MONAT TREATMENT SYSTEMS CLINICAL STUDIES

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These independent clinical studies were conducted at top manufacturing and research centers. These facilities approach hair care from a fundamental science perspective; closely examining the basic structure of hair, of hair care products, and interactions between the two from an ingredient position. Examiners within the facilities look to gain knowledge and understanding of the principles of hair and hair product interactions.

The results of these studies support MONAT's proprietary blend of naturally-based active biofunctional ingredients. No serious adverse side effects were reported from the treatments; instead, the clinical studies show that MONAT ingredient users experienced the following benefits:

- **Significant hair growth with an average increase in hair count per sq. in.**
- **Decrease of the thinning process**
- **Increased density and fullness**
- **Substantial decrease in hair fallout**
- **Increased rate of hair growth**
- **More manageability of the hair**
- **Overall better shine and condition of hair**

MONAT TREATMENT SYSTEMS CLINICAL INGREDIENTS.

Studies were scheduled and held independently utilizing one active ingredient per study. These ingredients included:

- **Capixyl™**
- **PROCATALINE™ ™**
- **Crodasorb™**

CAPIXYL™

Objective

The goal of the study was to evaluate a solution containing Capixyl™ concentration.

It was impartially evaluated by using instrumental measurements (digital trichogram with TrichoScan™). Measurements from a group of treated volunteers were compared with those

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(Extended Version)

of Placebo-treated ones. Each volunteer used the product on a daily basis. The volunteers were chosen using the following conditions: 200 hairs or less on digital trichogram hair count, and/or less than 70% hairs in the growing phase.

Volunteer Protocol

- Volunteers suffering from hair loss (average age 30-46).
- Volunteers were clinically evaluated and individual case histories were recorded in order to rule out possible abnormalities due to outside influences affecting ideal results.
- Products were applied in the evening and distributed on the testing area during 4 consecutive months.
- Every week, volunteers were given a plastic bag, where they had to collect all the hairs on their pillows, combs and clothes on a daily basis; they had to bring the bag to the laboratory for hairs to be counted.

Methodology of Trichoscan

TrichoScan is appropriate for the analysis of human scalp hair. The most important benefits are:

- Total hair counts can be analyzed within the same day.
- The same target site can be used to calculate the number of growing and non-growing hairs.

Determination of total hair density

1. A shaving mask is positioned on the volunteer head in order to shave a 1.8 cm2 area on the zone or zones to be studied.
2. Images were recorded with the equipment camera in order to evaluate the growing and non-growing phases. Volunteers were asked to not wash their hair for two days prior to the evaluation with TrichoScan.

Recording the images

After capturing, the digital images are transferred to a specific software for the analysis of the total hair density (growing + non-growing).

1. Original image
2. Detection of hair
3. Specific discernible hair
4. Detection of hair in growing and non-growing phases:

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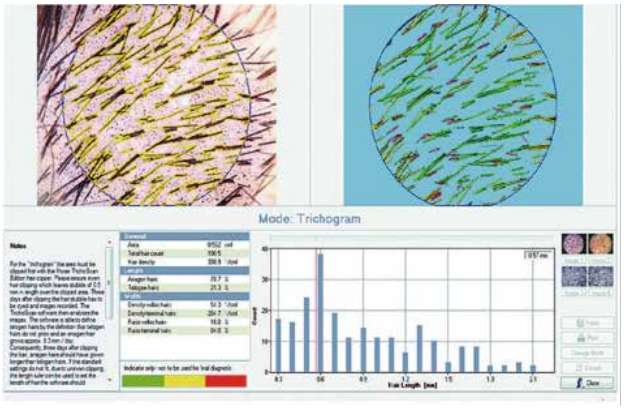
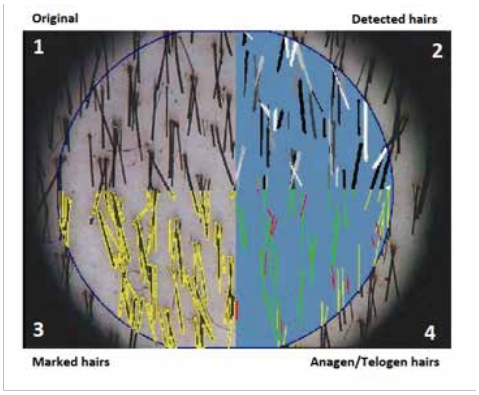
- Red: non-growing phase
- Green: growing phase
- Yellow: resting phase





RESULTS

Determination of growing hair count

The TrichoScan software defines growing hair based on the knowledge that hair grows at approximately 0.3 mm/day whereas non-growing hairs do not grow consistently. During successful testing, the growing hair count should increase and therefore this approach can be used to monitor a true response.

Determination of non-growing hair count

The software measures the length of hair and, by statistical analysis, discriminates between growing versus non-growing hairs.

The study demonstrates a clear 46% increase in the growing hair density of volunteers having used a solution containing Capixyl™ concentration in comparison with placebo after 4 months application.

The study demonstrates improvement in repair effect improving hair anchoring by 70%.

The study demonstrates a substantial reduction in DHT hormone, resulting from the action of 5a-reductase on testosterone by 48%.

The study also demonstrates a strong reduction in the non-growing hair density in volunteers having used a solution containing Capixyl™ concentration in comparison with the placebo after 4 months application.

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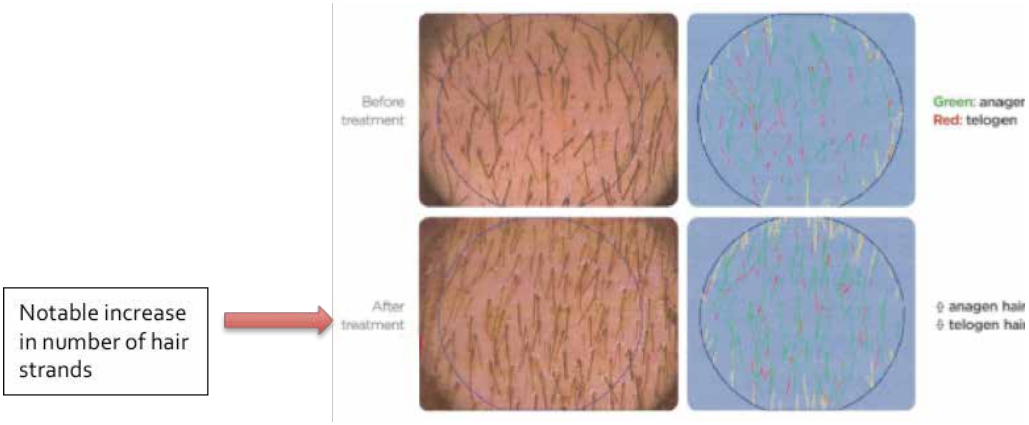
MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

Before & After Pictures



Irritation & Sensitization Patch Test

Objective

This test was done to determine the absence of irritation and sensitivity tendencies following repeated skin applications of a solution containing the ingredient CAPIXYL™ with a patch test.

This test is widely recognized to evaluate skin sensitivity and allergenic reactions.

Study Significance

Skin allergy is an occurrence of immune origin that transpires according to three phases:

- Close contact of a foreign allergenic substance with the skin
- Sensitivity of the immune system following this first contact
- Activation of immune reactions following a second exposure of the skin to the allergen

All 3 steps are required to document the allergenic potential of a given substance

Protocol

Test Group:

- Number of subjects: 112 volunteers, women and men, 18 to 84 years old.

Test application:

- Areas: on the back of each subject.
- Quantity: CAPIXYL™
- Frequency and duration:
    - Induction period: 3 weeks
    - Rest period: 1 week
    - Challenge phase: 1 week

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MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

Test Criteria
After each application, the patch is removed and the clinical examination is performed by the technician 30 minutes later.

The result of examination is negative if the skin looks normal.

The clinical examination is made on the back using the following criteria and scale (quotation 0 to 4):

Score	Response	Visible Change
0	Absent	None
1	Inflammation vascular dilation	faint, redness with poorly defined margins
2		Redness with well defined, margins Redness plus well defined edema
3	Inflammation infiltration	Redness plus papules, or vesicles or ulceration

RESULTS
Initial test:
No responses were noted on any of the 112 subjects who underwent at least one post-application examination. The absence of responses characterizes the product as one which is devoid of clinically significant skin-irritating tendencies.

Challenge test:
Original contact sites: no responses were noted on any of the 105 subjects who participated in this phase of the study. The absence of responses illustrates the product as one which is devoid of clinically significant skin sensitizing tendencies.

CONCLUSION
No significant dermal reactions were exhibited during either the induction phase or challenge phase of the study.

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MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

PROCATALINE™

Objective

The goal of the study was to evaluate a solution containing PROCATALINE™ concentration.

It was impartially evaluated by using instrumental measurements (digital trichogram with TrichoScan™). Measurements from a group of treated volunteers were compared with those of Placebo-treated ones. Each volunteer used the product on a daily basis. The volunteers were chosen using the following conditions: 200 hairs or less on digital trichogram hair count, and/or less than 70% hairs in the growing phase.

Methodology

Efficacy tests performed Ex vivo evaluation

UV damage

Hematoxylin and Eosin staining
Immuno-fluorescence staining

H2O2 damage

Hematoxylin and Eosin staining
Immuno-fluorescence staining

Melanin

Fontana-Masson staining

Material

- 6 mm punch biopsies of scalp skin
- Application: PROCATALINE™ biofunctional
- Stress: 5J/cm² UVA + 200mJ/cm² UVB Method
- Scalp skin treated with PROCATALINE™ biofunctional for 24h, then stressed with UV and kept in culture 24h again
- Punch biopsies were embedded in paraffin or in OCT and frozen in liquid nitrogen
- Hematoxylin and Eosin staining
- Immuno-fluorescence staining
- Detection by fluorescence microscopy

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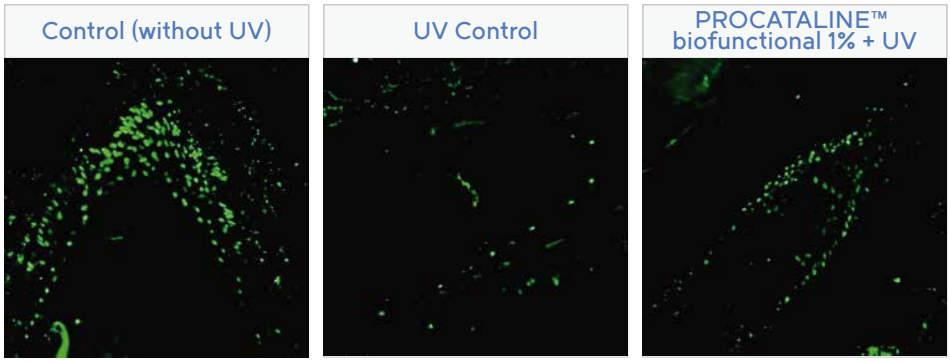
MONAT TREATMENT SYSTEMS CLINICAL STUDIES

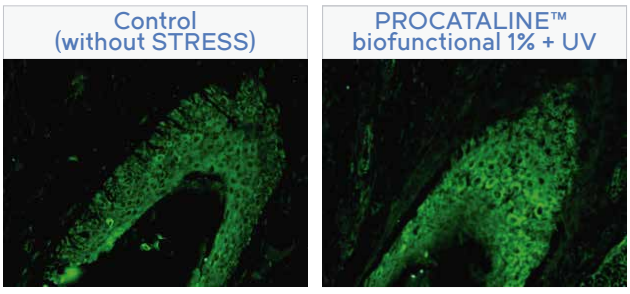
(Extended Version)

PROCATALINE™ biofunctional helps maintain P63 expression in hair follicle under UV stress, ex vivo.



PROCATALINE™ biofunctional treatment before UV exposure significantly maintained P63 expression. This helps to create a favorable environment to promote hair growth.

PROCATALINE™ biofuntional helps maintain high level of anti-oxidative enzyme, ex vivo.



PROCATALINE™ biofunctional helped boost the expression of catalase enzyme. Hair follicle appears better preserved when exposed to UV irradiation.

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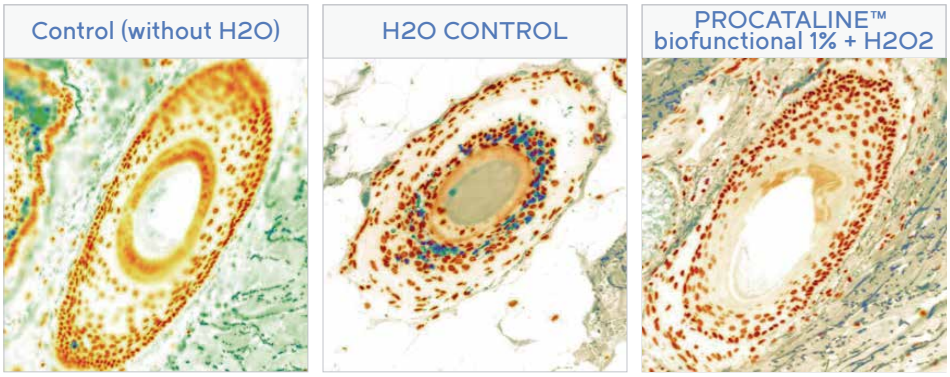
MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

PROCATALINE™ biofunctional helps limit cell death in hair follicle, ex vivo.



No caspase-3 staining was observed in the PROCATALINE™ biofunctional-treated follicle suggesting reduced cell death.

RESULTS

As shown by ex vivo studies, PROCATALINE™ biofunctional treatment before UV exposure may help to:

- Create an environment favorable to hair renewal and growth
- Preserve hair cells and increase the hair follicle strength by 35%
- Preserve hair follicle and structure from H2O2 damage
- Increase collagen production, directly increasing follicle size by 70%
- Preserve melanin in hair follicle under oxidative stress

Irritation & Sensitization Patch Test

Objective

This test was done to determine the absence of irritation and sensitivity tendencies following repeated skin applications of a solution containing the ingredient PROCATALINE™ concentration with a patch test.
This test is widely recognized to evaluate skin sensitivity and allergenic reactions.

Study Significance

Because human skin functions as a physicochemical barrier, molecules over 500 Daltons of molecular weight are usually unable to traverse the stratum corneum. Penetration of proteins/polypeptides through normal skin is extremely low and normally without

consequence. Proteins/peptides are not expected to interact directly with DNA or other chromosomal material. The protein extract of pea is not expected to either have genotoxicity potential or cause systemic toxicity by dermal exposure and no systemic toxicity studies are needed. Therefore, PROCATALINE™ is safe to use as a cosmetic ingredient at the recommended use level.

Dermal Irritation

PROCATALINE™, tested as supplied, was non-skin irritants, based on the in vitro Skin Irritation Test (SIT) Using the Epiderm™ Skin Model.

The skin irritation test using the EpiDerm™ skin model met the requirements of the ŒCD TG439 guideline and was conducted in full compliance with the GLP (Good Laboratory Practice) regulations. Three EpiDerm™ skin tissues were topically exposed to the PROCATALINE™, as supplied, for 60 minutes. After 42-hour post-treatment incubation, the EpiDerm™ skin tissue viability was determined by MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide) conversion assay. The relative viability of the test article-treated tissues was calculated and the skin irritation potential was evaluated. Based upon the mean tissue viability of 94.0%, PROCATALINE™, as supplied, was predicted to be non-skin irritants according to the prediction model validated by ECVAM and to the ŒCD Test Guideline 439.

Ocular Irritation

PROCATALINE™, tested as supplied, had minimum ocular irritation potential based on the Topical Application Ocular Irritation Assay Using the Epiocular™ Human Cell Construct.

The ocular irritation assay using the EpiOcular™ human cell construct was conducted in full compliance with the GLP regulations. The EpiOcular™ tissues were topically treated with PROCATALINE™ , as supplied, for 4, 8, 16, and 24 hours (2 tissues/ time point). The MTT conversion assay was used to assess cellular viability. The ocular irritation potential was evaluated by the duration of exposure required to reduce the EpiOcular™ tissue viability to 50% of controls (ET50). PROCATALINE™ showed insignificant cytotoxicity at all exposure times and the ET50 was determined as greater than the longest exposure time tested (ET50 > 24 hours). The results of the assay indicated that PROCATALINE™, as supplied, had minimum ocular irritation potential.

RESULTS

Repeated Insult Patch Test (RIPT)

In an RIPT completed by 214 human subjects, PROCATALINE™ demonstrated no potential for dermal irritation or allergic contact sensitization.

MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

Each of 214 human subjects received 0.2 ml of PROCATALINE™ as supplied on the upper back area. Following a 24-hour exposure period, test patches were removed and sites scored for erythema and edema. A series of nine induction patches was applied three times a week for three weeks. Following a two-week rest period, challenge patches were applied to a virgin site on the back and allowed to remain in skin contact for 24 hours. Challenge sites were scored for erythema and edema at 24 and 72 hours post patching. No significant dermal reactions were exhibited during either the induction phase or challenge phase of the study.

CONCLUSION
No significant dermal reactions were exhibited during either the induction phase or challenge phase of the study.

CRODASORB™
Objective
The goal of the study was to evaluate the effect of UV Radiation on hair with CODASORB™ concentration.

CRODASORB UV-283 has been shown to preserve the natural color of the hair. The fact that brown tresses do not lighten in color indicates that CRODASORB UV-283 prevents UV-B radiation from degrading melanin, the pigment that gives hair its color. During testing it was also discovered that both blond and gray tresses treated with CRODASORB UV-283 retained their natural color after UV-B exposure. This same color protection was not observed in the untreated tresses or in the tresses treated with Octyl Methoxycinnamate; blond hair tresses turned a brassy gold and gray hair tresses appeared to yellow. Such adverse color changes are an indication of Tryptophan degradation.

Methodology
Combing Studies

CRODASORB UV-283 prevents the photodamage that causes hair to develop undesirable combing properties after UV exposure, as seen in studies evaluating its effect on the combing work of tresses exposed to UV radiation. One study found that CRODASORB UV-283 reduced the work of combing by 58% in virgin hair and by 33% in bleached hair compared to the untreated, UV-exposed sample, a clear indication that CRODASORB UV-283 has prevented photodamage.

The combing study consisted of two parts, an independently run exposure phase and an in-house testing phase. During the exposure phase, treated and untreated tresses of virgin

MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

and bleached hair underwent 29 days of UV-A/UV- B exposure at 375.8 Joules/day. Untreated and unexposed tresses were used as controls. During the second phase of in-house testing, wet combing measurements for each of the sample tresses were obtained using the Dia-Stron tensile tester. These measurements were used to compare the combing work of UV-exposed tresses treated with CRODASORB UV-283 with that of UV-exposed tresses left untreated. The bar chart shown on the following page depicts these combing measurements. Values are expressed as total combing work (Joules) and represent absolute numbers, not percent reductions.

CRODASORB UV-283 Reduces Combing Work After UV Exposure

These dramatic improvements in wet combing indicate that CRODASORB UV-283 has not only prevented damage to the cuticle, but has also provided conditioning benefits.

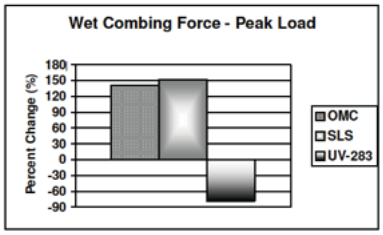


Figure 6. The much lower peak load for the UV-283 gray hair tress means CRODASORB UV-283 has made the hair easier to detangle.

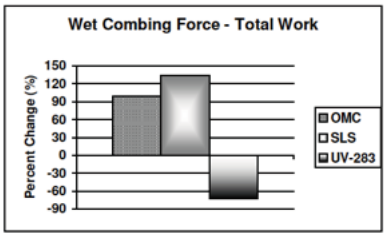


Figure 7. The large reduction in total work for the UV-283 gray hair tress means CRODASORB UV-283 has made the hair easier to comb.

Additional Studies

Tryptophan analysis, contact angle measurements, and fiber breakage testing all confirm that CRODASORB UV-283 prevents UV-B damage in hair and helps maintain the integrity of both the cuticle and the cortex. Prior to testing, treated and untreated hair tresses were placed in a temperature/humidity-controlled chamber set at 27°C and 65% RH and exposed to UV radiation using UV-B lamps which emitted 0.0025 Watts/cm², which is the equivalent of 8 times the daily UV exposure at Mauna Loa, HI.

Treatment:

Hair tresses were grouped into one of four categories and then treated as described below during the UV exposure period. Twenty hair fibers from each group were withdrawn for testing at Days 3, 6 and 12.

A. No treatment/No exposure to UV
B. Washed every 24 hours with solution containing CRODASORB UV-283
C. Washed every 24 hours with solution containing Octyl Methoxycinnamate
D. Washed every 24 hours with solution containing no UV absorber

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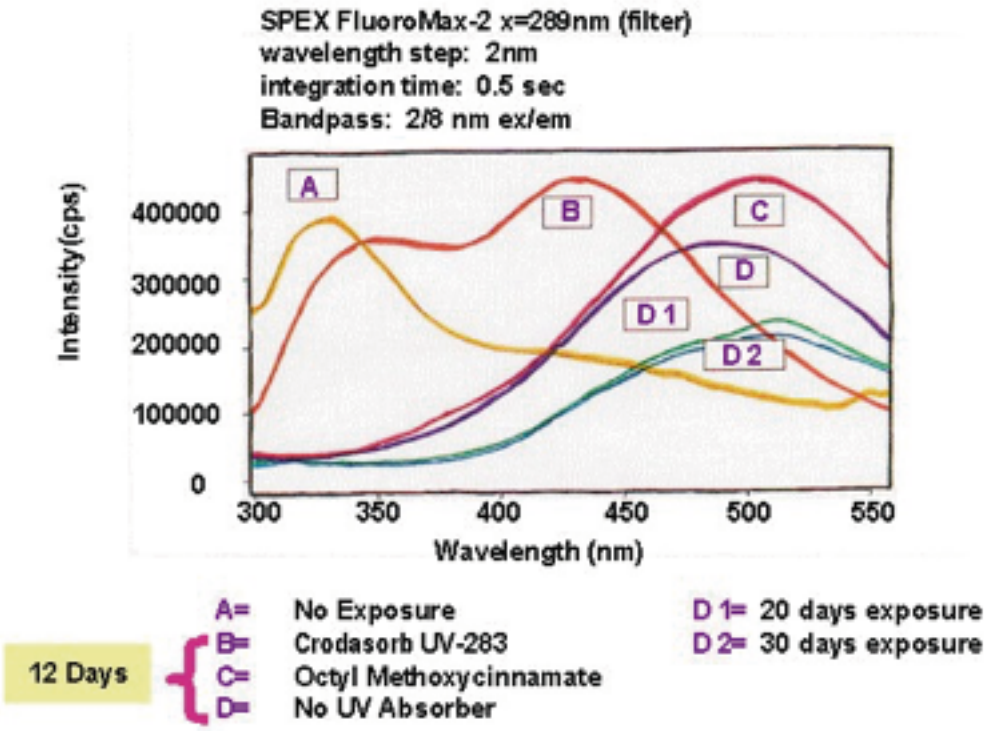
MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

Spectrofluorometric Analysis of Tryptophan

Tryptophan is an amino acid found in the hair. Since it decomposes on exposure to UV radiation, Tryptophan can be used as a marker for UV damage. Spectrofluorometric analysis shows that the peak for Tryptophan in unexposed hair is between 300 and 350nm (Sample A in the graph shown below). As the curves indicate, CRODASORB UV-283 (Sample B) is effective in preserving Tryptophan, while the other UV-B exposed tresses (Samples C, D, D1, D2) show complete degradation of the amino acid.



RESULTS

Laboratory results indicate that CRODASORB UV-283 exhibits significantly higher substantivity in the absence of anionic surfactants.

- CRODASORB UV-283 Reduces Combing Work After UV Exposure
- CRODASORB UV-283 is effective in preserving tryptophan, which when degraded is an indicator of UVB damage
- CRODASORB UV-283 Keeps Hair Stronger After UV-b Exposure

MONAT GLOBAL

MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

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- CRODASORB UV-283 has not only prevented damage to the cuticle, but has also provided conditioning benefits.
- CRODASORB UV-283 helps protect gray hair from the sun by preventing UV-B damage at the surface.
- CRODASORB UV-283 means the hair has maintained its elasticity and is less brittle.
- CRODASORB UV-283 protects the structural integrity of gray hair exposed to UV radiation.

Irritation & Sensitization Patch Test
Objective

An Epi-Derm study was used to assess the acute irritation potential of Crodasorb UV-283. Composition details: Crodasorb UV-283-LQ-(MH) is a mixture Cinnamidopropltirmonium Chloride and water.

Toxicological summaries for the components of the mixture.

1. Eye Irritation
2. Skin Irritation/Sensitization: Human Repeat Insult Patch Test
3. Skin Irritation: EpiDerm

RESULTS
Concentration Average Score

Distilled Water (100%) 1.75
Crodasorb UV-283

2. Skin Irritation/Sensitization – Human Repeat Insult Patch Test

An aqueous solution of Crodasorb UV-283 was evaluated to determine whether it would induce primary or cumulative irritation and/or allergic contact sensitization. The induction phase consisted of applying a 1 in. by ¾ in. semi-occluded patch containing 0.2 mL of the test article to the upper back of 56 human test subjects. After a 24-hour exposure period, the patch was removed and examined for signs of irritation. After a 24-hour rest period, the test was repeated and continued 3 times a week for 3 weeks. Upon completion of the induction phase and a two-week rest period, the test subjects were challenged with a single application of the test article adjacent to the original test site. After 24 hours, the patch was removed. The test site was examined for signs of sensitization 24 and 72 hours post application.

There were no visible skin reactions on any of the test subjects throughout the testing interval. Under the conditions of this study, Crodasorb UV-283 aqueous solution did not indicate a potential for dermal irritation or allergic contact sensitization.

MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

3. Skin Irritation

Crodasorb UV-283 was evaluated for corrosive potential utilizing the Mat Tek Corporation EpiDerm in vitro toxicity testing system. After the appropriate tissue preparation, 100 uL of the negative control article were added to the millicells containing the EpiDerm samples that were incubated at 37°C 5% CO2 and >90% humidity. After the appropriate exposure periods (1hr, 4.5hrs, 20hrs), each insert was individually removed from its plate and rinsed with phosphate buffered saline (PBS) to remove any residual material. Each was then rinsed a second time. Excess liquid was shaken off and each EpiDerm sample was placed into 300 microliters of MTT solution. The Epiderm samples were then returned to the incubator. After the 3 hour MTT exposure, each insert was removed and gently rinsed with PBS to remove any residual MTT solution. Excess PBS was shaken from each of the inserts, which were then blotted on the bottom using paper towels. The inserts were then each placed into 1 well of a 24 well extraction plate. Each insert was then immersed in 2 mL of extraction solution overnight. After the exposure the liquid was decanted back into the original well, agitated and a 200 uL aliquot was removed for evaluation.

Toxicological Assessment for Crodasorb UV—283

An automatic microplate reader was used to determine the absorbance of each extract at 570nm. The percent absorbance of the test and reference articles that were determined with the negative control was defined as 100%. According to the MatTek Corp. as a general guideline the following groups can be used in assuming expected in vivo irritancy response based on ET-50 results from the EpiDerm.

ET-50 (hours) Expected in vivo irritancy

< 0.5 = Severe, probably corrosive
0.5-4 = Moderate
4-12 = Moderate to mild
12-24 = Very mild
24 = Non-irritating

The Crodasorb UV-283 elicited and ET-50 of approximately 8.0 hours as per the above chart Crodasorb UV-283 has an in vivo dermal irritancy potential of moderate to mild.

CONCLUSION

No significant dermal reactions were exhibited during either the induction phase or challenge phase of the study.

MONAT GLOBAL

MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

REJUVENIQE™

Objective

The goal of the study was to evaluate a solution containing REJUVENIQE™ with Abyssinian Oil.

Many claims are being made to demonstrate the effectiveness of hair care products. These include aspects like hair manageability, protection, strengthening of the hair strands and anti-breaking properties. Furthermore a visible benefit like the enhancement of the natural shine of the hair is important to achieve customer satisfaction.

Volunteer Protocol

The tests were performed on Mulatto and Caucasian hair. Mulatto hair offers a combination of characteristics of different ethnic hair types mixed with African origin. Due to the ellipticity and high degree of curliness hair of African or Mulatto origin has a tendency to be very sensitive against damage. Therefore, an improved hair quality in this type of hair can demonstrate the benefit of a treatment with REJUVENIQE with Abyssinian Oil very efficiently. Caucasian hair can be characterized as having straight hair texture which is resistant to damage, but has a duller appearance.

RESULTS

Dry Combing Test

A repeated grooming test was performed to quantify the shine of the hair. The hair tresses were cleansed with a non-conditioning shampoo, dried overnight under controlled humidity (60%) and afterwards the oils were applied to the hair.

Based on the results of three different test methods we can claim that REJUVENIQE™ with Abyssinian Oil offers a high benefit in improving the manageability of the hair, enhancing the shine and strengthening the hair strands. It can be claimed as being a natural replacement to synthetic ingredients in hair care products like silicones, where shine, luster and a strengthening effect is needed.

Dry Combing Mulatto and Caucasian Hair

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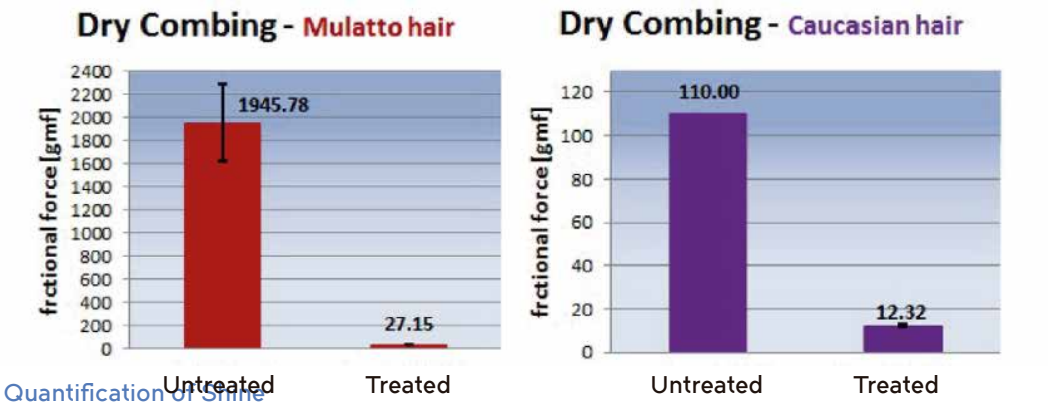
(Extended Version)



Quantification of Shine

Objective

The shine of the hair is a very highly appreciated attribute of healthy-looking hair and is often a claim of hair care products.
This test is widely recognized to evaluate luster and shine with light reflecting properties.

Protocol

The commercially-available SAMBA device by Bossa Nova was used to quantify the shine enhancement of REJUVENIQE™ with Abyssinian Oil. This method was developed to measure the luster and shine of the hair tress by light reflected from a curved hair tress. The quantification is based on an image analysis by scanning the light distribution of a hair sample across highlighted and dark areas. The resultant image was evaluated by using image analysis software with developed macros. In general the hair pigmentation has a significant effect on the optical properties of hair and on its luster. Hair with low pigmentation reflects the light which results in a broad light distribution. The luster is calculated as a function of light intensity and the distance along the hair tress, therefore dark hair has the narrowest light distribution. This results in increasing luster for increasing pigmentation of the hair. To ensure statistical relevance eight tresses were evaluated per sample. The Mulatto Hair that was used was non-chemically modified, the Caucasian Hair was bleached once.

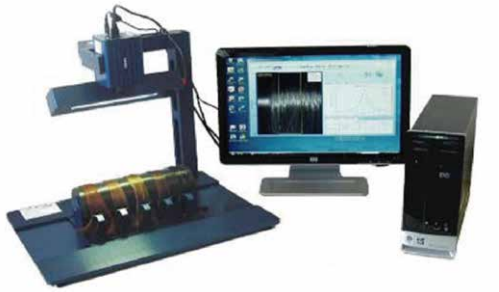
SAMBA device tester

RESULTS

The natural shine of untreated Mulatto Hair is around 165 technical shine units (in Reich-Robbins units). The effect of using REJUVENIQE™ with Abyssinian Oil to enhance the shine of the hair is impressive by almost doubling the apparent shine on the Mulatto hair in comparison to untreated hair up to 289 units. Typical values for bleached Caucasian hair by this method are around 18 – 20 units, which corresponds to a much duller initial state for this

MONAT TREATMENT SYSTEMS CLINICAL STUDIES
(Extended Version)

hair structure.



REJUVENIQE™ with Abyssinian Oil has the ability to increase the shine of Caucasian hair by 88%, which is more than 4.4 fold of the initial shine. Due to these results it can be claimed, that REJUVENIQE™ with Abyssinian Oil is a natural shine enhancer. It can be used as a natural replacement to synthetic oils like silicones in Hair Care products where shine and luster is needed.

CONCLUSION

REJUVENIQE™ with Abyssinian oil is a natural hair conditioning agent with numerous benefits. The great performance of REJUVENIQE™ with Abyssinian oil for hair care applications have been displayed in the test results presented in this report. It increases the manageability of the hair, strengthens it and makes is more resistant against external stress like grooming with an anti-breakage effect. Furthermore it is a very effective shine enhancer while being non-greasy. These benefits can be seen on different hair structures like Mulatto and Caucasian Hair. Therefore it can be used as a natural replacement for other oils used in hair care applications and synthetic ingredients like silicones and mineral oil.

Conditioning Effect

REJUVENIQE™ with Abyssinian oil increased the combability both on Mulatto and Caucasian hair. The positive effect is even more obvious on the kinky Mulatto hair, which is known to be more difficult in styling.

Anti-Breakage Effect

The repeated grooming test showed the capability of REJUVENIQE™ with Abyssinian oil to strengthen the hair and significantly reduce the breaking of hair fibers. Especially on the more sensitive and easily breaking Mulatto hair, REJUVENIQE™ with Abyssinian oil offers a dramatic benefit even outperforming the effect on Caucasian Hair.

Natural Shine Enhancer

The shine enhancing capability of REJUVENIQE™ with Abyssinian oil can be impressively demonstrated on both hair types, which had been evaluated and can almost double the shine of Mulatto hair, and the shine of initially duller Caucasian hair can be enhanced by 88%