EFFICIENSEA®

Offers efficient protection to irritated skin

*

Protects DNA

Keeps inflammation under control

Promotes a soothing effect

Gelyma

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SUMMARY

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INTRODUCTION

Reactive oxygen species have an important function in several homeostatic processes by acting as intermediate agents in essential oxidation-reduction (redox) reactions.

They can be generated through different oxidative pathways. Their production may be outstanding increased by exogenous sources such as ultraviolet radiations and oxidant air pollutants.

In low concentrations, reactive oxygen species are useful but in high concentrations they are toxic. Indeed, if biological molecules are oxidized, they are altered and can trigger cellular metabolism disorders.

A powerful protective defence system limits damage caused by reactive oxygen species. It coexists with the generation of reactive oxygen species in a balanced way. When this equilibrium is altered, it results oxidative stress which may cause cell injury, trigger physiological disorders and promote pathological processes.

In skin, the consequences of the generation of reactive oxygen species may involve harmful damage such as

- DNA alteration with strand breaks, DNA-protein cross-links and trigger lethal and mutagenic effects,
- aging acceleration with cross-linking of proteins (*e.g.* collagen and elastin), and oxidation of sulfhydryl groups causing disulfide cross-links which denature proteins and possibly contribute to the loss of elasticity,
- inflammation processes due to the peroxidation of membrane lipids.

Numerous structural and functional alterations result in intrinsic (chronological) aging and photoaging *e.g.:*

- loss of elasticity caused by extensive formation and accumulation of collagen cross-links,
- development of irregular pigmentation.

The marine active ingredient EFFICIENSEA® is able of providing effective protection against the main harmful effects caused by reactive oxygen species.

This patented multi-purpose agent against anti-aging, skin pigmentation and anti-inflammation derives from the brown alga *Pelvetia canaliculata* collected in Brittany.

Gelyma Patent FR 2 838 340.

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THE BROWN ALGA *Pelvetia canaliculata*

Pelvetia canaliculata (L.) Decaisne & Thuret belongs to the phylum *Heterokontophyta*, the class *Phaeophyceae*, the order Fucales and the family *Fucaceae.*
It is named after Dr Pelvet (a French naturalist) and the latin name c*analiculatus* (chancelled). It is known as “channel wrack” or “cow tang”.

➤ Morphology & Biology

The thallus of *Pelvetia canaliculata* consists of a basal part like hapters and upper axes. It appears firm in texture and tufted (Fig.1).

It can grow up to 10-15 cm. Its colour is olive-brown in winter and somewhat lighter in summer.

Axes are dichotomously branched, terete to compressed. They are deeply channelled on one side and rounded on the other.

Plants are bisexual.

Fig. 1 - Morphology of *Pelvetia canaliculata in situ*
Photo GELYMA.

➤ Ecology & Geographical distribution

Pelvetia canaliculata is the Fucalean species which grows farthest up in the eulittoral zone.

It is “a seaweed that shuns the sun”. Indeed it exhibits intolerance to prolonged submersion. It is remarkable in its high resistance to stress against drying. It may survive an emersion period of 4-6 days (Schonbeck & Norton, 1978 – J. Exp. Mar. Biol. Ecol. 31:303-313; 1979 – J. Ecol., 67:687-696).

Moreover, it is considered endemic to European Atlantic Ocean. Its distribution is restricted to the coasts of the English Channel and the Atlantic, from the northern part to Porto (Portugal). It is commonly found in abundance on the rocky shores between the high-water mark and the half-tide level, frequently in large quantities on the edge of the high-water mark. It is absent in the Bay of Biscaye, the coasts of the Mediterranean, the American Atlantic as well as the Pacific (Lüning, 1990- Seaweeds, their environment, biogeography and ecophysiology, Wiley).

➤ Utilizations

In many coastal areas, it becomes fertilizer. On the Orkney Islands, it serves as additional feed material for cows, when boiled. In Ireland it is used as pig feed.

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THE ACTIVE INGREDIENT EFFICIENSEA®

Specifications

on a control batch

- appearance : limpid liquid brown coloured
- odour : typical
- pH : 5.8 ± 1
- density : 1.017 ± 0.015
- dry residue (%) : 3.2 ± 0.5
- solubility : soluble in ethanol, propylene glycol, butylene glycol
  : insoluble in oils
- microbiology : bacteria : < 100 germs / ml
  : yeasts, moulds : < 100 germs / ml
  : pathogens : free.

Composition

Ingredients		Amounts %
Solvent	water	55
Brown alga	*Pelvetia canaliculata* extract	45
Preservative	*as required*	
Others (antioxidants …)	none	

INCI names water CAS n° 7732-18-5 EINECS n° 231-791-2
Pelvetia canaliculata extract CAS n° 223751-75-5

Storage

EFFICIENSEA® should be stored in the original sealed drums, under clean conditions between 15 to 25°C. 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, EFFICIENSEA® remains stable for at least 18 months.

Pack size: 1kg -5kg -10kg.

Safety

No animal experimentation.

Standard safety testing proves that EFFICIENSEA® is safe for cosmetic use. At the recommended use levels

EFFICIENSEA® exhibits

- slightly irritant potential for ocular irritation (Het Cam test)
- non irritant potential for dermal irritation (Human Patch test)
- no skin irritation , hypoallergenique (RIPT)
- non mutagenic / non promutagenic (ANES test).
- no direct genotoxic effect is detected (3D assay).

cf. Annex pp. 16-20.

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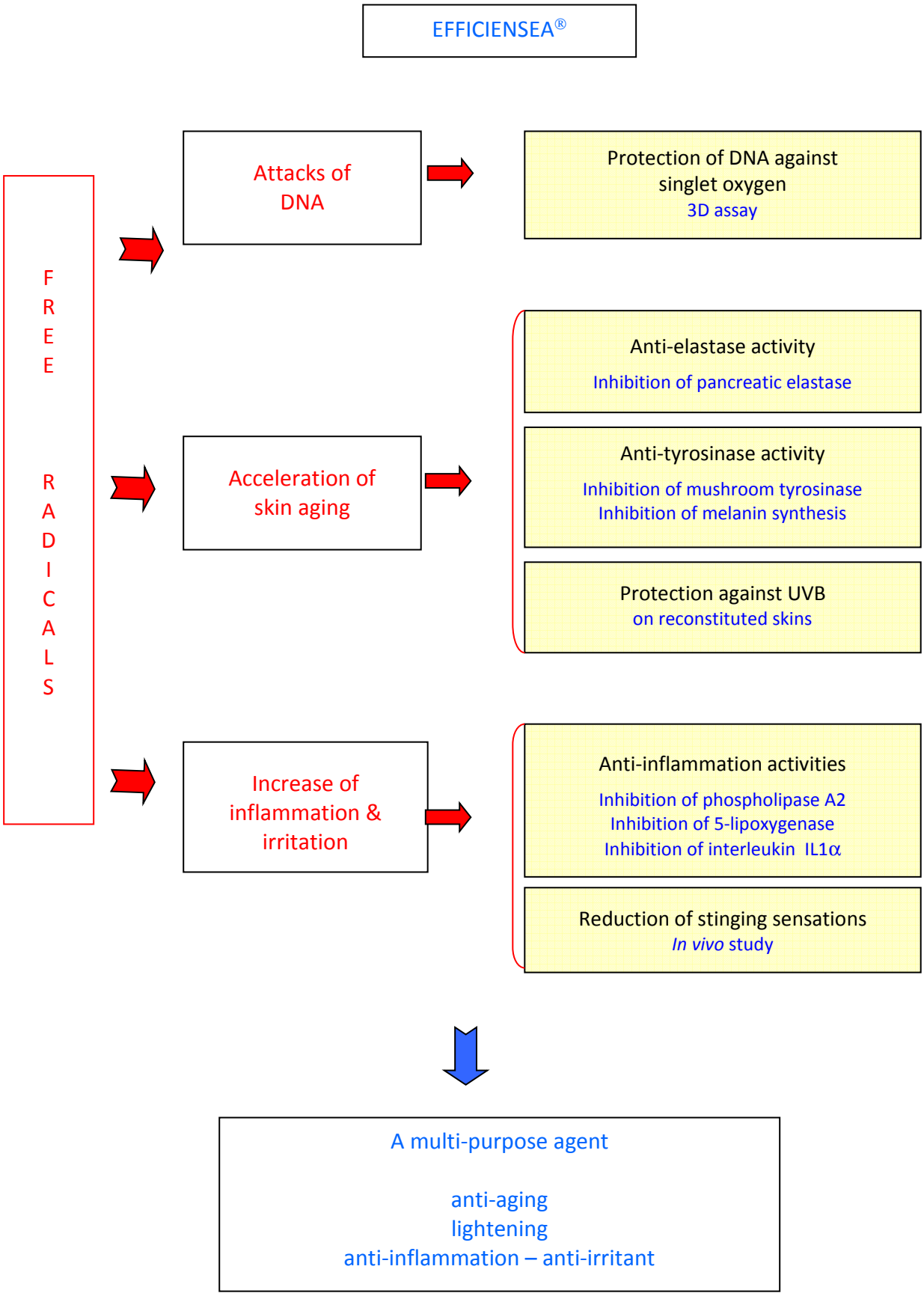
EFFECTIVENESS EVALUATION



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Protection of DNA against singlet oxygen

Singlet oxygen is not a free radical but it represents a very reactive and toxic form of oxygen capable of rapidly oxidizing many molecules such as membrane lipids and DNA.

It may cause harmful effects on DNA especially with single and double strand chain breaks, triggering lethal and mutagenic effects.

Method

This chemiluminescent 3D Assay (S.F.R.I., France) is based on a repair reaction of DNA (Salles *et al.*, 1995 – Analytical Biochemistry 232: 37-42, Patent FR n° 95003230).

DNA lesions are repaired by the excision repair pathway which implies an incision-excision reaction followed by DNA repair synthesis.

Plasmid DNA is adsorbed on sensitized microplates as the substrate.

In the present experiment, these lesions have been induced by the generation of singlet oxygen performed by photoactivation of methylene blue.

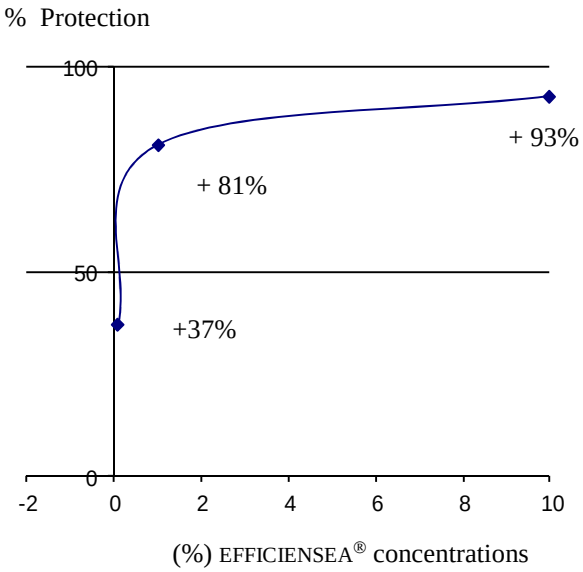
Results

Compounds	Concentrations	% protection in presence of reactive oxygen species	% non specific inhibition	% specific protection	Concentration giving 50% of protection
EFFICIENSEA®	10% 1% 0.1%	93 82 40	0 1 3	93 81 37	0.2%
Silymarin	1mg/ml 10^{-1} mg/ml 10^{-2} mg/ml	79 68 11	5 7 0	74 61 11	0.06 mg/ml

➤ EFFICIENSEA® protects DNA against genotoxic damage caused by singlet oxygen.

50% specific protection are obtained with a concentration of 0.2% only.

A dose-response relationship is visible.



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Anti-elastase activity

Elastase is the only enzyme able of degrading elastin. It is also able of attacking other major connective tissue matrix proteins such as collagen and proteoglycans.

Biologically, elastase activity significantly increases with age. This increase results in a reduced skin elasticity and in the appearance of wrinkles or strechmarks.

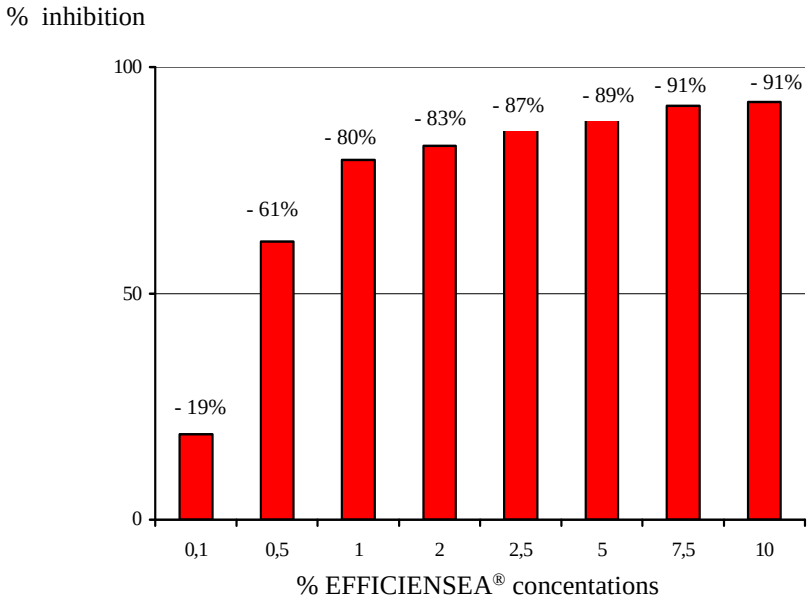
The poisonous effects of elastase are intensified with excessive UV exposure.

Method

Porcine pancreatic elastase is assayed using [N- succinyl-$(Ala)_3$-para-nitroanilide] as the substrate and monitoring the release of p-nitroaniline for 20 min at 25°C. The amount of p-nitroaniline is determined by measuring the absorbance at 410 nm (Bieth *et al.*, 1974 – Biochemical Medecine 11:350-357).

Results

Results represent the average of three experiments for each concentration tested ($\alpha = 0.05$).



➤ EFFICIENSEA® shows:

- more than 60% elastase inhibition at the concentration of 0.5%,

- more than 80% elastase inhibition at the concentration of 2%.

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Anti-tyrosinase activity

Tyrosinase catalyzes two distinct reactions: the hydroxylation of tyrosine to Dopa and the subsequent oxidation to dopaquinone.

It is the major regulatory enzyme involved in melanin synthesis. Dopaquinone is unstable and converted to dopachrome by tyrosinase or autoxidation. Melanin can be formed through the subsequent polymerization reaction. So the inhibition of melanogenesis may be achieved by antioxidation and inhibition of tyrosinase (Prota, 1996 – Cosmetics & Toiletries 111:43-51).

Inhibition of mushroom tyrosinase

Method

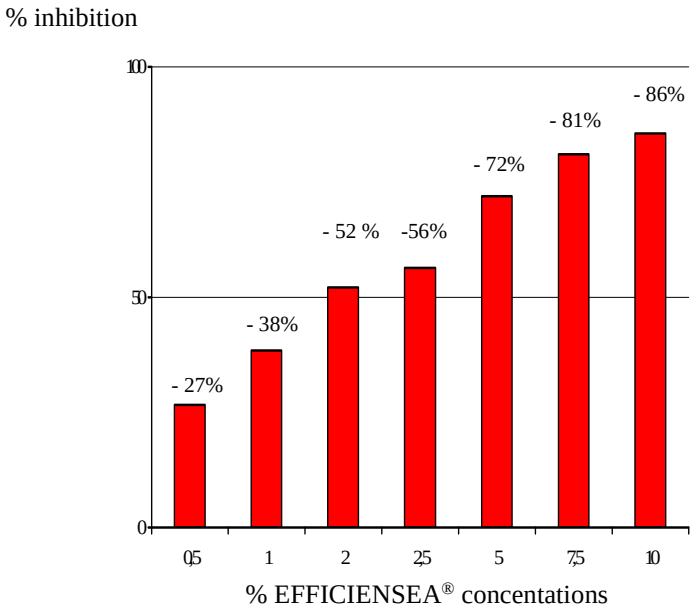
The assay is based on the formation of dopachrome from L-tyrosine after mushroom tyrosinase action. The optical density is measured at 480 nm. The inhibitory activity is expressed as the concentration of EFFICIENSEA® (IC 50) at which it inhibits 50% of the enzyme activity.

$$\text{Inhibition (\%)} = [(B-A)/A] \times 100$$

A = absorbance without test sample after incubation
B = absorbance with test sample after incubation.

Results

Results represent the average of three experiments for each concentration tested ($\alpha = 0.05$).



➤ EFFICIENSEA® shows:

- more than 52% tyrosinase inhibition at the concentration of 2%,

- more than 70% tyrosinase inhibition at the concentration of 5%.

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Inhibition of melanogenesis on separated human epidermis

Method

The reaction is performed on human melanocytes after coloration with a mixture of active ingredients (EFFICIENSEA® or kojic acid) and L-Dopa.

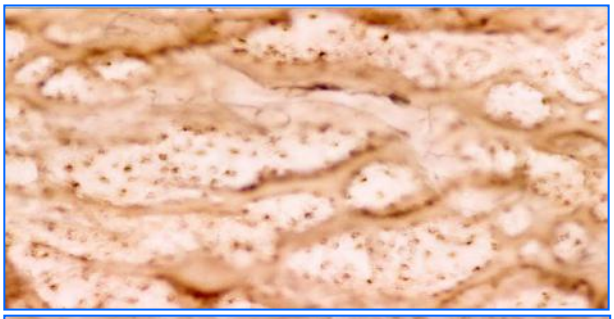
The lightening effect is visualized by the intensity of melanocyte decoloration on separated epidermis.

Study carried out by the company Bio-EC (Clamart-France).

Results

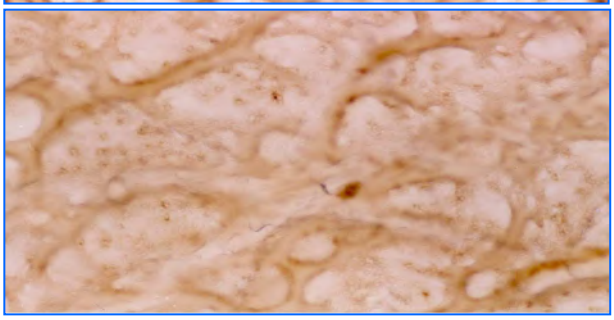
DOPA control

- Melanocytes appear well coloured



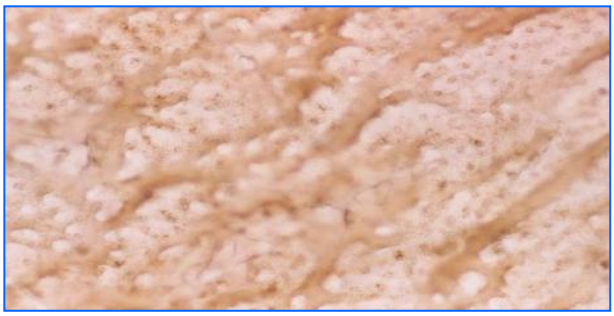
Kojic acid, concentration : 0.015%

- Melanocytes do not appear coloured



EFFICIENSEA® concentration : 5%

- Melanocytes appear very lightly coloured



- EFFICIENSEA® shows a lightening effect proved by the inhibition of both mushroom tyrosinase activity (IC 50 = 2%) and melanin synthesis on separated human epidermis at the concentration of 5%.

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Protection against UVB irradiation

Two experiments are performed on reconstituted skins (SkinEthic model) in order to study the eventual ability of EFFICIENSEA® to stimulate the viability as well in normal culture conditions (experiment 1) or after UVB irradiation (experiment 2).

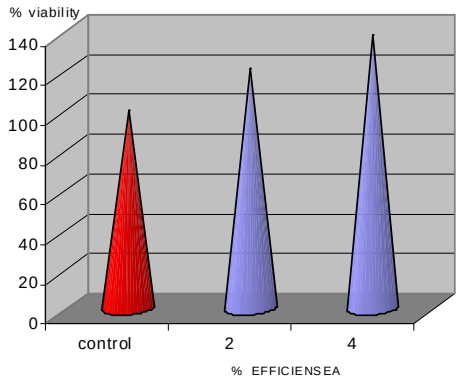
Experiment 1

Method

Reconstituted skins (SkinEthic model) are cultured in the presence or the absence of EFFICIENSEA®. The MTT test is performed 48 hours after. Optical density is measured in triplicate.

Results

Results are expressed as percentage of viability. 2% EFFICIENSEA® provide +21% better stimulation compared to untreated control (in red).



Results are validated by two statistical analysis: ANOVA, least significant difference.

- very highly significant difference between EFFICIENSEA® and control *** $p < 0.001$.
- very highly significant difference between 2% and 4% EFFICIENSEA® *** $p < 0.001$.

Accordingly, the recommended use level is 2%.

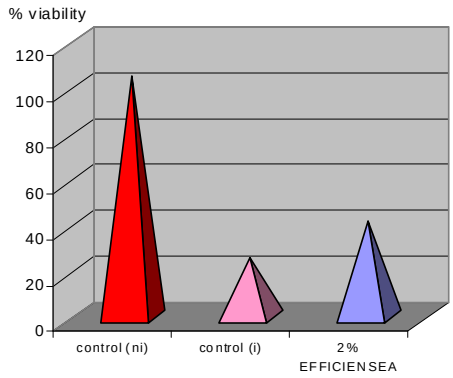
Experiment 2

Method

Reconstituted skins (SkinEthic model) are cultured in the presence or the absence of EFFICIENSEA® and submitted to UVB irradiation (dose : 300 mJ/cm²). The MTT test is performed 48 hours after. Optical density is measured in triplicate.

Results

Results are expressed as percentage of viability. 2% EFFICIENSEA® provide +26% better stimulation compared to irradiated control (in pink).



Results are validated by a statistical analysis : Student's test.

- very highly significant difference between 2% EFFICIENSEA® and irradiated control *** $p < 0.001$.

➤ EFFICIENSEA® protects skin cells against UVB irradiation.

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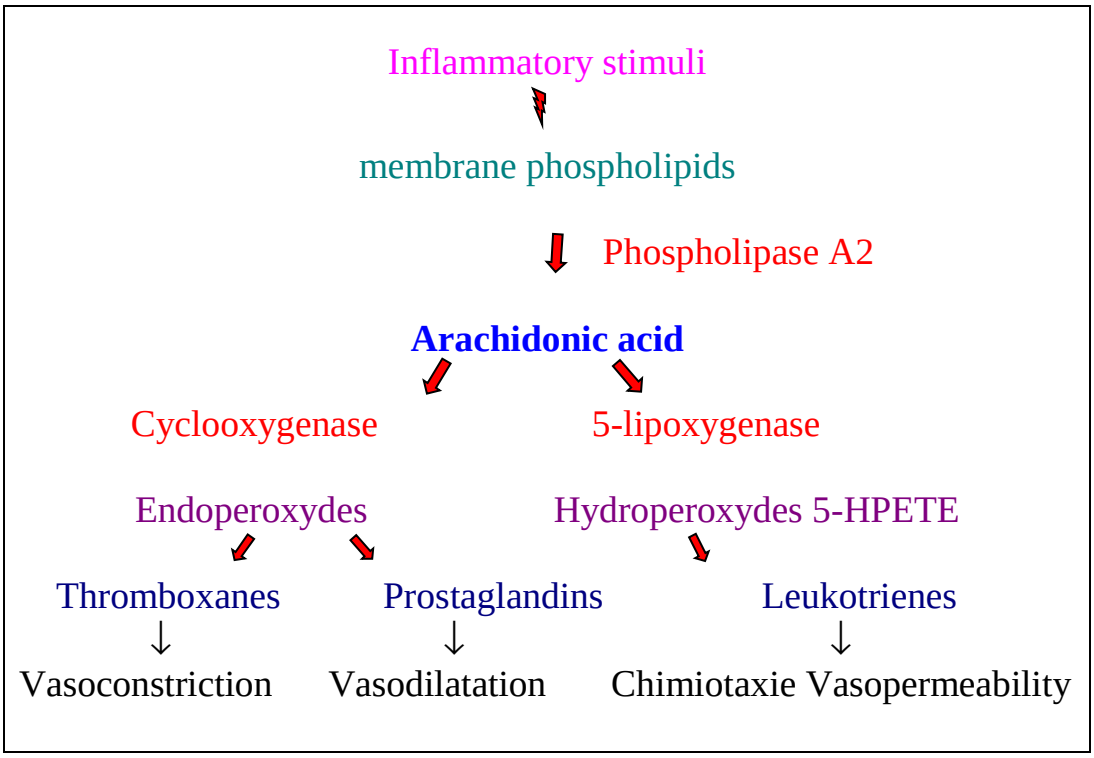
Anti-inflammation activity

Any skin irritation induces inflammatory processes which cause epidermal injury and the appearance of inflammatory syndromes in the dermis and the epidermal-dermal junction.

In cell membranes, phospholipids are altered according to the following diagram.



The arachidonic acid is released from membrane phospholipids upon cell stimulation through the action of phospholipases (A2 and C).

Then, the arachidonic acid is converted into bioactive substances according to two pathways

1- through the activity of 5-lipoxygenase : the oxidized compounds formed are hydroperoxydes which are the precursors of leukotrienes,

2 - through the activity of cyclooxygenase : the oxidized compounds formed are endoperoxydes which are the precursors of thromboxanes and prostaglandins.

In the present experiment, only the first pathway is taken into consideration.

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Inhibition of phospholipase A2

Phospholipase A2 belongs to a class of heat-stable, calcium-dependent enzymes.

It catalyzes the hydrolysis of phospholipids at the sn-2 position resulting in equimolar concentrations of free fatty acid and lysophospholipids.

It is involved in many physiological and pathological conditions (Balsinde *et al.,* 1999- Annu.Rev. Pharmacol. Toxicol., 39 :175-189).

Its role in the barrier function of the epidermis is supposed (Maury *et al*., 2000- J. Invest. Dermatol., 114: 960-966).

Methods

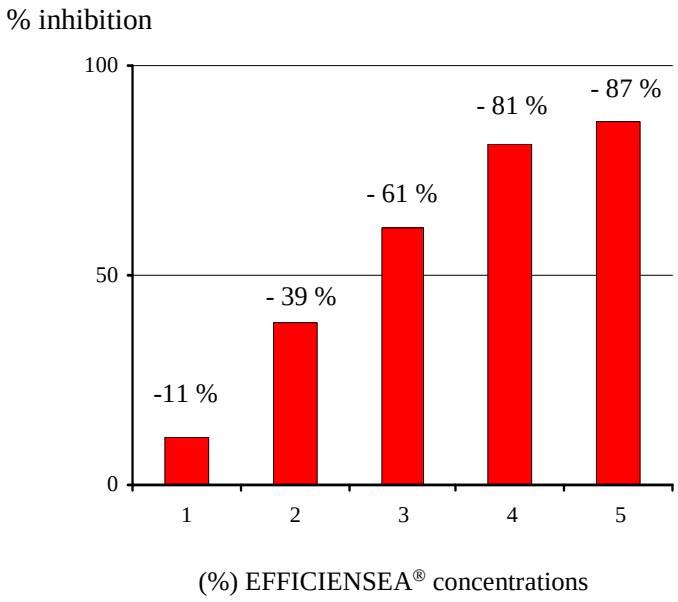
This method uses a phospholipid (dimyristoyl L-phosphatidylcholine) as the substrate.

In presence of the enzyme, lysolecithine is formed with liberation of an insoluble fatty acid into the reactionnel medium.
The reaction is followed by turbimetry using a spectrophotometer at 360 nm.

Results

Results are expressed in % of anti-phospholipase A2 activity comparatively to control realized without EFFICIENSEA®.

They represent the average of three experiments for each concentration tested ($\alpha = 0.05$).



➤ EFFICIENSEA® inhibits the activity of phospholipase A2 and stops the release of arachidonic acid.

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Inhibition of 5-lipoxygenase

Lipoxygenases are non-heme iron-containing enzymes which catalyze oxidation of arachidonate to bioactive lipid hydroperoxides.

It exists several forms of lipoxygenases such as 5-lipoxygenase founded mainly in leukocytes.

The 5-lipoxygenase generates hydroperoxydes which are the precursors of leukotrienes.

Leukotrienes have potent biological actions, such as degranulation and plasma exudation (Samuelsson *et al.*, 1987 – Science, 237: 1171-1176).

They also participate in host defence reactions and pathological conditions, such as immediate hypersensitivity and inflammation.

Methods

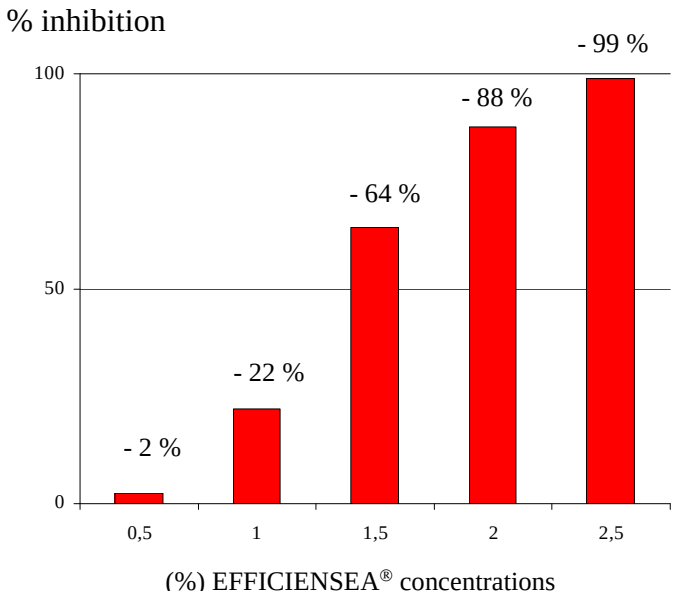
This method uses an insaturated fatty acid (the linoleic acid) as the substrate.
In presence of the enzyme, there is formation of a peroxide (5 HPETE: 5-hydroperoxy-6,8,11,14-eico-satetraenoic acid). The reaction is followed at 234 nm.

Results

Results are expressed in % of anti-5-lipoxygenase activity comparatively to control realized without EFFICIENSEA®.

They represent the average of three experiments for each concentration tested ($\alpha = 0.05$).

➤ EFFICIENSEA® inhibits the activity of 5-lipoxygenase (99% inhibition at 2.5%), which inhibits production of leukotrienes.



➤ EFFICIENSEA® acts within the arachidonic acid cascade at two different levels with dose-dependent effects

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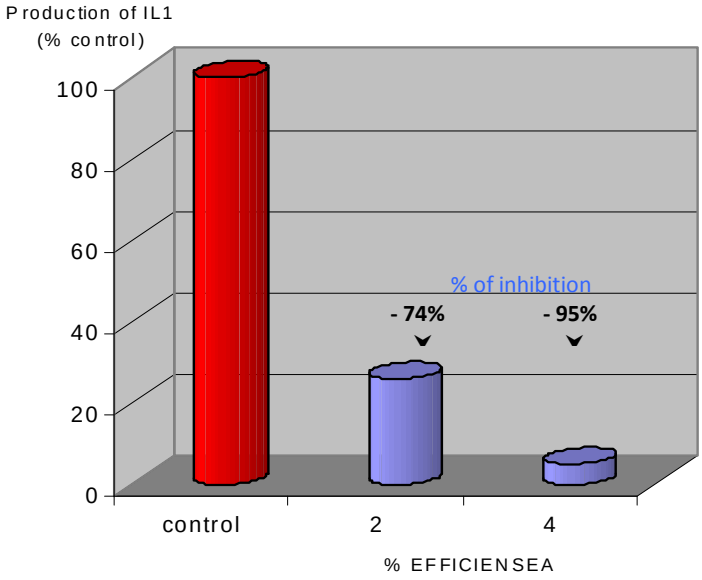
Inhibition of the interleukin IL1α

Methods

The production of IL1α is quantified by using ELISA kits (Bender MedSystems, Vienna) on the culture medium of reconstituted skins (SkinEthic model) submitted to UVB irradiation (dose : 300mJ/cm²).

Results

Results are illustrated by the graph below.



Adding of 2% and 4% EFFICIENSEA® in the culture medium inhibits respectively of 74% and 95% the synthesis of IL1α.

➤ These data confirm the powerful capacity of EFFICIENSEA® to mitigate the inflammatory response in skin.

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Reduction of stinging sensations

Clinical study

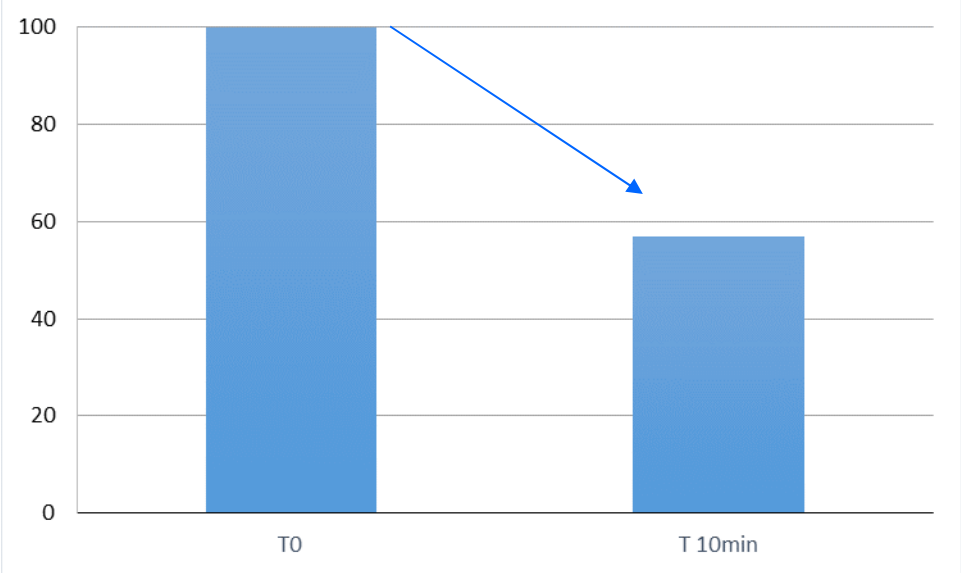
Methods

Evaluation of the anti-irritant properties of EFFICIENSEA® incorporated at 10% into a Carbopol gel on the nasolabial fold of 20 volunteers (17 female - 4 male of 19-70 years old) after irritation induced by a solution 10% lactic acid (stinging test) (IDEA-FRANCE).

The activity is evaluated after treatment at 10sec – 2min 30sec and 5 min.

Results

The topical use of a Carbopol gel added with 10% Sea Heather gives an average improvement of 53% (43.10%) against the stinging associated with the lactic acid test.



➤ EFFICIENSEA® reduces skin irritation to chemicals and promotes a soothing effect

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CONCLUSION & COSMETIC BENEFITS

EFFICIENSEA® is a patented aqueous and calibrated agent derived from the brown alga *Pelvetia canaliculata* collected in Brittany.

EFFICIENSEA® is able of providing effective protection against the main harmful effects caused by reactive oxygen species which induces DNA alteration, skin aging acceleration and inflammation processes.

EFFICIENSEA® prevents the DNA damage induced by singlet oxygen. 50% protection are obtained with a dose of 0.2% only.

EFFICIENSEA® protects against the enzymatic deterioration of the connective tissue matrix proteins. Elastase inhibition equals 60% with 0.5% and more than 80% with 2%.

Thanks to its strong tyrosinase inhibition activity, EFFICIENSEA® is valuable as an effective skin lightener. It is recommended to lighten the skin and to treat pigmented brown spots.

EFFICIENSEA® is a powerful inhibitor of the inflammation processes at two levels of the arachidonic cascade with dose-dependent effects.

It acts upstream from the release of arachidonic acid to regulate the mechanisms that trigger the propagation of the inflammation. Its anti-phospholipase A2 effect reaches more than 60% with a dose of 3%.

It inhibits the activity of 5-lipoxygenase, the enzyme responsible for the transformation of the cellular membranes arachidonic acid into leukotrienes (88% inhibition with a dose of 2%).

EFFICIENSEA® also inhibits the synthesis of the interleukin IL1α.

EFFICIENSEA® reduces skin irritation to chemicals and promotes a soothing effect

By restricting the generation of inflammatory mediators, EFFICIENSEA® prevents skin irritation and discomfort.

COSMETIC APPLICATIONS

EFFICIENSEA® can be incorporated into all soothing skin care for reactive and sensitive skins, after sun care, after depilatory products, after shave products, lightening gels and emulsions.

Recommended use levels: 1% – 10 %.

Vérifié par ECOCERT MATIÈRE PREMIÈRE COSMÉTIQUES

Vérifié par ECOCERT MATIÈRE PREMIÈRE COSMOS APPROVED

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Evaluation of ocular irritation

eurofins | ATS

N° Etude: 191889F01.doc
Version :N° 1
Page:8
P05.0.DOC.00023.01

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** : EFFICIENSEA
- **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.
- **Dates of study :** 12/12/2006
- **Place of study:** EUROFINS ATS, Pôle d'activité d'Aix en Provence
  Actimart, 1140, rue Ampère,
  13851 AIX EN PROVENCE cedex 3
- **Results :**

Denomination	ATS Reference	Initial concentration	Results	
			Score	Classification
EFFICIENSEA	167109	100%	**3.3**	**Slightly irritant**

- **Conclusion :**

According to the performed experimental conditions, the product EFFICIENSEA tested by the HET CAM method, at 100 %, can be considered as slightly irritant regarding its ocular primary tolerance.

Eurofins Scientific Test Center -Pôle d'activité d'Aix-en-Provence - Actimart - 1140, Rue Ampère - 13851 Aix-en-Provence Cedex 3 - France
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N° SIRET : 33761796300067 – Code APE : 743 B

GELYMA – Parc d'Affaires Marseille Sud (C4) – 1 Boulevard de l'Océan – 13009 Marseille – France.
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Evaluation of cutaneous irritation

eurofins | ATS

N° Etude: 191889F02.doc
Version : N° 1
Page : 15
P05.0.DOC.00017.01

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 :** EFFICIENSEA
- **Promoter :** GELYMA
- **Monitor :** Liliane PELLEGRINI, R & D 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,
  3 allée des Ingénieurs
  1140 rue André Ampère
  13851 AIX EN PROVENCE cedex 3
- **Investigator :** Doctor Mary CREST
- **Date of study:** from 28/11/06 to 30/11/06 and from 12/12/06 to 14/12/06
- **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 pure 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 alone.

- **Population:** 11 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 11 healthy adult volunteers, and according to the scale used for the interpretation of the results, the raw material **"EFFICIENSEA", Lot 06 03 250, can be considered as not irritant regarding its primary cutaneous tolerance.**

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Evaluation of genotoxic effects

Method

This chemiluminescent 3D Assay is an ELISA-like assay, realized by the well known company S.F.R.I.(St Jean d'Illac, France), by using plasmid DNA adsorbed on sensitized microplates as the substrate.

This method is based on a repair reaction of DNA (Salles *et al.*, 1995 – Analytical Biochemistry 232:37-42; Patent FR n° 95003230).

DNA lesions are repaired by the excision repair pathway which implies an incision-excision reaction followed by DNA repair synthesis.

In the present experiment, these lesions were performed by singlet oxygen, generated by methylene blue (10µg/ml in extrapure water).

EFFICIENSEA® is added according to 4 concentrations: 10 – 1 – 0.1 and 0.01%.

Results

The ability of a molecule to alter DNA is measured by the reparation ratio R.

R = RLU sample at a known dilution / RLU solvent alone
RLU: Relative Light Units

When R is inferior to 2, there is no genotoxicity,
When R is superior to 2, there is a significant genotoxicity.

Results represent the mean of two independent experimentations. They are expressed comparatively to control (irradiated or no-irradiated solvent).

EFFICIENSEA® concentrations (%)	genotoxicity ratio R
10	0.08
1	0.20
0.1	0.62
0.01	0.77

➤ No direct genotoxicity *in vitro* with the used conditions.

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Evaluation of mutagenicity

vivotecnia FINAL REPORT B-01202

FINAL REPORT **B-01202**

BACTERIAL REVERSE MUTATION TEST

EFFICIENSEA

Batch: 10 12 040

12 July 2011

3 SUMMARY

The bacterial reverse mutation test (Ames test) assesses the mutagenic or promutagenic potential of the test item EFFICIENSEA in the several bacterial strains.

The test was performed in accordance with OECD Guideline 471 for the Testing of Chemicals (Bacterial Reverse Mutation Test. Adopted 21st July 1997) and the test Method B13/B14 of Commission Directive 2000/32/EC.

No cytotoxic activity was observed at a test item concentration of 50.0µL/mL.

Five test item doses ranged between 5.00 and 0.06 µL/plate were assayed. None of the concentrations assayed for the test item showed an increase in the R value either with or without S9 metabolic activation regardless of the procedure.

No dose response for the test item EFFICIENSEA was observed in any of the tested bacterial strains.

Based on the results obtained in this study, it can be concluded that the test item does not induce point mutations or frame-shifts in the genome of the bacterial strains with or without metabolic activation regardless of the procedure.

Therefore, the test item EFFICIENSEA is considered to be **NON MUTAGENIC / NON PRO-MUTAGENIC** under the experimental conditions assayed.

Test facility
VIVOTECNIA Research S.L.
Parque Científico de Madrid
C/Santiago Grisolía 2, (PTM)
28760 Tres Cantos, Madrid
Spain

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Evaluation of sensitizing potential

ROBEN PRODUCTION GRUP SRL
CENTRUL DE CERCETARE A PLANTELOR
STRADA LUGOJ NR. 63 SECTOR 1, BUCURESTI, ROMANIA

EVALUATION DU POUVOIR SENSIBILISANT CHEZ LE VOLONTAIRE ADULTE SELON LA METHODE DE MARZULLI-MAIBACH

ASSESSMENT OF SENSITIZING POTENTIAL IN THE ADULT VOLUNTEER FOLLOWING THE METHOD OF MARZULLI-MAIBACH

Etude clinique sur 105 volontaires, tout type de peau
Clinical study on 105 volunteers, with all skin type

- Etude/ *Study*: 3.04
- Produit/ *Product*: RB10/0032

PRODUIT / *Product*	**: EFFICIENSEA**
CODE PRODUIT / *Code product*	**: RB10/0032**
DILUTION / *Dilution*	**: PUR** **PURE**
INVESTIGATEUR / *Investigator*	**: DR. ANNE-MARIE MARINESCU**

CONCLUSIONS/ *CONCLUSIONS*

Dans les conditions d'une application répétée de la procédure de patch-test conduite auprès d'un panel de 105 volontaires présentant tout type de peau, le produit **EFFICIENSEA, RB10/0032** a été «Testé dermatologiquement» et n'a pas présenté de risque d'irritation de la peau cliniquement significative ni montrer de réaction de type allergique au contact de la peau humaine.

Under the conditions of a repeated insult (occlusive) patch test procedure conducted in a panel of 105 subjects, with all skin type, the product **EFFICIENSEA, RB10/0032** *was "Dermatologist-Tested" and did not induce clinically significant skin irritation nor show any evidence of induced allergic contact dermatitis in human subjects.*

Le produit **EFFICIENSEA, RB10/0032** peut être considéré comme «hypoallergénique».

The product **EFFICIENSEA, RB10/0032** *can be considered as "hypoallergenic".*

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