

Cosmeceutical Market Opportunities Today and Tomorrow

In-Cosmetics Berlin,
April 14, 2005

Joerg Gruenwald, Ph.D., President,
Waldseeweg 6 • D-13467 Berlin • Germany
Tel.: +49-30-4000 8100 • Fax: +49-30-4000 8400
email: jgruenwald@analyze-realize.com
Internet: www.analyze-realize.com


a&r
analyze & realize

PhytoPharm
& consulting



Definition of Cosmeceuticals

- Cosmetic products that include ingredients designed not only to enhance the appearance but to also have a positive physiological effect at the cellular level
- Cosmetic products that produce lasting past removal changes
- Cosmetic product that satisfy both beauty and health needs

 © 2005

Cosmeceuticals14Apr05



Cosmeceutical History



3

- The Egyptians were the first to recognize the health-giving properties of cosmetic products
- Raymond Reed, founding member of the U.S. Society of cosmetic chemists, created the “Cosmeceutical” concept in 1961
- In the late 70’s, Albert Klingman reactivated interest by developing a formula to improve the appearance of UV-damaged and wrinkled skin, using retinoic acid
- The category rapidly expanded in the 80’s, due to alpha hydroxy acids (natural fruit acids), as exfoliants effective against wrinkles
- The cosmeceutical concept is mostly used in the USA and Japan
- Whichever term is used, cosmetic products with health claims are advancing worldwide



Synonyms

- The controversial position of the term cosmeceutical between COSMEtic and pharmaCEUTICAL
- Therefore, other expressions are often preferred:
 - Functional cosmetics
 - Dermaceuticals
 - Performance cosmetics
 - Bio-functional materials
 - Treatment ingredients



4



The Cosmeceutical Market

- Market evaluations vary depending upon the source
 - The cosmeceutical market is growing faster than other cosmetic sectors
 - The world cosmetic market is about US \$ 20 – 30 bn
- USA
2001: US \$ 3 – 10 bn
2007: US \$ 5 – 14 bn
 - EU
2001: US \$ 2 – 8 bn
2007: US \$ 4 – 10 bn
 - Japan
2001: US \$ 7 – 12 bn
2007: US \$ 8 – 17 bn

Sources: Japancorp, NutraceuticalsWorld, The Cosmeticsite, Freedonia, Denzil Phillips, a&r



The World's largest Cosmetic Markets in 2003 (World Market = US \$ bn 201)

Source: Euromonitor

Country	US\$bn	increase [%] '03	increase [%] '97
USA	45.4	0.7	24.3
Japan	21.9	3.2	8.1
France	12.1	5.0	33.6
Germany	11.6	1.4	22.8
UK	10.1	4.7	21.6
Italy	8.5	2.5	27.4
Brazil	7.3	12.2	113.7
China	6.0	7.8	63.2
Spain	5.7	5.6	56.7
Russia	5.3	14.3	31.3

7

The World's Fastest Growing Cosmetic Markets in 2003

- Fast growing markets particularly characterize emerging economies
- After years of sustained growth, the established markets are more or less stable

Country	% growth in 2002-03
Venezuela	81.4
Ukraine	22.4
Vietnam	19.3
Argentina	18.2
Indonesia	16.9

Source: Euromonitor

© 2005 Cosmeceuticals14Apr05

8

Worldwide Cosmetics Growth 2002 - 2003

Category	% Growth (2002-2003)
Depilatories	~4.2%
Oral Care	~3.2%
Men's Lines	~7.2%
Antiperspirant/Deodorant	~6.8%
Bath and Shower	~3.1%
Hair Care	~4.1%
Sun Care	~7.5%
Skin Care	~6.8%
Color Cosmetics	~4.5%
Fragrances	~3.5%

Source: Euromonitor

© 2005 Cosmeceuticals14Apr05

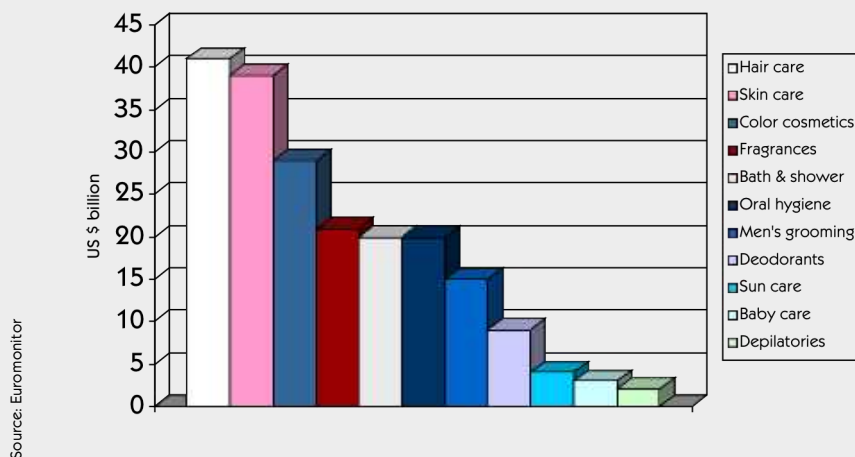


Trends

- Nevertheless, individual segments, such as skin care products, are growing worldwide
- In some cases, the evolution differs greatly, depending upon the country:
 - the men's grooming market is growing strongly in Italy (+6.4%), but decreasing in Germany



Global Performance by Product Sector in 2003



11




Skin Care

- The second largest cosmetic sector
- Third fastest cosmetic growth sector (not including sun care products)
- The main sector for cosmeceuticals
 - Acne treatment: classic target group are teenagers
 - Specific skin care: dry skin treatments and skin protection, etc.
 - Anti-aging



© 2005 Cosmeceuticals14Apr05

12

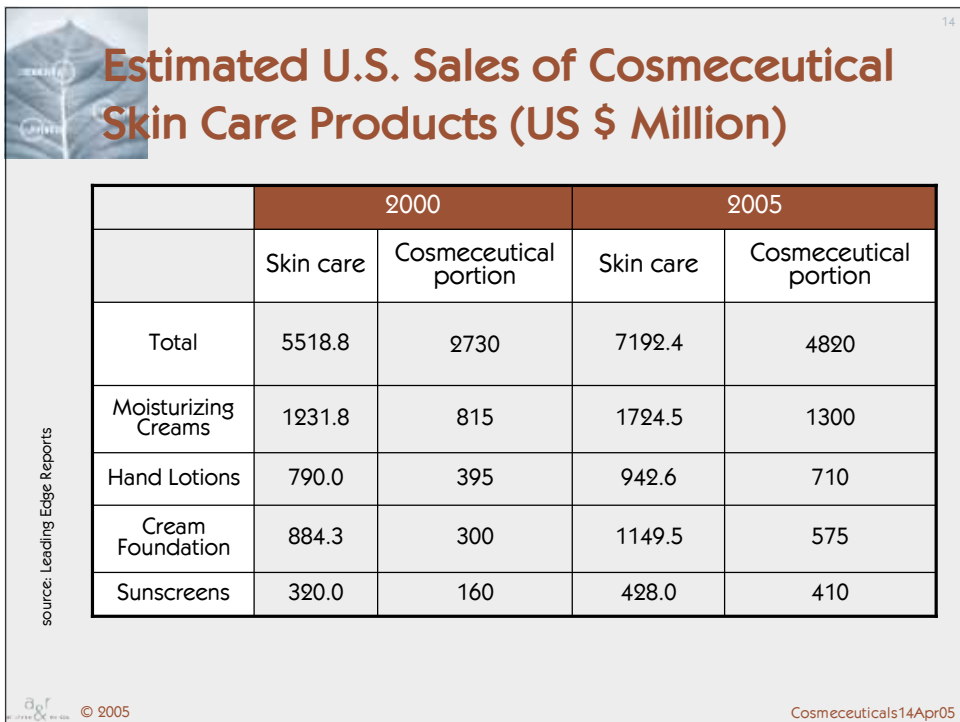


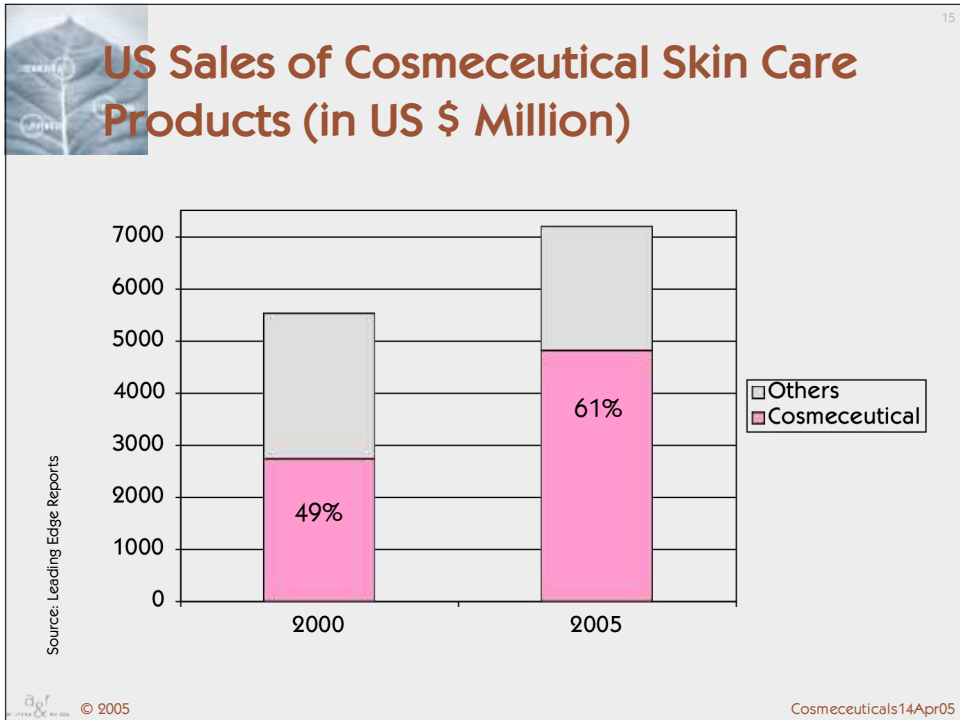
Cosmeceutical Product Demand

Category	Percentage
Skin Care	60%
Hair Care	15%
Professional	7%
Other	18%

Source: Freedonia


© 2005 Cosmeceuticals14Apr05





16

Market Access in the USA



- The FDA does not recognize cosmeceuticals
- If a health claim is made, then OTC drug status applies and OTC ingredients must be GRAS
- The FDA is responsible for both cosmetics and drugs
- FDA product definitions :
 - Cosmetics: must “not affect the structure and function of skin”
 - Drugs: “affect structure or function”

© 2005

Cosmeceuticals14Apr05



17



Regulatory Issues in the USA

- Conflict: every topical cosmetic product affects the structure of the skin.
- Cosmetics may have implied claims but these must be carefully worded to avoid the products being classified as drugs.
- FDA standards must be met before health claims can be made. Without health claims there is less regulatory scrutiny.




18


Dealing with Regulatory Realities

- In developing and marketing cosmeceuticals and preventing conflicts with drug status, the industry pursues a threefold marketing strategy
 - Inclusion of pharmaceutical ingredients that have been approved by the FDA (such as retinol or minoxidil) into cosmetics
 - Incorporating delivery systems to enhance the performance of the ingredients (deeper penetration, time release, etc.)
 - Use of antioxidants and natural extracts (with GRAS status and an extensive history of use), which do not require FDA approval (however, performance claims are not allowed if they have not been proven by rigorous testing)

19



Market Access in Japan



- Cosmetic products
- Quasi drugs (mild action on the body)
 - cosmeceuticals,
 - nutraceuticals,
 - functional foods
- Drugs

 © 2005 Cosmeceuticals14Apr05

20



Market Access in the EU

The EU Cosmetic Directive



- EU Directive 76/768/EEC:
the European cosmetic regulatory “Bible”
- “A cosmetic product means any substance ... intended for placing in contact with the various external parts of the human body ... or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them in order to keep them in good condition, change their appearance or correct body odors.”

 © 2005 Cosmeceuticals14Apr05



21

Market Access in the EU

The EU Pharmaceutical Directive 2001/83/EC

“a medicinal product is any substances or combination of substances presented as having properties for treating or preventing disease in human beings;

or any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”



22

Market Access in the EU

Allowed Effects for Cosmetic Products

- No legal limitation to the effect on the outer layer of the skin
- Possible conflict with medicinal regulations concerning physiological activities
- It must be taken into account that the cosmetic effect dominates
- Significance of the physiological activity must also be considered



Cosmeceuticals in Europe

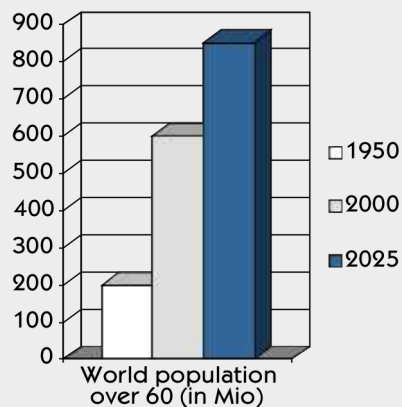
- Cosmetic designer brands with health claims are mainly sold through pharmacies
- Taking Italy as example, it was the strongest growing channel in 2003 (+8.2%)
- Herbalist shops were the second fastest growing channel (+7.7%), confirming the increasing demand for herbal cosmetics (nevertheless, it is still a niche market)

Source: Unipro



Anti-aging

- Youthful looks are widely perceived as desirable in all age groups
- Baby boomers are the target generation
- Preventing aging is driving the use of anti-aging cosmeceuticals to younger consumers
- The concept of age related beauty is becoming increasingly popular



Source: helpage international



25

Addressing Anti-Aging Issues

- Free radical scavenging effect
- Wrinkle defense systems
- Treatment of specific skin problems, such as spider veins
- Gender specific body care, such as cellulite treatment and breast firming
- Sunscreens (in the USA these are considered OTC) to prevent photo-damage
- In Asia: anti-aging often include skin whitening ingredients and sunscreens



26

Other growing Markets

- Men's grooming aids
 - Men are increasingly concerned with their appearance. Today, men make up 1/3 of the hand and body lotion market
 - Men's grooming products are the second fastest growing category
 - Men are particularly looking for convenience cosmetic products, e.g.
 - cosmeceutical active ingredients in shave products
 - hair care: anti-dandruff, hair regrowth products
- Sun Care
 - Growing concern about aging photo-damage.
 - At the same time, a healthy skin tone is still one of the most important beauty concerns for Caucasians -> sun care, sunless tanning
 - While in eastern Asia, skin whitening products and total sun block systems are demanded



27

Interactive Trend Factors

- **Product *price***

An increasing number of customers do not see cosmetic products as luxuries and therefore demand cheaper products

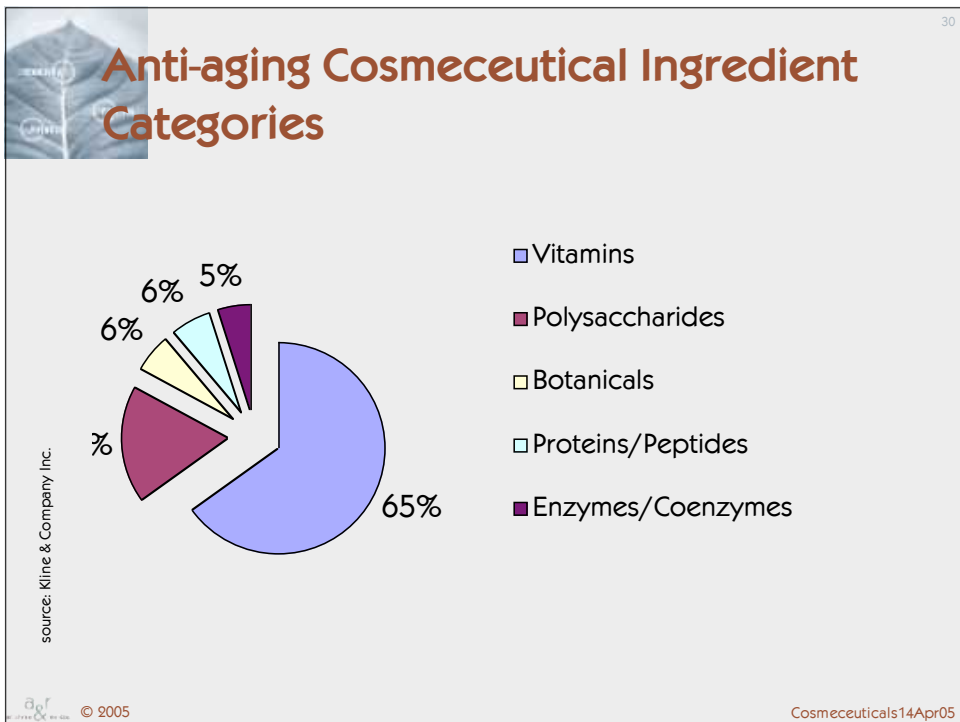
 - Cosmeceuticals are ever more present on the mass market
- **Product *nature***
 - Added value features such as natural and organic ingredients are increasingly demanded and customers are prepared to pay more for specific claims -> trend to natural cosmetics and ingredients
- **Product *effectiveness***
 - Consumers expect demonstrable, visual, sensory or functional benefits from cosmetic products -> trend toward cosmeceuticals



28

Cosmeceuticals Today and Tomorrow

- Suppliers of ingredients for the pharmaceutical and food industries, offer ever more cosmeceutical ingredients
- Today there is an increasingly scientific approach to active ingredients that demonstrate the efficacy of cosmeceuticals
- Natural actives are particularly in demand. New technology allows stabilization of natural ingredients and their availability in highly concentrated or chemically pure forms





Vitamins A & E

- Used particularly because of their anti-oxidant capacity (free radical scavenging effect, protective effect against photo-aging, etc.)
- Major suppliers are BASF, Roche, Cognis, etc.
- Vitamin A compounds
 - Oil-soluble antioxidants, biologically active form of vitamin A = all-trans retinoic acid (retinol)
 - improves the skin's texture. Essential for the generation of skin cells. Boosts the collagen content of the skin. Helps against acne.
 - 50% of total consumption value
 - 5-10% of consumption volume
- Vitamin E compounds (tocopherols)
 - Oil-soluble anti-oxidant. Stabilizes biological membranes. Skin protective
 - 40% of total consumption value
 - 70-75% of consumption volume



Monosaccharides, Polysaccharides and Vitamin C

- Vitamin C Compounds
 - *One of the most powerful water soluble antioxidants.*
 - *Acts as a collagen biosynthesis regulator.*
 - *Reverses photoaging.*
- Monosaccharides and Polysaccharides
 - holds moisture, creating a water binding film on the skin and hair
 - **Senna seeds** (*Cassia angustifolia*) -> Galactomannan
 - **Tamarind** (*Tamarindus indica*) -> Xyloglucan: skin repair action. Protects the skin and helps against premature aging
 - **Oarweed** (*Laminaria digitata*)
 - **Fructose**
 - acts as a moisturizer,
 - high content in baobab fruit pulp



33

Enzymes/Coenzymes

- Stimulate skin cell regeneration, affect collagen and elastin, modulate skin lipid and oil production and regulate cellular turnover.
- New techniques for enzyme stabilization and effective delivery at the site of action will increasingly promote these ingredients
 - Coenzyme Q10
 - A potent anti-oxidant, used in skin creams and oral care products to neutralize free radicals (used in natural cosmeceuticals). It is also used in hair care products because of its hair re-growth effect.



34

Proteins/Peptides

- The skin's „support“ matrix
- Applied topically, they help the skin's surface to appear firmer
 - Collagen
moisturizer, skin smoothing, enhances the healing process
 - Keratin
Surface protective, film-forming and moisturizing
 - Elastin
Surface protective agent, alleviates the effects of dry skin. Tightening.
 - Pentapeptides
New pentapeptides (KTTKS) are designed to resemble collagen fragments



35

Example: Milk/Whey Ingredients

- Perfect wound healing without excessive scar formation
- Skin nutrients
- Prevention of wrinkles and folds
- Adjuvant in sunscreen lotions
- Treatment of couperose
- Bioactive factors in milk: *enzymes, proteins, peptides, hormones etc.*
- Bioactive factors in whey: *lactalbumin, immunoglobulins, lactoferrin, lactose etc.*



36

Botanical Ingredients



- Consumer preference for natural botanical ingredients
- Plant ingredients are preferred over animal derived ingredients
- Fractions or isolates of plant chemicals increasingly dominate the market (plant peptides, isoflavones, hormones)
- GMO plant products are rejected by the consumer, especially in Europe
- Increased demand for organic ingredients instead of merely natural ones



Botanical Extracts in Cosmetics on the US Market

Item	1989	1993	1998	2003	2008
	(\$ MM)	(\$ MM)	(\$ MM)	(\$ MM)	(\$ MM)
Essential Oils	101	113	150	200	258
Plant Acids & Enzymes	19	37	65	106	173
Aloe Vera	38	46	63	86	115
Other	22	34	67	113	174
Botanical Extract Demand	180	230	345	505	720

Source: Freedonia.

- Plant acids, enzymes and Aloe are the most market relevant cosmetic botanicals
- Nature provides us with a great many useful botanicals, the active ingredients of which are being scientifically confirmed and are now being increasingly used in cosmetics




The Success Story of St. John's Wort

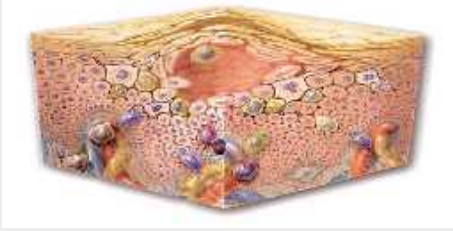
- Leading natural anti-depressant as nutraceutical/herbal drug
- Traditionally St. John's Wort was also used externally for burns and wounds
- But also a new cosmeceutical: a hypericum cream and lotion (Bedan, Lichtwer Pharma)
- With proven clinical effects in sensitive /atopic skin/ neurodermitis



39




Basic problems of atopic skin



- Dry skin ← supply of moisture, care
- Staphylococcus aureus ← antibacterial
- Inflammation ← anti-inflammatory


© 2005 Cosmeceuticals14Apr05

40

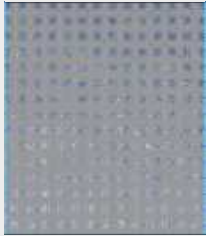


Antibacterial activity


Hyperforin (1 μM) inhibits multi-resistant Staphylococcus aureus



CONTROL



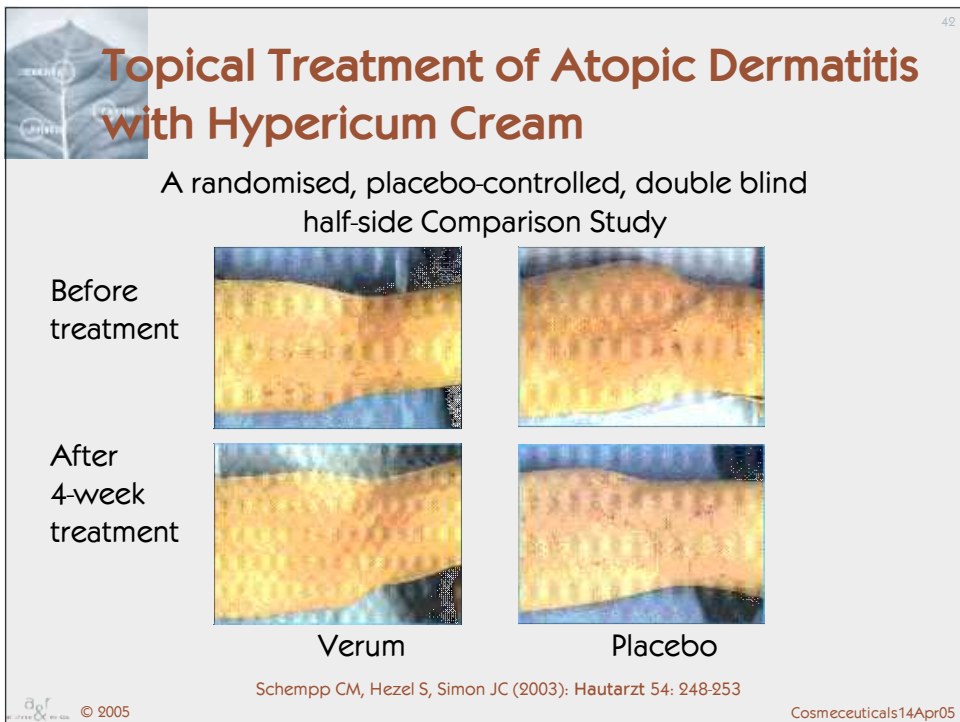
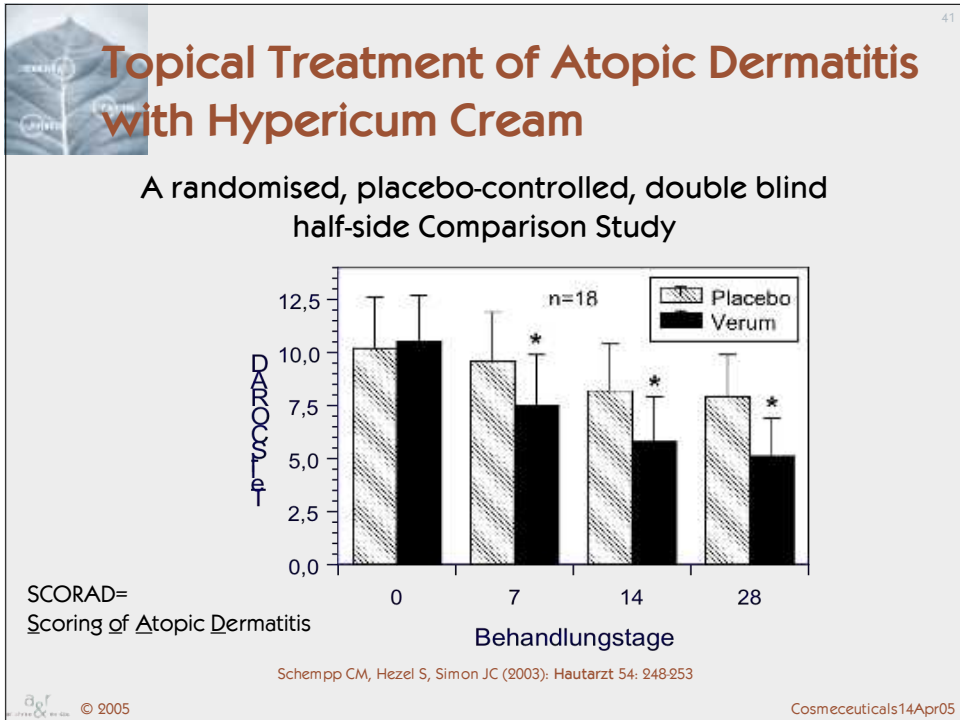
HYPERFORIN




PENICILLIN

Schempp CM, Pelz K, Wittmer A, Schöpf E, Simon JC (1999): The Lancet 353:2129

© 2005 Cosmeceuticals14Apr05



43



Efficacy and Tolerability of a St. John's Wort Extract for the Care of Atopic Skin

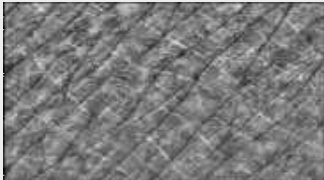
117 volunteers subjects with sensitive/atopic skin

- Statistically significant improvement
 - of skin hydration
 - trans epidermal water loss
 - skin surface
- Reduction of skin itchiness
- No adverse effects observed
- Excellent cosmetic acceptability

skin surface



Before treatment



after 4-week treatment with Bedan® Cream

Tronnier H, Heinrich U, (2003): Kosmetische Medizin 3-4

© 2005
Cosmeceuticals14Apr05

44



The Success Story of *Aloe vera* Across the Marketing Sectors

- An invaluable **cosmetic** ingredient for many years, due to its excellent skin-protective and moisturizing activity
- One of the most recognized skin care ingredients. As a powder additive aloe will inhibit cyclo-oxygenase as part of the arachidonic acid pathway
- A **medicinal** plant for dermal applications with a long tradition in the Western World
- increasingly used as an ingredient in dairy products



© 2005
Cosmeceuticals14Apr05



The Aloe vera Market

- Finished product market:
US \$ 35 billion/yr
 - Global raw material market:
US \$ 70-90 million/yr
(US: >60% shares*)
 - New market entrants: China**, India, Brazil
- *) World's largest Aloe farm operates in the Dominican Rep. (2020 ha)
- **) China's aloe industry is growing fast and is anticipated to reach 120 million within 5 years. Likewise, the Chinese demand for aloe derivatives is estimated to be US \$ 2.4 billion by 2010



Reasons for Success

- Tradition
 - Aloe was already a well known medicinal plant in ancient Egypt
- Science
 - Its composition has been well analyzed and the beneficial molecules identified
- Studies
 - A large number of clinical data exists, in particular for external use
- Preservation
 - Distribution of Aloe gel began only after an appropriate stabilization method was established
- DSHEA
 - The GRAS status of Aloe in the US simplified market authorization
- Consumer Trend
 - Consumers prefer natural products with noticeable inherent healing properties
- Marketing
 - An outstanding example of the success of the MLM concept



Noni (*Morinda citrifolia*)

- A popular internal health ingredient has a good possibility to be established as a cosmetic ingredient
- An example is Noni (*Morinda citrifolia*), a Polynesian plant, traditionally used internally, as well as for its skin moisturizing properties



Do you prefer coffee...

- Coffe Plant (*Coffea spp.* - Caffeine)
 - Tightening, draining and revitalizing effect, useful against bags under the eyes and cellulite
 - Hair growth stimulating





...or tea?

49

■ White and Green Tea (*Camellia sinensis*)

- **xanthines** suppress inflammation, irritation and reduces cellulite;
- **polyphenoles** have powerful antioxidant properties that are 20 times stronger than Vitamin E



Examples of Cosmetic Herbs (1)

50

■ Avocado (*Persea americana*)

- Nourishing and conditioning effect on dry skin and hair. Significantly increases the water-soluble collagen content in the dermis skin layer.
- Useful against pigmented moles.



■ Jojoba (*Simmondsia chinensis*), Almond (*Prunus dulcis*), Olive (*Olea europea*) Oils

- Aids in the treatment of dry skin. They are tonic, emollient and moisturizers. They acts as a lipidic delivery system for active ingredients.





51

Examples of Cosmetic Herbs (2)

■ Sea kelp

- Contains natural mineral active ingredients and vitamins.
- Sebum adsorbing
- Stimulate blood circulation
- Skin tightening



■ Yacón (*Smallanthus sonchifolius*)

- The leaf extract is rich in antioxidant polyphenols



 © 2005

Cosmeceuticals14Apr05



52

Examples of Cosmetic Herbs (3)

■ Soy (*Glycine max*)

- Rich in Isoflavones that increase skin thickness through their estrogenic effects
- Contains two serine protease inhibitors that inhibit melanosome phagocytosis, improve pigmentation, and lighten the skin.



 © 2005

Cosmeceuticals14Apr05



Examples of Cosmetic Herbs (4)

- **Comfrey plant** (*Symphytum uplandicum*)
 - Contains **Allantoin**, a strong anti-inflammatory ingredient, that has healing, soothing, and anti-irritating properties
- **Gotu cola** (*Centella asiatica*)
 - Active compounds (mainly **saponins**) are effective in scar management by aiding the production of collagen (type I and III)





The impressive African Baobab Tree (*Adansonia digitata*) - a new source for cosmetic products

- Its oil is rich in vitamins A, D, E and essential fatty acids
- Its fruit pulp is very anti-oxidative
- Moisturizing benefits for the skin and hair
- Excellent in formulations against eczema and psoriasis



55

Major Indications for Cosmeceuticals: Cellulite


- Anti-sagging ingredients that activate the microcirculation (also indicated for breast firming and against bags under the eyes)
 - Meadowsweet (*Spiraea ulmaria* - Extract)
 - Coffee Plant (*Coffea spp.* - Caffeine)
 - Ginkgo (*Ginkgo biloba*)
 - Birch (*Betula spp.*)
 - Common Ivy (*Hedera helix*)
 - Lemon (*Citrus lemon*)

© 2005 Cosmeceuticals14Apr05

56


Major Indications for Cosmeceuticals: Acne

- Regulators of sebum production
 - Saw palmetto (*Sereonnoa repens*)
 - Green Tea (*Camelia sinensis*)
 - Soy (*Glycyne soja*)
 - Burdock (*Arctium lappa*)
- antiseptic and germicidal
 - Tea Tree (*Melaleuca alternifolia*)
 - Green Tea (*Camelia sinensis*)
 - Chinese Sage (*Salvia miltiorrhizina*)
 - Bardana (*Arctium lappa*)
 - Lemon (*Citrus lemon*)
 - Tamanu (*Calophyllum inophyllum*)
- Anti-inflammatory
 - Wild Pansy (*Viola tricolor*)
 - Kiwi (*Actinidia chinensis*)
 - Kokum (*Garcinia indica*)
 - Licorice (*Glycyrrhiza glabra*)







© 2005 Cosmeceuticals14Apr05


57



Natural UV Filters

- Arnica (*Arnica montana*)
- Witch Hazel (*Hamamelis virginiana*)
- Walnut (*Juglans regia*)
- Pomegranate (*Punica granatum*)
- Edelweiss (*Leontopodium alpinum*)

 © 2005
Cosmeceuticals14Apr05

58



Skin Whiteners

- Research and production of skin whiteners has been mostly undertaken by Japanese companies
- But more and more European and American cosmetic companies are entering this market




- Bearberry (*Arctostaphylos uva-ursi*)
- Aloe (*Aloe vera*)
- Lemon (*Citrus lemon*)
- White Mulberry (*Morus alba*)
- Chinese Sage (*Salvia miltiorrhiza*)
- Liquorice (*Glycyrrhiza glabra*)
- Watercress (*Nasturtium officinale*)
- Amla (*Embelica officinalis*)

 © 2005
Cosmeceuticals14Apr05



Some Popular Botanical Remedies for Skin Problems in Europe and ... Polynesia

Europe

Yarrow - flowers (<i>Achillea millefolium</i>)	To Heal chapped skin
Oats – oat meal (<i>Avena sativa</i>)	To treat tired skin
Pot marigold – flowers (<i>Calendula officinalis</i>)	To treat reddened skin
Chestnut – bark (<i>Castanea sativa</i>)	To treat reddened skin
Hawthorn – fruits (<i>Crataegus monogina</i>)	Skin softener
Cucumber seeds (<i>Cucumis sativus</i>)	Against wrinkles

Polynesia

Semitake Mushroom (<i>Cordyceps sabolifera</i>)?	Skin protection
Wormwood (<i>Artemisia carvifolia</i>)?	Revitalising the skin
Oriental Horsetail (<i>Equisetum arvense</i>)?	Tightening slack skin
Tamanu (<i>Calophyllum inophyllum</i>)	To heal chapped skin



Hair care

- Useful against hair loss
 - Nettle (*Urtica dioica*)
 - Aloe (*Aloe vera*)
 - Coffee (*Coffea spp.*)
- Against hormonal hair loss
 - Black cohosh (*Cimicifuga racemosa*)
 - Saw Palmetto (*Serenoa repens*)
- Useful against dandruff
 - Olive (*Olea europea*)
 - Jojoba (*Simmondsia chinensis*)
 - Aloe (*Aloe vera*)
 - Sallow Thorn (*Hippophae rhamnoides*)
 - Chastity Flower (*Lugustrum lucidum*)
- Useful to nourish the scalp
 - Oriental Maiden Hair (*Trichomonas japonica*)

61



The World's Top 10 Cosmetic Companies in 2003


ranked by revenue from beauty products only

Company	Revenue in € billion
1. L'Oréal	1.8
2. Procter & Gamble	1.7
3. Unilever Group	1.7
4. Shiseido	1.7
5. Estée Lauder	1.5
6. Avon Products	1.4
7. Johnson & Johnson	1.4
8. Beiersdorf	1.3
9. Wella	1.1
10. Alberto Culver	1.1

source: WWD Beauty


 © 2005 Cosmeceuticals14Apr05

62



Summary

- Cosmeceuticals are among the fastest growing segments in cosmetics
- Beauty and health are more and more combined
- Functionality and clinically proven effects are reaching top prices
- Natural, and especially botanical ingredients are preferred by consumers
- The bio-diversity of plants and their ingredients offer wide ranges of opportunities for formulations and clinically tested products

 © 2005 Cosmeceuticals14Apr05

Our Services:

63

Market Research

Networking

Raw Materials

M & A

Extract
Technologies

Expert Reports

Patent/Protection

Medical Writing

Product
Development

Marketing
Strategies

Clinical Studies

Registration



 © 2005

Cosmeceuticals14Apr05

Some of our Publications:



Do you need further information?



www.analyze-realize.com

contact@analyze-realize.com