SEA MOIST COMPLEX®

*

Fights back against dry skin

by

replenishing depleted moisture

Gelyma

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SUMMARY

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INTRODUCTION

The dehydration of skin and hair is a very common problem in Cosmetic.

It is estimated that 25% of the population in France suffer from dry skin, 28% in Germany and 74% in Russia. According to Pierars (1987- Int. J. Dermatol. 26 : 167-168) it is not a unique, well defined conditions but represents a medley of total, unrelated changes in the structure of the *stratum corneum* which is associated with decreased water content of the *stratum corneum*.

Many causes can induce dry skin and at all ages. A change in the external environment (*e.g.* air conditioning, central heating, exposure to extreme weather conditions) very rapidly results in a skin dryness state. The surface of the skin turns flaky. It tends to chap slightly.

The incidence of dry skin increases with aging too. The water binding capacity of the *stratum corneum* decreases and skin's protection mechanism slows down.

Therefore, it is important to preserve or restore the normal moisture state of the skin by using suitable moisturizers in order to contribute to healthy looking skin, to compensate for the dehydration of exposed skin and to avoid skin premature aging.

Several physiological and external factors also induce hair dehydration. So, the exposition to sun, wind, pollutants or prolonged baths into sea water or chlorinated water damage hair.

Only adaptive treatments against dehydration bring suppleness and comfort to the skin, protection and gloss to the hair.

GELYMA offers SEA MOIST COMPLEX® a unique marine agent capable of moisturizing the skin and of protecting the hair against drying.

The strategy of SEA MOIST COMPLEX® is based on a synergistic association of natural osmotically active ingredients. Each one complements one another in sustaining moisture.

- Glycerin, quality natural Codex retains moisture loss and attracts water back into the skin from the environment.
- A seaweed extract from the red macroalga *Kappaphycus alvarezii* provides bioprotective oligosaccharides after modification through hydrolysis.
- Seawater contains minerals essential for the regulation of skin barrier homeostasis and the maintenance of healthy skin and hair.

THE RED ALGA *Kappaphycus alvarezii*

➤ Classification

The genus *Kappaphycus* belongs to :
Phylum : *Rhodophyta*
Class : *Rhodophyceae*
Subclass: *Florideophyceae*
Order : Gigartinales
Family : *Solieiriaceae* or *Areschougiaceae*

The genus *Kappaphycus* is become independent from the genus *Eucheuma* in 1988 according to the works of Doty on the basis of morphological, anatomical and biochemi-cal characters (In : Taxonomy of economic seaweeds with reference to some Pacific and Caribbean species, La Jolla vol.2, pp. 159-207).

The type *Kappaphycus* species occurs naturally in the Sulu Sea and the Sulu Archipelago.

It has been also naturalized in several western and central pacific localities for purposes of farming.

Kapppaphycus alvarezii Doty differs from other species of *Eucheuma / Kappaphycus* by its unique morphology and growth physiology (Doty, 1988 – *Ibid*).

➤ Morphology & Biology

The thallus of *Kapppaphycus alvarezii* shows a simple discoid hold-fast from whicharise a main axis with irregular branches. (Fig. 1).This axis can reach 3cm in diameter.

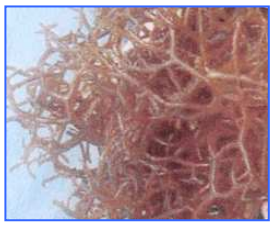


Fig1 – Morphology *in situ*

Reproductive life cycle includes three successive generations, as in *Chondrus crispus*.

As others *Eucheuma* & *Kappaphycus species*, *Kappaphycus alvarezii* shows intense regeneration ability that is useful for industrial cultivation. Three varieties of this species are recognized: var. *alvarezii, tambalang* and *ajak-assi*.. Presently, we use *Kappaphycus alvarezii* var. *alvarezii* (Fig.2).

Fig2 – Dry thalli used for SEA MOIST COMPLEX®
Photo GELYMA.

➤ Ecology & Geographical distribution

This alga takes its origin from Malaysia (Sabah).

Natural populations grow just below the O tide line to the upper subtidal portion of reef areas on sandy-corally to rocky substrates where water movement is slow to moderate.

➤ Utilizations

Kappahycus alvarezii is the raw material for the manufacture of Kappa-carrageenan with semirefined or refined products.

It is intensely cultivated. Commercial production is currently on the order of 80 000 to 120 000 dry tons per year in Philippines and surrounding countries.

The specific name *« alvarezii »* as applied to *Kapppaphycus alvarezii* by Doty commemorates Vicente B. Alvarez, a pioneer in the cultivation methods of *Eucheuma* in the Philippines.

Kapppaphycus alvarezii is known as various names:

- common names :Agal agal, Agal agal besar, Chilin-t'sai, Cottonii, Eucheuman, Guso, Kirinsai

- trade names : Alvarezii, Cottonii, Inerme, Interme, Striatum, Procrusteanum.

THE ACTIVE INGREDIENT SEA MOIST COMPLEX®

Specifications

on a control batch

- appearance : limpid liquid transparent to yellow coloured
- odour : typical
- pH : 6.0 ± 1
- density : 1.145 ± 0.020
- solubility : soluble in water, ethanol 100%, butylenes glycol, propylene glycol
  : insoluble in mineral oil and silicone oil.

Composition

Ingredients		Amounts %
Solvent	glycerin	49
	water	24
Red alga	*Kappaphycus alvarezii* extract	25
Sea water		2
Preservative	*as required*	
Others (antioxidants …)	none	

INCI names	Glycerin	CAS n° 56-81-5	EINECS n° 200-289-5
	Water	CAS n° 7732-18-5	EINECS n° 231-791-2
	Kapphaphycus alvarezii extract		
	Sea water		

Glycerin (glycerol) plays the role of a water trap on account of its hydroxyl groups. One molecule of glycerol takes up six molecules of water.

In skin xerosis, it is known to be very effective humectant, aiding the digestion of desmosomes which are abnormally retained in the superficial layers of the *stratum corneum* (Rawlings *& al.*, 1995 – Arch.Dermatol.Res.287:457-464).

To avoid the risk of obtaining a sticky composition, just a suitable amount is added to seawater.

The hydrolyzed extract of the macroalga K*appahycus alvarezii* brings oligosaccharides which are known help reinforce dermal structures and accelerate wound healing.

Mineral sea salts reinforce the skin natural ability to function normally.

The quantities of minerals present in SEA MOIST COMPLEX® (*on a control batch*) are listed below.

Macrominerals (ppm)	
Sodium	4980
Potassium	1540
Magnesium	1650
Calcium	90

Trace minerals (ppm)	
Silicium	4.3
Iron	1.4
Zinc	< 1
Copper	< 1
Manganese	< 1
Selenium	0.38
Iodide	< 0.25

We would draw special attention to the high content in sodium, potassium and magnesium. Such ions are known as important regulators in skin barrier homeostasis (Lee *& al.,* 1992 – J. Clin. Invest. 530-538); Denda *& al.,* 2002 – IFSCC magazine 5:107-110).

Potassium stimulates the activity of the Na/K pumps in the cellular membranes, what triggers an incoming flow of water into the corneocytes.

Calcium is also known to improve *stratum corneum* cohesion.

Silicon is need for healthy skin and hair.

Glycerin and minerals from sea water present in SEA MOIST COMPLEX® acts as osmotically active substances to maintain a suitable moisture level in the skin.

Moreover, it has been recently demonstrated that the addition of osmolytes enhances protein stability (Shimizu & Smith, 2004 – J. Chem Physics 121: 1148-1154) and skin hydration (Pirot *& al.,* 2003 – Exogenous Dermatology 2 : 252-25).

Storage

SEA MOIST COMPLEX® should be kept sealed in the original drums, under clean conditions between 15 to 25°C in a dry place. In order to avoid microbial secondary contamination, it is recommended to use the whole content of the drum once opened.

If stored under the recommended conditions, SEA MOIST COMPLEX® remains stable for at least 24 months.

Packs size: 1Kg - 5 Kg - 10 Kg.

Safety

No animal experimentation.

Standard safety testing proves that SEA MOIST COMPLEX® is safe for cosmetic use.

Ocular irritation : no irritation (Het Cam test)
Cutaneous irritation : no irritation (Human Patch test).

cf. annex pp 12-13.

EFFECTIVENESS EVALUATION

SEA MOIST COMPLEX®

A synergistic association of
natural osmotically algal active ingredients

Improvement of skin moisturization of the upper epidermal cell layers → *In vivo* studies
Corneometer measurements

Protection against dehydration →
Ex vivo studies
Observations of the fine structure of human skin explants
Transmission electron microscope study

Ex vivo studies
Observations of the fine structure of hair scales
Scanning electron microscope study

Potent balanced moisturizing composition
for
hydration & repair
of dry skin and hair

Improvement of skin hydration of the upper epidermal cell layers

In these *in vivo* studies of 8 volunteers with dry or very dry skin, the creams or gels containing SMC or the corresponding placebo, are applied under controlled conditions (single application of 0.2ml on an area of 35cm²).
The moisturizing efficacy of SMC is determined using a corneometer Courage & Khazaka CM 825. Readings are taken at regular intervals.
Results are expressed as percentage of moisturizing gain by taking into account the values of both control and treated area before application and at each time of application . They are validated by using Wilcoxon test.

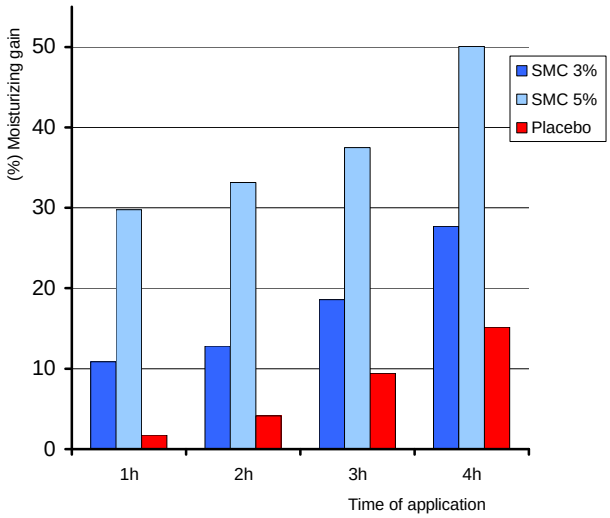
Immediate moisturizing effect

A cream containing 3% or 5% SMC provides rapid skin hydration compared to the corresponding placebo.

After 4h application, the epidermal moisturizing gain increases by :

⇒ 13% / placebo with 3% SMC

⇒ 35% /placebo with 5% SMC.



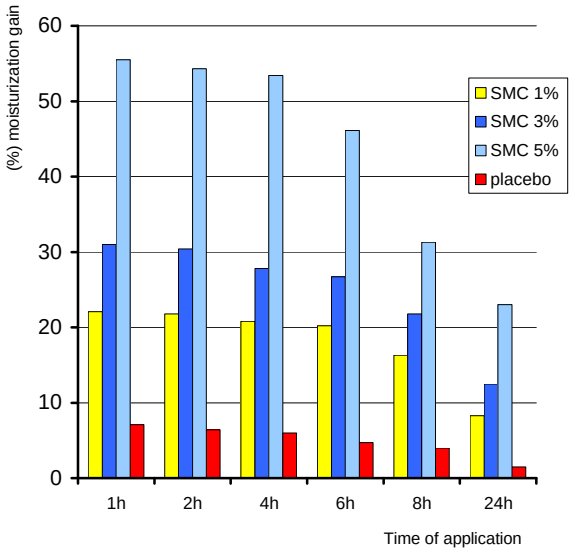
24 h moisturizing study

A gel containing SMC significantly increases skin hydration over 24-h period, compared to the corresponding placebo.

The moisturizing gain of a gel with 3% SMC reaches:

⇒ +18% /placebo after 8h application and

⇒ +11%/placebo after 24h application.

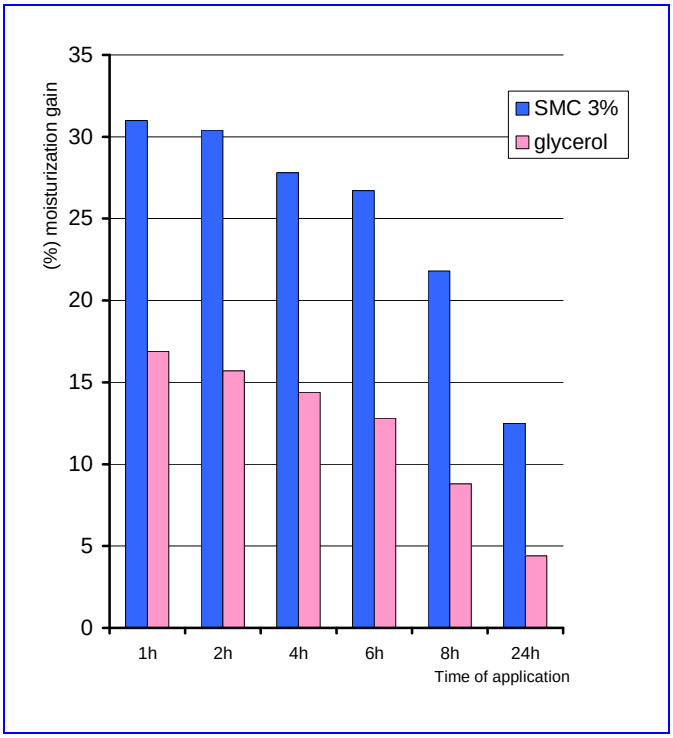


Hydration comparison

A gel containing 3% SMC offers skin hydration superior to the gel containing the same quantity of glycerin alone.

This graph proves the synergistic action between the marine fraction of SMC (alga + seawater) and glycerin.

The moisturizing gain of SMC is equal to + 13% / glycerin after 8h application (that is a period equivalent to a working day).

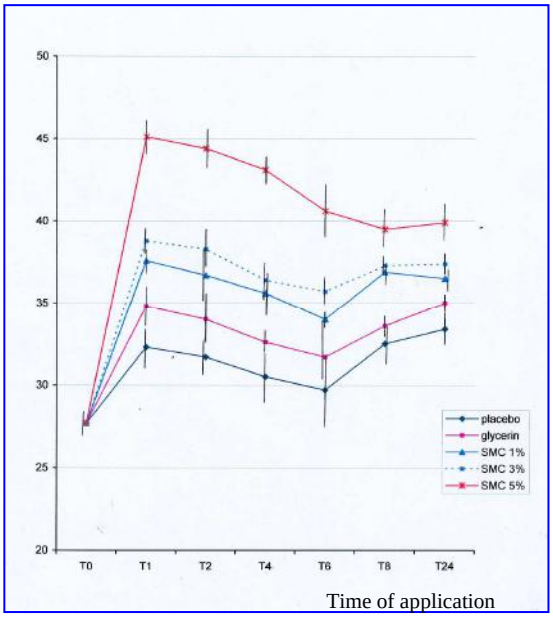


Statistical validation

The variations of the median values of hydration in function of time are illustrated on the opposite graph.

Vertical bars indicate confidence intervals with $p < 0.01$

% moisturization gain



➤ By maintaining a potent moisturizing level, SEA MOIST COMPLEX® guarantees excellent hydration ratio all day long.

Hydration comparison synergy

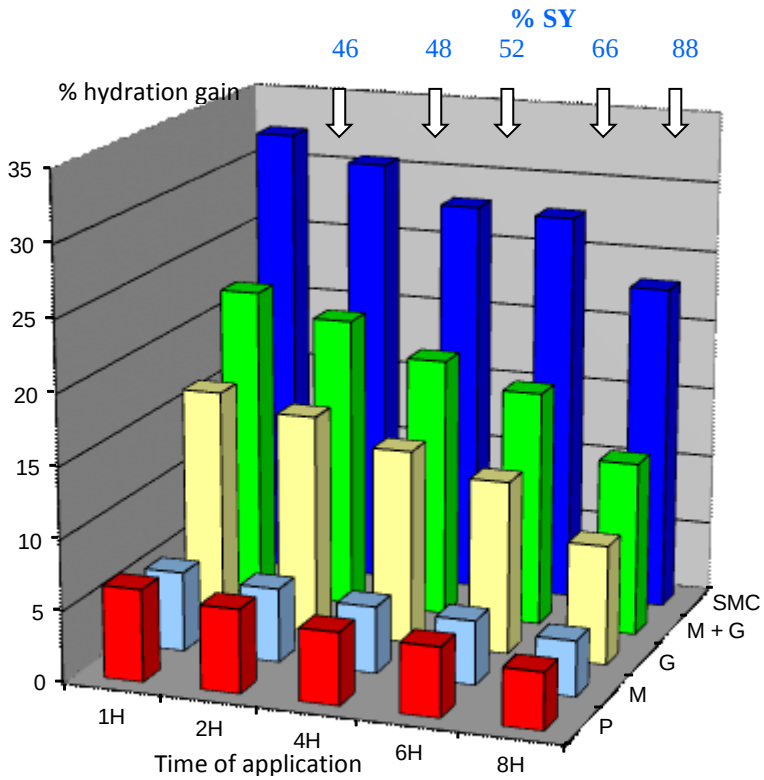
A gel of the same basal composition is supplemented with either

■ 3% SEA MOIST COMPLEX® SMC

■ or the same quantity of glycerin G

■ or else the same quantity of marine part M (algae extract + sea water) than those included in SMC and compared to the corresponding placebo P ■.

M+G is illustrated by ■ .



The % of hydration variation is calculated on the control areas and on the treated areas by the formula:

% hydration variation = [(Vtx – Vt0) *100 / Vt0)] – [(Vtx* – Vt0*) *100 / Vt0*]

with : Vtx : value at each time on the treated area
Vt0 : value before application on the treated area
Vtx* : value at the same time that “tx” on the control area
Vt0* value before application on the control area.

Statistical validation

Data are validated by the Wilcoxon matched-pairs signed-ranks test. The additive effect is indicated in % (% SY) on the graph.

The hydration rate due to glycerin is very highly significantly higher than those of the marine part.

The effect of synergy between glycerin and the marine part is significant to very highly significant.

Statistical data
from the Wilcoxon test

Time	M<G		M+G < SMC	
	α Significativity		α Significativity	
1h	0.0039	**	0.001	***
2h	0.0039	**	0.0391	*
4h	0.0039	**	0.0273	*
6h	0.0078	**	0.001	***
8h	0.0039	**	0.0029	**

➤ The benefit of glycerin (humectant) is reinforced by the addition of the marine fraction of SMC.

Protection against dehydration

Transmission electron microscope observations of skin

Hydration of the *stratum corneum* depends on multiple factors.

Desmosomes are proteinaceous complexes which rivet corneocytes together. Consequently they are responsible for cellular cohesion.

Lamellar bodies are the source of the precursors of the final lipid content of the stratum corneum barrier.

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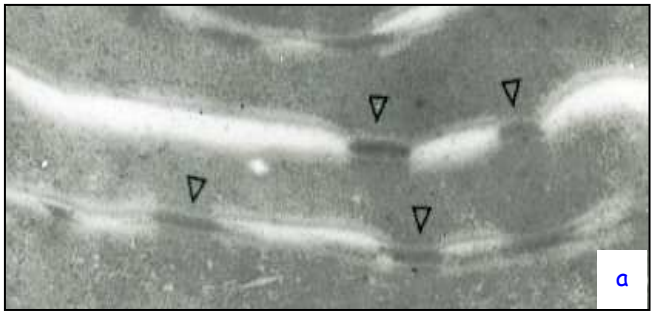
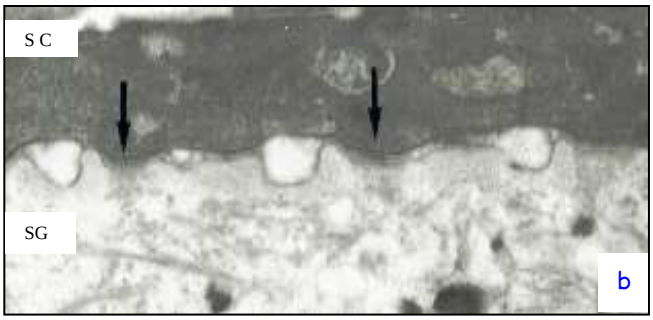
In these studies, human dry skin explants are treated for 12h with 3% SMC in PBS, compared to untreated control (in PBS only). Then, they are prepared for electron microscope observations.

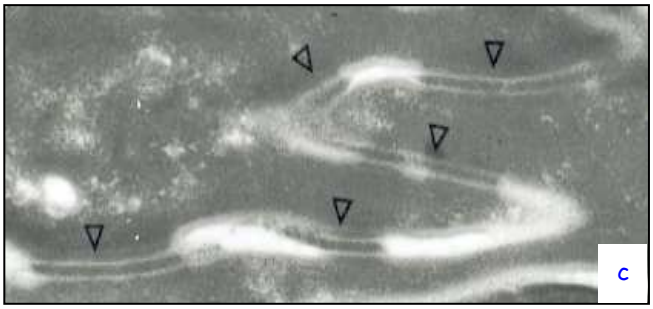
Control





The untreated skin exhibits small desmosomes (∇) (fig. a) and lamellar bodies (↓).

SMC treatment



➤ The treatment with SEA MOIST COMPLEX® enlarges desmosomes (∇), that enhances the structural integrity of the *stratum corneum* (fig.c).

Moreover, the treatment with SEA MOIST COMPLEX® increases the secretion of lamellar bodies (↓) at the interface between the *stratum granulosum* SG and the *stratum corneum* SC (fig. d) and consequently ameliorates the epidermal biosynthetic functions.

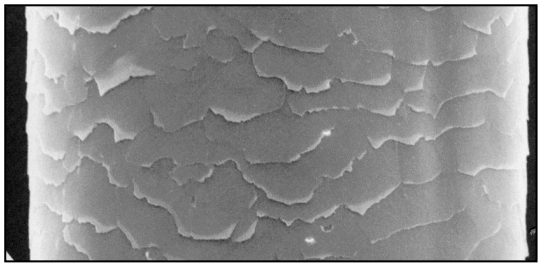
Scanning electron microscope observations of hair

Normal hair exhibits smooth and uniform cuticle scales whereas damaged dry hair shows raised cuticle scales.

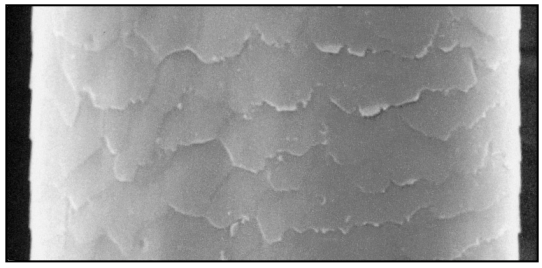
In these scanning electron microscope studies, hair care exposed to various experimental conditions.

Experiment A - Dry hair is only treated with an aqueous solution with 2% SMC (A2) compared to untreated control t (A1).

A1- Control

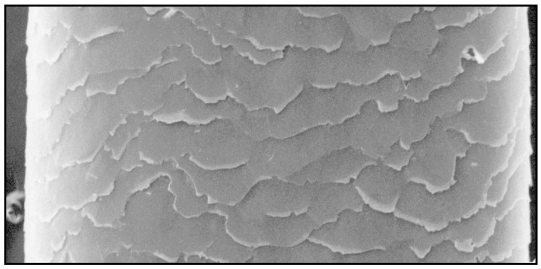


A 2

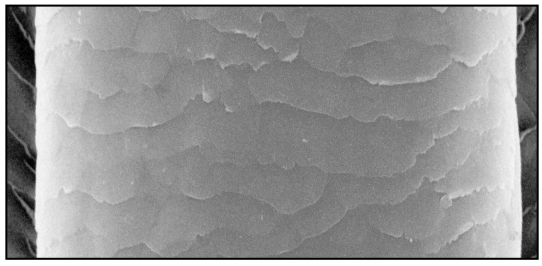


Experiment B – Dry hair is soaked rapidly in acetone, dried then treated with 2% SMC solution (B2) compared to untreated control (B1).

B1- Control

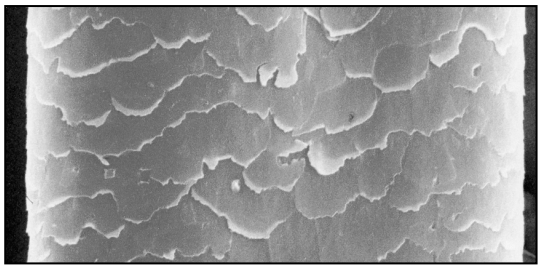


B 2

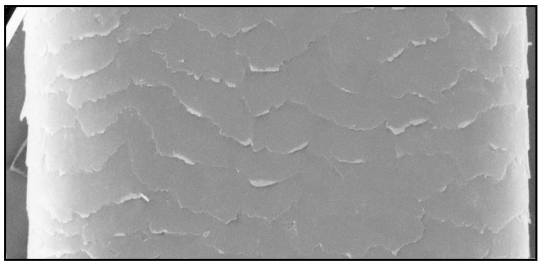


Experiment C - Dry hair is soaked in a solution of chlorine (0.03% Cl) for 1 minute, dried, then treated with 2% SMC solution (C2), compared to untreated control (C1).

C1- Control



C 2



The beneficial effect of SMC is clearly apparent on the figures A2 - B2 and C2.

➤ In each experiment, SEA MOIST COMPLEX® improves hair surface condition.
It flattens the uplifted scales of the cuticle and smoothes the hair fibres, what helps enhance gloss and restore shine.

CONCLUSION & COSMETIC PROPERTIES

The strategy of SEA MOIST COMPLEX® is based on a synergistic association of natural osmotically active ingredients: glycerin (plant origin) and a seaweed extract supplemented with seawater. The moisturizing action of glycerin is potentiated by the marine fraction.

SEA MOIST COMPLEX® offers a perfectly balanced composition for skin and hair care.

At the skin level, it acts as an extremely potent moisturizer for dry skin. It provides the skin with its ideal level of moisture and nutritive minerals. It helps maintain the hydration state of the skin all day long and regulate the skin homeostasis.

It combats dehydration by improving the structural integrity of the *stratum corneum* and the epidermal biosynthetic functions of dry skin.

SEA MOIST COMPLEX® reduces dehydration by improving the structural integrity of the *stratum corneum* and the epidermal biosynthetic functions of dry skin.

As results the skin appears smoother with healthy appearance and feeling.

At the hair level, it is also highly effective in protecting and repairing against dryness, what helps enhance gloss and restore shine.

Thus, SEA MOIST COMPLEX® is an ingredient of choice to treat and protect dry skin and hair.

COSMETIC APPLICATIONS

Daily and evening skin care - Body care - Protective care for dry and sensitive skin, make-up foundations and dry scalp treatments - Toiletries and shampoos.

Recommended use levels: 1% - 5%.

ANNEX

Evaluation of ocular irritation

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N° d'étude : 151406F01.doc
Version : 1
Page : 8

STUDY SUMMARY

EVALUATION OF THE POTENTIAL IRRITANCY OF A PRODUCT THROUGH ITS APPLICATION ON THE CHORIOALLANTOIC MEMBRANE OF A CHICKEN EGGSHELL: *Het Cam Method*

- **Tested product** : SEA MOIST COMPLEX
- **Promoter** : GELYMA
- **Objective**: To assess the irritant potential of the tested product
- **Methodology**: The principle of this study is based on the visual observation, by a trained person, of the possible irritations (hyperaemia, haemorrhaging, coagulation / thrombosis) that may appear during the five minutes that follow the application of the said product on the chorioallantoic membrane of an embryonic chicken egg after eleven days of incubation.
- **Place of study:** EUROFINS ATS, Pôle d'activité d'Aix en Provence
  Actimart, 1140, rue Ampère,
  13851 AIX EN PROVENCE cedex 3
- **Dates of study :** 13/12/2005
- **Results :**

Denomination	ATS Reference	Initial concentration	Results	
			Score	Classification
SEA MOIST COMPLEX	133869	5%	**1.5**	**Slightly irritant**

- **Conclusion :**

According to the performed experimental conditions, the product SEA MOIST COMPLEX, batch number 085 10 060 tested by the HET CAM method, at 5%, can be considered as slightly irritant regarding its ocular primary tolerance.

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N° SIRET : 33761796300067 – Code APE : 743 B

Evaluation of ocular irritation

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N° d'étude : 151407F01.doc
Version : 01
Page : 15

STUDY SUMMARY

EVALUATION OF THE CUTANEOUS TOLERANCE OF A COSMETIC PRODUCT AFTER A SINGLE APPLICATION UNDER OCCLUSIVE PATCH DURING 48 HOURS:
Patch test method

- **Product tested :** SEA MOIST COMPLEX Lot 05 10 060
- **Promoter :** GELYMA
- **Monitor :** L. PELLEGRINI, General Manager
- **Objective :** Assessment of the cutaneous local tolerance of the studied product after an epicutaneous test performed in occlusive conditions, during 48 hours.
- **Place of the study:** EUROFINS SCIENTIFIC TEST CENTER,
  ACTIMART
  3 allée des Ingénieurs
  1140 rue André Ampère
  13851 AIX EN PROVENCE cedex 3
- **Investigator :** Docteur Amélie MENARD
- **Date of study:** from 13/12/05 to 15/12/05
- **Methodology:**
  - ✓ ***Application modes:***

Area of application : on the back
Quantity of product : 0.02 ml
Frequency and duration : only one application during 48 hours
Conditions of application : product applied at 5%, under occlusive patch.

- ✓ ***Assessment method:***

A dermatologist makes the clinical observation, after the removal of the patches. The quantification of the cutaneous irritation is given according to a numeric scale (rash, oedema, dryness, blister). The average irritant score of the product to be tested is measured with the average of the quotations obtained for the whole volunteers, allowing ranking the product from "not irritant to very irritant". The assessment is always made by comparison with the "negative" control: patch with demineralised water.

- **Population:** 10 healthy adult volunteers.
- **Results:** The average irritant score of the product is 0,0.
- **Conclusion:**

According to the experimental conditions taken into account, after only one application of 0.02 ml of product, under occlusive patch and during 48 hours, on 10 healthy adult volunteers, and according to the scale used for the interpretation of the results, the raw material **"SEA MOIST COMPLEX Lot 05 10 060, can be considered as not irritant regarding its primary cutaneous tolerance**.

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