross the epidermal barrier, when alone, for its hydrophilic nature. The explanation of the extraordinary activity of CLA Glutathione is based on such a mechanism (Fig.2). Indeed, recent experimental evidence shows that CLA can induce an increase in the synthesis of intracellular GSH: a real sequence of self-feeding and self-boosting actions. The functional mechanism of the molecules of Stimucap and the synergic activity they perform, make this product adequate for the treatment of degenerative diseases of the scalp, such as alopecia.

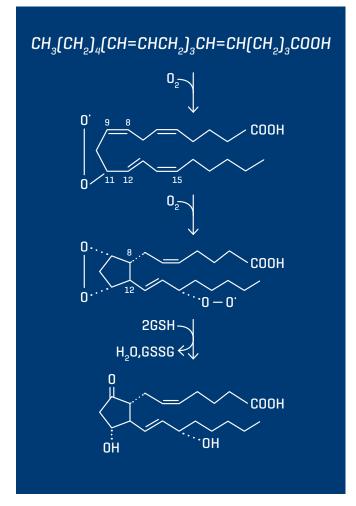


Figure 2: Synthesis of Prostaglandin E2 starting from Arachidonic Acid

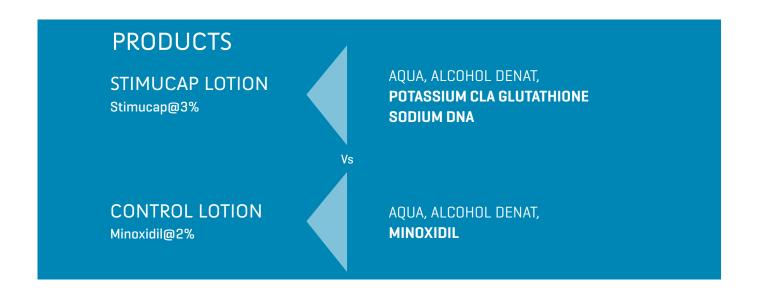


#### >> EFFICACY EVALUATIONS OF STIMUCAP

A series of instrumental and objective evaluations have **been carried out on 30 volunteers**, suffering from alopecia and telogen effluvium, in order to experimentally determine the anti-hair loss potential of Stimucap.

The 'hair resistance to traction' test (pull test) results, following 3 month use by volunteers, **demonstrate that Stimucap based lotion increases by 40,0% the hair fibres' resistance**, while Control lotion shows a non significant, more modest increase, equal to 17,6% (Fig.3). Subjects under testing also expressed their personal opinions about efficacy, tolerability and pleasantness of the treatment, thus giving a sensory response concerning the perceivable parameters (Fig. 4). **A statistically significant increase in the subjective tolerability and in the perceived efficacy** was detected after 2 and after 3 months of treatment with the Stimucap lotion.

The tested products resulted as being well tolerated and neither had negative effects, nor induced any irritation of the scalp.



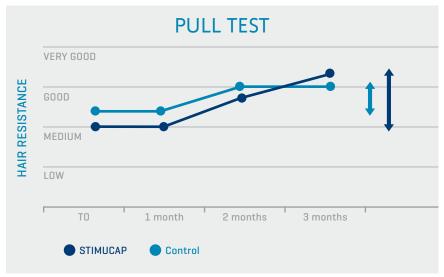


Figure 3: results of the Pull Test

By dermatological subjective evaluation, the global tolerability of the product and the onset and/or intensity of possible adverse local reactions, have also been tested. In all cases, Stimucap resulted to be very well tolerated and accepted.

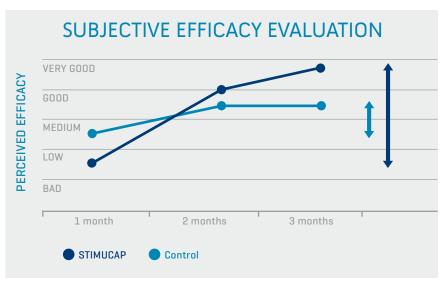


Figure 4: effect of the products on perceived efficacy

The standard "wash test" also demonstrates that, after daily application to the scalp for 3 months, the Stimucap based hair lotion can reduce hair loss. This effect takes place by a faster action when compared with the benchmark active, the well known Control (Fig. 5)

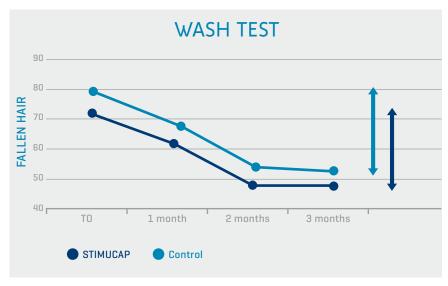


Figure 5: fallen hair

#### CONCLUSION

More hair resistance

Less hair loss

Well tolerated product

■ No negative effects

No scalp irritation

**EFFICIENT COADJUTANT** 

FOR TOPICAL TREATMENTS

IN THE PREVENTION

**OF HAIR LOSS** 

FORMULA: ANTI HAIR LOSS LOTION WITH STIMUCAP	%
STIMUCAP (SODIUM DNA, AQUA, POTASSIUM GLUTATHIONE ISOMERIZED LINOLEATE)	3
WATER DEMINERALIZED	57
ALCOHOL DENAT. (ALCOHOL DENAT.)	40

#### >> WAY OF USE

As the product is in an aqueous solution it is ready to be inserted in a cosmetic formulation; it does not require pre-treatment (such as solubilization or heating). We recommend adding it to the product at a temperature below 40°C. STIMUCAP must be inserted in the aqueous phase of the formulation. The product is stable also in hydro-alcohol solutions. Stimucap is a aqueous solution and it is soluble in water. It is not soluble in alcohol at 96°. It is soluble in Ethylic alcohol at 58° and less. Stimucap is not soluble at grades higher than 58°.

#### >> RECOMMENDED DOSES

Products for hair care: 1-10%

#### >> FORMULATION ADVICE

The product is compatible with anionic substances, non ionic and amphoteric; compatibility with cationic substances has to be verified by testing.

#### >> PRODUCT SPECIFICATIONS

INCI NAME and COMPOSITION:	CAS No	EINECS / ELINCS	RANGE %
SODIUM DNA	9007-49-2	Biopolymer	1-5%
POTASSIUM GLUTATHIONE ISOMERIZED LINOLEATE	-	Biopolymer	1-5%

PHYSICO - CHEMICAL ANALYSIS	METHOD	LIMITS
APPEARANCE	Visual	FROM TRANSPARENT LIQUID TO SLIGHTLY VEILED
COLOUR	Visual	COLORLESS
ODOUR	Olfactory	CHARACTERISTIC
pH DIRECT	Potentiometric	6.0 - 8.0
DRY RESIDUE	2 hours 105°C	6.5 - 7.5%
TOTAL MICROBE COUNT	by inclusion Ph. Eur. 7.0	< 100 UFC/g

SHELF LIFE: 12 months in the original containers.

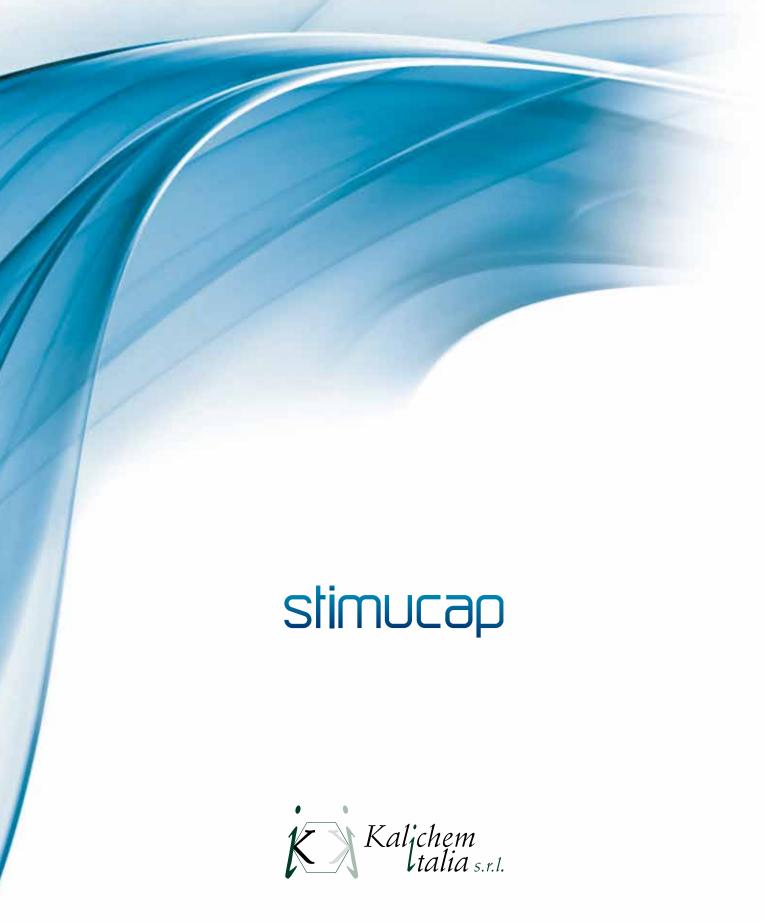
**COMPOSITION:** Aqueous solution of the blend:

- Reduced glutathione, combined by acylation with one molecule of conjugated linoleic acid and partially neutralized.
- Fractions of desoxyribonucleic acid, sodium salt, average MW 250-500 kD.

STORAGE CONDITIONS: Keep in a fresh and dry place, far from the reach of light and humidity, in well closed containers.

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