Oat® COM USP

An Extruded Colloidal Oatmeal

Benefits Sheet

App	Name	Monograph ID	%	CAS	EINECS	FDA VCRP
INCI	*Avena sativa* (Oat) Kernel Flour	9314	100%	134134-86-4	310-127-6	*Avena sativa* (Oat) Kernel
OTC	Colloidal Oatmeal	6522	100%	134134-86-4		Colloidal Oatmeal

Oat* Cosmetics Oat® COM – a proven anti-aging and skin protectant ingredient delivering a non-greasy and luxurious feel to skin care products

What is Colloidal Oatmeal?

Colloidal oatmeal is manufactured from the whole oat kernel, with both the external bran and flour being finely milled and processed to induce the colloidal effect. A 'colloid' is defined as a system in which finely divided particles are dispersed within a continuous medium in a manner that prevents them from being easily fractionated or subject to rapid settlement.
The bran layer of the oat in particular contains a high proportion of the natural actives such as oat beta-glucan, avenanthramides, lipids and protein.

Colloidal Oatmeal: A recognised Skin Protectant

In 2004 the US issued a monograph for colloidal oatmeal for topical applications as a skin protectant drug product for over-the-counter human use which are generally recognized as safe and effective. The monograph states that colloidal oatmeal protects and helps relieve minor skin irritation and itching due to eczema, rashes, insect bites and poison ivy, oak or sumac.

In order to meet the requirements of the FDA monograph colloidal oatmeal must meet the stringent parameters laid down by the United States Pharmacopeial Convention Monograph USP38. [USPC]. Whilst the monographs are not directly relevant for cosmetic applications they demonstrate the soothing and healing properties of colloidal oatmeal. Oat® Cosmetics Oat® COM is an optimised version of colloidal oatmeal meeting the US requirements.

The FDA (2003) defines colloidal oatmeal as a Type II Skin Protectant. The USP Pharmocoepia defines colloidal oatmeal with the following properties.

- A finely ground powder of whole oat grain
- Not more than 3% of the particles exceed 150um in size and not more than 20% of the total particles exceed 75um in size
- Lipids: Not less than 0.2%
- Nitrogen: Not less than 2%
- Total Ash: Not more than 2.5%
- Moisture: not more than 10%
- Total Aerobic Plate Count : Not more than 10,000 CFU/g
- Yeasts & Moulds do not exceed 150 CFU/g

The Manufacture of Traditional Colloidal Oatmeal

Traditional colloidal oatmeal is manufactured by ultra-fine milling the oat kernel followed by sieving to achieve a particle size where not more than 20% of the particles exceed 75 micron in size and not more than 3% exceed 150 micron.

The particle size profile was necessary in order to achieve the colloidal state, which is similar to an emulsion state, and will be influenced by the interfacial tension of the particles, the interfacial area, the temperature and the entropy energy of mixing [Gibbs Free Energy Equation]. Ultra-fine milling of the oat particles maximizes the interfacial area thereby enhancing the colloidal activity.

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Achieving such a small particle size is a challenge for oats, since a typical particle size of the oat starch granule is between 5 and 6 microns. This is similar to rice but as they are cup-shaped they tend to stack or agglomerate fairly easily to sizes of 30 microns upwards. Milling oats is not as effective as other cereal grains due to the high oil content located in the starch, as the particles do not easily fractionate. Without fine milling it is difficult to achieve stable colloids which may lead to visible fine particles in creams and lotions.

In practice, the difficulty of achieving the small particle size has resulted in a number of oat flours being marketed that describe themselves as colloidal oatmeal but in practice do not meet the exacting conditions laid down by the USPC.

Why is Oat® COM, Oat® Cosmetics Colloidal Oatmeal Different?

Oat® Cosmetics Oat® COM extruded colloidal oatmeal is optimised for cosmetic applications, by selecting high beta-glucan varieties of oat and employing a unique extrusion process prior to specialised fine milling. This process enhances the colloidal oatmeals properties in strengthening emulsion formation and the bioavailability of the active molecules.

In addition, excellent levels of microbial purity are achieved without the need for further processing. Cosmetic manufacturers mandate low microbial levels for natural ingredients and in most cases the use of irradiation is required, a process prohibited if the ingredient is required to be designated as 'natural' under Ecocert or COSMOS certification. Other methods employed to reduce microbial count such as UHT and autoclaving may result in the change of either physical and chemical properties.
The Oat® COM manufacturing process is protected under Finnish patent number 124441 with European EP2548448 and US patents US201213022562 pending.

Oat® COM Physical and Chemical Properties:

- A very fine particle size
- Optimised functionality and activity
- Excellent microbial purity
- Absorbs more oil than standard oat flours
- Elevated levels of beta-glucan
- Contains bioavailable actives

Oat® COM is an excellent choice for the formulator:

- A functional ingredient with activity
- Very stable suspensions
- Capability of absorbing increased amount of oil
- Easy and adaptable in formulation regimes over a wide range of temperatures
- Enhanced colloidal activity increasing the ease of formulation

Oat® COM benefits the consumer:

- Excellent textural characteristics giving smoother creams
- Reducing 'greasiness' and imparts luxuriant feel
- Anti-aging activity
- Moisturisation effects
- Soothing and restorative effect on sensitive skins
- 100% natural ingredient with no additives

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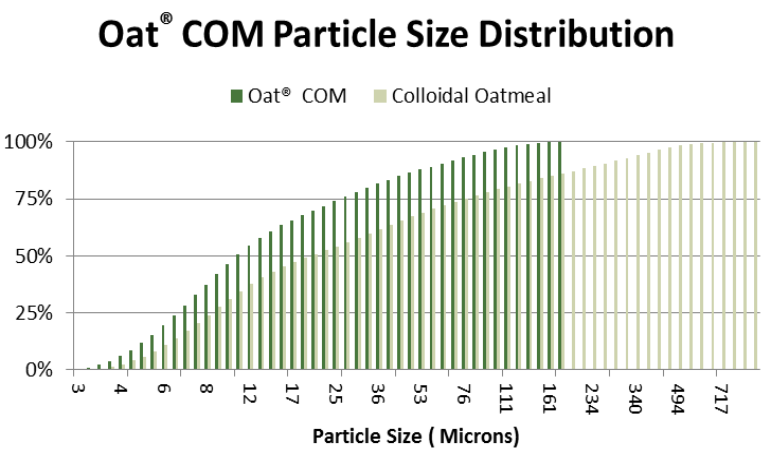
Oat® COM Properties

Particle Size

The mean diameter of oat starch particles is between 5 and 6 microns. They are angular in shape and tend to be unimodal in distribution (image 1 & 2). They are however synthesized in the form of compound granules 30 to 60 microns in size. Oat® COM's unique extrusion and milling process breaks down the compounded granules to achieve a fine particulate profile, which substantially reduces visible particles in formulations and enhances colloidal strength and stability.



Oat® COM particle size distribution compared to a standard colloidal oatmeal. Particle size distribution measured by a Beckman Coulter LS 230 using liquid module and Milli-Q water as a carrier showing the fine particle size produced by the patented process.

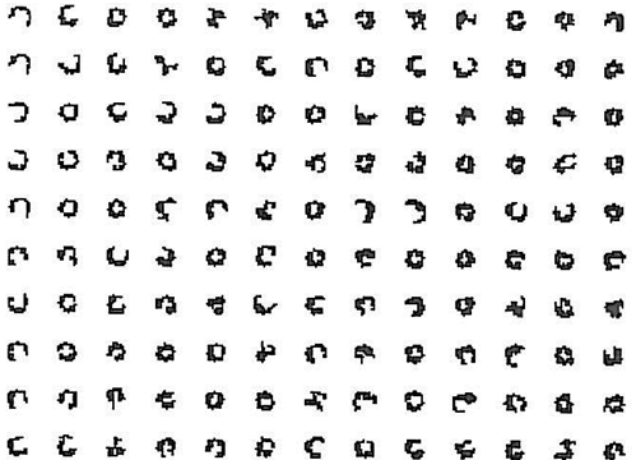


Image 1: *Dynamic image analysis using a pulsed laser light source. A selection of particles in the 40.45 to 40.49 micron range showing the highly unusual 'J' and 'O' shapes possibly caused by the specific milling technique coupled to the oat starch particles capability to form ionic bonds*

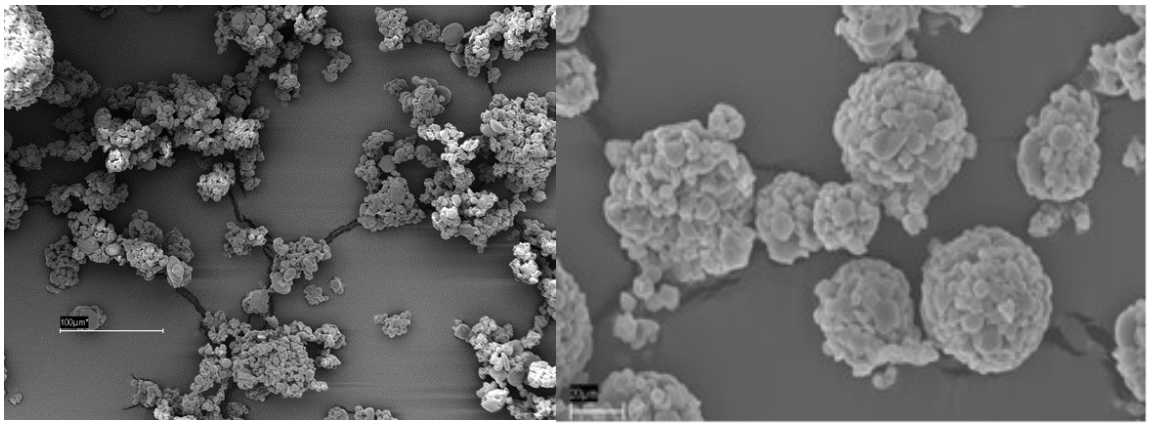


Image 2: *Electron microscope images of oat starch particles demonstrating their ability to agglomerate in dry systems probably due to their ionic bonding as well as hydrophobic interaction due to presence of naturally-occurring lipids. In wet systems these break and disperse as individual particles.*

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Excellent microbial purity

The unique manufacturing method of Oat® COM results in a significant reduction of microbes, yeast and mould to levels well below 100 cfu/g, without requiring chemical or radiation sterilisation (see table 1)

	Flour	Test 1	Test 2	Test 3	Test 4
Temp (^{O}C)		120	120	110	110
Inlet Moisture	13%	13%	19%	13%	19%
Outlet Moisture		7.5%	12.2%	7.2%	11.9%
Water Activity	0.6	0.4	0.6	0.3	0.6
Microbes (cfu/g)	7×10^5	<10	<10	<10	<10
Yeast (cfu/g)	5400	<10	<10	<10	<10
Moulds (cfu/g)	730	<10	<10	<10	<10

Table 1: *Table showing microbial data on 4 batches of Oat® COM*

Absorbs 30% more oil than standard oat flours

A standard colloidal oatmeal and Oat® COM were compared for oil absorbing capacity, measured in grams of rapeseed oil bound by 100g of oatmeal.

The increase in oil binding capacity 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 (see table 2)

Colloidal Oatmeals	Average Weight Increase (g)	Percentage Increase
Standard	3.00	
Extruded	3.91	30%

Table 2: *Oil binding Capacity of Oat® COM compared to standard colloidal Oatmeal*

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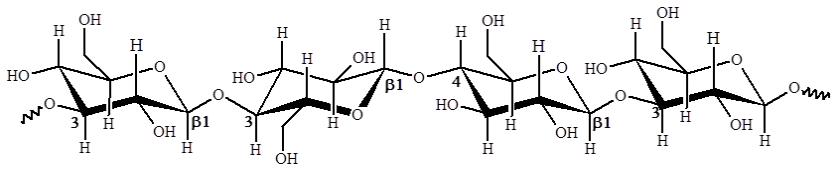
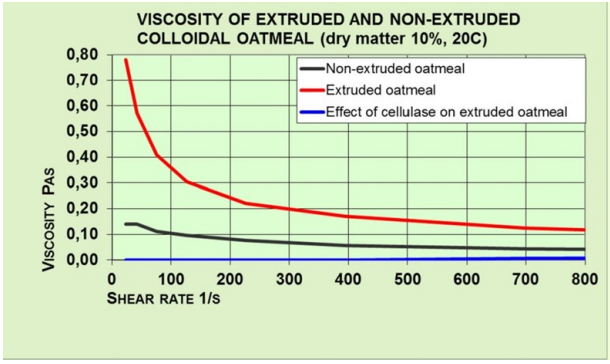
High levels of beta-glucan



Unbranched linear glucose polymer, 1—4 glycosidic links (x 4), 1-3 glycosidic links (x1).

A specific Finnish oat variety 'Peppi' is used in the production of Oat® COM as this variety has significantly higher levels of beta-glucan than other oat varieties. Oat® COM's extrusion and milling process maximizes the availability of beta-glucan, which is an important active in enhancing the moisturizing, soothing and restorative properties in skin care products.



Graph 1: *Measure of the rheology of Oat® COM (red) and a competitor colloidal oatmeal* ***(black)*** *at 10% concentration.*

In order to compare Oat® COM's superior characteristics to other colloidal oatmeals, the rheology curve of Oat® COM and other colloidal oatmeals were compared (graph 1). Oat® COM exhibited a much higher thixotropic curve. A beta-glucanase cellulase was also added to the test samples. The addition of beta-glucanase produce a Newtonian liquid demonstrating that it is the beta-glucan content (not the starch), which creates the viscosity.

Oat beta-glucans have been reported to increase collagen deposition, assist in preventing the effects of extrinsic and intrinsic aging and aid skin repair by stimulating collagen synthesis, as well as reducing IL-1, a pro-inflammatory cytokine.

Beta-glucan has been proved to penetrate to the epidermis and dermis levels despite its high molecular weight, providing deep skin hydration while forming a thin film barrier on the skin. Studies have shown beta-glucan reduces wrinkle depth and height, together with overall roughness.

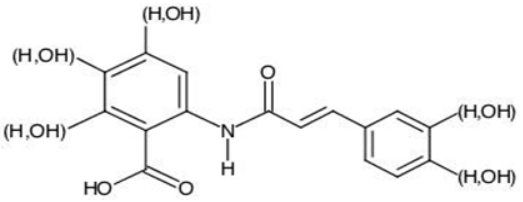
Avenathramides

The avenanthramides are a unique group of polyphenolics found only in oats.

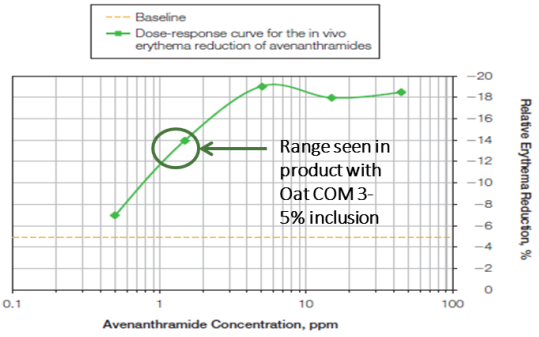
Avenanthramides have been shown to be the main molecules responsible for the anti-inflammatory, antipruritic (anti-itch), and antihistamine properties demonstrated by colloidal oatmeal. They protect the skin from lipid peroxidation, alleviate redness and reduce inflammation and swelling.

Avenanthramides are extremely potent, exhibiting anti erythema in concentrations of less than 1ppm (graph 2). Erythema was calculated 24 hours after irritation with 1.5 minimal erythema dose UV light, with oat fractions diluted in 50% ethanol to a constant volume, relative to baseline.

Oat® COM typically contains 60ppm of avenanthreamides, therefore if incorporated at the recommended inclusion rate of 3-5% graph 2 shows that a reduction of erythema will be still be observed (approx 1.8ppm – 2.5ppm).



Molecular structure of Avenanthramides



Graph 2: *Adapted with permission from Schmaus et al*

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Oat Lipids

Oats are unique amongst cereals in containing whole oil bodies, distributing the oil through the endosperm as well as the bran layer. The oil contains approximately 26% phospholipids including a combination of emulsifiers and skin acting lipids including ceramides.

Content of Oat Polar Lipids	%
Monogalactosyldiacylglycerols [MGDG]	10%
Unknown Glycolipid	13%
Ceramides	35%
Digalactosyldiacylglycerols [DGDG]	4%
Phosphatidylethanolamine	8%
Phosphatidic acid/Phosphatidylglycerol	4%
Phosphatidylinositol	7%
Phosphatidylcholine	10%
Pigmented Material	10%

Emulsion Stability and Strength

The stability of emulsions is affected by the interfacial tension, the interfacial area, temperature and the entropy of mixing. Oat® COM maximizes these factors, by milling and screening to a very fine particle size which increases the particle surface area.

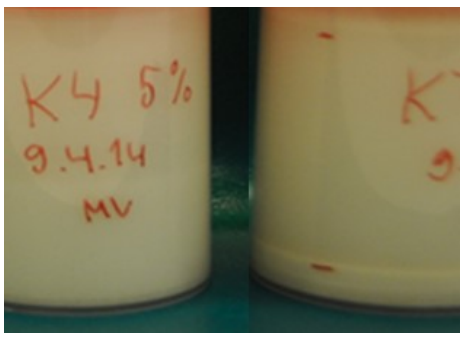
The amylose content of oat starches has been reported to be in the range 25.2 to 29.4, made up of free amylose and approximately 9 to 19% amylose bound in lipid complexes.

During extrusion the lipid complexed amylose increases, which has an important influence on structure, texture and other functional properties of the extrudate. The lipid complexed amylose contains the lysophospholipids known to have high emulsifying capability.

When oats are extruded under the conditions of the patent, the extruded and fine milled flour exhibits significantly enhanced emulsification properties. This can be seen by adding water to a mixture of flour and oil, resulting in a stable emulsion formed by gentle mixing with spoon.

Other studies have demonstrated this effect:

Oat® COM was mixed in a 5% water suspension and did not settle within 1 hour, when other colloidal oatmeals showed clear signs of settlement.



Oat® COM showed a clear ability to stabilize emulsions with clear stability after seven days, when standard colloidal oatmeals had settled.

Oat® COM created a margarine-like emulsion, when first mixed with oil and then appropriate amount of water. The emulsion was easy to create in cold process. The oil and water fractions did not separate from the emulsion during storage.

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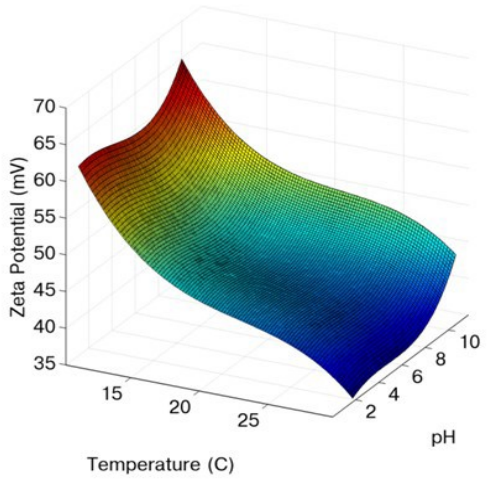
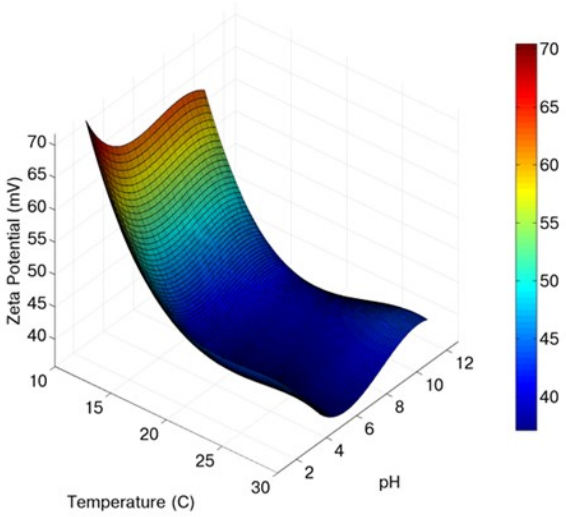
Oat® COM Formulator Benefits

Easy and adaptable in formulation regimes over a wide range of temperatures

The extruded colloidal oatmeal shows significantly higher zeta potential and therefore enhanced stability over a wider range of temperatures and pH, which makes this ingredient adaptable to cold processing. The zeta potential value can be related to the stability of colloidal dispersions. It indicates the degree of repulsion between adjacent, similarly charged particles in dispersion. For molecules and particles that are small enough, a high zeta potential will confer stability, i.e. the solution or dispersion will resist aggregation. When the potential is low, attraction exceeds repulsion and the dispersion will break and flocculate. So, colloids with high zeta potential (negative or positive) are electrically stabilized while colloids with low zeta potentials tend coagulate or flocculate as outlined in the table 3.



Zeta Potential: Extruded Colloidal Oatmeal (Oat® COM)



Zeta Potential: standard Colloidal Oatmeal

Zeta potential [mV]	Stability behaviour of the colloid
0 to 10	Rapid coagulation or flocculation
10 to 30	Incipient instability
30 to 40	Moderate stability
40 to 60	Good stability
Above 60	Excellent stability

Table 3: *Explanation of zeta potential values*

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Oat® COM Consumer Benefits

Oat Actives	Activity	Application
Avenanthramides	Anti-irritant and redness reduction (Anti-histamine effect similar to Tranilast) Anti-oxidant activity (such as superoxide dismutase)	Soothe & relieve dry skin
Avenacins (Saponins)	Anti-inflammatory and immuno-regulatory properties in the treatment of atopic dermatitis (AD)	Skin cleansing properties through sebum
Flavonoids	Antioxidants	Anti-microbial
Simple & Complex Phenolics	Antioxidants, Prevention of lipid peroxidation, anti-inflammatory	Anti-pruritic
Beta-glucan	Immuno – stimulant Reduce fine lines and wrinkles Hydrating agent Thin film barrier protection	Skin moisturiser Aids skin repair
Lipids/Oils	65% triglyceride, Vitamin E, phospholipids Effective emulsifying and antioxidant activity Unique lipophilic antioxidants	Replenish skin provide pH buffering Vitamin-E precursors
Starch	Adsorption and absorption properties Physical barrier	
Oat Proteins/Peptides	Collagen and elastin promoters by stimulation of the fibroblasts Thin film barrier	Skin pH buffering Maintains barrier integrity

Table 4: *Oat® COM colloidal oatmeal displays multi-functional activity*

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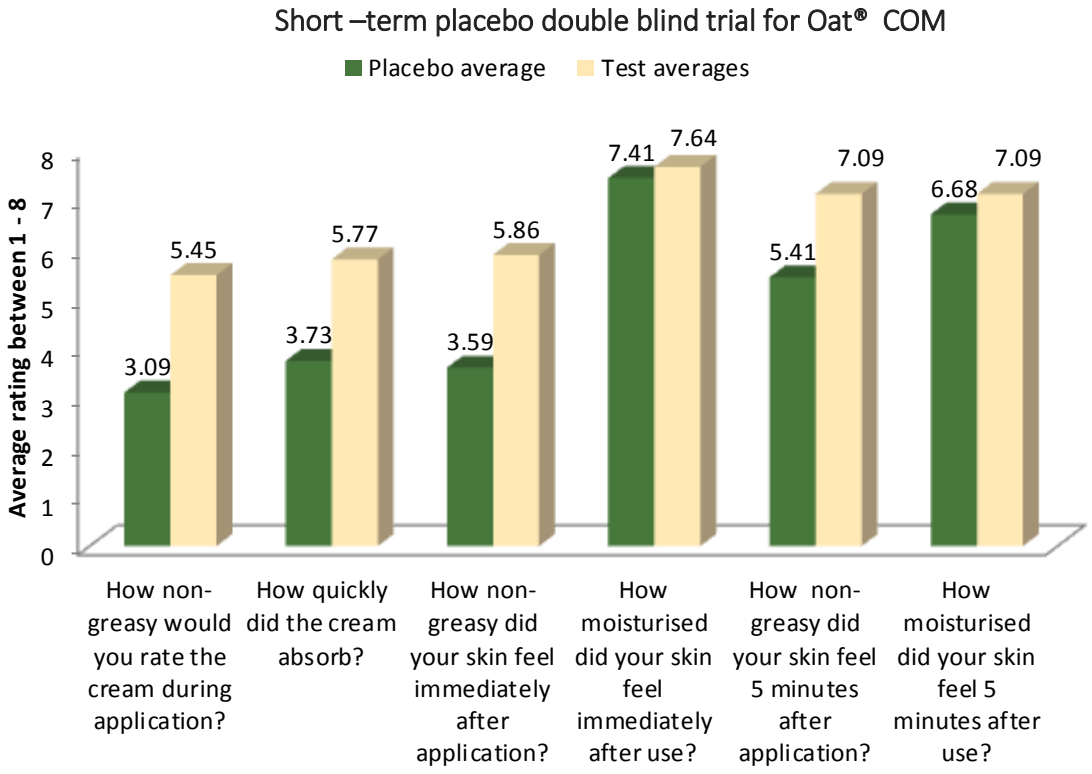
Consumer Trials

Short Term Trial assessing Oat® COM's ability to reduce greasiness and impart luxuriant silky feel

- Half-face double blind trial
- Night cream with 3% Oat® COM, tested over a period of 5 minutes
- Compare to a placebo cream (without Oat® COM)
- 22 subjects



The trial demonstrated a clear perception by the subjects that the test cream was less greasy during application, and this remained noticeable even after full absorption into the skin. This provided confirmation that Oat® COM displays increased ability to bind oil. This ability improves the textural qualities of oil based creams which account for the results obtained as the test cream absorbed faster and felt less greasy on 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 effect was observed. This was most likely due to the high beta-glucan level.

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Long Term skin trials assessing texture, and effects on types of skin

An independent research facility conducted a single placement once per day study with 53 female participants all over the age of 40 years old.

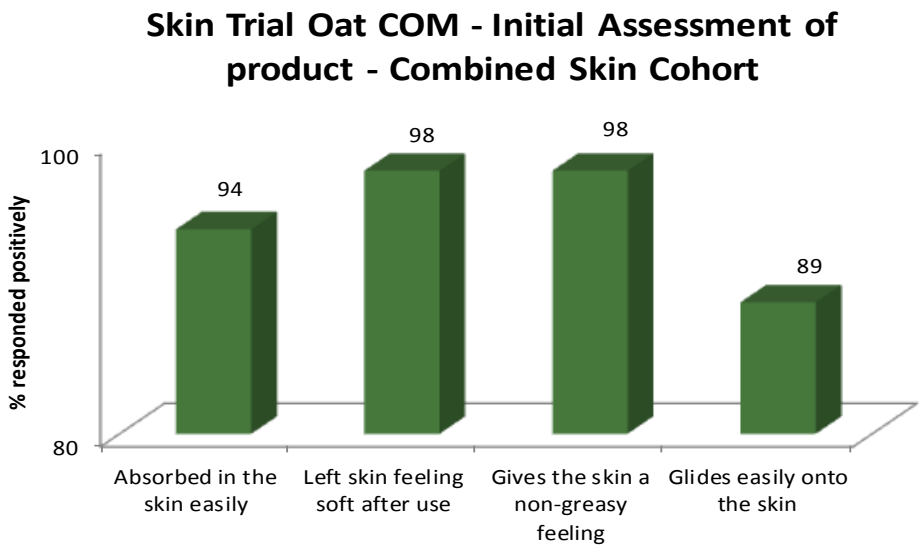
- Normal, dry and sensitive skin types were equally represented
- Skin types were assessed both as a single cohort (combined) as well as individual cohorts
- Benefits were assessed after 6, 12 and 24 hours (trial 2) followed by the long term after 30, 60 and 90 days
- Test cream was a market relevant passive base formulation with a 3% Oat® COM extruded Colloidal Oatmeal inclusion:

Formulation for long term skin trial

Trade Name	INCI	% w/w	Function
Oat® COM	*Avena sativa* Kernel Flour	3%	Rheology, Emollient, Active
Oat® Lipid e	*Avena sativa* Kernel Oil	3%	Emollient
Arlatone 2121	Sorbitan Stearate, Sucrose Cocoate	3%	Emulsifier
Cetyl Alcohol	Cetyl Alcohol	1%	Co-emulsifier
White Paraffin	Petrolatum	2.5%	Emollient
Mineral Oil	Paraffinum Liquidum	8%	Emollient
Sunflower Oil	Helianthus Annuus Seed Oil	3%	Emollient
Sepigel 305	Polyacrylamide, C13-14 Isoparaffin, Laureth-7	2.5%	Thickener, stabilizer
Neolone CapG	Caprylyl Glycol, Methylisothiazolinone	1%	Preservative
Purified Water	Aqua	to 100%	

1. Textural Results

On initial application of the cream all test subjects gave positive responses for skin feel, lack of greasiness and moisturisation properties. Over 93% felt that the product left their skin feeling soft after use by selecting either 'agree' or 'strongly agree'.



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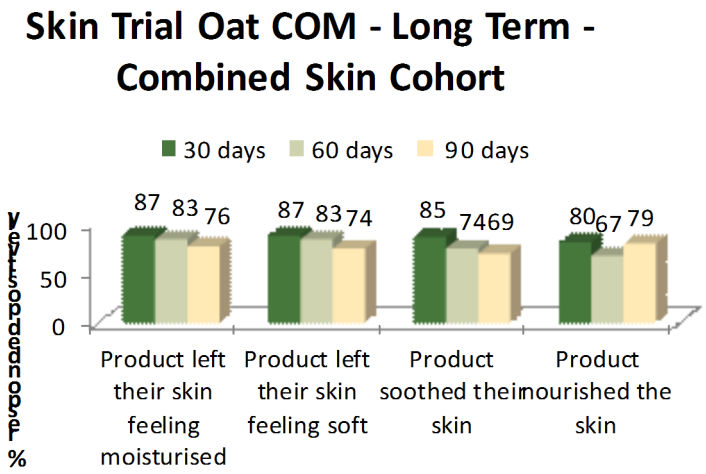
Skin changes are amongst the most visible signs of aging, including fine lines, wrinkles, uneven tone and texture, loss of firmness, thinning, dullness and dehydration. The study was extended for a further 90 days to assess whether specific benefits could be sustained and to investigate the overall anti-aging efficacy of Oat® COM over 30, 60 and 90 days.

2. Anti-ageing activity over all skin types



Graph 3: *Long Term Trial results for Oat® COM: Combined Cohort*

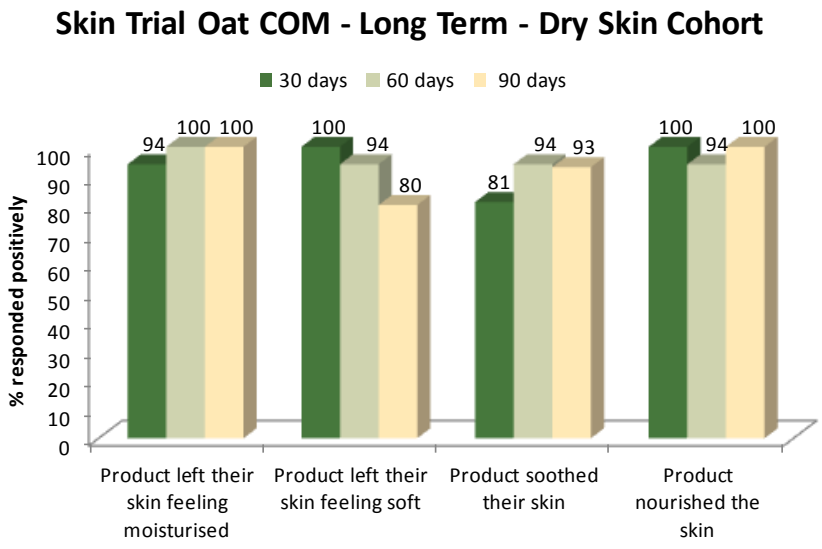
The combined cohort trial was designed to show Oat® COM's ability to demonstrate anti-ageing activity over all skin types. The subjects were asked to assess the products moisturising, soothing, nourishing and skin feel properties.

The results demonstrated that Oat® COM, at a low inclusion rate of 3%, displayed remarkable rapid and sustained anti-aging effects. The results were very impressive after 30 days but continued to be high over the whole 90 day period (see graph 3). This demonstrated that Oat® COM provides excellent long-term skin care benefits as an effective active over all skin types by moisturising, soothing and nourishing the skin.

3. Moisturisation effects on dry skins

One of the key challenges for individuals with dry skin types is the requirement for continual and consistent moisturisation. The subjects were therefore asked whether they agreed whether the product left their skin feeling moisturised, silky soft, soothed and nourished (see graph 4).

The subjects instantly recognized the moisturising effects and equally acknowledged that the effect was sustained across the entire 90 day period. When subjects with dry skin conditions test moisturisers, it is expected that good short-term observations will be made, however long-term and sustained moisturising effects are rare. Dry skin conditions are often accompanied with related issues such as redness, irritation or flaking. Therefore the perceived soothing effects were also very encouraging. The results show Oat® COM as a moisturiser ideal for alleviating the symptoms of dry skin conditions.



Graph 4: *Long Term Trial results for Oat® COM: Dry Cohort*

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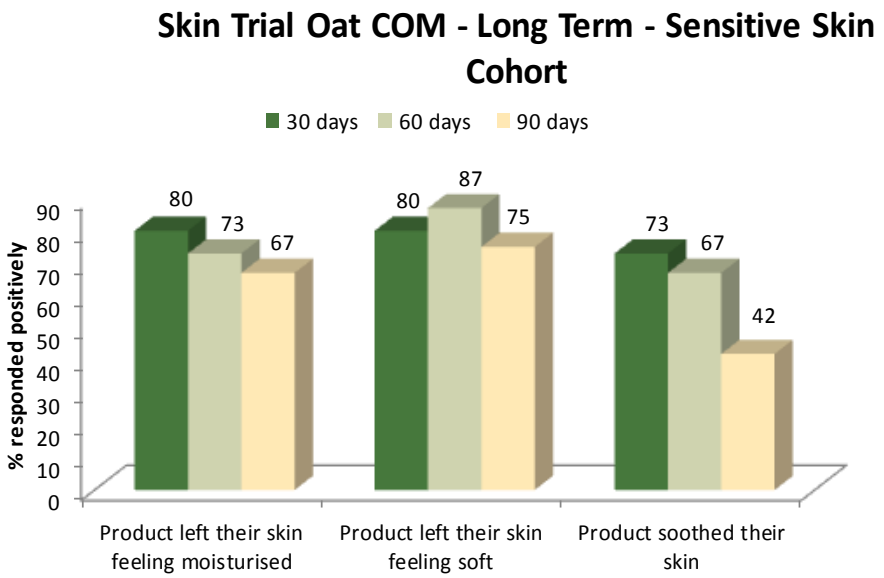
4. Soothing and moisturising effect on sensitive skins

Sensitive skins are a major challenge as the definition covers a wide range of mild to more chronic conditions. Subjects were asked whether they agreed the product moisturised, soothed and left their skin feeling soft.

The results received were encouraging, as this is typically a very hard demographic to please and the data confirms Oat® COM as a powerful moisturising agent (see graph 5). As sensitive skin conditions tend to flare up at different times the consistency of results was noted, showing Oat® COM as a reliable soothing and moisturising agent over this longer period.

The dry and sensitive skin cohort results show Oat® COM to be a versatile anti-aging ingredient.

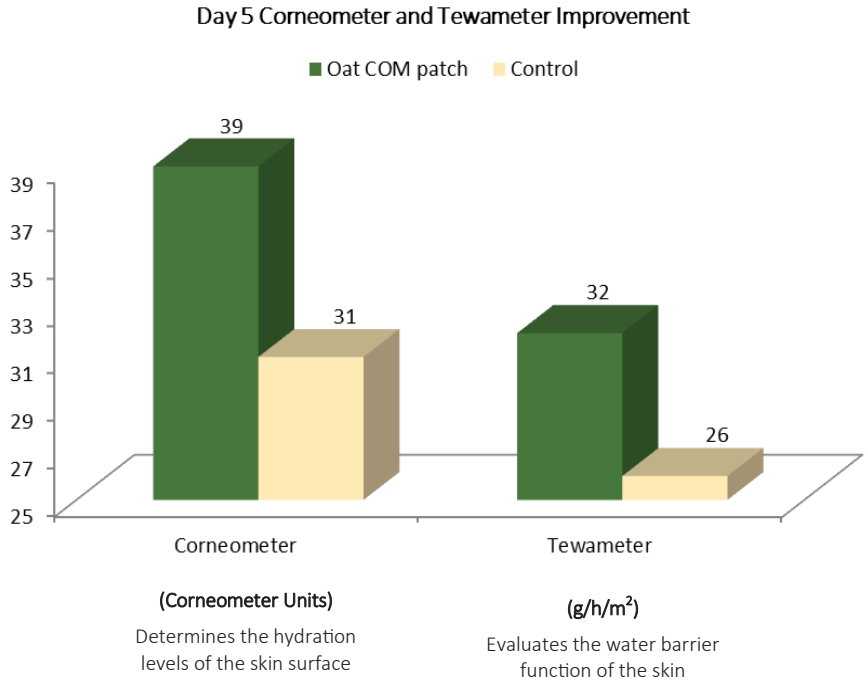


Graph 5: *Long Term Trial results for Oat® COM: Sensitive Cohort*

Skin Repair Properties

This study was carried out on 15 healthy adult subjects over a period of 10 days. Two skin areas on the volar forearms were pre-irritated using a 0.5% Sodium Dodecyl Sulphate solution, one area was covered with a patch coated with 0.6% Oat® COM and the other an uncoated control. The test sites were assessed at the start, day 1 and day 5. Rate of recovery was compared.

The combination of Tewameter and Corneometer results showed that Oat® COM supported the increased rate of repair of the skin (see graph 6).



Graph 6: *Long Term Trial results for Oat® COM: Sensitive Cohort*

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Visual Grading Assessments		
	Day 1	Day 5
Oat® COM patch	2.4	0
Control patch	2.43	1.43

VISUAL ASSESSMENT GRADING SCALE

0.0 No apparent cutaneous involvement.

1.5 Well-defined erythema or faint erythema with definite dryness, may have epidermal fissuring.

2.5 Moderate erythema with barely perceptible oedema or severe erythema not involving a significant portion of the patch (halo effect around the edges), may have a few papules or moderate-to-severe erythema.

The data additionally shows statistically significant better recovery than the control site on Day 5 for assessments of skin hydration, skin cracking and visual erythema. Visual erythema scores were extremely impressive. The assessment scores at day 1 showed skin damage rating from moderate to severe erythema with oedema. This damage was completely resolved at day 5 in the Oat® COM coated patches with the control test site still showing well-defined erythema.

Oat® COM range

Oat® COM, extruded colloidal oatmeal is available to formulators in three grades, each created from carefully selected varieties of oats that are naturally high in phyto-actives for versatility, activity and functionality. The grades have been specifically created with the cosmetic industry in mind, they are easy to use and formulate with. Whether you are developing products for the Natural, Organic or OTC sector, there is a grade suitable for your requirements:

Grade	Description
Oat® COM USP	For general use as a functional ingredient with activity designed as a skin protectant with soothing capabilities ECOCERT/COSMOS approved natural
Oat® COM ORG	An organic version of Oat® COM USP Certified at 100% organic by Ecocert Greenlife according to Cosmos and Ecocert standards available at http://cosmetics.ecocert.com
Oat® COM IRR	A sterile version of Oat® COM USP designed for OTC applications

For more formulation ideas download our formulation ebook from our website http://oatcosmetics.com/formulation-ideas/

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