Oat COM
DATA PACK

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Oat COM

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Contents

Microbial Purity

PATENTED EXTRUSION PROCESS

Oat COM is manufactured by a unique patented process whereby the coarse whole oat flour is extruded prior to being fine milled to the USP particle size specification. Four samples of the coarse oat flour were tested for Water Activity, Microbial Count (cfu/g), Yeast (cfu/g) and Moulds (cfu/g) prior to passing through an extruder. Once extruded they were then tested again.

RESULTS

	Inlet Moisture	Outlet Moisture	Water Activity	Microbial Count cfu/g	Yeast cfu/g	Moulds cfu/g
Flour	13%		0.6	7×10^5	5400	730
Test 1	13%	7.5%	0.4	<10	<10	<10
Test 2	19%	12.2%	0.6	<10	<10	<10
Test 3	13%	7.2%	0.3	<10	<10	<10
Test 4	19%	11.9%	0.6	<10	<10	<10

All four samples showed a significant reduction of Microbes, Yeats and Moulds to levels well below 100 cfu/g. In addition, the patented extrusion process also reduced the water activity of the flour to such a level (below 0.6) that microbe proliferation was stopped completely.

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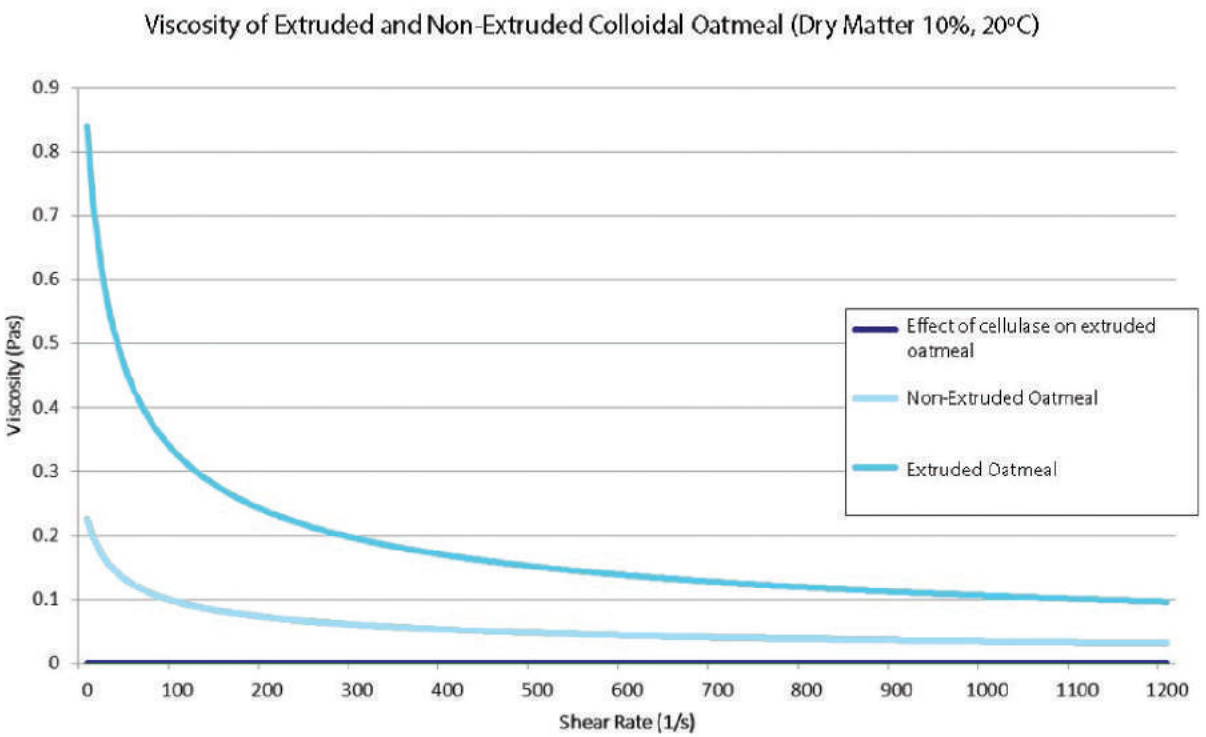
Enhanced β-Glucan Levels

Oat COM is made from a specific variety of *Avena sativa*, which is selected for it's higher content of 1, 3 - 1, 4 beta-D-glucan. It has also been demonstrated that pre-solubilising the starches by extrusion improves dispersion and suspension of the colloidal oatmeal without the need for further grinding, thus preserving the molecular weight of the beta-glucan.

BETA-GLUCAN AVAILABILITY

A rheological assessment was conducted to test and compare the beta-glucan content between Oat COM and a standard colloidal oatmeal. Dissolved beta-glucan concentrations of Oat COM (extruded) and a competitor colloidal oatmeal (non-extruded oatmeal) suspensions were evaluated at 10 % w/w dry matter.



RESULTS

In comparison to the competitor colloidal oatmeal, the Oat COM dispersion showed much stronger shear thinning behaviour. This would indicate that the material contained more 1, 3 - 1, 4 beta-D-glucan and its molecular weight has been preserved.

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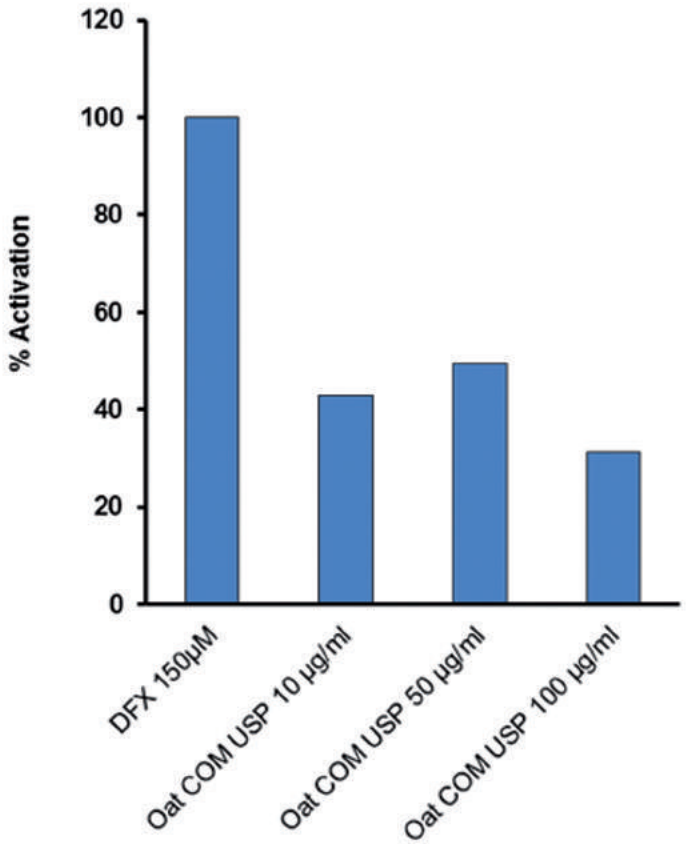
HIF-1α Pathway (Induction and Inhibition)

TESTING WITH THE SIMDERMA® PLATFORM

Oat COM was tested at three different concentration levels (10µg/ml, 50µg/ml and 100µg/ml) using the SimDerma® Platform from SimCosmetic Biotech. HaCaT-EPO-Luc cells (50x104 cells/mL) were preincubated with increasing concentrations of the compounds or the hypoximimetic DFX for 6 h. Luciferase activity was measured in the cell lysates and results are represented as the fold induction over basal levels.



RESULTS

Oat COM USP strongly stimulated HIF-1α activation. The role of HIF-1α in skin homeostasis is vital as it is involved in the integrity of epidermal structural proteins such as integrin and thus important as regards structural dysfunction and aging processes in the skin.

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Water Absorption Capacity

WATER ABSORPTION

Water absorption capacity was determined by dispersing 100g of Oat COM in water and centrifuging the mixture at low speed. The water absorption capacity is defined as the amount of water retained per solid (Lin et al., 1974). The same experiment was then undertaken with a standard colloidal oatmeal for comparison purposes.

Colloidal Oatmeal	Average Weight Increase (g)	Water Binding (g/100g)	Percentage Increase (%)
Standard	2.28	24	111
Oat COM	4.46	45	211

RESULTS

The increase in water binding capacity of the Oat COM was demonstrated to be 88%. This enhanced capacity to absorb water helps build stable emulsions by binding up to 88% more water than standard colloidal oatmeal. This is possibly due to the change in structure of the free amylose/amylopectin ratio and the overall particle size leading to absorption of the oil by the starch particles.

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Oil Absorption Capacity

OIL ABSORPTION

Oil absorption capacity was determined by dispersing 100g of Oat COM in Rapeseed Oil and centrifuging the mixture at low speed. The oil absorption capacity is defined as the amount of oil retained per solid (Lin et al., 1974). The same experiment was then undertaken with a standard colloidal oatmeal for comparison purposes.

Colloidal Oatmeal	Average Weight Increase (g)	Oil Binding (g/100g)	Percentage Increase (%)
Standard	3.00	60	
Oat COM	3.89	78	30

RESULTS

The increase in oil binding capacity of the Oat COM was demonstrated to be 30%, possibly due to the change in structure of the free amylose/amylopectin ratio and the overall particle size leading to absorption of the oil by the starch particles.

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Short Term Skin Greasiness Reduction Trial

DOUBLE BLIND TRIAL

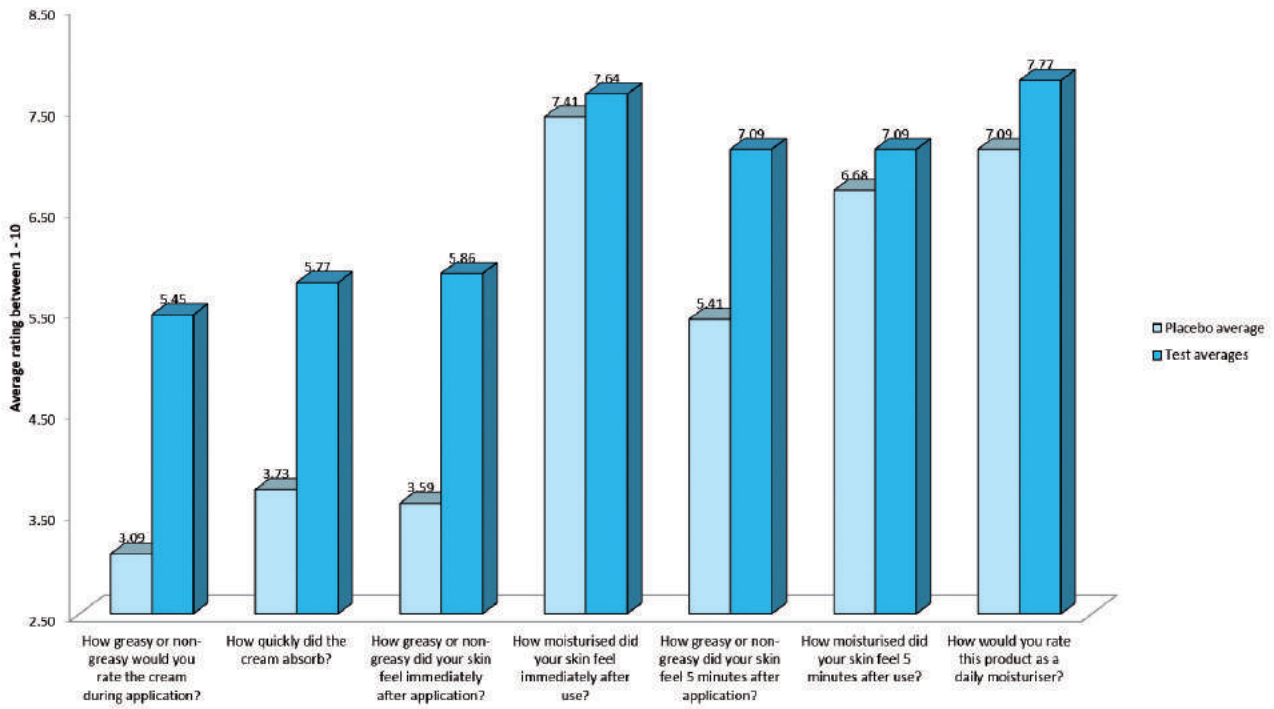
A half-face double blind trial was conducted to assess the ability of Oat COM to reduce skin greasiness. A total of 22 subjects were tested over a period of 5 minutes. The subjects were asked to compare a moisturing cream, containing Oat COM at a 3% inclusion rate, and a placebo cream.

FORMULATION

Trade Name	INCI	% w/w
Oat Lipid e	*Avena sativa* (Oat) Kernel Oil	3%
Oat COM USP	*Avena sativa* (Oat) Kernel Flour	3%
Arlatone 2121	Sorbitan Stearate, Sucrose Cocoate	3%
Cetyl Alcohol	Cetyl Alcohol	1%
WhiteParaffin	Petrolatum	2.5%
Mineral Oil	Paraffinum Liquidum	8%
Sunflower Oil	Helianthus Annuus Seed Oil	3%
Sepigel 305	Polyacrylamide, C13-14 Isoparaffin, Laureth-7	2.5%
Neolone CapG	Caprylyl Glycol, Methylisothiazolinone	1%
Purified Water	Aqua	to 100%

RESULTS

The trial demonstrated a clear perception by the subjects that the test cream was less greasy during application and that this feeling remained after absorption into the skin. The observed difference in moisturisation was minimal which was surprising since the base cream was designed to be highly moisturising and it was thought that the inclusion of Oat COM powder would decrease the perceived moisturisation, however, the opposite was observed.



These results confirm Oat COM's ability to bind oil and that it's inclusion in creams and lotions improves skin feel.

Study independently designed by AGR International 2013.

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Long Term Skin Trial

HUMAN PERCEPTION STUDY

A human perception study was undertaken to elucidate the benefit of Oat COM in reducing the perceived greasiness, absorptive and emollient properties of skin care products. A total of 22 subjects used a moisturising cream, containing Oat COM at a 2% inclusion rate, over this long-term skin trial. Data was analysed by AGR systems in real-time (Ayton Systems Software).

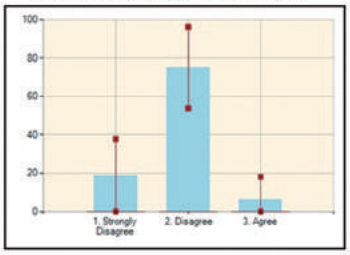
FORMULATION

Trade Name	INCI	% w/w
Purified Water	Aqua	54.6
Disodium EDTA	Disodium EDTA	0.1
Euxyl PE9010	Phenoxyethanol	1
Betafin BP20	Betaine	1
Oat COM USP	*Avena sativa* (Oat) Kernel Flour	2
Glycerin	Glycerin	1
Oat Lipid e	*Avena sativa* (Oat) Kernel Oil	1
Cetearyl Alcohol	Cetearyl Alcohol	1.5
Montanov 68	Cetearyl Alcohol, Cetearyl Glucoside	3
Caprylic/Capric Triglyceride	Caprylic/Capric Triglyceride	5
Xiameter 200-350cst	Dimethicone	2
Crodamol AB	C12-15 Alkyl Benzoate	8
Arlacel 165	Glyceryl stearate, PEG-100 Stearate	1.5
Uvinul A Plus B	Diethylamino Hydroxybenzoyl Hexyl Henzoate	15
Tinosorb S	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	3
Sepiplus 400	Polyacrylate 13, Polyisobutene, Polysorbate 20	0.3

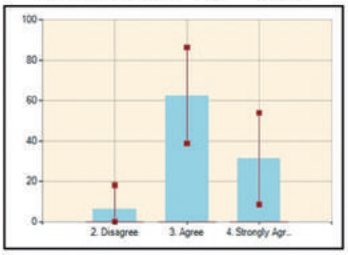
RESULTS

The consumer evaluation clearly shows that the addition of Oat COM into a formulation improves moisturisation, imparts soothing properties and leaves a non-greasy feel.

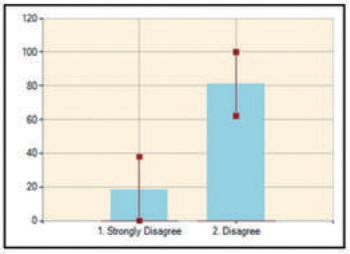
Skin Tackiness - SD = 0.5

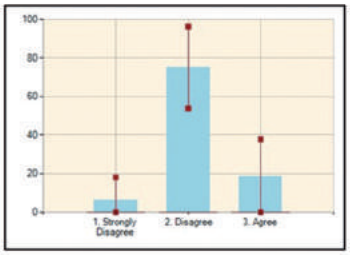


Ease of Glide - SD = 0.58

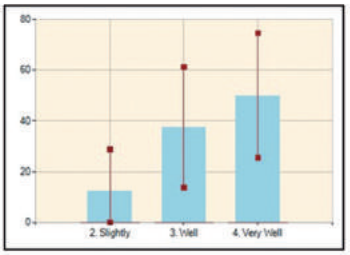


Greasy Feel - SD = 0.4

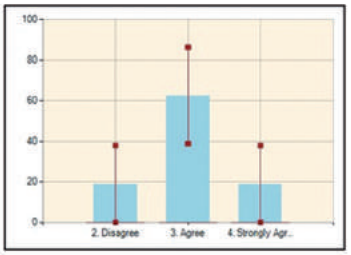




Leave Skin Shiny - SD = 0.5



Skin Absorption - SD = 0.72



Soothes Skin - SD = 0.63

Study independently designed by AGR International 2013.

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In-Vivo Skin Repair Study

BACKGROUND

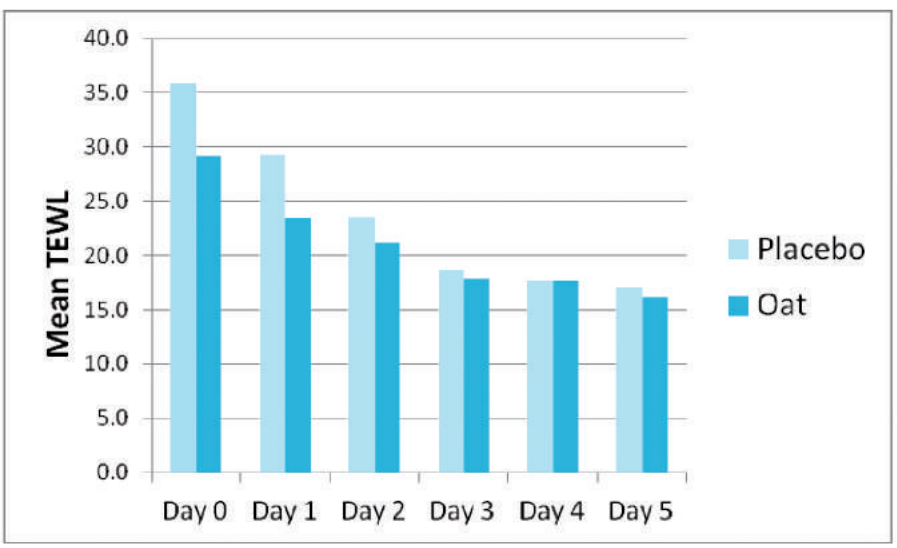
Oat Cosmetics' in-vitro cell biology testing found that Oat COM strongly stimulated HIF-1α, which stimulates production of fibroblasts, keratinocytes and structural proteins used in skin repair. To prove this has a practical application, an in-vivo study was conducted to assess the ability of Oat COM to repair the skin.

CLINICAL STUDY

A 5-day clinical study was conducted to ascertain the effects of Oat COM on already inflamed skin. A total of 15 subjects were tested over a period of 10 days. Two skin areas on the volar forearm were pre-irritated with 2% aqueous sodium lauryl sulphate (SLS). The skin was then treated with Oat COM versus a placebo containing no Oat COM and measurements for skin moisturisation, skin barrier function, skin colour and visual scoring of erythema were taken over 5 days.

RESULTS

Effect on Trans epidermal Water Loss (TEWL): As the study progressed a decrease in TEWL was seen indicating barrier repair. Analysis of the relative performance of the 2 formulations showed that the Oat COM formulation TEWL values were significantly lower than those of the control formulation. This is indicative of accelerated barrier recovery compared to the placebo formulation.



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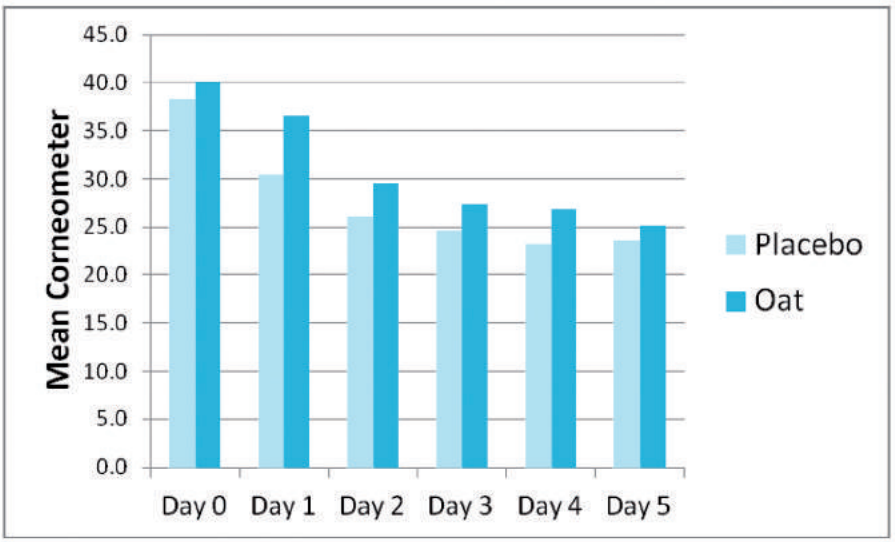
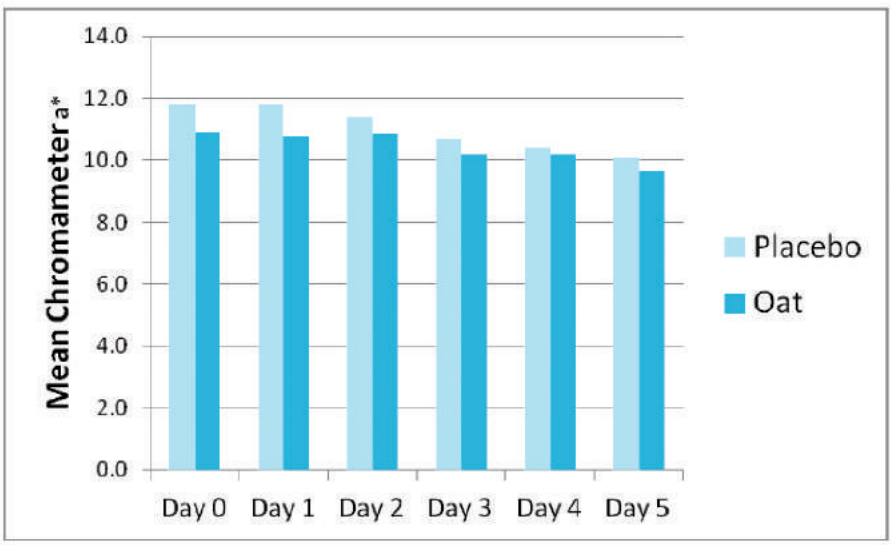
In-Vivo Skin Repair Study

RESULTS CONTINUED

Effect on Skin Hydration: The mean values for the Corneometer measurement of skin surface moisture for the Oat COM formulation were higher than those with Placebo formulation during the study. This shows that the Oat COM formulation has benefits in terms of skin surface moisturisation.



Effect on Skin Redness: The mean values for the Chromameter measurement of skin surface redness (a*) for the Oat COM formulation were lower than those with Placebo formulation during the study, demonstrating that the Oat COM formulation reduces skin surface redness.



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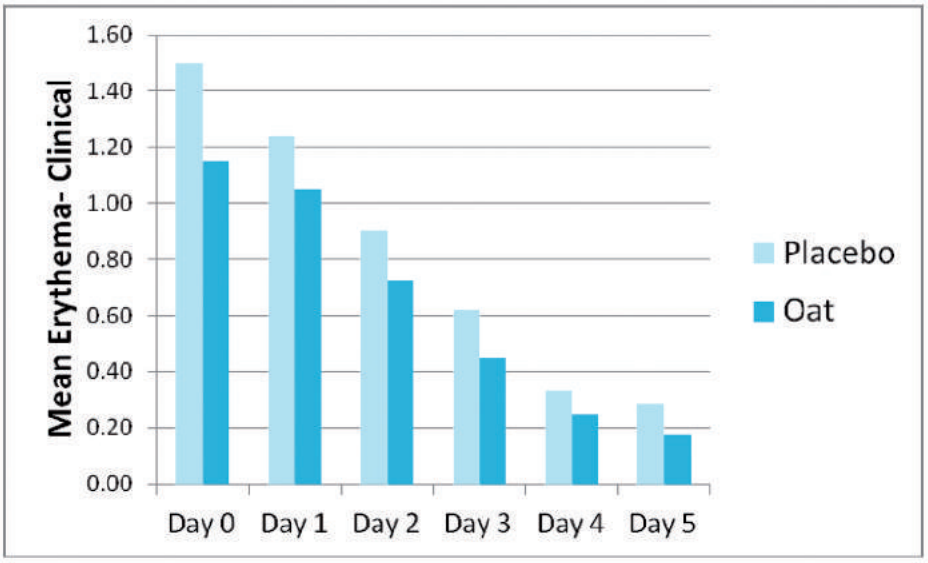
In-Vivo Skin Repair Study

RESULTS CONTINUED

Clinical Assessment of Erythema: The mean values for the clinical assessment of erythema for the Oat COM formulation were lower than those with Placebo formulation during the study, with statistically lower values measured at Day 1, Day 5 and for AUC, using Wilcoxon Rank Sum test. This data shows the Oat COM formulation leads to visible improvements in skin redness from first application and with sustained improvement, relative to the placebo formulation.



CONCLUSION

In conclusion, the in-vivo skin repair Studies demonstrated that the Oat COM formulation leads to visible improvements in skin redness and scaliness, accelerated barrier recovery and enhanced moisturisation compared to the placebo formulation.

TEWL, hydration capacitance and erythema reduction all showed statistically significantly improved results after day 1 with the Oat COM formulation compared to the placebo, showing that Oat COM increases the overall skin repair capability.

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Effect of Oat COM on Excessive Handwashing (Consumer Evaluation)

BACKGROUND

Excessive washing of the hands can have a significant impact on overall skin health and appearance. Alcohol and surfactant ingredients in soap and hand sanitisers are irritating and may initiate an inflammatory response in the skin. The increased dryness and scaling of the skin resulting from the use of hand washing products has been attributed to a decrease in the production of the water-binding natural moisturising factor (NMF) in the outer stratum corneum.

A hand washing trial was performed to assess the ability of a product containing Oat COM USP to repair and hydrate the skin. The volunteers were asked to assess the condition of their hands before and after use of a hand cream containing 2% Oat COM USP and a placebo hand cream.

METHOD

For four weeks, 35 volunteers – men and women aged between 20-60 with a mix of skin types - had to regularly wash their hands at least 5 times a day for 20 seconds or more with antibacterial soap. After doing this for 1 week and applying no product, the volunteers were asked to apply the hand cream containing 2% Oat COM USP for one week and the placebo for one week. The volunteers continued to excessively wash their hands throughout the full 4 weeks. To ensure the trial was fair, 50% of volunteers applied the placebo first and 50% Oat COM USP first.

Data was analysed by AGR systems in real time (Ayton System Software).

Phase	Trade Name	INCI	% w/w
A	Purified Water BP	Aqua	70.323
A	Mekirol Rapeseed	Glycerin, aqua	7.650
A	Variosoft TA-100	Distearyldimonium chloride, aqua	4.750
A	Oat COM USP*	*Avena Sativa* Kernel Flour	2.00
A	Amaze Nordic Barley	*Hordeum Vulgare* Flour	2.00
A	Sodium Chloride Emprove Essential	Sodium Chloride	0.050
A	Potassium Hydroxide	Potassium Hydroxide	0.027
B	Surfacare IPP	Isopropyl Palmitate	8.400
B	Lanette O	Cetearyl Alcohol	1.300
B	Microcare DM350	Dimethicone	1.300
B	Snow White PET USP	Petrolatum	1.000
B	Kemol FA 18	Stearyl Alcohol	0.400
B	Primesurf Seareth-20	Steareth-20	0.100
C	Benzyl Alcohol	Benzyl Alcohol	0.700

Oat COM USP Hand Cream Formula
*Removed from placebo formula and remaining % made up with water

RESULTS: PART 1

For the following section the volunteers were asked identical questions regarding the condition of their skin after 1 week of excessive hand washing (before applying the product), after applying Oat COM USP and after applying the placebo.

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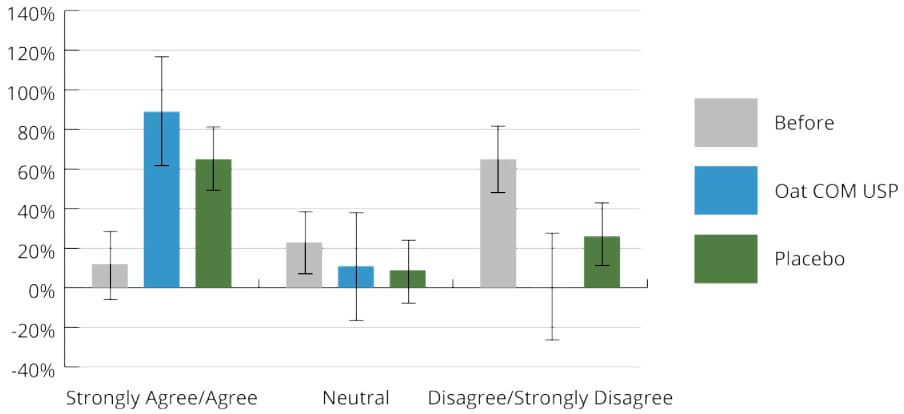
Effect of Oat COM on Excessive Handwashing (Consumer Evaluation)

Effect on Skin Dryness:

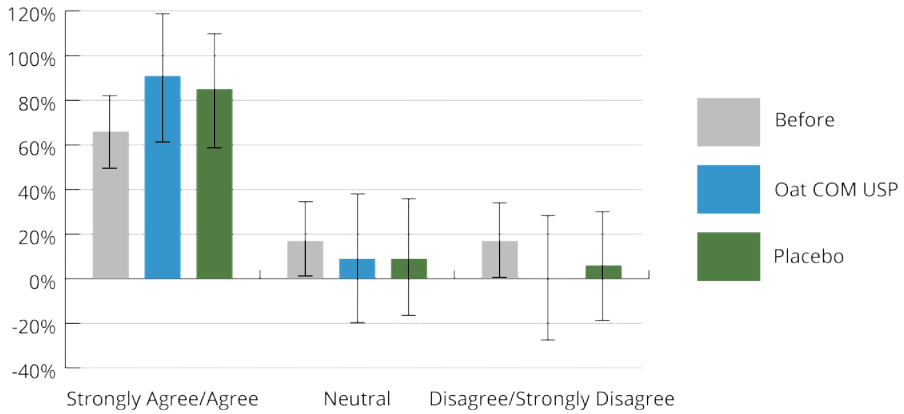
Perception Statement: 'Hands Do Not Feel Dry'



After applying the Oat COM USP hand cream for one week, 0% of volunteers reported their hands feeling dry versus 65% reporting dryness before use. 26% of volunteers reported their hands feeling dry after using the placebo for 1 week.

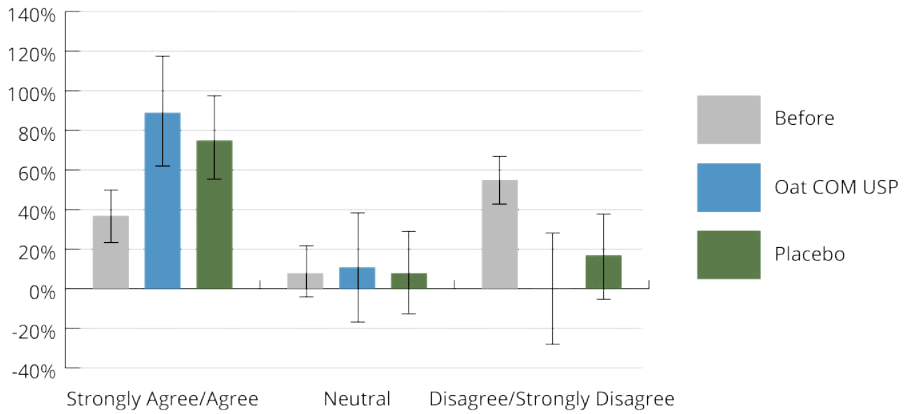
Effect on Skin Redness and Damage:

Perception Statement: 'Hands Do Not Look Red and Damaged'



0% of consumers reported their hands feeling red and damaged after using the Oat COM USP hand cream compared to 6% when using the placebo and 17% before using the product.

Perception Statement: 'Hands Do Not Have Visible Dry Patches'



55% of volunteers reported their hands having visible dry patches before application of Oat COM USP. All of these volunteers reported that the patches disappeared after application of the product.

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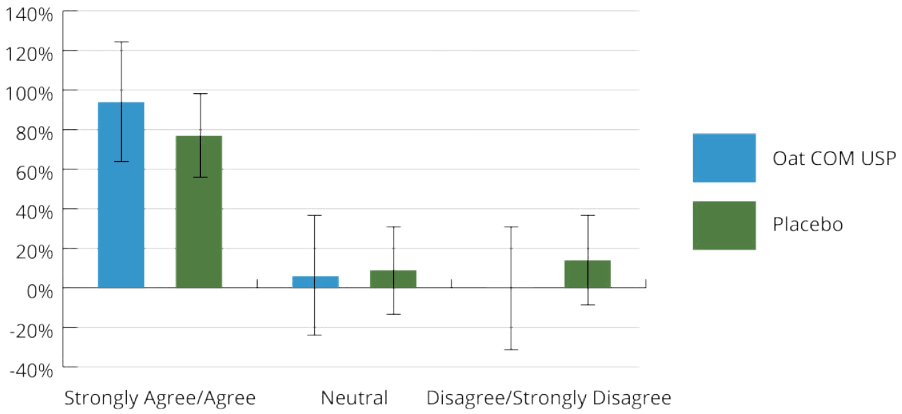
Effect of Oat COM on Excessive Handwashing (Consumer Evaluation)

RESULTS: PART 2

For the following section the volunteers were asked to answer the questions regarding the condition of their skin when using the product containing Oat COM USP versus the placebo.

Effect on Skin Irritation:

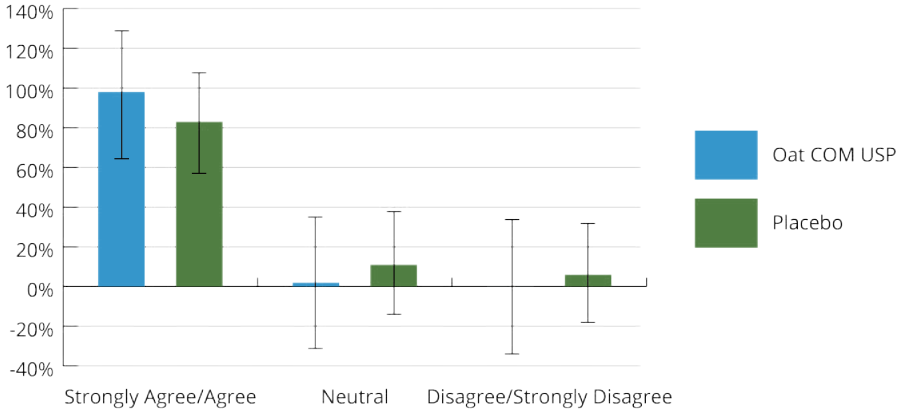
Perception Statement: 'Hands Feel Less Irritated Than Before Using Product'



94% of volunteers reported their hands feeling less irritated after using Oat COM USP compared to only 77% after using the placebo.

Effect on Skin Hydration:

Perception Statement: 'Hands Feel More Moisturised Than Before Using Product'



14% more volunteers reported their hands feeling more moisturised after using Oat COM USP compared to the placebo. In fact, 54% strongly agree that their hands feel more moisturised with use of Oat COM USP.

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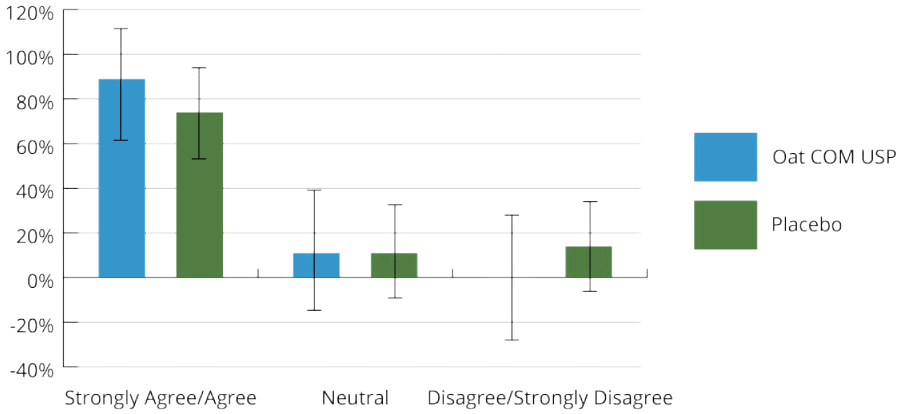
Effect of Oat COM on Excessive Handwashing (Consumer Evaluation)

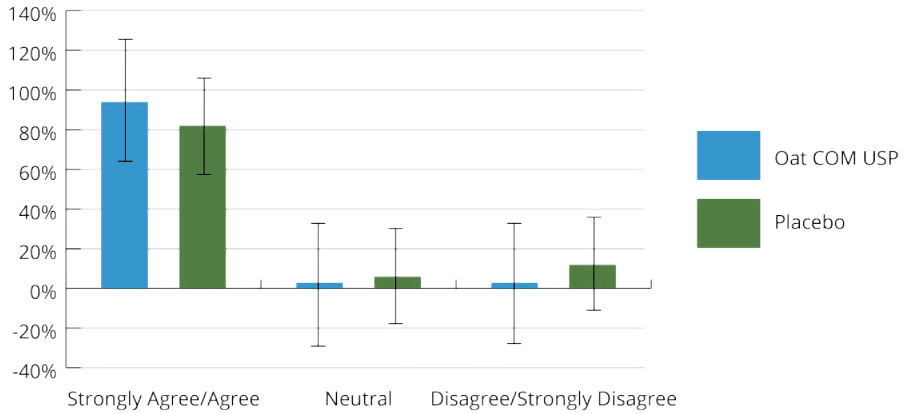
Effect on Skin Condition:

Perception Statement: 'Hands Feel Soothed After Using Product'



17% more volunteers reported their hands feeling more soothed after using Oat COM USP compared to the placebo. In fact, 46% strongly agree that their hands feel soothed after use of Oat COM USP.

Perception Statement: 'Hands Feel Soft and Rejuvenated After Using Product'



13% more volunteers reported their hands feeling softer and more rejuvenated after using Oat COM USP compared to the placebo.

CONCLUSION

Oat COM USP is a colloidal oatmeal which is a recognised skin protectant and best known for its ability to reduce the adverse effects of atopic skin conditions. It has a broad spectrum of efficacy that includes anti-inflammatory, anti-pruritic and moisturisation properties. Colloidal oatmeal is rich in antioxidants, particularly avenanthramides, that give rise to these anti-inflammatory properties. Oat beta-glucan is another molecule found in Oat COM USP that will benefit dry, damaged hands as it contributes significantly to the formation of an occlusive film as well as acting as a humectant. This film enables stratum corneum water retention and improvement of a dysfunctional skin barrier, thus enhancing moisturisation and helping to relieve irritation and pruritic sensations.

This is verified with this consumer evaluation which shows that 2% Oat COM USP alleviates signs of red and irritated skin, improves moisturisation and imparts soothing properties.

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Human Repeat Insult Patch Test (In Vivo)

BACKGROUND

A Human Repeat Insult Patch Test (HRIPT) was carried out to determine the cutaneous irritation (contact dermatitis) and sensitisation (contact allergy) potential of 6 oat-derived ingredients (Oat COM USP; Oat Lipid e; AvenaPLex; and **aura***firm* P, N, and S) when applied to the skin of healthy participants.

METHOD

The study consisted of 52 volunteers (male and female aged 20-78) and 3 phases: Induction, in which 10 patches were repetitively applied over the course of 3 weeks; Incubation, a rest period; and Revealing, a challenge phase. Repeated contact with a potential allergen in the formula, if present, generates a series of immunological reactions in the body of the test subject (the volunteer) and induces a visible reaction on the application site. Any reactions were observed, recorded and evaluated by a dermatologist to confirm the allergenicity of the product and hence the product's safety.

Repeated Skin Contact Test (Induction Phase): Prior to applying the patches, the test area - upper back, between the two shoulder blades - was carefully examined. A patch containing the test products and the control was applied to the test area and left in contact with the skin for 48 hours. When this first patch was removed at the laboratory 48 hours after application, the observation area was rinsed with water, dried, and examined for any skin changes. Following the examination, a new patch with fresh test product was applied.

The test products were applied on the selected zones every second day, 3 times per week, over 3 consecutive weeks.

Rest Period (or Incubation Phase): After the completion of the Induction Phase, a Rest Period of 10 to 14 days took place.

Challenge Phase (or Revealing Phase): The application site used during the Challenge Phase was different to the one used in the Induction Phase. For this phase, the patch was removed at the laboratory 48 hours after application. The test site was cleaned and examined for any signs of intolerance or irritation.

Throughout the study, the test products (Oat COM USP; Oat Lipid e; AvenaPLex and **aura***firm* P, N, and S) were applied at 100% except for Oat COM USP which was diluted with Vaseline.

RESULTS

None of the products tested (Oat COM USP, Oat Lipid e, AvenaPLex; or **aura***firm* P, N or S) produced any signs of cutaneous irritation or skin sensitisation. That is, no volunteers showed presence of oedema, vesicles, blisters or ulcerations or reported immediate or delayed reactions such as redness, irritation, itching or other sensations.

CONCLUSION

Oat COM USP, Oat Lipid e, AvenaPLex, **aura***firm* P, **aura***firm* N and **aura***firm* S can be considered both hypo-allergenic and non-irritant. Furthermore, given the control provided by a dermatologist during the study, the test products may also bear the claim "tested under the control of a dermatologist" or "dermatologically-tested".

Independently tested by Evalulab, Nov 2020. Full report available on request.

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Biodegradability Study (Manometric Respirometry Test)

BACKGROUND

A study was undertaken to measure the ready biodegradability of 4 oat-derived ingredients (Oat COM USP, Oat Lipid e, AvenaPLex, and Oat SILK 12) in a freshwater environment. Biodegradability is the mechanism whereby microorganisms such as bacteria and fungi break down the organic matter of a product and use the nutrients for energy and growth or make it available to the environment. This degradation is defined as the ratio of the Biochemical Oxygen Demand (BOD) to either the Theoretical Oxygen Demand (ThOD) or the Chemical Oxygen Demand (COD) within 28 days.

METHOD

The 28-day BOD was determined by a procedure following the OECD Guidelines for Testing of Chemicals reference 301F. To begin, the test products were added to water with mineral nutrient stock to allow the development of bacteria. The inoculum used for this test was activated sludge from a sewage treatment works receiving predominantly domestic waste. Following this, air was brought into a bottle to bubble up in a solution that works to capture the carbon dioxide. The air then passed into a test tube in which the bacteria used the oxygen to breathe and produce carbon dioxide, comprised of the oxygen present in the air and the carbon present in the substance. Finally, the carbon dioxide passed into a third bottle where there was again a solution to capture it.

The OXITOP^{R} measuring heads (a data collector used to determine how much carbon dioxide has been rejected by the bacteria) recorded readings of biodegradation every 112 minutes for 28 days. The test solutions were stirred at 20.2 – 23.3°C for the duration of the study.

An equation was used to calculate how much carbon dioxide was given off by the bacteria. The amount of oxygen taken up by the microbial population during biodegradation of the test substance is expressed as a percentage of ThOD or, less satisfactorily, COD. After 28 days the percentage of break down was assessed. It is standard to consider a substance to be easily biodegradable when this exceeds 60% in 28 days.

RESULTS

AvenaPLex, Oat SILK 12, Oat Lipid e and Oat COM USP all gave a positive result, exceeding 60% degradation relative to the ThOD value - or the COD value in the case of Oat Lipid e - with a maximum average degradation of 101%, 98%, 96%, and 91% achieved respectively on day 28.

CONCLUSION

When a product is biodegradable, it decomposes and the carbon and other elements in its molecules can be assimilated into new biomass so they can reappear in another form later. The findings of this study mean it can be concluded that AvenaPLex, Oat SILK 12, Oat Lipid e and Oat COM USP are readily biodegradable under environmental conditions.

Independently tested by Chemex Environmental International Limited, Sept 2020. Full report available on request.

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