Oat Lipid e

DATA PACK

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Oat Lipid

DCI: Revision No: 5 Issue Date: 05 Jan 2021

Contents

Ceramide Content Analysis

QUANTITATIVE ANALYSIS

Ceramide content measurement was undertaken by using the sphingolipid analysis as described by Markham and Jaworski 2007:

Rapid measurement of sphingolipids from Arabidopsis thaliana by reversed-phase high-performance liquid chromatography coupled to electrospray ionization tandem mass spectrometry. Rapid Commun. Mass Spectrom. 21: 1304–1314.

RESULTS

The results indicate an average total ceramide content in Oat Lipid e of 1.49% of total lipids. Analysis of the ceramide species showed the following fractions:

Type	Skin Identical Ceramides Including Isomers	Skin Identical Ceramides Including Isomers and Analogs
NS	3.1%	23.3%
NP	35.1%	35.1%
EOH	6.3%	26.6%
AS	5.6%	11.9%
AP	3.2%	3.2%

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Lipid and Fatty Acid Profile Comparison

OIL COMPARISON

An analysis of the Lipid and Fatty Acid Profiles of some of the most commonly used cosmetic oils was undertaken and then compared to that of Oat Lipid E.

RESULTS

The results show that oat Lipid e is unique amongst the oils tested for containing a polar lipid fraction along with a balanced saturated, monounsaturated and polyunsaturated profile.

	Oat® Lipid e	Almond (Sweet)	Argan Oil	Canola	Daikon Radish Seed	Jojoba Golden	Macadamia Nut	Meadow Foam	Rosehip	Hemp	Wheat Germ	Safflower
Lipid Profile												
Neutral Lipids	90.00	98.6	96.5	97.2	96.4	97.7	98.1	98.8	96.4	95.6	92.4	97.2
Pigmented material	3.62	3.6	2.8	1.2	3.6	3.5	2.8	2.3	1.4	4.4	7.6	1.9
Polar lipids	6.38	0	0	0	0	0	0	0	0	0	0	0
Fatty Acid Profile												
Total Saturated	16.84	9.69	18.62	8.79	10.82	1.34	18.24	1.19	6.32	10.7	18.24	11.38
Total Mono-unsaturated	43.85	64.73	52	54.53	68.72	97.96	76.83	80.8	15.1	14.71	14.31	15.35
Total Poly-unsaturated	39.32	25.58	29.38	36.7	20.45	0.71	4.93	18.01	78.58	74.59	67.45	73.28

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Antioxidant Comparison

OIL COMPARISON

An analysis of the antoxidant content of some of the most commonly used cosmetic oils was undertaken and then compared to that of Oat Lipid E.

RESULTS

The results show that Oat lipid e contains potent natural antioxidants, including the tocotrienols, tocopherols, together with the alkyl phenolates, which are known to be as effective an antioxidant as Butylated hydroxytoluene (BHT).

	Tocotrienol **					Tocopherol **				
	Alpha	beta	gamma	delta	total	Alpha	beta	gamma	delta	total
Oat® Lipid e	379	25	56	17	477	131	18	2	2	153
Wheatgerm	2.5	8.2	0.24	-	11	191	65	tr	0.55	257
Coconut	3	0.17	0.64	0.1	4	0.2	tr	0.12	-	0.32
Corn	0.94	tr	1.1	0.26	2	18	1.1	44	2.2	65
Sesame	tr	-	0.34	-	tr	7.9	0.41	36	1.2	46
Walnut	tr	-	0.17	tr	tr	6.6	-	39	4.6	50
Linseed	-	-	-	-	-	1.2	tr	52	0.95	54
Sunflower	0.11	-	tr	0.27	tr	59	2.4	1.4	0.27	63
Rapeseed	-	-	-	-	-	24	tr	39	0.98	64
Camelina	-	-	-	-	-	3.8	0.09	72	1.3	77

** These typical levels of naturally occurring molecules may vary between batches.

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28-Day Comedogenicity Study

STUDY OBJECTIVES

A study was undertaken to assess the comedogenicity potential (the tendency of an ingredient or product to clog pores) of Oat Lipid e. The objective of the study was to evaluate whether Oat Lipid e caused non-inflamed lesions (comedones) or inflamed lesions when used regularly over a 28-day period.

STUDY DESCRIPTION

The study was a single-centre, open, controlled user study carried out by a group of thirty 18-40-year-old females.

Subjects were provided with Oat Lipid e to apply once each morning to the face during the 4-week study period. Oat Lipid e was worn for at least 8 hours each day and subjects recorded each application and removal in a diary.

Subjects had facial comedones (non-inflamed lesions – blackheads and whiteheads) and inflamed lesions (papules and pustules) counted at baseline and after 2 weeks and 4 weeks of product use. The assessor also analysed the full face for signs of dermal irritation and questioned the subjects regarding experiences of subjective irritation.

The output of the study therefore focused on three areas:

- Lesion Count
- Tolerance Assessment (Dermal Signs Trend)
- Subjective Tolerance Assessment

The study was independently performed for Oat Cosmetics by Alba Science Ltd between the 17th August and 15th September 2017.

LESION COUNT

At each assessment (Baseline, Day 14 and Day 28) a lesion count was undertaken by a trained assessor using a x4 magnification Northlight lamp. The lesion assessments were carried out by the same assessor at each time point.

Counts were made for:

- Number of blackheads (overall)
- Number of whiteheads (overall)
- Number of papules (overall)
- Number of pustules (overall)

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28-Day Comedogenicity Study

TOLERANCE ASSESSMENTS

At each assessment (Baseline, Day 14 and Day 28) the trained assessor assessed the full face for signs of dermal irritation (erythema, oedema and dryness). Each sign of dermal irritation was recorded using a 5-point scale:

- 0 = None
- 0.5 = Very slight
- 1 = Slight
- 2 = Moderate
- 3 = Severe

SUBJECTIVE TOLERANCE ASSESSMENTS

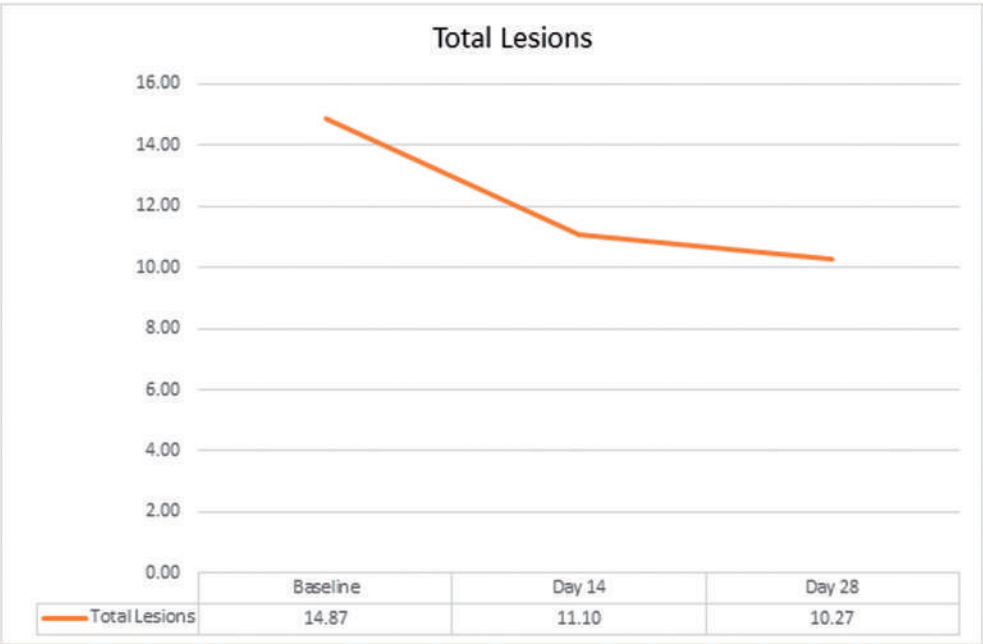
At each assessment (Baseline, Day 14 and Day 28) the subject was questioned by the trained assessor regarding experiences of subjective irritation on the face - stinging, tightness, itching, redness and warm/burning sensations.

At Day 0 (Baseline) the trained assessor reviewed a period of 7 days prior to Baseline with the subject; at Days 14 and 28 the assessment covered the period since the previous visit.

Each subjective tolerance parameter was recorded using a 5-point scale:

- 0 = None
- 0.5 = Very slight
- 1 = Slight
- 2 = Moderate
- 3 = Severe

LESION COUNT RESULTS



The above graph shows the mean scores for total lesions for the 28-day duration of the study.

Independently tested by Alba Science Ltd., 2017. Full report available upon request.

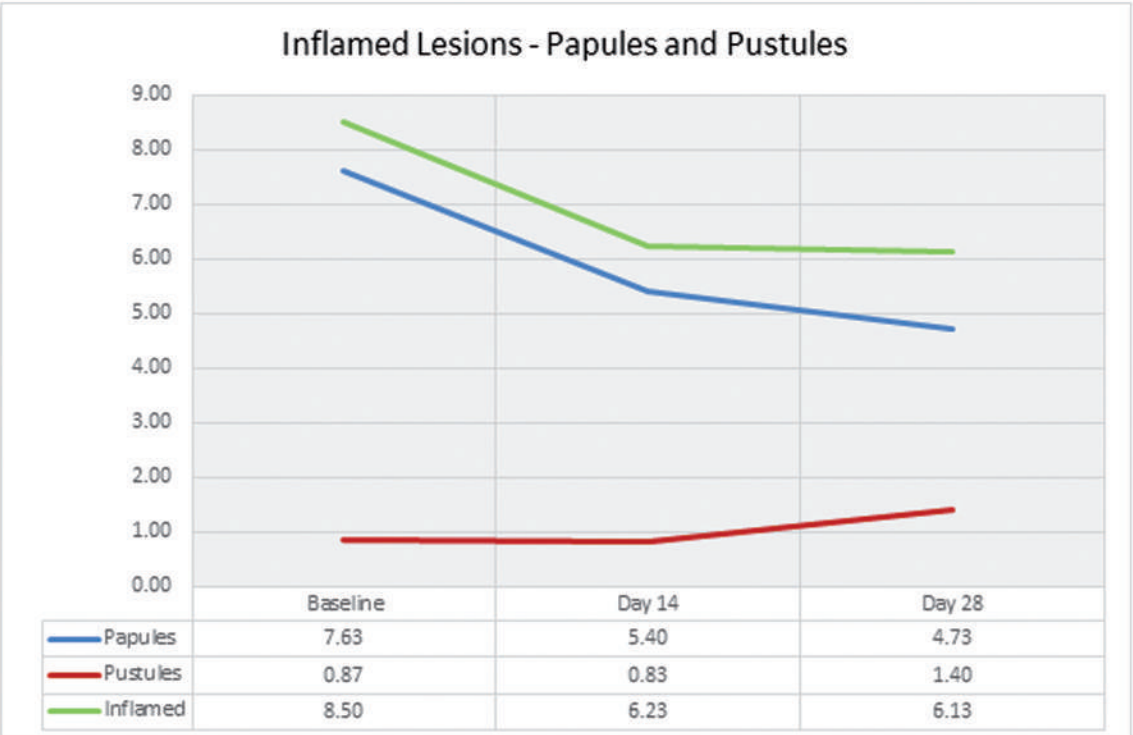
28-Day Comedogenicity Study

LESION COUNT RESULTS (CONT.)

The following table summarises the mean lesion counts recorded at Baseline, Day 14 and Day 28 for the 30 subjects included in the analysis.

Lesions							
	Papules	Pustules	Blackheads	Whiteheads	Inflamed	Non-inflamed	Total Lesions
Baseline	7.63	0.87	5.53	0.83	8.50	6.37	14.87
Day 14	5.40	0.83	4.30	0.57	6.23	4.87	11.10
Day 28	4.73	1.40	3.73	0.40	6.13	4.13	10.27
Change from Baseline							
Δ Day 14	-2.23	-0.03	-1.23	-0.27	-2.27	-1.50	-3.77
Δ Day 28	-2.90	0.53	-1.80	-0.43	-2.37	-2.23	-4.60
Percentage Change from Baseline							
Δ Day 14	-29.26%	-3.85%	-22.29%	-32.00%	-26.67%	-23.56%	-25.34%
Δ Day 28	-37.99%	61.54%	-32.53%	-52.00%	-27.84%	-35.08%	-30.94%

INFLAMED LESIONS



The above graph shows the mean scores for inflamed lesions (papules and pustules) for the 28-day duration of the study.

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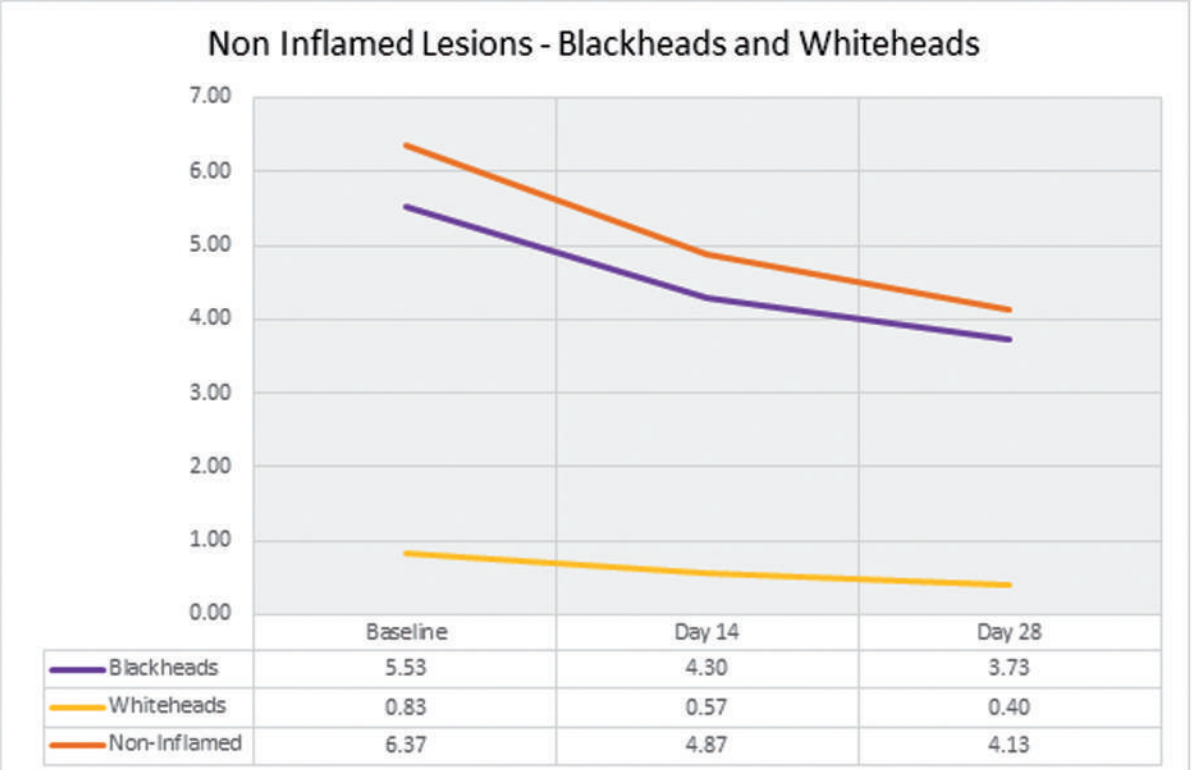
28-Day Comedogenicity Study

LESION COUNT RESULTS (CONT.)

NON-INFLAMED LESIONS



	Baseline	Day 14	Day 28
Blackheads	5.53	4.30	3.73
Whiteheads	0.83	0.57	0.40
Non-Inflamed	6.37	4.87	4.13

The above graph shows the mean scores for non-inflamed lesions (blackheads and whiteheads) for the 28-day duration of the study.

TOLERANCE ASSESSMENT RESULTS

DERMAL SIGNS TREND

The following table summarises the dermal signs recorded at Day 14 and Day 28 for the 30 subjects included in the analysis.

Dermal			
	Erythema	Oedema	Dryness
Baseline	0.22	0.00	0.23
Day 14	0.22	0.00	0.28
Day 28	0.22	0.00	0.20
Change from Baseline			
Δ Day 14	0.00	0.00	0.05
Δ Day 28	0.00	0.00	-0.03

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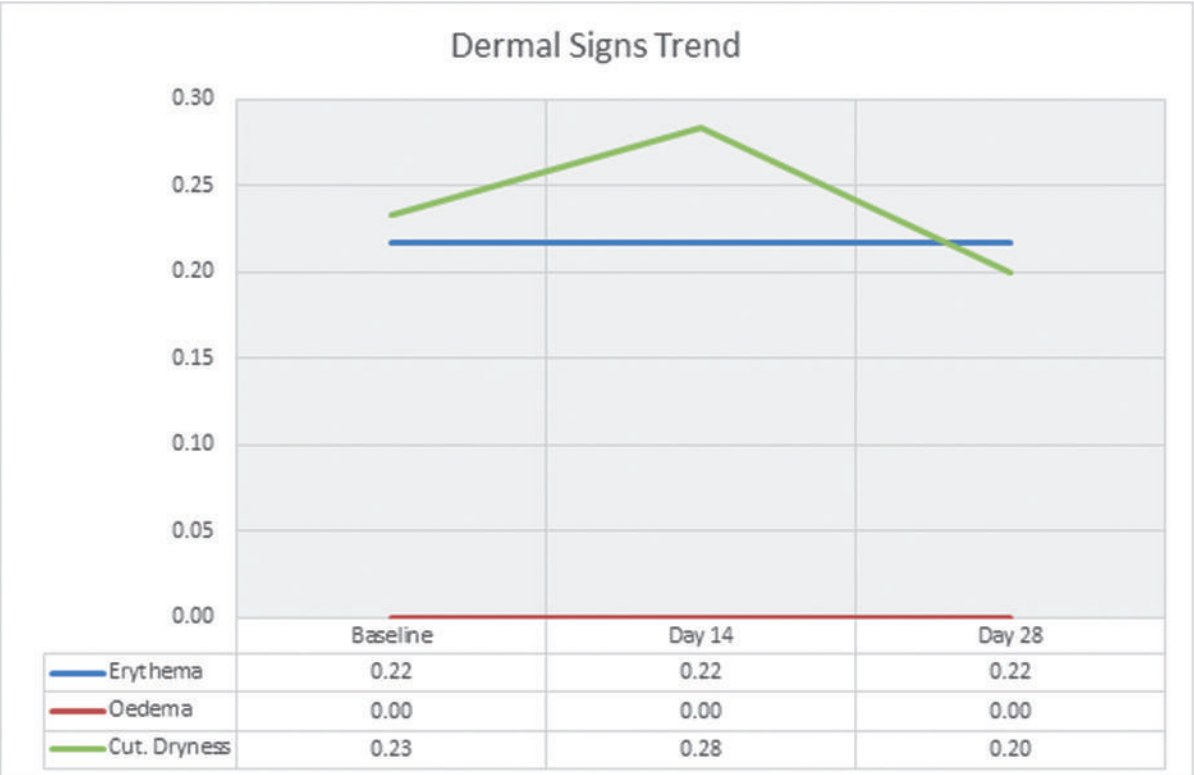
DERMAL SIGNS TREND (CONT.)



The above graph shows the mean scores for all the dermal signs for the 28-day duration of the study.

SUBJECTIVE TOLERANCE ASSESSMENT RESULTS

The following table summarises the subjective signs recorded at day 14 and day 28 for the 30 subjects included in the analysis.

Subjective					
	Stinging	Tightness	Itching	Redness	Warm/ Burning
Baseline	0.00	0.10	0.00	0.00	0.00
Day 14	0.00	0.03	0.00	0.00	0.00
Day 28	0.00	0.03	0.00	0.00	0.00
Change from Baseline					
Δ Day 14	0.00	-0.07	0.00	0.00	0.00
Δ Day 28	0.00	-0.07	0.00	0.00	0.00

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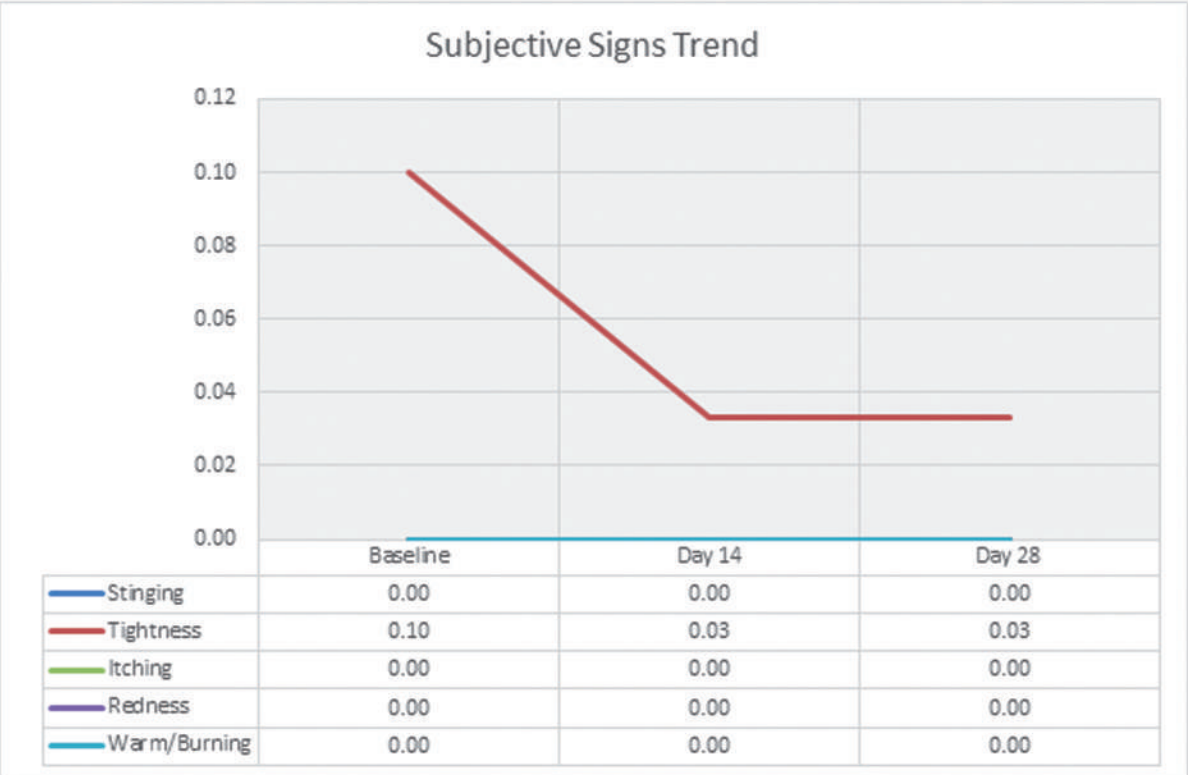
SUBJECTIVE TOLERANCE ASSESSMENT RESULTS (CONT.)



	Baseline	Day 14	Day 28
Stinging	0.00	0.00	0.00
Tightness	0.10	0.03	0.03
Itching	0.00	0.00	0.00
Redness	0.00	0.00	0.00
Warm/Burning	0.00	0.00	0.00

The above graph shows the mean scores for all the subjective signs for the 28-day duration of the study.

CONCLUSION

All lesion counts, except for pustules, decreased at the Day 28 post-baseline assessments.

Statistical significance was achieved in the following data sets:

- Reduction in Papules at Day 14 and 28
- Reduction in Blackheads at Day 14 and 28
- Reduction in Whiteheads at Day 14
- Reduction in Inflamed Lesions at Day 14 and 28
- Reduction in Non-Inflamed Lesions at Day 14 and 28
- Reduction in Total Lesions at Day 14 and 28

There were no statistically significant increases in any lesion counts at day 14 or day 28 of the study. Assessments made by the trained assessor showed a reduction in skin dryness, whilst subjects themselves felt a reduction in skin tightness when using Oat Lipid e.

These results categorically show Oat Lipid e to be non-comedogenic.

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Oxidative Stability Study

BACKGROUND

Oil rancidity is the result of the oxidation or hydrolysis of unsaturated fats into short chain aldehydes and ketones giving rise to an unpleasant odour and taste. It is generally expected that oils containing high levels of unsaturated fats are less oxidatively stable than those with lower levels.

STUDY DESCRIPTION

A study was undertaken to assess and compare the oxidative stability of Oat Lipid e against two other oils rich in unsaturated fatty acids - Sunflower Oil and Wheat Germ Oil.

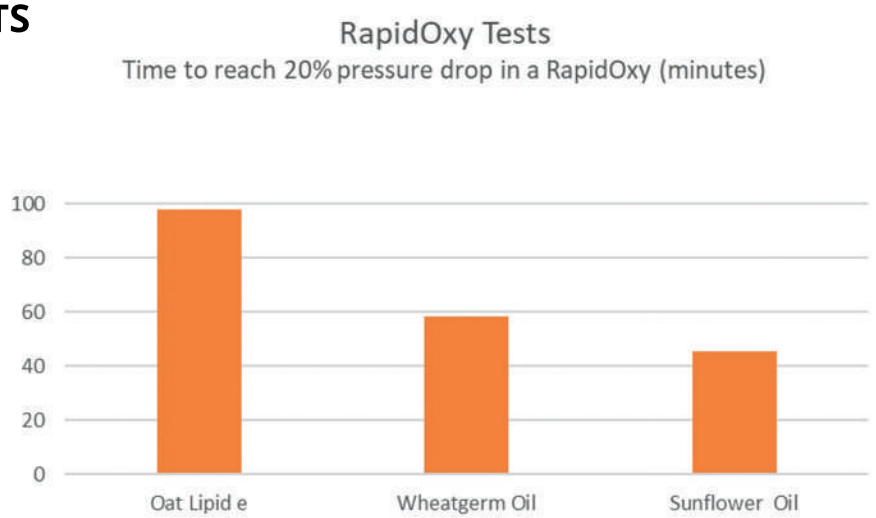
Oil	Approx. Unsaturated Fatty Acid Content
Oat Lipid e	83%
Wheat Germ Oil	82%
Sunflower Oil	91%

The stability was assessed using a RapidOxy device. The RapidOxy is based on Anton Paar's patented measuring principle of ASTM D7545, a well-established method to test the oxidation stability. Under this test method, samples are sealed into the test cell, pressurised with pure oxygen and heated. This initiates a very fast oxidation process. A defined pressure drop determines the end of the test. The test duration is directly related to the oxidation stability of the sample.

Oil samples (10ml) were pipetted into a glass dish that was placed in the sample chamber of a RapidOxy. The sample chamber was filled with oxygen to an initial pressure of 7 bar and heated to the set temperature (140°C). The oxidative stability of the sample was determined by recording the time taken for the pressure to decrease by 20%.

The result reported is the mean value of duplicate analysis.

RESULTS



The results demonstrated that Oat Lipid e was significantly more stable than Wheat Germ Oil, with Sunflower Oil being the least stable.

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STABILIZING EFFECT OF OAT LIPID E ON A LESS STABLE OIL

In a further experiment, using the same methodology, 3% Oat Lipid e was added to the Sunflower Oil. This resulted in a 10% improvement in the time taken for sunflower oil to reach the 20% cut point.

CONCLUSION

The Oxidative Stability Study shows that Oat Lipid e is not only an inherently stable oil but that it also confers stability to less stable fats and oils. It is likely that the antioxidants including caffeic and ferulic acid, tocotrienols and tocopherols contained within the Oat Lipid e have a significant effect on the inherent stability of Oat Lipid e, making it far more stable than its unsaturated lipid profile would indicate. These antioxidants are able to be donated to act as stabilisers for other oils in a shared system.

It has been claimed that oat oil inhibits skin lipid peroxidation in response to ultraviolet irradiation of the skin (Lapsed patent US5620692A). Skin lipid peroxidation can lead to skin ageing and inflammatory responses. This study indicates that this claimed inhibition may actually be due to the same mechanism described above.

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Effect of Oat Lipid e on Excessive Handwashing (Consumer Evaluation)

BACKGROUND

Excessive washing of the hands can have a significant impact on overall skin health and appearance. The skin cells in the stratum corneum, the outermost layer of skin, contain water-soluble compounds that absorb water from the lower layers. Each of these skin cells are surrounded by lipids: fats which prevent water on the skin from evaporating into the external environment. Excessive water and cleanser exposure may rid the skin of this protective lipid barrier which normally functions to keep skin optimally supple and comfortable.

A hand washing trial was performed to assess the ability of Oat lipid e to repair and replenish the skin. The volunteers were asked to compare a hand cream containing 5% Oat Lipid e and a placebo cream.

METHOD

For four weeks, 35 volunteers – men and women aged between 16-60 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 5% Oat Lipid e 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% applied Oat Lipid e first.

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

Phase	Trade Name	INCI	% w/w
A	Purified Water BP	Aqua	71.55
A	Mekirol Rapeseed	Glycerin, aqua	2.50
A	Euxyl PE9010	Phenoxyethanol, Ethylhexylglycerin	1.00
B	Surfac MCTG	Caprylic/Capric Triglyceride	8.00
B	Oat Lipid e*	*Avena Sativa* Kernel Oil	5.00
B	Cutina GMS V	Glyceryl Stearate	3.50
B	Surfac Stearic Acid	Stearic Acid	3.50
B	Lanette O	Cetearyl Alcohol	2.85
B	Beeswax	Cera Alba	1.00
B	Surfacare Vit E Acetate	Tocopheryl Acetate	0.20
C	Surfac Triethanolamine Pure 90%	Triethanolamine, aqua	0.90

Oat Lipid 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 Lipid e and after applying the placebo.

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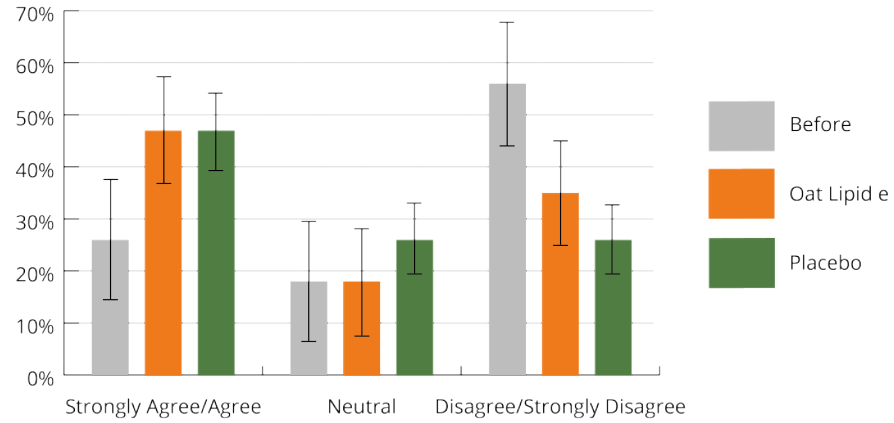
Effect of Oat Lipid e on Excessive Handwashing (Consumer Evaluation)

Effect on Skin Dryness:

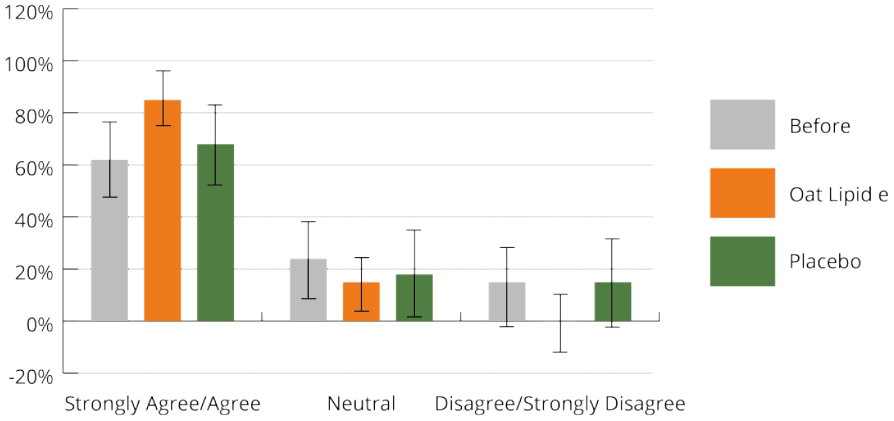
Perception Statement: 'Hands Do Not Feel Dry'



After applying the Oat Lipid e hand cream for one week, 47% of volunteers reported that their hands did not feel dry (though 0% strongly disagreed with the perception statement) versus 26% reporting that their hands did not feel dry before use.

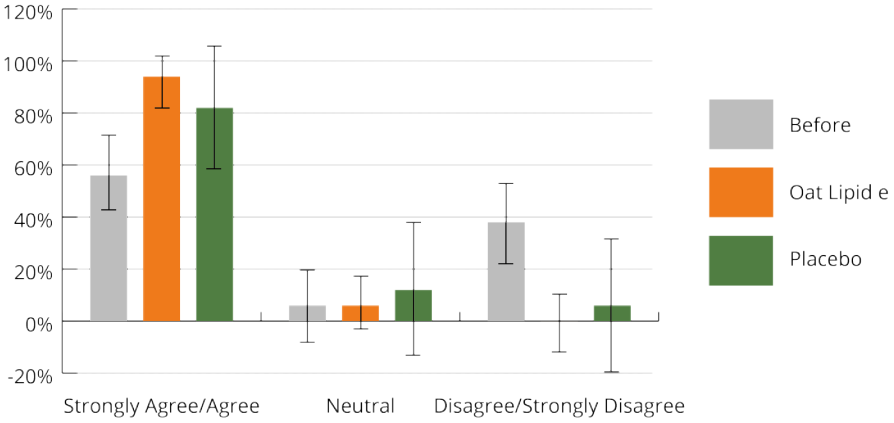
Effect on Skin Redness and Damage:

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



0% of consumers reported their hands feeling red and damaged after using the Oat Lipid e hand cream for one week compared to 15% when using the placebo and before using the product.

Perception Statement: 'Hands Do Not Have Dry Patches'



38% of volunteers reported their hands having visible dry patches before application of Oat Lipid e. All of these volunteers reported that these patches had disappeared after application of the Oat Lipid e hand cream.

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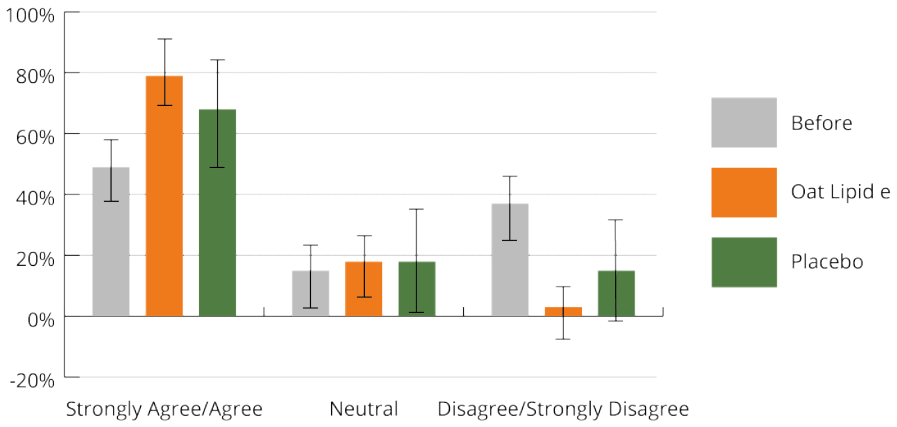
Effect of Oat Lipid e on Excessive Handwashing (Consumer Evaluation)

Effect on Skin Comfort:

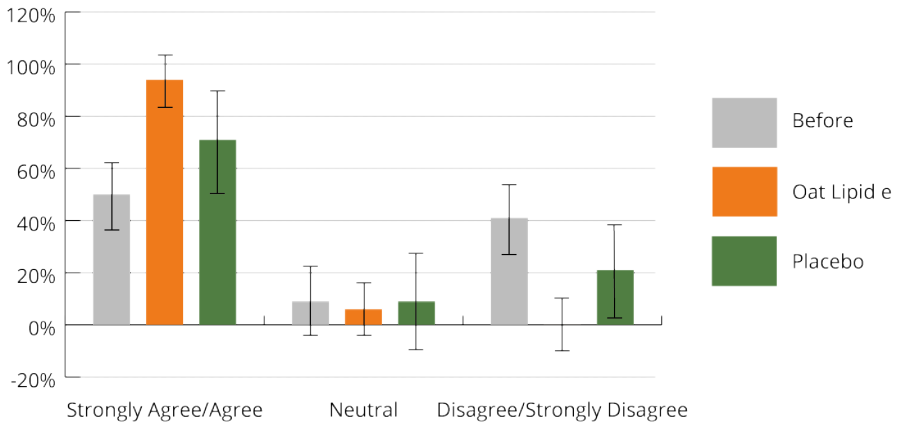
Perception Statement: 'Hands Do Not Feel Uncomfortable'



37% of volunteers reported their hands feeling uncomfortable before using the product, 15% after using the placebo and only 3% after using the Oat Lipid e hand cream.

Effect on Skin Texture:

Perception Statement: 'Hands Are Smooth'



24% more volunteers reported their hands feeling smooth after using the Oat Lipid e hand cream compared to the placebo and 46% before using the product.

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 Lipid e versus the placebo.

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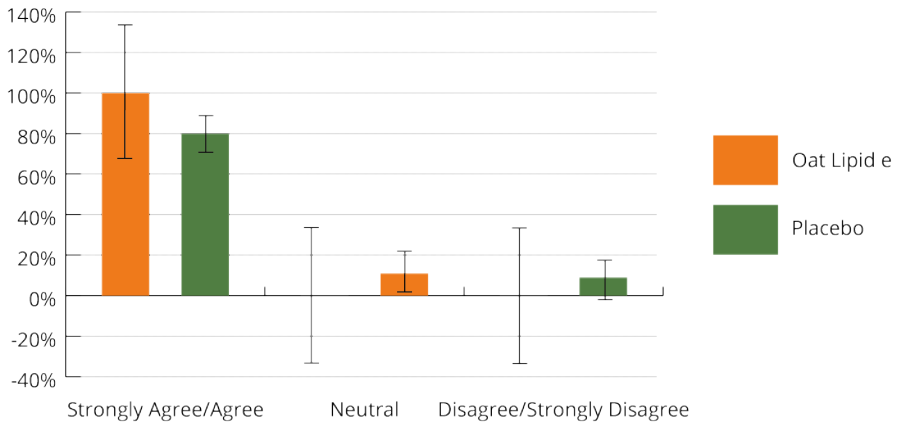
Effect of Oat Lipid e on Excessive Handwashing (Consumer Evaluation)

Effect on Skin Hydration:

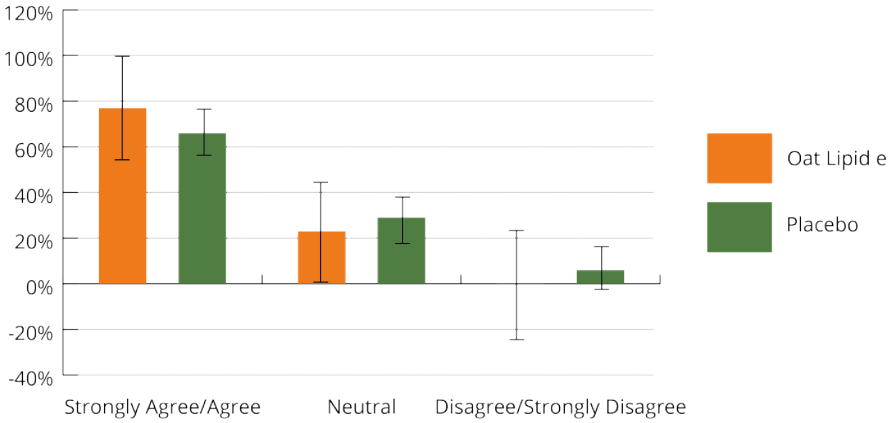
Perception Statement: 'Hands Feel More Moisturised After Using Product'



100% of the volunteers agree that applying 5% Oat Lipid e for one week improves moisturisation of the hands.

Effect on Skin Irritation:

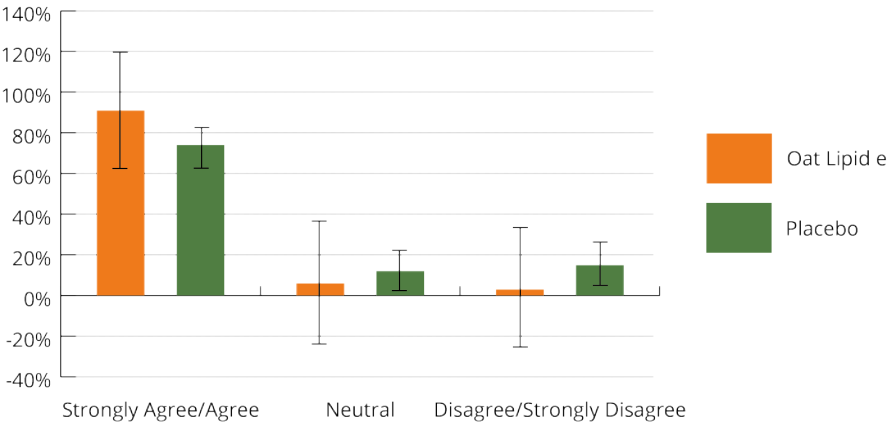
Perception Statement: 'Hands Feel Less Irritated Than Before Using Product'



14% more volunteers reported their hands feeling less irritated after using Oat Lipid e compared to using the placebo.

Effect on Skin Condition:

Perception Statement: 'Hands Feel Soothed After Using Product'



After applying the Oat Lipid e hand cream for one week, 91% of the volunteers reported their hands feeling more soothed - 19% more than the placebo.

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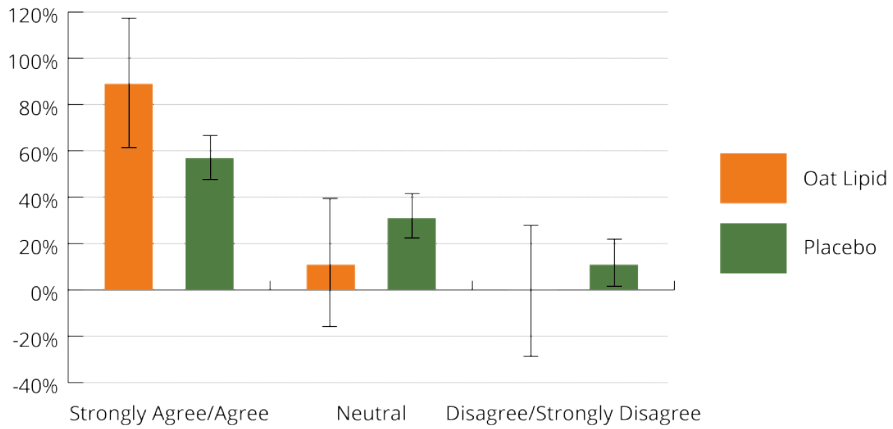
Effect of Oat Lipid e on Excessive Handwashing (Consumer Evaluation)

Perception Statement: 'Hands In Better Condition Than Before Using Product'



After one week of application of the Oat Lipid e hand cream, 89% of the volunteers reported that the product improved the overall condition of their skin, 36% more than the placebo.

CONCLUSION

The polar lipids (ceramides and phospholipids) and neutral lipids (phytosterols and PUFAs) found in Oat Lipid e replenish the skin's lipid barrier and restore the hydrolipidic film following disruption. Ceramides, phospholipids and phytosterols, which are known as a key part of the stratum corneum's "cement", can migrate between cells and help to restore the skin barrier, whilst PUFAs stay on the surface of the skin and help to prevent trans-epidermal water loss (TEWL).

This is verified with this consumer evaluation which shows that 5% Oat Lipid e alleviates signs of skin damage, improves hydration and smooths the skin.

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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® 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.

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