



the science of beauty

Vol 9 No 1

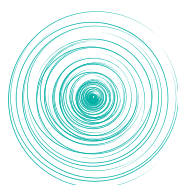
August 2019



A S Harrison & Co



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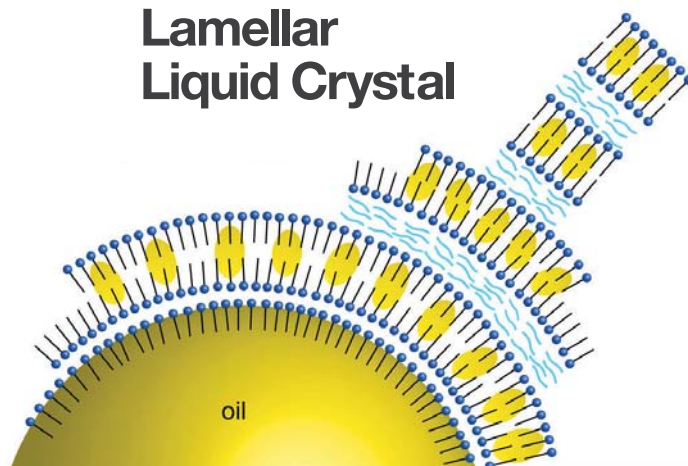
+ 100% Natural + Amino Acid-Based + Quat-Free Cationic Charge

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INCI: Brassica Alcohol (and) Brassicyl Valinate Esylate (and) Brassica Glycerides

Lamellar Liquid Crystal



AminoSensyl™ SC and HC amino lipid technology, exclusive to INOLEX and is distributed by A S Harrison & Co. Refer to our article ***“INOLEX Amino Lipids: 100% Natural and Eco-Friendly Breakthrough Hair Care Actives”*** for more information on AminoSensyl™ HC hair care.

Learn more about how AminoSensyl™ SC and HC can become your new hero – contact us for more details, starting formulations and samples.



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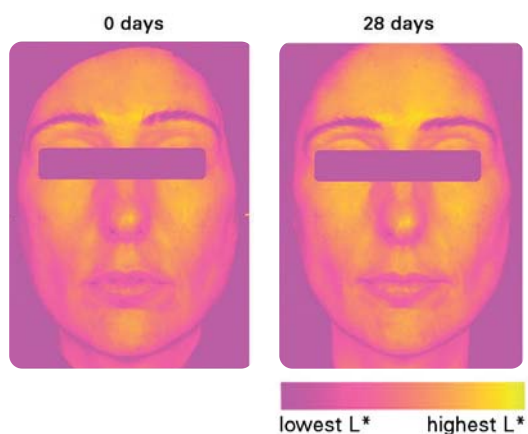
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1% **dawnergy™** peptide solution C

- Skin luminosity **increased** significantly
- The visibility coefficient of **wrinkles** **decreased by 15.4%**
- Overall **anti-fatigue effect** for active lifestyles

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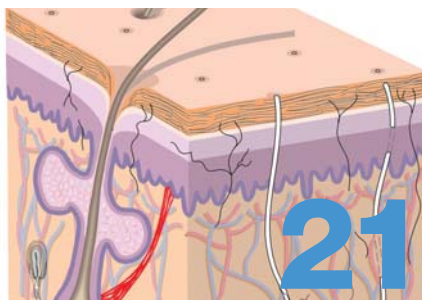
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Call for Papers

2020 Annual Conference of the Australian Society of Cosmetic Chemists



**CROWN CONVENTION CENTRE, MELBOURNE,
VICTORIA, AUSTRALIA
19th-21st May, 2020**

Are you involved in the Personal Care Industry as a raw material supplier, finished product manufacturer, brand owner or other related discipline such as packaging, marketing/trends or IP? Then the ASCC Conference is an excellent opportunity to highlight new and exciting technologies/ research, update attendees about the latest market trends or provide a hands-on experience that people will be talking about well after the event. In the last few years the ASCC Conference has continued to grow and attract a diverse range of delegates all with a link to the Personal Care Industry both in Australia and Internationally. The geographical position of Australia makes it a unique asset for the cosmetic industry, merging Asia, Europe and America in a unique place. With the continuous growth of the Personal Care Industry locally along with the attractiveness of the "Made in Australia" connection which resonates with a lot of Asian consumers, the ASCC Conference will be an excellent opportunity to showcase your latest innovations.

Located at the Crown Convention Centre in Melbourne, Australia in May 2020, the Organising Committee is looking to focus on the global trend towards Sustainability and "Clean Beauty". The 52nd Annual ASCC Conference is looking to attract experts from all areas of the globe and our industry to showcase the 2020 Vision for a Clean and Sustainable Future.

Persons interested in presenting papers or workshops at this Conference are invited to submit abstracts.

Conference programming requirements dictate the following timing:

- Papers should take 20 – 25 minutes to present.
- Workshops should be of 55 minutes duration. These should be of an interactive/ hands-on nature and encourage a high level of participation by attendees. There will be a set of basic lab equipment available to be used for sensory/ formulation workshops.

With your abstract, please ensure that you include the following information:

- Paper title, name of author(s), name of presenter, company or organisation
- Postal address, phone (with country and area code) and email address
- Please indicate clearly whether you are submitting a paper or workshop and for workshops indicate if there is a maximum number of attendees and any special resources required.
- Please provide as much detail as possible within your abstract as this will form part of the selection process. For workshops an understanding of the concept and how you will engage the audience is highly recommended to be included with your submission.
- Please provide a short biography of the proposed presenter and a passport size photograph.

The abstract shall be submitted by email in the following format:

- The abstract must be typed double spaced, in English, preferably Arial font 12 point, and be between 100 and 200 words in length.
- The title must be in capital letters and include the name(s) of the author(s), with the presenting author's name underlined. If the presenter is not one of the authors, that must be clearly stated.

There are four awards presented at the Conference. In brief they are:

- Lester Conrad Award – Best paper presented at the Conference
- Jack Jacobs Memorial Trophy – Best paper based on original research conducted in Australia or New Zealand
- ASCC Educational Paper – Best educational paper not fitting into the criteria of either the Lester Conrad award or the Jack Jacobs Memorial Trophy.
- Peter Strasser Memorial Award- Best Educational Workshop at the Conference.

Full guidelines and eligibility criteria for these awards can be found on the ASCC Website (www.ascc.com.au)

**Abstract submissions are to be sent to the Conference Technical Organising Committee;
c/- the ASCC Secretary Kate Paulett (ascc@ascc.com.au)**

Call for Papers/ Abstracts will close on 30th November 2019

All accepted submissions will be notified by 31st January 2020

Full papers and presentations must be submitted by 31st March 2020

We look forward to seeing you in 2020.



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The viewpoints and opinions
expressed in the articles appearing
in this magazine are those of the
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responsibility for the information
supplied.

meet the team...



WENDY FREE has degrees in Science (B.Sc) and Technology Management (M.Tech Mngt) and is a member of a number of industry associations including Australian Society of Microbiologists, Royal Australian Chemical Institute, Association of Therapeutic Goods Consultants and is a Fellow of the Australian Organisation for Quality. With more than 25 years industry experience, Wendy's current roles include APVMA GMP auditioning, contributing to the Cochrane Collaboration and on a day to day basis, Scientific Director Quality Matters Safety Matters Pty Ltd (QMSM) that has over the last decade Wendy has provided expertise to over 400 Australian and International businesses. She specialises in regulatory compliance, commercialisation, troubleshooting and GMP systems, and considers cosmetics amongst the most challenging and enjoyable part of her work.

JULIAN JONES, the founder and Managing Director of ikonsulting Pty/Ltd, is Passionate about the Personal Care Industry in Australia and Globally. Julian has been an active member of the ASCC for over thirty years. During this time he has served as President and Chairman of the Victorian Chapter of the ASCC. He is widely known and well respected both nationally and internationally for his knowledge and skills in developing and marketing the best Personal Care Products.

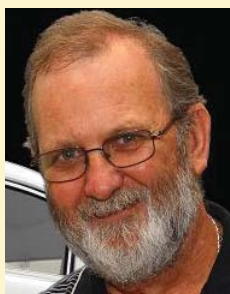


JOHN STATON has a background of over 40 years experience in the pharmaceutical and healthcare industries. John is a life member of the ASCC and serves in a number of industry representative roles with ASMI, ACCORD, TGA and Standards. He is the Australian representative to the ISO Committee on Sunscreen Testing-TC 217. (The committee for development of sunscreen standards). John is also in demand as a speaker on the International Conference Circuit.

TONI OVENELL is a formulation chemist and consultant for Queensland Cosmetic Formulators. She has worked in the cosmetic industry for many years in a range of roles covering areas of technical sales, quality, supply chain, manufacturing and product development. Most recently Toni has worked for a small contract manufacturer as technical manager, prior to setting up her own business. Toni is passionate about sharing her knowledge, maintaining a viable cosmetic industry in Australia and helping people bring their product ideas to market. She also likes champagne and hockey.



PAM JONES has worked in the Personal, Homecare and Pharmaceutical markets for more than 30 years. She has been working out of Asia since 1996 and is well versed and connected with the Asia Market. Her experience covers technical, sales, marketing, management and training roles. She has qualifications in Chemistry, Marketing and Management. Her company PCA Consulting is well known for its training programmes. Pam has worked with and consulted to companies such as ICI, Croda, Ashland, Huntsman, Reed Exhibitions (in Cosmetics) and Connell to name a few. She is currently serving on the ASCC Technical Committee and volunteers as Technical Editor for this magazine.



RIC WILLIAMS was educated in Sydney obtaining his Bachelor of Science in Pure and Applied Chemistry from the University of New South Wales (1980) and a Diploma of Environmental Studies from Macquarie University in 1983. Ric has had 40 years experience in the industry working for many companies and operating his own consultancy business for many years. He has presented many lectures and workshops at national conferences for the Australian Society of Cosmetic Chemists (ASCC), the Association of

Professional Aestheticians of Australia (APAA), Cosmetic and Pharmaceutical Special Interest Group (CAPSIG) and also beauty colleges nation wide.



MARG SMITH is the owner of Syndet Works – an Australian company established in 1984 to formulate and produce soap free skincare bars. Syndet has developed an enviable reputation for custom formulated and manufactured skincare that now extend well beyond the origins of the business.

JEN SEMPLE is Innovation & Education Manager at Accord Australasia, the peak national body for formulated chemical products. She is passionate about communicating the benefits of our industry's products to wider society and has authored a number of public education websites such as furchies.org.au, sunsible.org.au and hygieneforhealth.org.au. Jen also manages Accord's sustainability initiatives and seeks opportunities to build relationships between industry and academia. She has a PhD in Chemistry and Graduate Diploma in Education, and is a member of the Royal Australian Chemical Institute.



EMANUELA ELIA is the Director of Ozderm, which specialises in *in vivo* testing and clinical trials for cosmetic and personal care products. Emanuela Elia has a law degree from Rome and a Master of International Business from the University of Sydney. She had collaborated with Australia's longest serving Contract Research Organisation Datapharm for a few years before setting up a cosmetic and personal care products testing facility in 2009. Emanuela is enthusiastic about improving the quality of cosmetic and personal care products' research in Australia through science.



STEVE WELSH is a cosmetic packaging specialist with over 20 years experience across all mediums of packaging. As the director of Weltrade Packaging, Steve leads a team of designers, technicians, printers and supply chain professionals. To ensure the best exposure of your beauty, skincare or cosmetics brand. Steve's philosophy is to design your packaging correctly, right from the start, so you can elevate your brand and move more product. Steve works closely with leaders in the cosmetic industry to ensure that your packaging consistently

stands out on the shelves within this highly competitive market.



JAMES GILLARD is the Principal of Insurance Made Easy whose services include – business insurance, travel insurance and financial services. Insurance Made Easy has a client list of over 2000 businesses from all industries. The relevant major insurance schemes are – Hair and Beauty, Pharmaceutical Companies and Natural Therapists.

TINA ASPRES has worked as a Pharmacist for almost 20 years in retail, industry and academia as well as being a Cosmetic Chemist. Currently she works in industry and has vast experience in both the pharmaceutical and healthcare arenas. In addition to this she is a casual academic at UTS, School of Health, (Faculty of Pharmacy in Pharmaceuticals). Tina has a great interest in clinical research in dermatology and the treatment of skin disease and conditions and is Clinical Trial Coordinator at South West Sydney Dermatology. She is a keen researcher in transdermal drug delivery systems. Tina is a Member of the Pharmaceutical Society of Australia and a Member of the Australian Society of Cosmetic Chemists. She regularly consults pharmaceutical companies in the area of acne, eczema and skincare especially in the area of cosmeceuticals and has devised and written numerous support, training and education material for companies aimed at both professionals and consumers. Tina consults for the Eczema Association Australasia and is on their Integrity Assessment Panel and has worked with Choice Magazine on numerous reports. Tina has presented at the Annual Scientific Meeting of the Australasian College of Dermatologists and has published within the pharmacy and medical literature in the area of sun protection, Vitamin D, skin cancer prevention and eczema as well as co-authoring the book 'All About Kids' Skin – The Essential Guide' published by ABC Books



GINT SILINS is a registered patent and trade marks attorney, and a principal of Spruson & Ferguson Patent & Trade Mark Attorneys (incorporating Cullens). He holds a Bachelor of Science degree in chemistry with honours in biochemistry, and a Doctor of Philosophy degree in biochemistry. Gint specialises in protecting branding and innovations largely in the health care, personal care, animal health, food and beverage, biotechnology, industrial chemical, clean energy and agricultural sectors. His practice includes: conducting brand and innovation availability and registrability searches; IP audits; registering patents, trade marks and designs worldwide; enforcing intellectual property rights; resolving IP disputes; and, providing infringement and validity advice.



Sometimes, it's **not** about the product...

by Julian Jones

Over the last 35 years or so I have had many opportunities to seek advice, help, products or services from hundreds of companies – big and small.

In my professional life and in my personal life I have experienced both the best and worst of “Customer Service” – and I use that term to describe all of these interactions!

When you decide to reach out to a company you are their customer from that first point of contact, on. Everything you experience will influence your opinion about them as your supplier. Even if your first contact is via a website or social media touch point, the quality of the experience has been designed by a person.

As the customer, receiving consistently great results is one of the best ways to ensure you will keep coming back to them and become an unpaid positive representative for their offering, whatever it may be.

As a supplier or service provider, it helps to always consider that if you were the customer, would you be happy with the service or experience you or your staff offer? Giving great customer experiences is really challenging! The most important experience is the very first point of contact. It is often said that you only get one chance to make a great impression. That's true and you should

focus on getting that right, but don't forget that, as in all relationships, it is an ongoing experience!

So often, as the customer, I have been overpromised and under delivered. The times I have been really impressed with a company or person is when they continue to delight me with their ongoing commitment to great service.

I'm going to give you a wonderful example of consistently great service, but I won't actually name the provider – for commercial reasons!

Many years ago, I met the owner and Managing Director of a small start-up manufacturing company. From day one, he was warm and welcoming, generous with his time and knowledge even though there seemed little in it for him or his company at the time. Over the following years we maintained a close and friendly relationship, both interested in how our businesses were progressing and growing. I shared my knowledge and contacts with him, as he did with me. Eventually, there was an opportunity for us to work together, as I developed a new direction for my business.

Do you know the first person I turned to with that new opportunity? Of course, you know the answer! Long story short, we now have a business cooperation that is very successful and will continue for years to come. The key



point here is, way back at the beginning, neither of us knew what the future might hold but the experience of getting to know each other was not predicated on “what's in it for me?” (WIIFM).

In my long experience, being genuinely interested in people, curious to learn what makes them tick and keen to listen to them is a great way to build a positive vision of the world. It's not always easy to maintain a positive attitude and we all sometimes relate to people in a less than ideal way. But, trying to keep an open mind and looking for the best in everyone goes a long way to building cooperation and tolerance in your world and ultimately the whole world!

Hopefully, these thoughts cause you to reflect on your experiences and focus on the good ones!

See you next time! Cheers

Julian



It all started with Citronella Oil...

For over 25 years, New Directions Australia has grown to become one of the largest wholesalers of pure essential & certified organic oils, Australian manufacturer of natural skincare, and a reseller of natural raw materials, ingredients, and associated packaging.

We have always focused on providing advice, assistance, information and resources to customers small and large, all of whom are important to us whether they be formulators, manufacturers, natural therapy practitioners, beauty salons, brand owners, or lovers of what nature has provided for us.

Our wide range of products are readily available in many different pack sizes designed to specifically suit the needs of our clients. In addition, our re-pack facilities provide an easy supply of quality pre-made cosmetic and skincare products for our customers labelled with their own brand.

With an overall governing ethos of product innovation and environmental awareness, we have developed a strong culture of embracing natural and ethical wellbeing products, and we pride ourselves in offering our customers the best service and quality that we possibly can.

In an era where manufacturing in our country has dwindled considerably, New Directions Australia has chosen to remain committed to manufacturing in Australia through investment in its facilities and employment of our people.

Our focus is to educate and empower our customers, whether it be through our interactive workshops or our free natural chemistry and formulating advice. We remain highly regarded in our industry as being at the forefront of innovation.

We invite you to visit our incredible Marrickville showroom, where you can browse and sample products for as long as you like, drink coffee or tea to your heart's content, pick the brains of our chemists, or even shop in our supermarket.

New Directions Australia is the perfect resource to turn your idea into reality.

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newdirections.com.au



Dr. Fred Züllli of Mibelle Biochemistry workshop entitled Plant stem cells and their application in the cosmetic industry

people and events in our region

Dear Readers,

In the July issue I wrote about introducing you to some of the associations in Asia connected to our cosmetic and personal care industry

It is opportune to report that the 14th Asian Society of Cosmetic Scientists (ASCS)* Conference took place on the 3rd-5th June with the theme of “Bridging the Beauty Intelligence of East & West”

The conference was organised by the Hong Kong Society of Cosmetic Chemists (HKSCC)**.

Over 300 attendees from Japan, Korea, Italy, USA, Singapore, Taiwan, Australia, Hong Kong, and China attended.

The conference was a joint conference with the 3rd Intercontinental Personal Care Excellence (IPCE). What is the IPCE, some of you may wonder? The IPCE emerged in 2016 with the joining together of the USA Society of Cosmetic

Chemists (SCC), the Society of Italian Cosmetic Chemists (SICC), and the Society of Cosmetic Chemists Japan (SCCJ)

Two pre-conference workshops with the joint support of City University of Hong Kong were given by two world-renowned scientists Dr. Fred Züllli of Mibelle Biochemistry and Mr. Elio Corrado Mignini of the Italian Society SICC.

The opening ceremony took place at the City University of Hong Kong. Dr. Jürgen Lademann, the president of the International Federation of Societies of Cosmetic Chemists (IFSCC), delivered the opening remarks and Elaine Chan, the president of HKSCC, gave the official opening speech of the conference.

The two-day conference was held in the Dr. Kao Auditorium of Hong Kong Science and Technology Park (HKSTP).



by Pam Jones

The conference podium presentations were organised into four distinct sessions:

- 1 Skin Biology and Cosmetics
- 2 Innovation of Ingredients
- 3 High-Tech in Personal Care Industry
- 4 Balancing between Efficacy & Safety.

The conference concluded with the award ceremony and gala dinner at the Hong Kong Kerry Hotel. Dr Masako Katsuyama of Shiseido Co. Ltd. Japan won the best paper while Akiko Sawada of Mandom Corp. Japan earned the best IPCE presentation.

Awards	Award winner, Company, Country
1 Best ASCS paper	Characteristic Odor Emanating from Skin at Times of Emotional Tension Dr. Masako Katsuyama, Shisedo Co., Ltd., Japan
2 Best IPCE speaker	A New Approach Using Cultured Cells to Understand How Female Sex Hormones Affect the Skin Barrier Function Akiko Sawada, Mandom Corp, Japan
3 Young scientist awards	(1) In-Hwan Choi, Kolmar, Republic of Korea (2) Dr. Xia Jiang, Lubrizol, China (3) Mr. Chijin Kashin, Seiwa Kasei Co., Ltd., Japan (4) Dr. Subhashree Mahapatra, Lubrizol, Singapore (5) Takuya Akutsu, Milbon, Co. Ltd., Japan

*Asian Societies of Cosmetic Scientists (ASCS)

Asian Societies of Cosmetic Scientists (ASCS) is a combination of 13 Societies of Cosmetic Scientists, including Japan, Korea, Australia, Taiwan, India, Malaysia, Hong Kong, Indonesia, New Zealand, Philippines, Singapore, Middle East and China. Established in 1992, ASCS is an affiliate member of The International Federation Societies of Cosmetic Chemists (IFSCC). The aim of ASCS is to promote the interchange of knowledge pertinent to cosmetic and related sciences.

****Hong Kong Society of Cosmetic Chemists (HKSCC)** is an affiliate member of The International Federation of Societies of Cosmetic Chemists (IFSCC). Established in 2003, HKSCC currently has around 50 members. But due to the reciprocal arrangement with China-SCC, they have app 300 members in total. Miss Elaine Chan is the current President.

PAM JONES has worked in the Personal, Homecare and Pharmaceutical markets for more than 30 years. She has been working out of Asia since 1996 and is well versed and connected with the Asia Market. Her experience covers technical, sales, marketing, management and training roles. She has qualifications in Chemistry, Marketing and Management. Her company PCA Consulting is well known for its training programmes. Pam has worked with and consulted to companies such as ICI, Croda, Ashland, Huntsman, Reed Exhibitions (in Cosmetics) and Connell to name a few. She is currently serving on the ASCC Technical Committee and volunteers as Technical Editor for this magazine.

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Mr. Dicky Lo, Immediate Past President
Mr. Simon Chan, Founding President
Mr. Albert Leung, Vice President.
taipun@alumni.cuhk.net
Mr. Lisa Tian, Secretary
Mr. Chris Pang, Treasurer

Dr. Shuting Hu, Scientific Committee
Ms. Liza Kwan, PR committee
Mr. Gavin Chung, Educational Committee
Mr. Francis Kwan, Membership Committee
Dr. Ka Yiu Yip, Committee



Dr. Jürgen Lademann, IFSCC president and Elaine Chan, HKSCC president joint-hosting the Lion Dance Ceremony



100% recycled cosmetic plastic packaging

If you are not using or planning to use 100% recycled PET in your skin care packaging, that is still recyclable and so clean that it's food grade certified? WHY NOT?

At Weltrade Packaging we've set the standard! And skin care Consumers are loving it.

Globally there has been a major push to lower emissions and create a greener and cleaner earth by reducing the use of plastic. Recently in QLD there was a ban on single use grocery bags and now consumers are becoming more conscious of brands who offer environmentally friendly packaging to those who don't.

The stats tell the story – 88% of

consumers would like brands to be more environmentally friendly when it comes to their packaging (forbes.com). Furthermore, 55% percent of global consumers across 60 countries say they are willing to pay more for products and services if there is a positive environmental impact (pkgbranding.com).

As an owner of a beauty and wellness packaging company 'Weltrade Packaging,' I understand how important it is to meet consumer's needs. This means, as a company we are constantly trying to innovate to provide our clients with the most advanced, sustainable and quality made packaging in the market.

We are pleased to announce that we

can now supply cosmetic grade bottles made from up to 100% recycled plastic. These recycled bottles can be made with both our PET and HDPE plastics and are available in hundreds of different shapes, colours and sizes.

The process involves plastic that has been previously marked for recycling from the food and water industry. This plastic is gathered up, washed, dried and then remade into pellets, allowing us to transform into our packaging which is also recyclable. The material is FDA approved for food packaging. This process is like a never-ending loop of sustainability. Previously we have only been able to supply bottles that are made



by Steve Welsh

with virgin plastic and that are fully recyclable, but we have not been able to sell recycled plastic until recently.

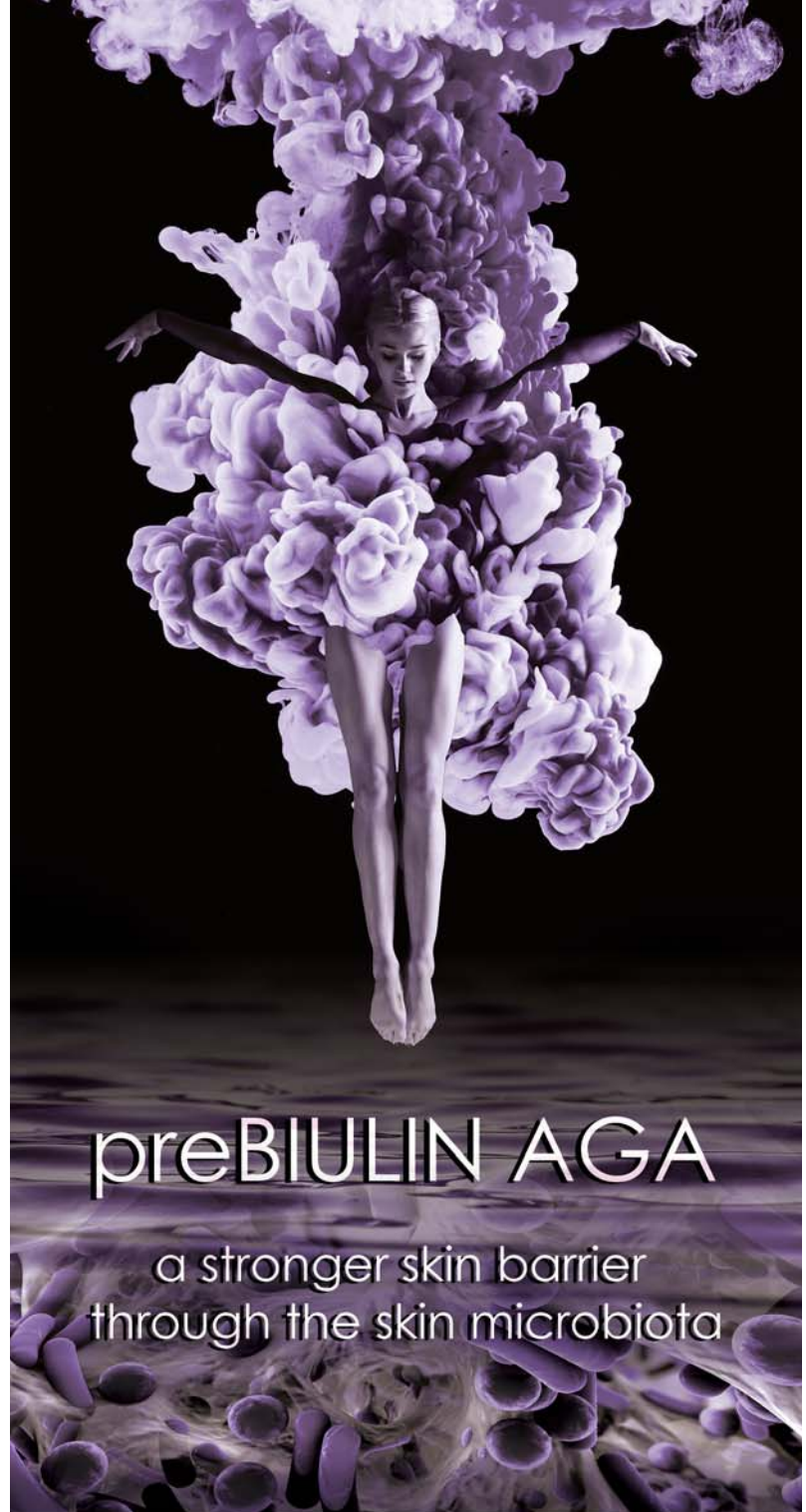
These recycled bottles will feel the same as virgin plastic bottle, but aesthetically may differ. For example, the recycled PET plastic will have a very slight straw colour tinge which may be noticed on clear and white bottles, however if anything this helps sells the brands marketing story even more.

Reclaiming plastics from what's out there to make new packaging makes common sense.

Previously too difficult and too expensive, it's now not only possible and the consumer demand removes any obstacles from the equation.

If you are interested in Recycled Plastic Packaging and would like to know more, please don't hesitate to reach out. You can contact us via our website weltradepackaging.com.au

But what we prefer is to talk in person, our team at Weltrade Packaging is ready to assist, to educate and make the process stress free and personalised. Let's start a conversation today.



preBIULIN AGA

a stronger skin barrier
through the skin microbiota

Moisturises faster and better
than Hyaluronic Acid by over 68%

Supports and maintains the skin
balance barrier

Repairs hidden damage
done by preservatives



Natural & Sustainable



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call: +61 02-88144300
visit: www.trapeze.net.au
e-mail: giz.travers@trapeze.net.au

trapeze

Headline:

IN THE INFORMATION AGE, IT ISN'T A MATTER OF *IF* IT WILL HAPPEN – AS *WHEN* IT WILL HAPPEN

by James Gillard

Whether your vocation in the Australian Beauty Industry is as an exporter, importer, manufacturer, distributor, wholesaler, retailer or as a training organisation, we are all largely dependant on technology to keep our business's running. Given that dependance, we need to be ever mindful of the threat of criminal 3rd parties hacking into our computer systems, destroying software and data, stealing client's private information, and as a result bringing our businesses to a halt.

As the headline reads, we can all be vulnerable to such Cyber attacks at some stage and when that happens businesses need a safety net like Cyber Insurance to cushion the financial impact incurred due to data disruption, re installing software programs, re establishing your firm's reputation in the market, and retrieving lost data.

The number of cybercrimes are continuing to rise and Australian businesses are becoming an easy target for local and international attackers. Cyber Insurance provides the opportunity for Businesses to mitigate their losses against Cyber-attacks, recover from loss of business, be reimbursed for Cyber-attack associated costs, provides 24/7 help from Cyber specialists and provides access to Cyber Risk related libraries and resources so you and your people can be more Cyber savvy.

So, what exactly is Cyber Insurance?

Cyber insurance is an insurance product used to protect businesses and individual users from Internet-based risks, and more generally from risks relating to information technology infrastructure and activities. A Cyber



insurance policy can be customised to protect every business AND is different from commercial crime insurance. With appropriate Cyber insurance cover, your insurer can rapidly respond to the incident. Their 24/7 assistance hotline and a team of Cyber experts are there to help you mitigate any loss and co-ordinate recovery from the incident.

Every business should highly consider having Cyber insurance.

What are the key features provided by Cyber Insurance policies for my Business?

Cyber Extortion	Cover for the damages and costs associated with mitigating a cyber extortion incident, including ransom payments where the law allows
Theft & Loss of Data restoration	Covers incidents where an information asset went missing, whether through misplacement or malice. Includes cost of Data loss, restoration including decontamination and recovery
Business Interruption	Cover for losses due to a network security failure or attack, human errors, or programming errors. Covers reasonable costs to bring your business back to the condition it was immediately before the cyber event
Breach of Privacy Liability	Cover for liability arising from failure to maintain confidentiality of data
Regulatory investigation expenses	Cover for regulatory fines (where the law allows), regulatory action defence costs and consumer redress payments
Crisis communication expenses	Cover for crisis management and mitigation measures to counter a credible impending threat to stage a cyber event against your IT infrastructure
Incident response and investigation costs, supported by a 24/7 emergency assistance service including Cyber learnings	Access to an incident response hotline supporting clients throughout the process using a network of forensic, cyber extortion, legal, notification, fraud remediation and public relations experts Access also to a range of tips, tools and Cyber related information
Social Engineering	When you or your client's emails are intercepted by a hacker and bank account details are hacked

13 point checklist on how to be more Cyber Savvy

1	Use strong passwords that avoid using personal information. e.g. birthdays, your children's names
2	Change your common passwords at least once every 90 days
3	Install required anti virus and malware software on your computer systems
4	Regularly backup to an external hard drive or the cloud
5	Be careful when surfing the web, the sites that you visit, and any two-way activity that you engage in, such as chatting on forums
6	Re-think any "click here" buttons on such sites or emails. This is done to steal your IP address (your location) and use it elsewhere unlawfully
7	Have a strong firewall and use a trusted professional to provide advice
8	Educate yourself, your employees and even your clients on the risks that are associated in keeping information, whether on hardware or software, safe on-line habits to practice and data protection
9	Stay on top of any breaches, watch for email alerts
10	Have an incident response plan in place to know what to do should this happen to you and test your privacy control
11	Look into resources that you can use to train your staff
12	Ask questions and find out what else you can do to improve your security
13	Check any requests for payment of accounts if a request is received for change of account details to which a payment is to be made

If you would like to know more about Cyber Insurance and you need a professional advisor to review your insurances, and to discuss your own individual circumstances, please contact the friendly team at IME Insurance Brokers. Ph 1800 641 260

James Gillard
Managing Director

Entrepreneur leads high-tech manufacturing boom

Clunies Ross Awards

Entrepreneur of the Year 2019

Dr Jane Oppenheim

Scientific and Operations Director,
Ego Pharmaceuticals Pty Ltd



Australian Academy of
Technology & Engineering



A scientist whose leadership has seen a manufacturing plant expand ten times, creating valuable jobs, has been recognised with one of Australia's top awards.

Dr Jane Oppenheim was presented with the Clunies Ross Entrepreneur of the Year Award at a gala event in Sydney last night (Thursday 13 June), organised by the Australian Academy of Technology and Engineering.

Jane is the Scientific and Operations Director of Ego Pharmaceuticals in the Melbourne suburb of Braeside and leads the development of skin products all based on strong science that help resolve issues like skin tears and eczema, including well-loved brands such as QV Skincare and Sun Sense sunscreen.

With exports now making up over 50% of the business's sales, demand for Ego's products across 24 nations has grown by a compound average of 12 percent over 30 years, laying the basis for continuous modernisation of manufacturing facilities and the

provision of jobs here in Australia.

Academy President, Professor Hugh Bradlow FTSE, congratulated Dr Oppenheim. "The Clunies Ross Awards have been offered since 1991, recognising people who have applied outstanding technological achievements for the benefit of Australia.

"The nation's future prosperity depends on embracing new technology to address critical national challenges.

"More than ever, we need knowledge creation, technology and innovation that can be harnessed to drive commercialisation and economic and social benefit.

"Dr Oppenheim has made a tremendous contribution – delivering skin products that change people's lives and in the process creating export-based jobs."

Dr Oppenheim said she was honoured to be given a Clunies Ross Award.

"My focus is on creating and manufacturing products that can treat and prevent skin problems.

"Use of our QV Skin Lotion twice daily reduces skin tears in residents of aged care home by up to 51 percent – which is significant, given up to 40 percent of residents can suffer tears, each of which costs \$488 to treat.

"I'm also proud of our work on improving eczema among children. Our QV Intensive Moisturiser reduces children's hospital stays and gets them back to school and family faster.

"At Ego, we're constantly upgrading our production facilities so we can manufacture better products, more efficiently. Our next step is industry 4.0 – having all our machines connected and 'talking' to each other."

Sir Ian Clunies Ross, born in 1899, was best known for his pioneering work in veterinary science. In 1949, he became Chairman of the newly renamed CSIRO.

The Clunies Ross Awards are administered by the Australian Academy of Technology and Engineering.



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dark under eye circles

by Tina Aspres

Dark circles are defined as bilateral symmetrical uniform hyperchromatic macules primarily involving the lower eyelids. They are a cause of tremendous distress to those whose dark circles portray them in public as chronically sad, overworked and sleep-deprived. Finding a solution to this centuries-old problem has proven as elusive to dermatologists, cosmetic physicians and aesthetic professionals as eliminating stretch marks and growing hair on a bald scalp. It's hard to understand how despite all the advances in medicine and science no-one can shift a bit of annoying pigment from below the eyes.

So, what do we know about dark circles? Who gets them? Why do they occur occur? Is there anything helpful that one may recommend?

Epidemiology

Whilst there are no available epidemiological studies to determine its prevalence, a google search for "dark circle treatments" returned 128 million results, indicating dark circles are a major concern for a lot of people.

Most individuals are aged between

15-25 when they first become aware of increasing periorbital pigmentation. With time, the hyperpigmentation can also affect the upper eyelid skin, even extending to the nasal root region. As the decades pass the pigmentation tends to increase.

Like most things in medicine, genetics play a big part. The condition is more common in certain ethnic groups (increased incidence in Fitzpatrick skin types IV-VI) and is very often noticed within multiple members of the same family.

Classification of dark circles

Dark circles of the periorbital region can be subdivided into primary and secondary types.

Primary dark circles are of unknown cause (idiopathic cutaneous hyperchromia of the orbital region). Typically, the pigmentation is brownish-black in colour, mirroring the shape of the lower orbital rim in its distribution and not infrequently also affecting the upper eyelid skin. Primary dark circles are the commonest subtype accounting for over 50-60% of cases.



Secondary dark circles arise due to a number of local factors, and may also occur superimposed on pre-existing primary dark circles. The commonest causes of secondary dark circles include:

- Post-inflammatory hyperpigmentation (PIH): PIH associated with atopic dermatitis or contact dermatitis may lead to the appearance of dark circles. In contrast to primary idiopathic dark circles, the hyperpigmentation in the PIH type dark circles is poorly defined, brownish or grey in colour and may be associated with other tell-tale signs of dermatitis such as dryness (xeroderma), scratch markings (lichenification), acute vesiculation, and a history of

dermatitis elsewhere.

- Vascular dilatation of dermal veins: Due to the transparency of the overlying eyelid epidermis (the thinnest skin of the body) dilated dermal veins may lead to a bluish discoloration of the lower eyelid, often with the underlying dilated veins also visible on magnification. With chronicity, vasodilatation also leads to a slow leak of red blood cells out of the vessel into the dermis where degradation adds haemosiderin staining further adding to the dyschromia. Any cause of venous congestion such as sinusitis or allergic rhinitis further exacerbates the dark circles.
- Lipoatrophy: Ageing is associated with loss (atrophy) of the infraorbital fat pad which normally lies above the orbicularis oculi muscle (a circular sphincter type muscle that is found around the upper and lower eyelids). As a result of lipoatrophy, the blueish-purple colour of the underlying orbicularis oculi muscle becomes visible through the overlying skin.
- Shadowing: Increased shadowing across the infraorbital region may result from a number of factors including wrinkles (rhytides), bony resorption of the orbital rim seen in ageing, a deep prominent tear trough or bagginess of the lower eyelids.
- Less common causes: These include melasma (rarely seen on the eyelid skin), acanthosis nigricans, anaemia, ocular refractory problems and thyroid disease.

Exacerbants of dark circles

Irrespective of a primary or secondary cause, the following have been reported to worsen the appearance:

- Lack of sleep is thought to worsen the appearance of dark circles due to greater and more persistent vasodilation of dermal blood vessels.
- Rubbing of the eyes not only traumatises conjunctival blood vessels leading to a more “blood-shot” appearance, but also creates low grade perpetual inflammation of the skin resulting in PIH.

- Stress and worsening of dark circles is frequently described by patients, and can be explained by the stress response of the hypothalamic-pituitary-axis secreting cortisol and melanocyte stimulating hormone which stimulate melanogenesis.
- Ageing changes interplay to worsen the appearance of dark circles by thinning of the epidermis, increased shadowing around the orbit and exposure of underlying dermal veins and ocular muscle. Gravity forces the eyelid skin to move downward thus becoming thinner, the infraorbital fat pad undergoes atrophy and ultraviolet radiation damages the skin thinning the epidermis and increasing wrinkle formation.

Treatment of dark circles

Any successful treatment will firstly require proper assessment of the origin of the dark circles and the taking of baseline pre-treatment photos. There is not much that can be done to change one's genetics, but various measures can be taken to try and at least minimise the appearance of dark circles.

Accurate examination requires the following approach:

- Eyelid stretch test: By stretching the overlying skin the epidermis thins (much like a rubber band thins when you stretch it). If the dark circles worsen on stretching then the dark circles are due to sub-dermal fat pad loss and/or dermal dilatation of veins
- Direct light illumination test: Illumination with direct light (such as a hand-held torch) will reduce or eliminate the dark circles if due to a shadowing effect.
- Woods light examination: Hyperpigmentation is very well defined when examined by Woods light. If the hyperpigmentation is due to epidermal pigment then the dark circles are accentuated by Woods light. If on the other hand, there is no accentuation of pigment then the dark circles are due to dermal hyperpigmentation, increased dermal

vascularity or loss of fat pad

Once baseline photos and accurate assessment is complete, the following treatment plan can be followed:

(i) Treat the cause

In most cases, dark circles have multiple causes but following a thorough history and examination any secondary triggers must be corrected. This may include treating underlying dermatitis (post inflammatory dark circles) with topical therapy, eliminating dilated dermal veins via laser or sclerotherapy, treating any chronic sinusitis or rhinitis with medication or surgery, dermal filler to improve tear troughs and to create a barrier between the overlying epidermis and underlying orbicularis oculi muscle, laser resurfacing for lower eyelid wrinkles, and blepharoplasty to reducing shadowing from lower eyelid bagginess.

(ii) Camouflage

Concealers and cosmeceuticals are an essential part of managing dark circles. Mineral makeup foundation is recommended to blend the colour of the skin to mask undesirable darker pigment in the infraorbital region or adding illuminators or light diffusers in skincare products.

(iii) Prevent further pigment gain

Once any obvious cause is addressed and simple camouflage steps are commenced it is important to put the brakes on further development of hyperpigmentation of eyelid skin. This requires the following general skin care advice be followed to ensure no epidermal irritation, no dermal vasodilatation and no melanogenesis.

- Minimum 8 hours sleep
- Soap free gentle liquid cleanser
- Bland fragrance-free emollient
- Avoidance of rubbing or scratching
- Avoid skin contact with cigarette smoke and airborne irritants (such as dust mite)
- Protect against ultraviolet radiation
- Mineral make up as camouflage (the fewer ingredients the better)

- Cold compresses to eyes to help reduce puffiness (eg cold tea bags)

(iv) Promote pigment loss

If the dark circles are primary in origin, or persist despite removal of triggers and general skin care measure, then further treatment will be required.

Promoting pigment loss is the most challenging area of treatment, as the usual approach when treating hyperpigmentation of topical lightening agents such as hydroquinone, alphahydroxy acids and topical retinoids will invariably fail and will often be complicated by irritation triggering PIH and worsening of the dark circles. As a result, managing patient expectations is first and foremost and the adage of under-promising and over-delivering should be headed at all times. When treating dark circles, no two patients will respond the same way and for every great success there will be many frustrating failures. Improvement is the goal as cure

is seldom achievable.

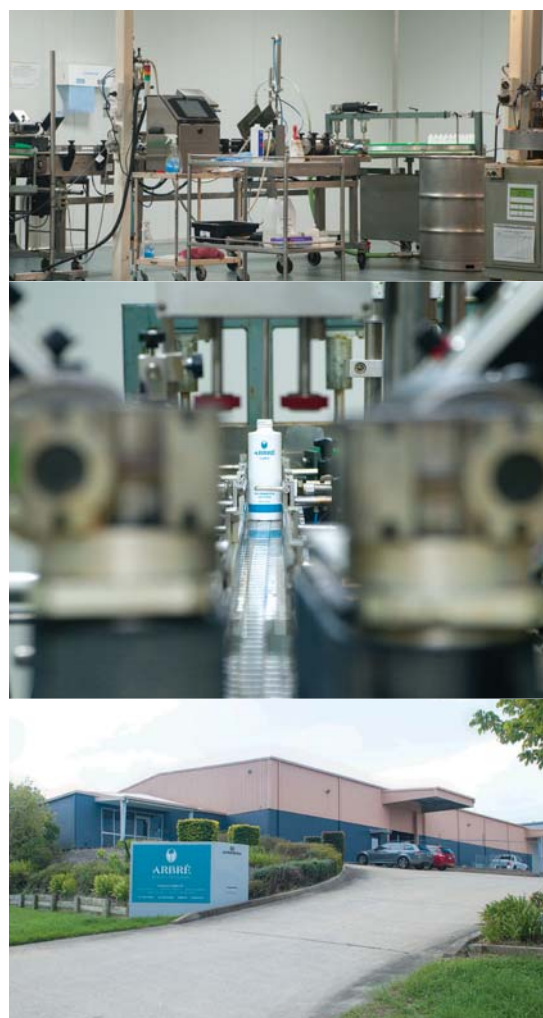
Topical agents formulated with ingredients such as niacinamide, hyaluronic acid (and other humectants), L-ascorbic acid, vitamin E, licorice and caffeine (a vasoconstrictor) are generally preferred to compounded low dose hydroquinone and/or tretinoin based products. Treatment needs to be continued for 3-6 months to achieve maximum results.

Chemical peels can be considered in recalcitrant cases and include TCA peels (10-15%) and arginine peels. Arginine is an amino acid derived from brown sugar and can be combined with lactic acid for keratolytic benefit and allantoin to reduce inflammation and erythema. It tends to be well tolerated in all skin types.

Microneedling, fractionated laser and resurfacing procedures despite much promotion are generally unhelpful.

In summary, dark circles remain one of the most distressing cosmetic

concerns affecting a large number of people. Despite the great number of available topical medications and devices purported to relieve dark circles, there are no evidence-based studies to support their use. The challenge of finding a universally successful treatment remains.



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BEAUTY PROGRAMS

objectively assessing the skin barrier function

by Emanuela Elia



In a previous article, we talked about the stratum corneum (SC), or, skin barrier. This is derived from the Latin name, meaning horned layer, which represents the outermost layer of the skin epidermis. We also mentioned that the skin barrier performs an important barrier function – it protects underlying tissue from infection, dehydration, chemicals, and mechanical stress.

Many cosmetic and dermatological products are specifically formulated to maintain or restore the SC to optimal levels, or to protect it from external factors that can compromise its healthy state.

Three important and measurable parameters can indicate an alteration (or otherwise healthy functioning) of the SC:

- 1 Skin hydration
- 2 Erythema (skin redness)
- 3 Transepidermal Water Loss (TEWL)

These parameters can be assessed through objective skin measurement instruments (probes) either in the short term (e.g. assessing changes occurring within a few hours) or in the long term (changes occurring over the course of several weeks). As you can imagine, these parameters can be influenced by

many external and internal factors such as weather, temperature, health, and so on. As a result, careful study design, and an understanding how these parameters can be influenced is even more crucial in order to ensure your study can deliver accurate and relevant results.

As such, studies should be purpose-designed to investigate how various products interact with the skin barrier depending on the specific efficacy claims to be supported. Here, we are going to describe three common scenarios, with what should be observed and expected:

Products that do not inhibit the skin barrier

If the objective of the study is to prove that the product respects the skin barrier, in the sense that it is gentle to the skin and does not interfere with normal functioning, the study will involve subjects with normal (i.e. 'healthy') skin. Assessments will be conducted at baseline and then following use of the test product at different intervals, either in the short or long term. A positive outcome would be that skin measurements record a similar level of skin hydration, erythema and TEWL

before, during and after use of the product.

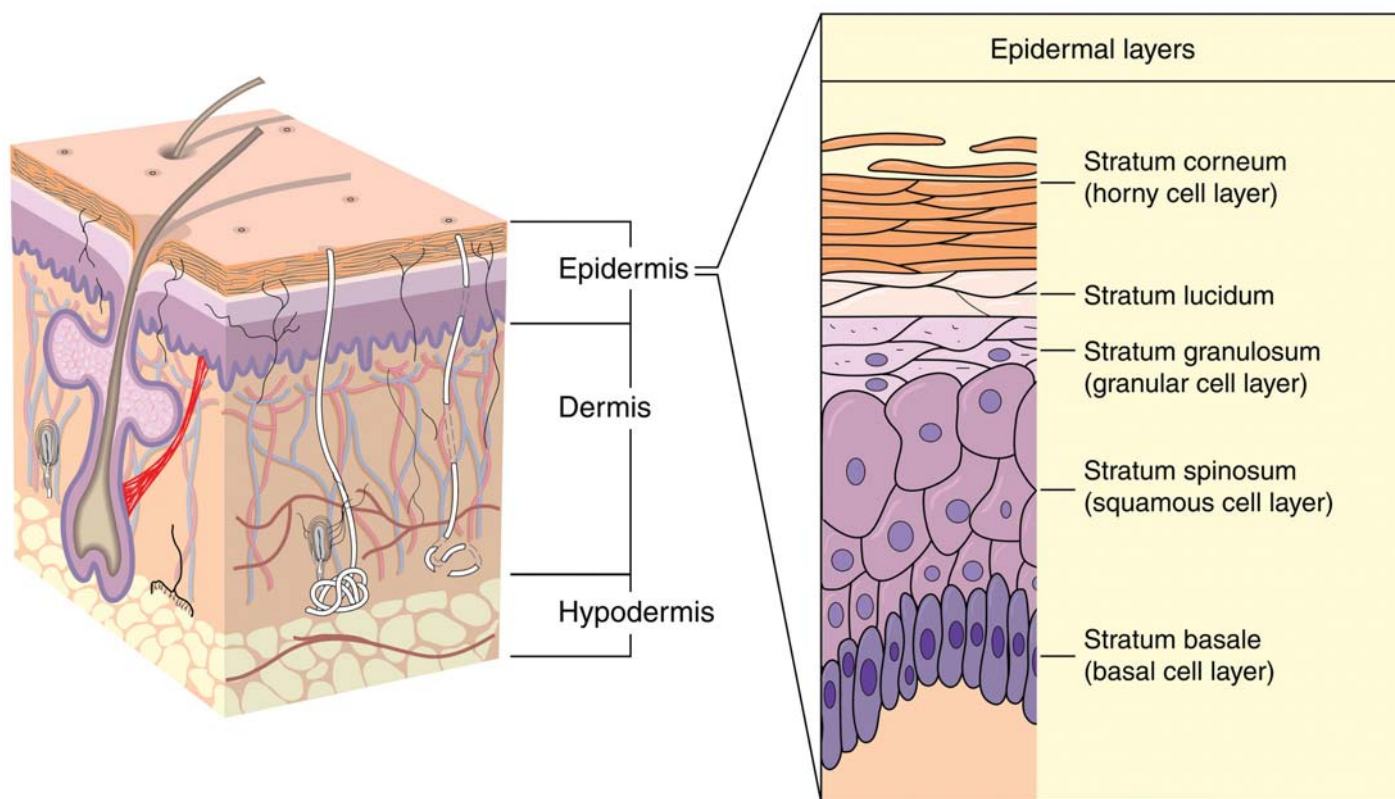
Skin is healthy before »

Product »

Skin remains healthy after

Products that restore the skin barrier

If the objective of the study is to prove that the product has a soothing effect and act as an emollient that can 'restore' damaged skin barrier due to various causes (e.g. certain skin conditions, exposure to chemical or mechanical stress, infection etc.), the study will seek to enrol subjects with a compromised skin barrier. In some cases, where the product is mainly



intended for skin barrier repair due to external factors such as localised and temporary chemical or mechanical stressors, the study can involve subjects with healthy skin where a temporary skin barrier disruption is caused to mirror real-world changes, in order to assess whether the skin recovers following product use.

Compromised skin before (either naturally occurring or simulated) »

Product »

Skin is healthy after

Products creating a barrier effect

A third study option can be adopted if the objective of the study is to prove that the product creates a protective barrier (e.g. thin layer) which cares for the skin by augmenting its natural resistance to being disrupted. In this case, the study will involve subjects with healthy skin and the product will be applied prior to an event, naturally occurring or simulated, causing skin barrier disruption (i.e. skin irritation). The aim of the study is to assess whether use of the product can (in the short or long term) minimise the effect

of events causing damage to normal skin barrier.

Product »

Event that can compromise the skin barrier (either naturally occurring or simulated) »

Skin is healthy after

There are many ways to look at healthy SC and skin barrier function. Various functions of products can be tested by the variation of initial subject characteristics, timing of product application, and parameters to be measured. Based on the claims and the intended purpose of the product, a suitable study can be designed to investigate the efficacy and safety of products specifically formulated to protect, restore, or otherwise not interfere with skin health.

EMANUELA ELIA is the Director of Ozderm, which specialises in *in vivo* testing and clinical trials for cosmetic and personal care products. Emanuela Elia has a law degree from Rome and a Master of International Business from the University of Sydney. She had collaborated with Australia's longest serving Contract Research Organisation Datapharm for a few years before setting up a cosmetic and personal care products testing facility in 2009. Emanuela is enthusiastic about improving the quality of cosmetic and personal care products' research in Australia through science.

INOLEX Amino Lipids:

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The **AminoSensyl™** range from INOLEX is eco-friendly, high performance and 100% natural and contains two products, easily differentiated by their suffix. **AminoSensyl™ HC** is an optimised blend for Hair Care, and **AminoSensyl™ SC** is an optimised blend for Skin Care. This article will cover **AminoSensyl™ HC**, and for further information on Skin Care there is also a full-page ad in this issue for **AminoSensyl™ SC**, highlighting its benefits in Skin Care products.

The global Hair Care category continues to demand high performance and is evolving to include diverse consumer needs. In the trend-setting Brazilian market, 43% of consumers look for damage claims and 55% look for moisturising benefits in their hair care products. Adding to the diversity of hair care product expectations, women in China are concerned with scalp health – 50% choose conditioner with scalp care benefits. In the United States, consumers are not only focused on performance claims. Ingredient claims are very important with 28% of US consumers perceiving that natural conditioners are “better” for their hair.¹ This multitude of global needs creates challenges for even the most experienced formulator.

The hair treatments and conditioners ingredient toolbox has typically centered around cationic surfactants. Conditioning cationic surfactants are used ubiquitously in rinse-off and leave-in hair care formulations to improve wet and dry combability and repair damaged hair. However, the majority of cationic surfactants used in personal care applications have environmental toxicity concerns, specifically poor aquatic toxicity profiles. They also carry skin irritation or skin corrosion labels that may be carried over into finished product formulations.² Additionally, quats, esterquats, or amidoamines are not possible to manufacture as 100% plant-

derived compositions. These conventional materials deliver performance benefits but are not able to meet the next level of consumer product needs.

Amino Lipids bring 100% natural and eco-friendly innovation

The 12 Principles of Green Chemistry, published in 1998 by Anastas and Warner, have promoted significant advances in molecular design for improved sustainability.³ These principles guide development of safer chemicals made from renewable feedstocks and produced with superior environmental profiles. The increased availability of renewable, bio-based alternative feedstocks has provided a pathway for innovation in the hair care category.

AminoSensyl™ amino lipids are high performance hair care ingredients, made possible by green chemistry design. The unique and proprietary molecular design of these amino lipids incorporates a quat-free cationic head group and a readily biodegradable ester linkage, both derived from a naturally sourced amino acid. The lipophilic alkyl tail group is derived from vegetable fatty alcohols. The synthetic process is strongly aligned with the Principles of Green Chemistry. It employs a heavy metal-free, one pot process where the only by-product is water. The resulting amino lipids are 100% natural, nontoxic to humans and the environment, and readily biodegradable. They meet the rising consumer demand for scalp care products – safe and gentle to skin – and natural & environmentally-friendly ingredients – 100% natural, including all manufacturing components.

The latest introduction in this space is the amino lipid Brassicyl Valinate Esylate. This 100% renewable hair care active provides a 2X increase in hair strengthening in both

leave-in and rinse-off conditioning applications. It inhibits the formation of fly-aways even in low humidity environments, moisturising the hair and giving a smooth and defined appearance. Additionally, Brassicyl Valinate Esylate performs a conditioning function so it can be used as both the hair active and conditioning agent in rinse-off and leave-in formulations. Brassicyl Valinate Esylate accomplishes these high-performance hurdles due to its unique amino lipid design. The amino acid Valine provides a cationic charge for hair substantivity. Brassica alcohol provides an optimised mixture of C18 – C22 carbon chains for strengthening and conditioning performance. The resulting amino lipid delivers high performance and provide substantial benefits for both hair and scalp. This breakthrough technology provides formulators with a new ingredient that satisfies the multitude of global hair care needs: high performance, scalp benefits, natural ingredients, and environmental safety.

INOLEX's patented **AminoSensyl™** range, a portfolio of next generation hair care and skin care ingredients, is ideal for the natural products marketplace. The amino-acid based, 100% natural, eco-friendly, and high-performance systems are based on sustainable green chemistry principles—and offer the benefits of being petrochemical-free; palm-free; quat-free⁴; readily biodegradable (OECD 301B); non-GMO; and free from animal testing. Each product is optimised for its respective category.

AminoSensyl™ HC is a pre-neutralised, natural hair care active system that provides higher performance and ease of formulation in hair conditioning & treatment products.

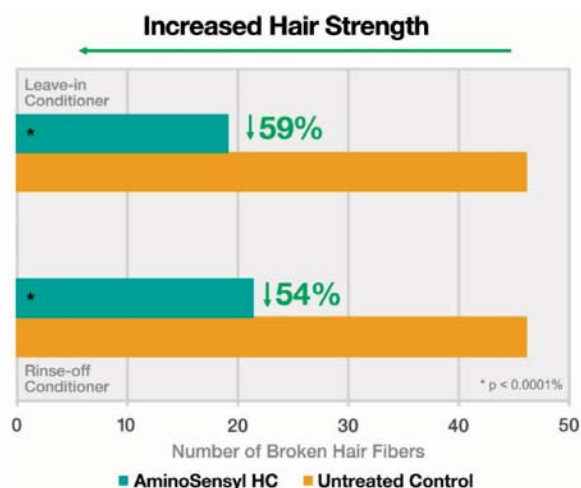
The system contains the amino lipid Brassicyl Valinate Esylate, which has a non-quat cationic charge for hair substantivity and a better aquatic toxicity profile than traditional conditioning or strengthening hair care ingredients. **AminoSensyl™ HC** delivers significant strengthening, conditioning, smoothness, and definition in hair applications.

AminoSensyl™ SC is a natural formulation system designed for all-natural, luxury skin care products that are gentle to skin and eyes. The patented amino lipid technology enables self-emulsifying formulations that stabilise high oil loads and deliver a soft, velvety aesthetic. The system combines the primary active cationic structuring agent, Brassicyl Valinate Esylate, with the nonionic structuring agents, Brassica Alcohol and Brassica Glycerides, in an optimised ratio for ease of formulation.

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2. S. Gheorghe, et al. Ecotoxicological Behavior of some Cationic and Amphoteric Surfactants, (Biodegradation, Toxicity, and Risk Assessment), In Biodegradation: Life of Science, 2013, doi: 10.5772/56199
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4. Quats (Quaternary Ammonium Compounds) are known to exhibit health and environmental hazards, including aquatic toxicity.

*A S Harrison & Co offers the range of Inolex **AminoSensyl™** amino lipid technology – for more information and samples please contact your A S Harrison & Co account manager or email performanceingredients.ash@harrison.com.au or call us on +61 (0)2 8978 1016*



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- 2X increase in hair strength in both rinse-off and leave-in conditioner applications

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This creamy conditioner provides deep moisturization to combat damage and dryness for healthier, nourished tresses.

* Patent Pending

Intensive Conditioning Bar	Trade Name	Ingredient (INCI)	%(w/w)
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	LexFeel™ N5 ¹	Diheptyl Succinate (and) Capryloyl Glycerin/Sebacic Acid Copolymer	1.00
	Coconut Oil	Cocos Nucifera (Coconut) Oil	3.00
	Shea Butter	Butyrospermum Parkii (Shea) Butter	3.00
	Spectrastat™ ¹	Caprylhydroxamic Acid (and) Caprylyl Glycol (and) Glycerin	1.00
	Glycerin	Glycerin	1.00
	Pink Salt & Water Lilly ²	Fragrance	1.00
			100.00
	¹ INOLEX ² Lebermuth		HC-1101

Radiant skin first thing in the morning

Today's agenda is full, as ever. Get to the office soon, assist to many meetings, take my son to the doctor, pick up my daughter from football or go to the supermarket... Could I escape to the gym half an hour? and that dinner with friends, pending for so long!

Empowered women choose to make the most of their life, without missing any opportunity, but the problem is that the natural rhythms of the body cannot adapt to this accelerated pace, which doesn't allow to have sufficient or restorative sleep. Skin dryness, dullness and early aging signs, among others, are problems

related to this active lifestyle.

Skin complexion varies through different moments of the day due to the biological rhythms and tends to present lower barrier function, water content and cutaneous microcirculation in the early morning compared to noontime. These biological processes are regulated down to the level of each individual cell, which has a precise molecular machinery that consist of clock genes. JARID1a acts on clock genes as a molecular switch that turns on the cell every morning, activating its physiologic functions.

Nonapeptide developed with the aim to wake up the cells of the skin, DAWNERGY™ peptide increases JARID1a and clock gene levels, enhancing early morning functions of the skin as if it was noon. It also provides an energizing effect on skin cells and has evident anti-fatigue effects even after a night out. The efficacy of the new peptide has been proven with several tests.

A unique clinical study was performed on female volunteers that applied a cream containing a dose equivalent to 1% peptide solution or a placebo cream once a day in the morning for seven days. After a dinner and a party on day seven and sleeping only four hours at night, a 16.9% decrease in volume of bags under the eyes as well as a 7.0% increase in the cutaneous blood flow were observed, suggesting an anti-fatigue effect despite little rest.

Another *in vivo* test was carried to evaluate the skin radiance and anti-aging effect of the nonapeptide. After 28 days of active treatment, macrophotographs of the face were acquired with a high-resolution camera, and images were processed with the Luminosity software, which allows to visualize the rang of

Awakening skin radiance

0 days



28 days



Anti-aging effect

0 days

28 days



luminosity values in a color map. The luminosity parameter increased after treatment, showing a glowing radiant complexion.

To determine variations in wrinkles, macrophotographs were taken before and after the treatment. A decrease of 15.4% in the coefficient of visibility of wrinkles in the crow's feet was observed after 28 days, suggesting a rejuvenated skin appearance.

DAWNERGY™ peptide activates the

cellular alarm clock to help the skin wake up earlier, visibly improving the skin complexion through its revitalizing and anti-aging activities.

It can be incorporated into formulations aiming to improve skin appearance in the morning or any time of the day by reducing signs of fatigue and providing a revitalizing treatment and can be widely used in all kinds of formulations to improve the appearance of aging signs and to awaken the radiance of the complexion.

Like an energizing breakfast, DAWNERGY™ peptide awakens skin radiance, perfect for those with an active lifestyle.

For more information, please contact Robert McPherson, Account Manager for Australia and New Zealand, at Robert.McPherson@Lubrizol.com or Tel: +61 (02) 9741 5237.

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sunscreen highlights

by John Staton

Reefs and Oceans – *protection or overkill?*

In responding to recent actions to protect the reefs and oceans of planet earth have we gone too far? Not only have we proceeded to ban the use of sunscreens in geographical “hot spots” in some US States, Puerto Rico and Palau, but the micro-plastics side, we are now seeing moves in Europe to extend the definition of plastics to include other polymers (1) Potentially, this includes those used in sunscreens in order to achieve water resistance efficacy.

It would seem to be contrary to the objectives of reef protection to disallow the use of such ingredients, since they assist in retention of the film and reduced wash off. This is particularly evident for those conforming to the Australian New Zealand Standard, AS/NZS 2604.

Prescription Only Sunscreens!

It does not help the cause of promoting of sunscreens for every day use for safety reasons to have sunscreen products

containing currently FDA approved actives given prescription only status. (2)

We haven't put our heads in the sand!

Cosmetics and personal care industry associations in Europe, USA and Australia have all called for more evidence to be collected in order to provide a true perspective (3). PCPC in USA has conducted a careful review of research published to date and this



has shown that almost all studies are deficient in scientific rigour. (3) (4)

Will UVA's most Valuable Tool be Lost?

Caught up in the ban of selective UV actives is octocrylene, commonly used to stabilize Avobenzone. Avobenzone is one of the very few globally approved actives we have in our reducing suite of permissible actives with sufficient UVA protection to provide the mandated UVAPF ratio considered necessary to protect from long term skin damage and cancers. Even avobenzone itself has come into question (5) due to environmental persistence classification.

Are we our own worst enemy?

Promoting a product as "Reef Safe" may seem to be a platform for implying that a product is more ethical, but the following needs to be considered ...

Is it really reasonable to extrapolate this claim only by not including those

actives currently reported to be potential issues?

- Reef Safe does not have a recognized or approved definition.
- Does sufficient conclusive evidence exist to confirm that competitor products are, in fact, unsafe?
- Is it helpful to the credibility of sunscreens in general to enter yet another area of marketing based on discrediting efficacious products?
- 4 UV filters have recently been banned in Palau (6), so are all of these absent from your formulation?
- Will a product promoted as "reef safe" satisfy consumer protection against false and misleading claims?
- As there is potential for a shift in focus from marine to the freshwater environment, will your product strategy have to change again – are you working yourself into a dead end?

The major industry associations all express the need for a united and consistent approach to both of these issues related to ocean pollution (7).

At this time the jury is out until the potential risks are put into true perspective.

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*biotic skincare . . .

by Wendy Free

According to Wikipedia Hippocrates (460 – 370 BC), the father of medicine, was the first to write of the medicinal virtues of fresh milk; thereafter Cleopatra (69 – 30 BC) used to bathe in Donkey Milk and in the Roman era goats and donkey milk was recognised Pliny the Elder (23 – 79 AD) in his encyclopaedic work, *Naturalis Historia*, who wrote extensively about its health benefits.

More recently in 1908, Elie Metchnikoff shared the Nobel prize for Medicine (Chemistry), and attained ‘immortality’ as the father of cellular immunology when theorised that “health could be enhanced and senility postponed by manipulating the intestinal microbiome (the gut) with host-friendly bacteria present in naturally fermented milk”; that is he discovered probiotics... **but somehow we think this is all new?**

But let’s take a step back....

What are these *Biotics?

Pro-biotics are bacteria, yeast and other micro-organisms that are considered beneficial to living things.

Pre-biotics are food for these beneficial bacteria, yeast and other micro-organisms

Syn-biotics are combined pro-and prebiotics, together in one product or

mixture.

About Probiotics... perhaps the one thing that makes our world different from everywhere is that its literally infested with life, from the bottom of the oceans to the upper reaches of the atmosphere, microscopic life in particular is everywhere. All of these life forms depend on some other part of our world, be it light, warmth, water or food sources. Even we are infested with life, scientists call this our microbiome, and apparently in each of us, numerically there are more of them than there are us... but I digress. Both inside and out we are populated by other living organisms. Some are ‘bad’ that is, cause diseases, some are good, they help us defend ourselves against the bad guys; and some are just ‘there’.

Probiotics are (typically) live bacterial cultures that, when applied topically, influence the composition of skin microflora. Through the fermentation process, probiotic bacteria produce acidic compounds like lactic acid, reducing the pH of skin. Acidifying the skin discourages the growth of most pathogens favoring growth of resident flora. Probiotic strains produce potent antimicrobials such as bacteriocidins, organic acids and H₂O₂ that prevent pathogen adhesion. Although probiotic bacteria have documented skin benefits, live cultures are generally not preferred in



cosmetics¹.

About Prebiotics... prebiotics are things that our probiotics feast on but we can’t use metabolically. Well known examples include dietary fibre, less well-known examples can include ‘oligo-saccharides’ (also called glycans) sugars that can be digested by our complement of microbes but we ourselves can’t use.

Prebiotics are non-digestible plant-based carbohydrates that discourage the growth of pathogens while preserving beneficial bacteria. Prebiotics can be readily incorporated into skincare products and are an excellent alternative to live bacteria. Bacterial cell lysates are also used in cosmetic formulations. Lysates contain cell walls, bacterial metabolites and dead bacteria².

Milk in particular contains a wide

range of prebiotics, mammals have adapted their milk to include specific Milk-oligosaccharides (MOS) also so that that the gut of their newborns develops a healthy balance of good microbes. Manufacturers of baby formula also include MOS to help promote the health and well-being of bottle-fed infants. *Other animals supplement their infants by regurgitating food for their young, having mixed it with their own microbes...*

* * *

Over that last couple of years, or decades... depending on how long you've been looking, probiotics have been on the up and up, and prebiotics are following not too far behind, especially in the food sector.

It's thus NO SURPRISE that some clever souls have thought to adapt cosmetic products to take advantage of 'new' awareness and develop a range of pro- and prebiotic products for skin care. By adding good bacteria and/or the food for good bacteria to our skincare regime to our skin care products we can 'bit by bit' look to improve our skin health and well-being.

SPOILER WARNING! 1

Australia is an island, and one of our federal government agencies works exceptionally hard to keep it free of diseases that could decimate our crops, our environment, our animals, ourselves.

Importing any sort of biological materials, ESPECIALLY live micro-organisms requires a formal risk assessment and there after a permit. See <https://bicon.agriculture.gov.au/BiconWeb4.0> **PLEASE DO NOT EVEN THINK** about importing any "M***** DIRT" or probiotics, probiotic cosmetics **without first going down this pathway.**

SPOILER WARNING! 2

So what about using un-pastured milk?

Remember the guy who won that 1908 Nobel prize? His mentor was Louis Pasteur, the guy who saved literally millions of lives with his discoveries of the principles of vaccination, microbial fermentation and ... **pasteurisation.**

That is heat treating milk (and other products) to killing off the bad (damaging / disease causing) organisms.

Pasteurisation kills bad germs (as well as good), and while a couple of germs are perhaps OK direct from the source, over time they and their toxic waste products can build up and infect your whole facility and your products. **DON'T use unpasteurised milk.**

SPOILER WARNING! 3

Not all bugs are good all of the time. If you use the types of organism usually used in yogurts you'll probably be 'OK' (No guarantees) BUT PLEASE don't breed your own! Breeding germs is very easy, most of us do this at home, in our kitchen's etc without even meaning too but improper fermentation can literally kill 3. Also be careful, some of the probiotics are patent protected, make sure that you can use them before you do please.

BUT I REALLY WANT to do *Biotic skincare...

You can! But its 'real science' not just whack this "SUPER INGREDIENT" in.

It's interesting to note that probiotics (bugs) don't necessarily need to be alive to convey skin care (and other) benefits, and that there are lots of little things you can do to make your products more biome friendly.

Beneficial ingredients in probiotic bacterial lysates include hyaluronic acid, sphingomyelinase, lipotechoic acid, peptidoglycan, lactic acid, acetic acid and diacetyl. Hyaluronic acid improves moisturization and barrier function, while sphingomyelinase upregulates ceramide production. Lipotechoic acid and peptidoglycan stimulate the production of antimicrobial peptides (AMPs), including beta defensins, and stimulate innate immunity via induction of toll-like receptors (TLR). Lactic acid acts as a natural moisturizing factor and antimicrobial, and acts on epidermal and dermal remodeling. Thus, bacterial cell lysates provide broad biologic activity that can be harnessed to provide skin benefits⁴.

To do *Biotic skincare you'll need

to think about the whole formulation. The information on skin care products is plentiful but little is scientifically documented...

promotions are based on effects, evoked by actives that are delivered through vehicles that rely on specific technologies... these products are in direct contact to the target tissue, their vehicle and ingredients are able to profoundly modulate the characteristics of the skin and some of its functions. ... many assign either the 'active' or the 'vehicle effect' (e.g., ointment, cream, gel) to a product's entirety and not unfortunately to the sum total of ingredients forming the product that remains on the skin after application⁵.

First of all, think (whisper it) **preservative**, how are you going to stop your product 'breeding' on the way to the consumer's skin, but take off once it's on the skin? Most preservatives are 'abiotic' which means that they stop bugs reproducing but they don't kill them, just like holding them in suspended animation, so when the circumstances (environment around it) changes, the bugs can do what they please. Possibly the best way to deal with this issue is to produce products that are low water activity? You may have other ideas, *but do think about it.*

Next **surfactants, solubilisers and emulsifiers**... All of these guys work by bringing together oils and water, while this creates a great cosmetic rheology it doesn't do much for functional micro-biologicals systems that work best by compartmentalising these systems; letting each do its own thing. Many of surface active are in themselves partially abiotic, that is they help to stop bugs proliferating; many anionic and cationic surfactants are good examples. Both work differently on different types of bugs but help to create an environment that is less conducive to growth than what it otherwise might be.

Then consider essential oils and perfumes, anything containing 'terpenes' really, we've worked so hard to make our products abiotic... it's a real paradigm change to make them pre- or probiotic!

*Biotics can be more than the *next* big thing but you'll need some science

behind you to make it more than hype...

Yours in biologically perfect biomes, Wendy.

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Interesting READING

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GARDENING – as an EXTREME sport

Now before you all go “WHAT THE HECK” “She has gone off altogether”, let me pull you back into your chair, get you strapped in and have a whizzy sporty moment with me.

Dora said I should do more “work/ life balance” stuff in my writing and suggested a topic on exercise. After I adjusted my active wear, I gave the idea some thought.

I went back to work and met a couple who had brought in some earth that they wanted to make into a really great face mask. Really nice people with an idea that they wanted to bring to life. One of the pair was very funny and when I told him part of this tale about bugs, bacteria and fungi, declared with some incredulity, that “gardening was an extreme sport”. Bloody fabulous and it inspired me to write this article.

Anyone familiar with me, will know that I am into this sport called gardening

BIG TIME. I have just come in from being extreme this morning. Lucky that when the sun is out, some parts of the garden, even in mid-winter (and by golly this winter has certainly lived up to its name) are sunny and very warm, and one can get very hot indeed, especially when there is activity.

Gardening, in my experience, has always been good for ones soul, brain and offers quite a bit of the Dora type exercise.

In researching this, if one searches extreme and gardening, most sites are about muscle strain, warming up before digging, bending, planting. Otherwise they contain beautiful piccies of wayout plants and design. All very fab but not what I wanted to discuss.

One of the reasons I love gardening is for the pleasure it brings me together with the therapeutic aspects of being close to nature. Often I do some of my



by Margaret Smith

best thinking while pottering amongst the plants – without really focussing on anything other than the plants in front of me. This has allowed me to crack hard nuts I cannot during normal work hours. However, as a safety aware gardener, I do wear protective gear. Gloves, long trousers and sleeves, actual shoes not sandals. I have not started wearing face masks... Yet. What I am weaving here is

the interconnections of the natural world and the cosmetics and I guess marketing world.

In the last very short while, our factory has had a number of enquiries from prospective clients about making cosmetics using their gorgeous natural dirt, mining byproduct or mud. It is introduced to us using many names be it clay, mineral, mud or whatever, but basically what we are being asked about something that more often than not is an unvarnished, unbleached and unsterilised material.

I listen and ask questions like, 'has it been sterilised for use on the skin'? Or 'has it been sieved and is 100% free of all foreign lumps'?

Sometimes the questions are clearly not ones that have been considered before our meeting because the silence can be deafening. Generally if we get a reply, it is about that is has not hurt them or it is for food so it must be OK for cosmetics.

So here is my reply why I want to know.

In July this year, there was an article in The Age newspaper about the Buruli Ulcer. A very nasty SOB that now has been identified as a flesh eating bacteria that is 99% thought to have once been a dormant bacteria until it was disturbed from the depths through floods, mining, bore drilling and the like. Now out in our environment (ie the surface layer soil we are exposed to) it is being spread about via vectors like possums and mosquitos. It is also "caught" by gardeners with maybe a scratch or prick digging about in soil that contains the bacterial.

Now a few hundred cases of this horror have been reported around the Mornington Peninsula over the years, and that may seem all that many, however there have been thousands of cases over the decades both in Australia and "over there", and usually after a flood or volcanic eruption or both. Not a lot of floods or active volcanoes around Melbourne, so it is surmised the bug resides in our ancient soils and is just waiting on being disturbed then fertilised.

So ancient bugs get spewed up from the damaged earth and are fed in the air and sunlight, possums dig about, get the bug, ulcer up, mosquitoes transfer said bug from the purulent possum and give it to some poor bugger sitting on their deck enjoying a chardonnay in Blairgowrie or Brighton.

Not only the chardy sippers are coping it. Now it is gardeners just happily digging and fertilising away that have ended up victims of this very nasty little critter. It is nasty and can cause amazing pain and suffering to those who are the unfortunate victims.

Buruli bug is not alone.

Just a handful of other delights are Legionellosis, the little devil that will get into your lungs and kill off the susceptible, whilst they are dreaming of the delphiniums they will not get to see bloom.

Tetanus is well known for those who insist on being tough amongst the roses without gloves. Even I got tetanus once as a kid, but that was me trying to feed a feral cat in the front yard. Yep it fed, on my fingers.

Another rose growers nemesis is "rose gardeners disease" which appears to be a mixture of *Aspergillus* and *Sporothrix* fungi. It is another flesh eating ulcery type of thing.

Then there is Melioidosis, this gives the gift of feeling really crap. Most commonly found in tropical climates, the positive is that in Queensland, it has a lower mortality rate of only 21% against over 50% in some other overseas tropical climes. Not fun at all. So there is a low side of living in the sun, apart from the crocodiles!

Then there is the old standby Sepsis that can just happen in the garden to an open wound or resulting from untreated ulcers and abscesses that knocks one or two limbs off if not the entire body. As I mentioned earlier, gardening as a sport can be EXTREME.

So there are just a select few of the greeblies that could infect you, if one just willy-nilly used a natural muddy product on one's skin. Given that many face masks are targeted to a group that may

have angry or even compromised skin in the first place, this is not a good idea.

All the natural things I have tested that have been passed onto me from customers over the years have never been below 1,000,000 colony forming units (cfu). Aloe Vera, honey, lots of vegetal extracts and of course the said dirt, once mixed with good sterilised water can grow "sea monkeys" (as I call the things that proliferate in vast numbers). Cosmetics generally contain water. We have had "special" water given to us to use in cosmetics too, and this must be sterilised, due to a usual high bug count containing our nemesis, *pseudomonas*.

In a couple of cases I have refused point blank to use a Gamma sterilised material provided to us, mainly because the pH was totally wrong for skin. The pH adjustment would be so extreme in itself that it changed the entire point. It also had *pseudomonas* and or something else nasty that quite frankly I don't want to get anywhere near my facility.

Sterilising does not interfere with the therapeutic delights in dirt or mud. Indeed most mud purveyors make a point of telling us that their products are clean of bugs and have been Gamma irritated for protection.

Now in the whole scheme of things a million cfus is nothing, and our skin can handle it as long as it still has plenty of the good guys to combat potential 'nasties'. However regulatory authorities in much of the world have a tolerance to natural materials of about 1,000 cfu and some parts, well they have ZERO tolerance. So, from a regulatory point of view it is more about the overall numbers and less about whether the cfu's detected are 'good' or 'bad'.

So not worth pushing it. Not with the regulators or with a cosmetic manufacturer who has to do massive decontamination everytime they process an order using said materials.

Modern preservatives are effective, however, the low levels required by consumers and authorities mean that they do not act as a biocide and knock off all bugs like they used to.

Cosmetic manufacturers like us much

prefer to start with clean materials and add as little preservative as possible to keep the final product stable and safe.

If the product has a positive bug count it may be non-conforming to the regulations of the land and could well be basically dangerous and downright stupid.

A small word about bugs (bacteria) and fungus. Most are OK, even cool. Michael Mosley (the famous TV doctor) has embraced the zoo that lives on and in us...except for the SUPER BUGS.

It looks to me like Buruli is one of them. Some people cannot shake it.

Microbiota just hanging about on our bare skin ranges between I think 20,000/cm² to a couple of million. Most are fine, in fact a necessity to our general wellbeing. If a bad boy microbiota clings on, this little army usually despatches them. Our skin is a fabulous battlefield, as long as we keep the good stuff fed with nice nutrients at the right pH.

There are other things that can be

in dirt, like heavy metals, sewage, pollen and greywater. And don't forget always animal waste, always in dirt and much on plants. No amount of Gamma sterilisation is going to help clean out that.

Leave the bugs in the ground, put a do not disturb sign on it.

And if you must, keep it clean.

Now back into the extreme active wear with extreme gloves and out into the sun!



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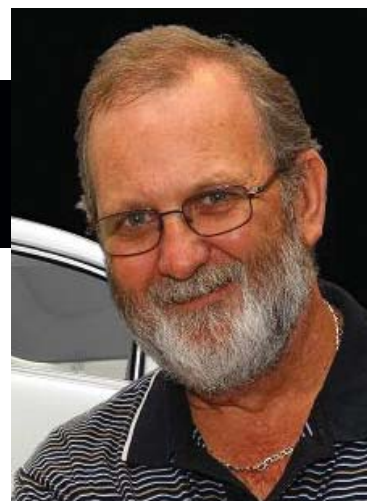
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by Ric Williams

Part 47 –

Irritation and Sensitisation

Irritation

Irritation is a chemical or mechanical reaction on the surface of the skin in response to an external stimulus such as hot water or strong acid or base. With the exception of strong mechanical or chemical reactions, an irritant response may or may not recur; it also can be affected by seasonal variation. For example, much more soap irritation is observed in winter because the skin has become somewhat compromised by the cold and dry weather. Irritant response also can be concentration-driven.

Sensitization

Sensitization is a warning mechanism designed to protect the body from a strong allergic reaction that could be fatal, such as a bee sting. It is an immune response that is slower to develop, taking days of repeated exposures. A person can be exposed numerous times before experiencing the classic allergic response, as opposed to some irritant responses that can be immediate or take a short time to develop.

Once a person is allergic, he or she is always allergic. The body never forgets and exposure to a much lower concentration of allergen can cause an allergic reaction. Again, this is a good thing because a minimal response prevents people from further and continued exposure that could lead to a strong and possibly deadly reaction.

Inflammation

The body's normal reaction to a threat is manifested in "Inflammation". In order to eliminate the danger, the body's immune system initiates a cascade of reactions (a process where the immune system produces various chemicals including, cells, small peptides named cytokines, hormones etc. to battle an antagonist such as bacteria, radiation or a chemical.), resulting in "inflammation" as a visible sign. The visual "inflammation" is due to the body elevating the temperature at the site, increasing blood flow and nerve sensation, etc. This appears as redness (erythema), swelling (edema) and local heat.

Infection

The invasion and multiplication of microorganisms such as bacteria, viruses, and parasites that are not normally present within the body. An infection may cause no symptoms and be subclinical, or it may cause symptoms and be clinically apparent.

Summary

an *irritation* is a surface response to a stimulant;
an *allergic reaction (Sensitisation)* is a biochemical response to repeated exposures
Irritants can irritate one day and not the next, whereas an allergic response is forever.
Inflammation may result from an irritation or sensitization.

Ric Williams B.Sc. Dip.Env St.
Cosmepeutics International

This column is intended not only as an education tool for non-technical people or beginners in our industry, but as a forum for those wishing to enlighten all about recent technology advances and new ideas. I hope experienced scientists will also contribute to this ideal and if you wish to do so please email me at: ric@cosmepeutics.net.au and I will publish your comments.

When you get skin irritation (increased sensitization) there could be many factors, some of which are not related to an external stimulus or the formulation you suspect (eg a person's health, medication being taken, or specific diet effects). All of which can affect skin's reaction to common (normally non-irritant) materials.

There are many other factors may also be implicated in skin irritation, such as:

Structure of skin

hair density, skin thickness and physical health of skin have an effect. Note people normally exposed to outside environmental conditions may have a greater resistance to irritation/sensitization due to changes in skin structure.

Biochemistry of skin

lipid composition and concentration (from diet), moisture content (dependent on external humidity) and the general energy levels (fitness) of the subject have an effect.

Sex

male skin tends to be a greater barrier than female skin.

Age

the older you get the less penetration occurs due to the loss of

general structure of skin, however this may be offset by older skin becoming thinner, hence have less barrier protection.

Heredity

some may have enhanced protective ability because of heredity factors such as thick skin or colouration.

Disease

dermatological (eg exposure of lower layers of skin increasing absorption) and systemic (hardening of the blood vessels slowing down transfer to the circulatory system), plus any damage to the immune system will offer less protection when it comes to external attack.

Physical damage

scarring will prevent absorption while abrasion or cuts will increase absorption.

Environment

increasing temperature and increasing humidity will increase absorption and possibly increase irritation.

Diet

Nutrition will affect absorption, as healthy skin will behave



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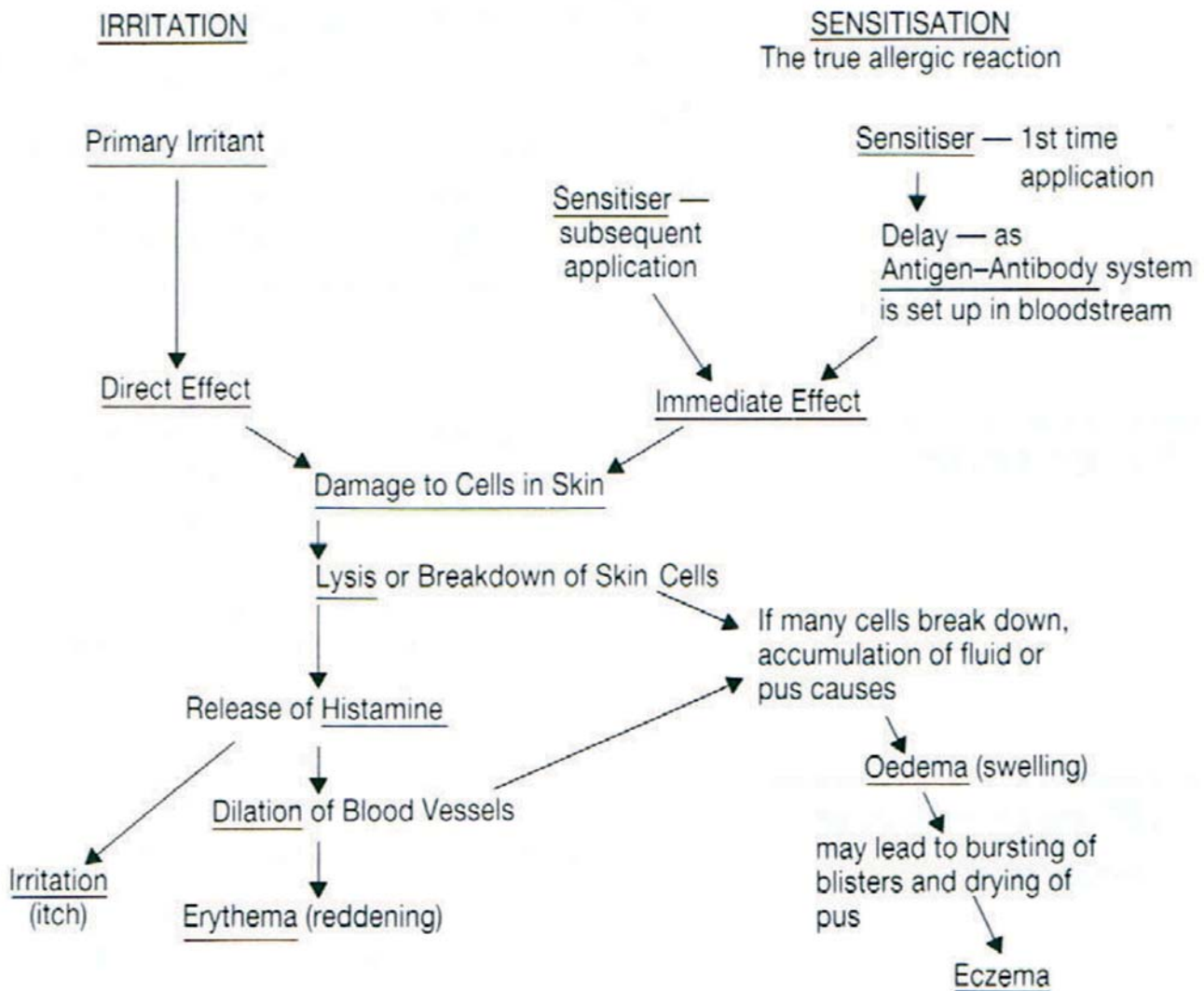
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normally and unhealthy skin may either have greater or less potential to irritation.

Drugs

drugs (either prescribed or not) will affect absorption, as some drugs will alter skin physiology and either aid or decrease skin absorption.

Both diet and drugs can affect blood flow and glandular function which in turn affect absorption.

We cannot guarantee that any product, no matter how careful we formulate to mildness, will not cause any problem in some person somewhere, sometime. That is there is no 100% guarantee, and to try and identify a culprit would be far too onerous a task.

Natural vs Synthetic

One realizes that the term “Natural”, used in today’s advertising, infers that the material or product is safer than a synthetic chemical. This cannot be further from the truth. You will notice that the definition of “Natural Ingredients” (as any material which has been harvested, mined or collected, and which subsequently may have been processed, without chemical reaction, to yield a chemical or chemicals that are identifiable in the original source material) does not contain the word “safe”. Natural ingredients should be, where possible,

minimally processed in a manner consistent with the product to preserve its natural properties.), in common with nearly all variations on the theme, does not mention ‘safe’, in the same breath as ‘natural’. This is important since the two words are not synonymous – some natural materials are safe, but many may be quite hazardous or even fatal if incorrectly or inappropriately used. Belladonna extract is a known deadly poison, “Rotten Egg Gas” (or Hydrogen Sulfide) is far more deadly a gas than Hydrogen Cyanide – the only reason they use Hydrogen Cyanide in gas chambers is that it is odourless (a little more humane?), almost all the pure essential oils, we use, are considered poisons or irritants by the government regulatory authorities – the list goes on. The corollary is also false – it is a fact that many synthetic chemicals used in cosmetics are amongst the safest (with respect to toxicology, skin irritation or allergic reactions) as they have been scientifically engineered to be so, also undergoing some of the most stringent testing – something a lot of natural ingredients have not.

Allergic Reactions

The human body contains a class of substances called histamines that are activated in response to different materials, chemicals, or odours it finds offensive. When a histamine is activated the body reacts by:

1. Sweating
2. Itching
3. Swelling
4. Becoming red
5. Skin irritations such as rashes
6. Uncomfortable sensations under the skin.

Some of the most common allergies are asthma, eczema, poison ivy and hay fever.

There are thousands of substances that can cause an allergic reaction many of which are found in the environment (smog, pollen, etc.). From cosmetics, perfumes or preservatives are the most common ingredients likely to cause an allergic reaction. Even the so-called “Hypoallergenic” products can cause allergic reactions as the word “hypo-allergenic” only means that a product is less prone to cause a skin allergy. There is no guarantee that a product will not cause a reaction as many contain little or no fragrance. Don’t feel guilty if a client develops an allergic reaction. It is not anybody’s fault – not yours or the manufacturers. At some stage anybody can develop an allergic reaction to almost anything. It may be influenced by diet, by medication, by the environment they have been in. People have been allergic to pure cotton or other soft materials. Advise your clients about allergies and how to recognise them. If a client feels any of the symptoms after you have applied a skin care product, remove it immediately with a cleansing pad soaked with water. Then spray the skin using the cold spray machine filled with distilled water. Apply a soothing mask.

Test for an allergy to cosmetic products by:

1. Cleanse the skin with surgical spirit.
2. Dab onto the forearm a small quantity of the cosmetics you are testing.
3. Mark onto a strip of paper the products being tested.
4. Seal the products with adhesive skin tape and examine 24 hours later.
5. If an allergic reaction has occurred an itchy skin eruption with redness and swelling will be apparent.
6. Note the product that reacts from the strip of paper.

Photosensitisation

Photosensitisation is a skin reaction that occurs in the presence of ultraviolet light. Certain constituents of essential oils are capable of absorbing energy from ultraviolet light much more effectively than the skin. Essential oils listed as photosensitisers are hazardous only in this context. To simply apply these oils to the skin diluted or undiluted will not itself produce a photosensitisation, which can only be achieved if the skin is covered in a photosensitising oil and then exposed to the sun or any other source of ultraviolet light.

The most common phototoxic agents are psoralens, otherwise known as furocoumarins. These polycyclic molecules whose structure gives them the ability to absorb ultraviolet light (photons), store them for a while, and then release them in a burst on to the skin.

Citrus oils extracted by direct expression without distillation

are the major group of phototoxic essential oils containing furocoumarins. Bergamot and other expressed citrus oils contain small quantities of a furocoumarin known as Bergapten (or 5-Methoxypsoralen or 5-MOP).

As can be seen from the table below, the phototoxic potential of citrus oils is minimised when the furocoumarin content can be reduced to 0.0075%.

Phototoxic Essential Oils

Bergamot, Cold Pressed Lime, Cold Pressed Bitter Orange, Angelica Root, Cumin, Rue and Opoponax.

Mild Phototoxic Essential Oils

Cold Pressed Grapefruit, Cold Pressed Lemon, Cold Pressed Sweet Orange, Cold Pressed Tangerine, Fig Leaf Absolute, Verbena Oil and Tagetes,

Essential Oil	Furocoumarin Average Content	Phototoxicity at 100%	Level when not phototoxic
Bergamot	0.4400%	Strong	1.0 – 2.0%
Lime	0.2500%	Strong	2.0 – 3.5%
Bitter Orange	0.0720%	Moderate	3.5 – 7.0%
Lemon	0.0032%	Weak	5.0 – 10.0%
Grapefruit	0.0012%	Weak	10.0 – 20.0%
Sweet Orange	0.00005%	Mild	No Limit
Tangerine	0.00005%	Mild	No Limit
Mandarin	trace	Mild	No Limit

The risk of phototoxicity will remain for up to 12 hours, following the topical application of any phototoxic essential oil.

The best advice regarding the use of essential oils that may cause a phototoxic reaction is to use less than 1% in the blend. Also to wear protective clothing and a sunscreen that will block out the ultraviolet light or not to go out into the sun for at least 12 hours after a treatment or product use.

Allergens in Toiletries . . . Information for Labelling

The 7th amendment to the EU Cosmetics Products (Safety) Regulations 2003 required allergens of certain listed varieties to be included in the list of ingredients on toiletries in the following concentrations (as a %age of the overall ingredients of the finished product)

Leave-on products (eg. skin creams) 0.001%

Rinse-off products (eg. soaps, shampoos, shower gels) 0.01%

The list of allergens required to be indicated on the label if registering your product in Europe, if present, is:-

Amyl Cinnamal
Benzyl Alcohol
Cinnamyl Alcohol
Citral

Formulator's Forum

Continued on page 59

why register a design?

by Gint Silins



Product shapes and appearances can be of commercial importance to businesses and hence worth protecting. The Australian Designs Act 2003 allows for the protection of visual features of a product (or part of it), namely its shape, configuration, pattern and/or ornamentation. However, the Act does not protect what the product is made from or how it works. These may be protected by patents.

The Act aims to give the owner exclusive rights to apply the design to mass-produced products for a limited period of time. Examples of commercially important designs in the personal care industry that have been registered under the Act are shown and include: shapes of packaging and containers (eg. perfume bottles and jars), shapes of products themselves (eg. soap bar shapes, toothpaste extrusion patterning and beauty masks), as well as get-ups, graphic designs, logos and labels. The images were obtained from IP Australia's Australian Design Search Database at <https://search.ipaustralia.gov.au/designs/search/quick>.

A design registration has effect throughout the whole of Australia and can provide protection for up to 10 years.

The process is initiated by filing a design application that includes images of the product's appearance as well as details of the designer (the design's author) and

owner. However, in order to obtain a valid design registration, there can be no public or unrestricted disclosure of the design prior to the filing of the application.

A formalities check is carried out by the Designs Office shortly after filing the application and the design will be registered if all formalities have been met. Although registered, the owner of the design registration will not be able to commence infringement proceedings against an alleged infringer until the design registration has been certified.

Certification entails requesting substantive examination of the registered design. Substantive examination can be requested at any time after registration. If the Designs Office, after carrying out a search of earlier designs, deems the design to be 'new and distinctive' and not 'substantially similar in overall impression' to an earlier design, the design will be certified. If not, the registration will be revoked and all rights will cease.

The initial term of the design is five years. Provided that a renewal fee is paid within five years from the date of the application for registration, the term can be extended to 10 years.

Searches of IP Australia's Australian Design Search Database should be carried out to ensure that commercial use of that design won't infringe on the

design rights of others.

On a similar note, searches of IP Australia's Australian Design Search Database should be carried out to ensure that the design is likely to be registrable.

Business owners should keep in mind that, once products bearing a design are mass produced, the design may or will lose protection under the Copyright Act 1968 (as amended). However, there are exceptions to this rule, particularly in relation to two-dimensional designs (pattern and ornamentation).

It is suggested that businesses in the personal care industry carefully review their packaging, products and artwork, and register those (if still possible) that are commercially valuable.

This article is intended to provide general information only and the contents should not be relied upon as legal advice for any specific case.

New Water Resistant Film Former for High SPF Emulsion Sunscreen with Improved Aesthetic Properties

by Jane WANG, Brian Patten

Jane.wang3@nouryon.com, AkzoNobel Surface Chemistry

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From water-resistant products for use at the beach, to daily-wear moisturizers, today's sun care products demand both superior function and consumer-pleasing form. Products need to feature easy application, rinse-off and rub-off resistance as well as excellent aesthetic properties and providing stable, broad spectrum UV protection.

For emulsion sun care products, a new upgraded Acrylates Copolymer provides effective and durable film formation, enabling the formulation of long-lasting, high SPF systems. Easy-to use and cost effective, the acrylates copolymer helps to create a wide range of products that provide excellent skin feel on application and dry-down and appeal to consumers seeking the best in sun protection.

Supplied as a liquid aqueous emulsion, the new acrylates film forming copolymer is easily dispersed in the water phase of oil-in-water emulsions. The polymer can either be added into the water phase prior to forming the emulsion or post added after the emulsion is formed. It requires no heat or neutralization and can be used in either hot or cold emulsification processes. The material can be used at typical sunscreen formulation pH ranging from 4 to 7.

Film forming polymers designed for use in emulsion-based sunscreens were

evaluated in SPF 50+ emulsion sunscreen system, which is listed in table 1, for rub resistance, in-vivo static and 80 minute very-water resistant SPF test as well as Aesthetic properties.

Table 1 SPF 50+ Emulsion Sunscreen System

	Ingredient	Weight %
Phase A	Deionized Water	50.46%
	Dissolvine® NA2-S chelate	0.10%
	Propylene Glycol	2.00%
	Phenoxyethanol (and) Ethylhexylglycerin	1.00%
	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0.40%
Phase B	Avobenzone	3.00%
	Homosalate	13.00%
	Octisalate	5.00%
	Octocrylene	8.00%
	Glyceryl Stearate (and) PEG-100 Stearate	2.50%
	C12-15 Alkyl Benzoate	5.00%
	Dimethicone (350 Cst)	2.00%
	Polymer B, C	1% active
Phase C	Triethanolamine-99%	0.60%
	Deionized Water	4.00%
Phase D	Polymers A, D	1% active
Phase E	50% Citric Acid Solution	0.13%
pH 6.0	Total	100.00%

A: Acrylates copolymer

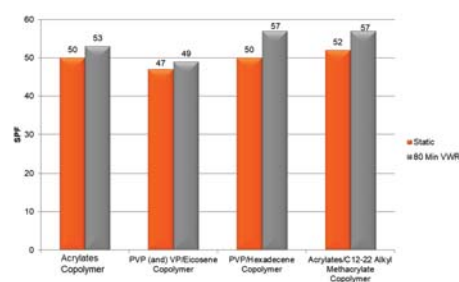
B: PVP (and) VP/Eicosene Copolymer-

C: PVP/Hexadecene Copolymer- Ganex V216 (ashland)

D: Acrylates/C12-22 Alkyl Methacrylate Copolymer- Allianz OPT (ashland)

In-vivo SPF in both static and 80 minute very-water resistant performance is listed in Figure 1, which shows that 1% acrylates copolymer offers acceptable static (SPF50) and VWR data (SPF53) to the emulsion-based sunscreen using the FDA protocol¹. The competing polymers also offer similar performance.

Figure 1 Invo SPF and Water Resistance testing



Rub resistance test was done via applying the sunscreen films onto a glass plate, let it dry out, then rinse for 1min to check the loss weight% of the sunscreen film. Test data suggest that addition of 1% this acrylate copolymer will help to retain ~82% of the sunscreen film. It's superior than addition of 1% PVP (and) VP/Eicosene Copolymer, PVP/Hexadecene Copolymer and Acrylates/C12-22 Alkyl Methacrylate Copolymer

Polymer in Formula	Average % Substantivity
New film forming polymer	82.71
PVP (and) VP/Eicosene Copolymer	68.01
Acrylates/C12-22 Alkyl Methacrylate Copolymer	62.80
PVP/Hexadecene Copolymer	55.25

Aesthetic properties were evaluated using training panels. As demonstrated in below table 2, the new acrylates copolymer essentially brings no negative feeling compared the base formula without polymer. It offers a lighter feel with pleasant aesthetics and less tack on skin compared to a benchmark acrylates copolymer, while is similar to another competitive benchmark, PVP and VP/Eicosene Copolymer, in most aesthetic categories.

In summary, this new film forming acrylate copolymers can provide essential water resistance properties to high SPF emulsion sunscreen product, with good rub resistance as well as light in use aesthetics performance.

Department of Health and Human

Table 2 Aesthetic panel testing result

	Spread-ability	Slip	A. of Residue	Greasiness	Oiliness	Stickiness	Prefer
New polymer	=	=	=	=	=	=	=
Blank (no polymer)	=	=	=	=	=	=	=
New polymer	+	=	+	=	+	+	+
Acrylates Copolymer	-	=	-	=	-	-	-
New Polymer	=	=	=	+	=	=	=
PVP(and) VP/Eicosene Copolymer	=	=	=	-	=	=	=
New polymer	=	=	+	=	+	+	+
Acrylates/C12-22 Alkyl Methacrylate Copolymer	=	=	-	=	-	-	-
New polymer	=	=	=	=	=	=	=
PVP/Hexadecene Copolymer	=	=	=	=	=	=	=

A “+” means that the product performed more favourably in that category, i.e. a “+” in stickiness means the formula tested less sticky.

Services; Food and Drug Administration; Center for Drug Evaluation and Research (CDER). Labelling and

effectiveness testing; sunscreen drug products for over-the-counter human use. Fed. Regist. 2011, 76, 35620–35665.

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Spray: experiencing polymer gels release

by Emmanuelle Merat¹, Marion Dumaine¹, Alicia Roso¹, Frederick Santos

¹SEPPIC, 50 Boulevard National, 92250 La Garenne-Colombes, France

Introduction

Cosmetic users need claims supported by efficacy studies. However, the ease of use of a product contributes greatly to the perceived quality and overall satisfaction, integrating packaging. Spray is, on one hand, a common delivery way for sun protection, moisturizing, body mist, hair care, etc. In the other hand, it remains a formulation challenge to combine stability and suitable distribution on skin. In this purpose, the quest of key parameters to control is still an open debate. Due to their leading influence on formulas' rheology profile, polymers are key ingredients, both for stability and spray diffusion. Moreover, they are inescapable components from aqueous gels to cream gels and emulsions composition. Last investigations were done to discriminate the quality of spray through shadowgraphy technique, trying to find answers to THE question: "what are the criteria to control".

Material and methods

The spray ability of polymers obtained by different technologies, but with the same polymeric backbone, was challenged at realistic use levels, at an equivalent content in terms of polymeric

active matter 0.5% (table 1). Resulting texturized waters are at equivalent Brookfield viscosity, i.e. 20,000 mPa.s (spindle 4, speed 6).

	Trial P-NC74505	Trial L-NC74506
Raw material	% trade product	
Demineralized water	Up to 100	Up to 100
Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer = Powder polymer	0.62	/
Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer & Iso- hexadecane & Polysorbate 60 = Liquid polymer	/	1.22
Preservative : Phenoxyeth- anol & Ethylhexylglycerine	1.00	1.00

Table 1: Quantitative compositions of the aqueous gels

The first screening consists of an in-house protocol, very simple but effective to discriminate the sprayed formulas given a wide diameter (positive standard is water) from others with a reduced diameter at the impact (figure 1).

The measured parameter is the diameter at the distance of 7cm, which is an approximate value, enable to select acceptable diffusion in a first step.

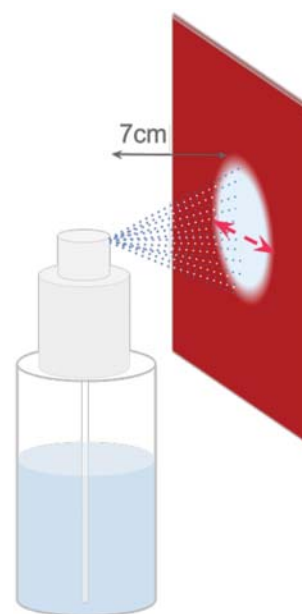


Figure 1: Measure of the fluid emission diameter on a tinted card support (mm)

Texturized waters are further evaluated by shadowgraphy technique (R&D Vision, France), that allows objective measurements of spray angle, speed, size and concentration of droplets. The assembly consists of a high-speed camera associated either with a standardized background to visualize the shadows of the spray (figure 2) or with a laser beam for measurements in cross section of the jet (tomography).

The capacity of the camera in terms

of speed is adapted to the width of the view: 4,000 frames per second for the large view (up to 15cm from the nozzle) to study the general morphology of the spray, 10,000 frames per second for the narrow view, to measure the genesis parameters for instance. As a reference point, the camera of a smartphone films at 20 frames per second! In the case of granulometry study, the camera synchronized with the laser beam takes some pictures at 8 megapixels (standard is 5 megapixels).



Figure 2: shadowgraphy assembly

The parameters analyzed from the dynamic frames are: the general behavior of the spray with the genesis, the cone and its angle, the fragmentation, the propagation speed, the penetration distance (course of drops before falling back to the ground), the distance of fragmentation (distance at which the cone splits into mist of droplets), the PIV or particle Image Velocimetry (mapping of instantaneous speed fields). Some complementary parameters extracted from tomography at different distances from the nozzle (3 or 4 or 7cm) are: the sphericity and size of the droplets with a statistical analysis for complete granulometry result. At last the impact (diameter of the fictive wet zone) is determined at 7cm from the nozzle, as the in-house protocol.

Results and discussions

In-house protocol



P-NC74505	L-NC74506
Mean diameter 115,75 mm (n=3, sd 18%)	Mean diameter 109,5 mm (n=3, sd 14%)
	

Table 2: Comparison of spray diameter at 7cm from the spray nozzle

The trials have both a good spray ability. The in-house protocol shows a lack of discriminating power between both aqueous gels because of a poor accuracy. Each may have different properties, for recommended applications, this is essential to switch to

another method, the shadowgraphy.

Shadowgraphy

Results from large and narrow view are summarized in Table 3 below. Different or equivalent results between the two products have been respectively

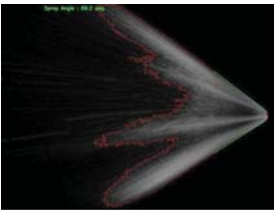
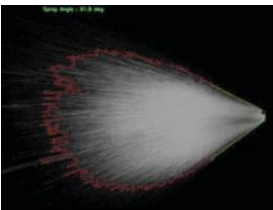
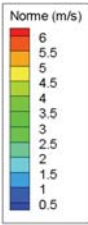
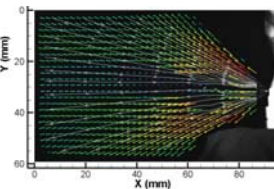
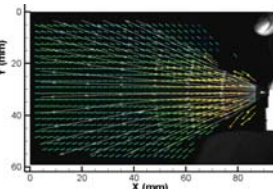
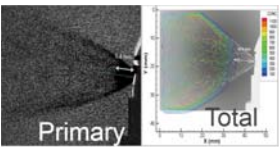
Properties ≠ or =	P-NC74505	L-NC74506
Dynamic (large view) ≠	Initiation phase 25.8ms Stationary phase 29.4ms "Stable jet "	Initiation phase 31.7ms Stationary phase 24.5ms "Turbulent jet"
Angle (large view) ≠	70.6° 	64.4° 
PIV (Particle Image Velocimetry) ≠ 	 less homogeneous speed of droplets, some faster droplets (up to 6m/s or 20km/h)	 more homogeneous speed of droplets
Genesis (narrow view) - phasage =	Initiation 12ms Stationary phase 33ms End 7.8ms	Initiation 14.7ms Stationary phase 29.6ms End 7ms
Genesis (narrow view) - atomization distances (at stationary phase) ≠ 	primary (network) 5.9mm secondary 5.4mm total (droplets) 11.3mm	Primary (network) 5.2mm secondary 3.9mm total (droplets) 9.1mm

Table 3: Comparison of spray characteristics by shadowgraphy – part 1

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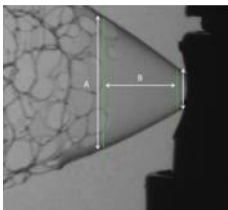
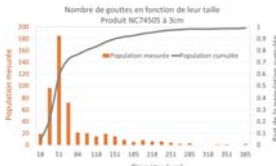
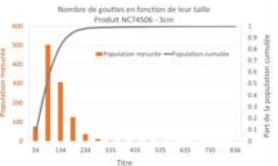
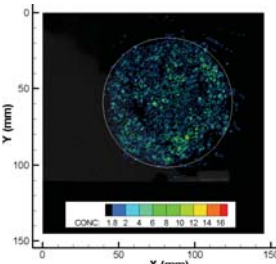
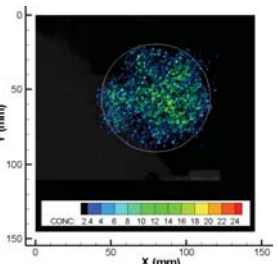
Properties \neq or $=$	P-NC74505	L-NC74506
Genesis (narrow view) - angle (midtime in stationary phase) \neq 	63°	57.2°
Granulometry (Filter: size, sphericity, circularity, contrast) \neq	At 3cm distance D50=47µm; D90=152µm  At 7cm distance D50=44µm; D90=97µm	At 3cm distance D50=80µm; D90=166µm  At 7cm distance D50=54µm; D90=112µm
Impact 7cm - diameter (Cumulation of particle density and diameter measurement after removing the first decile concentrations) \neq	85.25mm 	64.75mm 

Table 3: Comparison of spray characteristics by shadowgraphy – part 2

highlighted by the signs “ \neq ” or “ $=$ ” in the first Column.

Conclusion and perspectives

Thanks to the shadowgraphy technique, it has been possible to differentiate the two fluid aqueous gels in terms of spray profile:

- Dynamic of the spray: Powder polymer (stable) / Liquid polymer (more turbulent)
- Droplets speed: Powder polymer (faster but less homogeneous) > Liquid polymer (more homogeneous)
- Stationary phase: Powder polymer > Liquid polymer
- Atomization distance: Powder polymer > Liquid polymer
- Spray angle: Powder polymer > Liquid polymer with consistent results between large and narrow view experiments
- Droplets thinness: Powder polymer > Liquid polymer
- Wet zone diameter: Powder polymer > Liquid polymer (higher density in the middle of the spray)

In conclusion, spray characteristics can be objectively determined after image processing and beyond, spectacular images and videos are obtained. Two texturized waters with a good spray ability were discriminated and could meet different targets, such as body spray for the powder rheology modifier (wider spray, faster and thinner droplets), or delicate mist for face for the liquid rheology modifier (more concentrated spray and slower droplets), as examples of applications.

Cosmetic Claims and the implications if you get it wrong

by Ric Williams

Cosmepeutics International Pty Ltd

Abstract

for consideration of platform presentation at the
ASCC Annual Conference 2019

Cosmetic Claims and the Implications If You Get It Wrong

Many companies make cosmetic claims not knowing if what they are saying is actually allowed (ie is it true or accurate for their product), but rely on “Well they are saying it so why can’t I?”. This can lead to many consequences such as regulatory letters (ie please explain) from government bodies such as TGA, NICNAS or ACCC, in extreme cases, court action from competitors or those regulatory bodies, or product failure in the market place if the consumer does not believe you or finds your product does not work as expected.

This paper will define, firstly, what are Cosmetic Claims, then discuss;

Cosmetic Claims and the Trade Practices Act,
Country of Origin Labelling,
Deceptive Packaging,
Considerations of Substantiation of Cosmetic Claims,
Types of Cosmetic Claims, and
Types of Test Methodology.

Resulting in the Four Principles for Building Effective Claim
Support Packages.

I will also discuss implications of recent developments in

Animal Testing Bans,
Free-from ... Claims; and
Recent court actions regarding cosmetic claims.

Cosmetics are made from a range of ingredients, which are regulated as industrial chemicals under the Industrial Chemicals (Notification and Assessment) Act 1989 (ICNA Act).

Commercial importers and/or manufacturers of cosmetics, including packaged products and chemicals used in the formulation of cosmetic products, must comply with the ICNA Act as well as other legislation.

Part A – Regulations – Australia – Cosmetics Definitions

Cosmetic products first needs to be classified and labelled according to requirements for the mandatory standard by the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991[1].

The standard defined cosmetic products as substances or preparations intended for placement in contact with any external part of the body, including the mouth and teeth, for the purpose of:

- altering the odours of the body
- changing the appearance of the body
- cleansing the body
- maintaining the body in good condition
- perfuming the body
- protecting the body.

Changes to the regulation of cosmetics – 2018 [2]

- a. the cessation of the Cosmetics Standard 2007, as of October 1, 2018.
- b. the transfer of products, mentioned in the Cosmetics Standard 2007 to the control of the TGA (Therapeutic

Goods (Excluded Goods) Determination 2018 as of October 1, 2018.

- c. the remaining products (listed below) are continuing to be regulated as “Industrial Chemicals” under the IC(NA) Act ie the Industrial Chemicals (Notification and Assessment) Act 1989, and under the control of National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The definition of Cosmetics in the IC(NA) Act [3]

By this reference a “cosmetic” means:

- (a) a substance or preparation intended for placement in contact with any external part of the human body, including:
- (i) the mucous membranes of the oral cavity; and
 - (ii) the teeth;
- with a view to:
- (iii) altering the odours of the body; or
 - (iv) changing its appearance; or
 - (v) cleansing it; or
 - (vi) maintaining it in good condition; or
 - (vii) perfuming it; or
 - (viii) protecting it; or
- (b) a substance or preparation prescribed by regulations made for the purposes of this paragraph; but does not include:
- (c) a therapeutic good within the meaning of the Therapeutic Goods Act 1989 ; or
- (d) a substance or preparation prescribed by regulations made for the purposes of this paragraph.

However some limitations exist, ie.

The product must NOT be for preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons. However, this does not preclude the use of the words prevent/preventing/prevention for general cosmetic purposes. This is the definition of a therapeutic good and is controlled by the Therapeutic Goods Association (TGA),

AND

The product must not be scheduled by S2, S3 or S4 Or S8 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). If it is a poison then it is immediately a therapeutic good.

AND

The product must be marketed as a cosmetic taking into account the labeling, packaging, advertising and/or the label statements:

- The product must have full ingredient disclosure in accordance with the Trade Practices (Consumer Product Information Standards)(Cosmetics) Regulations 1991;
- The product must be presented as being explicitly for cosmetic purposes only; and
- The product name would NOT of itself make the product a therapeutic good, unless the name makes a reference to a disease, ailment, defect or injury in persons.

AND

The product must meet any applicable conditions detailed in the new Cosmetic Standard (made under section 81 of the

ICNA Act). The Cosmetics Standard sets out the standards (or conditions) that apply to certain product categories. These requirements are described in Table B of Part D of these Guidelines

AND

The product must NOT contain chemicals prohibited for use in cosmetics or meets restrictions specified for chemicals used in cosmetics (see the List of Prohibited or Restricted Cosmetic Chemicals in Part F).

Cosmetic products include but are not limited to:

- Oral care – mouthwash and toothpaste
- Skin washes – soaps, bath gels, body washes, hand washes and acne washes
- Hair care – shampoos, conditioners, hair dye, hair styling products
- Body odour care – deodorants, antiperspirants, hygiene powders
- Skin care – facial and body moisturisers, cleansers, acne creams and washes, lip balms, anti-ageing creams, hand/foot skin creams, , hand and feet emollients, anti-ageing cream, anti-wrinkle cream, face masks and scrubs
- Make up and beauty – foundation, facial powder, beauty balms, concealers, blush and eye shadow, mascara, lip and eye liners, nail polish
- Hair removal – shaving creams/foams, depilatory creams and waxes
- Scents – perfumes and perfumed sprays
- Some baby care – including creams, lotions, powders, wipes

Part A – Regulations – Australia – Therapeutic Goods [4]

The Therapeutic Goods Act (the Act) provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are used in, imported into or exported from Australia.

Definition

A therapeutic purpose is defined as a use in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury, or in connection with influencing or modifying a physiological purpose in humans or animals.

Following on from this definition there are several factors which can influence whether a product is a cosmetic or therapeutic good, including:

- 1 the primary use or purpose of the product,
- 2 the ingredients in the product and their effects on the body,
- 3 how the product is applied and/or administered, and
- 4 how the product is promoted, represented, presented or labelled.
- 5 which are represented as having a therapeutic purpose; or
- 6 which are likely to be taken as having a therapeutic purpose;

or

7 which are declared by the TGA as having a therapeutic purpose.

All therapeutic goods which are manufactured in Australia or supplied for use in Australia must be entered on the Australian Register of Therapeutic Goods (the ARTG) unless those goods are exempt or are subject to an approval or authority under the Act, and the offence of importing, exporting, manufacturing or supplying unregistered therapeutic goods carries heavy penalties.

Where advertising of therapeutic goods to the general public is permitted, advertisements in magazines or newspapers, electronic media, marketing displays, public transport, billboards, and other types of media must meet certain conditions. Advertisements which consist of more than simple product information (that is, brand name, price, type/style of goods, photographs of the product, location and availability of goods) must be approved by the Complementary Healthcare Council, in the case of complementary medicines and by the Australian Self-Medication Industry in the case of over the counter pharmaceuticals.

Added to this definition is the products, mentioned in the Cosmetics Standard 2007 but transferred to the control of the TGA (Therapeutic Goods (Excluded Goods) Determination 2018 as of October 1, 2018 [3]. These are;

1 Face and nail

1.1 Tinted bases or foundation (liquids, pastes or powders) with sunscreen

1.2 Products intended for application to the lips with sunscreen

For a product imported into, or manufactured in, Australia before 1 August 2018, both:

- (a) the product must be a secondary sunscreen product within the definition of secondary sunscreen product in:
 - (i) AS/NZS 2604:1998; or
 - (ii) AS/NZS 2604:2012; and
- (b) any protection factor or equivalent category description stated on the product's label must be in accordance with:
 - (i) clauses 6.2 and 6.3 of AS/NZS 2604:1998; or
 - (ii) clauses 5 and 6 of AS/NZS 2604:2012.

For a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following:

- (a) the product must be a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:2012;
- (b) any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 5 and 6 of AS/NZS 2604:2012;
- (c) if the product's label states a protection factor, the label must meet the requirements of clauses 7.1 and 7.3 of AS/NZS 2604:2012;
- (d) the product must meet the performance requirements for a broad-spectrum product set out in:
 - (i) Table 1 in clause 5.2 of AS/NZS 2604:2012; and

(ii) clause 6.3 of AS/NZS 2604:2012.

2 Skin care

2.1 Moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products

2.2 Sunbathing products (eg oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15

For a product imported into, or manufactured in, Australia before 1 August 2018, all of the following:

- (a) the product must be a secondary sunscreen product within the definition of secondary sunscreen product in:
 - (i) AS/NZS 2604:1998; or
 - (ii) AS/NZS 2604:2012;
- (b) the product must:
 - (i) not be presented as having a sun protection factor of more than 15; and
 - (ii) not be presented as water-resistant; and
 - (iii) if it is not stable for at least 36 months—include an expiry date or use-by date on its label; and
 - (iv) have a pack size not larger than 300mL or 300g; and
 - (v) not have a therapeutic claim, including any representation about skin cancer, made for it;
- (c) any representation in connection with the product about premature skin ageing linked to sun exposure may be made only if the product meets the performance requirements for a broad-spectrum product set out in:
 - (i) clause 7.2 of AS/NZS 2604:1998; or
 - (ii) both: (A) Table 1 in clause 5.2 of AS/NZS 2604:2012; and
(B) clause 6.3 of AS/NZS 2604:2012;
- (d) any protection factor or equivalent category description stated on the product's label must be in accordance with:
 - (i) clauses 6.2 and 6.3 of AS/NZS 2604:1998; or
 - (ii) clauses 5 and 6 of AS/NZS 2604:2012.

For a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following:

- (a) the product must be a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:2012;
- (b) the product must:
 - (i) not be presented as having a sun protection factor of more than 15; and
 - (ii) not be presented as water-resistant; and
 - (iii) if it is not stable for at least 36 months—include an expiry date or use-by date on its label; and
 - (iv) have a pack size not larger than 300mL or 300g; and
 - (v) not have a therapeutic claim, including any representation about skin cancer, made for it;
- (c) the product must meet the performance requirements for a broad-spectrum product set out in:
 - (i) Table 1 in clause 5.2 of AS/NZS 2604:2012; and
 - (ii) clause 6.3 of AS/NZS 2604:2012;

- (d) any protection factor or equivalent category description stated on the product's label must be in accordance with clauses 5 and 6 of AS/NZS 2604:2012;
- (e) if the product's label states a protection factor, the label must meet the requirements of clauses 7.1 and 7.3 of AS/NZS 2604:2012.

3 Skin care

Antibacterial skin products

The product must:

- (a) be presented as being active only against bacteria; and
- (b) not be presented as being:
 - (i) active against viruses, fungi or other microbial organisms (other than bacteria); or
 - (ii) for use in connection with disease, disorders or medical conditions; or
 - (iii) active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or
 - (iv) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or
 - (v) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or
 - (vi) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or
 - (vii) for use in connection with a procedure involving venipuncture or delivery of an injection.

4 Skin care

Anti-acne products (including spot treatments, cleansers, face scrubs and masks)

The product must be presented as controlling or preventing acne only through cleansing, moisturising, exfoliating or drying the skin

5 Oral hygiene

Products for care of the teeth and the mouth (eg dentifrices, mouth washes and breath fresheners)

Both:

- (a) the only benefits claimed to result from the use of the product must be consequential on improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and
- (b) benefits in relation to other diseases or ailments, eg gum or other oral disease or periodontal condition, must not be claimed to result from use of the product.

6 Hair care

Anti-dandruff products

The product must be presented as controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp.

Part A – Regulations – Australia – ACCC – Fair Trading [5]

The Australian Competition and Consumer Commission (ACCC) is an independent Commonwealth statutory authority whose role is to enforce the Competition and Consumer Act 2010 and a range of additional legislation, promoting competition, fair trading and regulating national infrastructure for the benefit of all Australians. It is responsible for regulating cosmetic safety, cosmetic claims and cosmetic ingredient labelling legislation.

The Code of Practice (<http://trove.nla.gov.au/version/17605425>), is handled by the various state Fair Trade Departments in Australia, the last version in NSW being published in 1996:

The requirements of the Code cover features of packaging that are likely to deceive consumers.

These relating to cosmetics include:

- Free space or ullage – maximum ullage must not exceed 25%
- Recesses – the aggregate volume of recesses must not exceed 10%
- Cavities – aggregate volume of cavities must not exceed 15%
- Claims – A deceptive label may include a claim that cannot be substantiated as discussed above for example 'contains apple seed oil from the Swiss alps' when the apple seed oil is not from the Swiss alps and cannot be backed up via any technical documentation and is in fact from another source would be seen as deceptive.

Where a claim about a cosmetic is misleading or deceptive the ACCC can provide fines, or take the company to court to stop the offending action.

Part A – Regulations – Australia – False or misleading claims

There are laws in place to protect the public from being misled about the products and services they buy.

Creating a false or misleading impression

Businesses are not allowed to make statements that are incorrect or likely to create a false impression.

This rule applies to their advertising, their product packaging, and any information provided to you by their staff or online shopping services. It also applies to any statements made by businesses in the media or online, such as testimonials on their websites or social media pages.

For example, businesses cannot make false claims about:

- the quality, style, model or history of a product or service
- whether the goods are new
- the sponsorship, performance characteristics, accessories, benefits or use of products and services
- the need for the goods or services
- any exclusions on the goods and services.

It makes no difference whether the business intended to mislead you or not. If the overall impression left by a business's

advertisement, promotion, quotation, statement or other representation creates a misleading impression in your mind—such as to the price, value or the quality of any goods and services—then the behaviour is likely to breach the law.

There is one exception to this rule. Sometimes businesses may use wildly exaggerated or vague claims about a product or service that no one could possibly treat seriously or find misleading. For example, a restaurant claims they have the ‘best steaks on earth’. These types of claims are known as ‘puffery’ and are not considered misleading.

False or misleading advertising

These are some of the most common types of false or misleading advertising reported to the ACCC.

Fine print and qualifications

It is common practice for advertisements to include some information in fine print. This information must not contradict the overall message of the advertisement. For example, if an advertisement states that a product is ‘free’ but the fine print indicates some payment must be made, the advertisement is likely to be misleading.

Comparative advertising

Some advertisements or sales material may compare products or services to others on the market. These comparisons may relate to factors such as price, quality, range or volume.

Comparative advertising can be misleading if the comparison is inaccurate or does not appropriately compare products.

Bait advertising

Bait advertising takes place when an advertisement promotes certain (usually ‘sale’) prices on products that are not available or available only in very limited quantities. It is not misleading if the business is upfront in a highly visible, clear and specific manner about the particular product ‘on sale’ being in short supply or on sale for a limited time.

Environmental (‘green’) claims

Environmental claims may appear on small household products such as nappies, toilet paper, cleaners and detergents through to major white goods and appliances. They may include statements about environmental sustainability, recycling, energy and water efficiency or impact on animals and the natural environment, for example ‘green’, ‘environmentally safe’ or ‘fully recycled’.

Businesses making these claims must be able to substantiate them.

Part A – Regulations – Australia – Specific Areas of Claims

Deceptive Packaging [7]

Definition (BusinessDirectory.com)

“Product packaging intentionally designed to mislead the

customer. The packaging may make it seem as though the buyer will get more quantity than what is actually enclosed, or that the item will be of higher quality.”

Deceptive labelling can include both the packaging and the product inside the packaging.

Deceptive labelling is governed by the Competition and Consumer Act 2010 which says ‘you can’t give false, deceptive or misleading information to customers’.

For deceptive packaging an example is a 15ml product sold in a box that is large enough for 1000ml would be viewed as misleading as a consumer would think they are purchasing a large sized product.

Cosmetic Labelling: Ingredient Listing [7]

A mandatory standard for ingredient labelling applies to products manufactured and sold within Australia and products which are imported into Australia. The ACCC has a mandatory standard for cosmetic labelling came into effect on 29 October 1991 and was last amended 23 May 2008.

Key requirements include;

- Listing of ingredients in descending order by volume or mass (except colour) in concentrations of 1% or higher.
- Ingredients that are under 1% will be listed next in any order (except colour).
- Lastly colour additives must be listed in any order under the ‘may contain’ or +/- heading. Important to note a colour additive that is not in the product may be listed if it could be potentially added for colour matching when batching or it is used in one or more of a range of cosmetic products.

In addition;

- This list must be clearly legible and prominently shown on the packaging.
- This standard does not require the % of ingredients to be written or disclosed.
- It is also important to note that this information must be available to consumers at the point of sale.
- The listing of ingredients must be on the product itself. Where the container space/size is limited the label information is required to be displayed to allow consumers to be informed.
- The names of the ingredients may be either written as their English names or their International Nomenclature Cosmetic Ingredient (INCI) names. The INCI format is preferred especially for exporting overseas.
- If the Products include any flavours (i.e. a material or combination of materials to produce or to mask a particular flavour), the list of ingredients must include one of the following words: flavour, flavours, aroma, aromas.
- If the Products include any fragrances (defined in the Regulations as a substance used to impart an odour to a cosmetic product), the list of ingredients must include one of the following words: fragrance, fragrances, parfum, parfums.

- Cosmetic products which are exempt include free samples or testers and therapeutic goods.
- All ingredients in a cosmetic product must be listed on the Australian Inventory of Chemical Substances (AICS) or notified to NICNAS for pre-market assessment unless an exemption applies. All ingredients not on the AICS and notified to NICNAS will be subject to public health, work health and safety and environmental risk assessment.

Country of Origin [8]

Australian Rules of Origin are used to determine whether a product is Australian made or not and what terminology can be used on labelling, packaging, logos and advertising.

Section 53 of the Trade Practices Act prohibits businesses from making a false or misleading representation of the origin of goods.

Under the Australian Consumer Law (ACL) it is not mandatory to declare country of origin on the label, although other laws may do so.

Claims are expressed as: Made in; words or images such as a flag are acceptable.

There has been major changes to the Country of Origin Guidelines (ACCC) that took effect as of July 1, 2018, with changes to the guidelines that may require the removal of the “Australian Made” (AM) logo from some cosmetics and most nutritional capsules.

Making a country of origin claim

In general, businesses are free to make any representation they wish to about their goods. However, any claims a business does make must not be false, misleading or deceptive.

When it comes to country of origin claims, it is up to individual businesses to determine what type of claim to make. This self-assessment should include a careful consideration of the origin of each ingredient or component in the good as well as the country or countries in which any manufacturing or processing has occurred.

‘Grown in’ claims

A claim that a good was ‘grown in’ a particular country is often used for food products but may also be used for other naturally derived products.

A good may safely represent to have been ‘grown in’ a country if:

- each significant ingredient/component of the goods was grown in that country, and
- all, or virtually all, processes involved in the production or manufacture of the goods happened in that country.

‘Product of’ claims

If you want to safely represent that a good is the ‘product of’ a certain country, you must be able to demonstrate that:

- each significant ingredient/component of the good originated in that country, and

- all, or virtually all, processes involved in the production or manufacture of the goods happened in that country.

‘Made in’ claims

A claim that a good was made, manufactured, or otherwise originated in a particular country is simply a representation about where the good itself was created. Unlike the ‘grown in’ or ‘product of’ claims, the source of a product’s individual ingredients or components is not relevant to a ‘made in’ claim. This means that a good doesn’t need to contain any ingredients or components from a country to be able to claim that it was ‘made’ in that country.

Under the ACL, a good may safely represent that it was made in a particular country if the business can demonstrate that it underwent its last substantial transformation in the country claimed.

Australian Made Campaign Limited (AMCL) oversee the use of ‘Australian grown, Australian made’ kangaroo logo.

This will enable the sponsor to put the “Australian Made” logo on their pack as a claim. Ie



This is the claim (“Made in Australia”) that is most applicable to cosmetics however, the issue is, the requirement to prove substantial transformation. No longer is the test that Australia is where the greatest cost, of producing the product, was incurred.

From the guidelines (and the “Australian Made Campaign” interpretation, it appears that;

- a. Cosmetic creams, lotions, pastes, etc are substantially transformed.
- b. Solutions and Serums, etc may not be substantially transformed.

Therefore, proof of substantial transformation will have to be provided by the

“Substantial Transformation” test.

Goods are substantially transformed in a country if:

- they were ‘grown in’ or ‘produced in’ that country, or
- as a result of processing in that country, the goods

are fundamentally different in identity, nature or essential character from all of their imported ingredients or components. Note; proof of this may be difficult.

Sensitive Skin – Irritation and Sensitisation

An irritant is a relatively rapid response. The severity of the response is more or less proportional to the concentration of the irritant on the skin, to the degree of penetration of the irritant and the length of time the irritant is on the skin. An irritant enters live skin cells and these cells die. When the cell

is destroyed it releases enzymes (to dissolve cell remnants, and it is this that causes swelling or oedema) plus histamines that, firstly, trigger pain nerve endings (to signal to the brain of the irritation), and secondly, to cause dilation of the blood capillaries, to cause more blood flow and quicker dispersion of the irritant, but also cause reddening or erythema.

Sensitisation may seem similar to irritation but the mechanism is quite different in that a sensitizer causes an immune-response. The first time a sensitizer attacks your skin there may not be any visible response, but antigens and antibodies are released into the blood stream. Subsequent contact with sensitizers activates the immune response resulting in much more widespread effects.

Where a product claim is made with respect to product “mildness” or a “sensitive skin” claim, then safety testing, such as a Repeat Insult Patch Test (RIPT), is usually carried out during the development stage, although many other tests can be used.

You notice I have so far neglected the term “Hypoallergenic”. This is considered by TGA and ACCC as a claim without scientific basis (“Hypo” meaning “more than”, but, without comparison, “more than” what?) and is not approved for use in Australia. I know it is being used but it can be challenged and if so the TGA or ACCC would rule the claim should be retracted.

Ban on cosmetic testing on animals

During the 2016 Election campaign, the Australian Government committed to introduce a ban on animal testing of cosmetic products.

The Australian Government has announced its commitment to implement a ban on testing cosmetics on animals. This commitment recognises the strong view many Australians have on this issue and brings Australia into line with similar policies implemented in other countries. The Government will ensure that the impact to business, trade and industry is taken into account and is minimised in the approach going forward, whilst continuing to maintain Australia’s high standards in protecting public health, worker safety and the environment.

In late 2016, the Australian Government commenced a phased consultation process to better understand and consider ideas, key issues and views in the development of the policy.

Following a series of stakeholder workshops, the Department released an online survey and background paper, which sought to provide an open opportunity for the general public and stakeholders to continue to engage in the consultation process. This survey closed on 16 December 2016.

The Australian Government has decided to reform the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to:

- make regulatory effort more proportionate to risk
- promote safer innovation by encouraging the introduction of lower risk chemicals
- continue to protect the Australian people (both workers and

the public) and the environment from any harmful effects of industrial chemicals.

The consultation process has helped develop advice for Government on the best way to implement the reforms. The result is the introduction of legislation to Parliament to establish a new scheme called the Australian Industrial Chemicals Introduction Scheme (AICIS).

This is scheduled to be introduced in July 2019.

The legislation is principles-based and will establish a new legal framework for the regulation of industrial chemicals in Australia. Much of the technical detail supporting the new framework will be in delegated legislation. This will allow flexibility to adapt to scientific and regulatory developments.

Part 9 presents the details to be included in the delegated legislation to implement the national ban on the use of new animal test data for chemicals used exclusively as cosmetic ingredients.

REACH vs EU Cosmetics Directives

A common misapprehension is that when an animal test ban is introduced, as in Europe (2009), it will mean a complete cessation of animal testing relating to cosmetics. It will not in Australia, just as it has not seen a complete cessation of animal testing in Europe.

The reason is the Humane Society have been trying this for 14 years to ban all animal testing and they have succeeded in Europe, but only partially, with cosmetics regulations banning animal testing for evidence as to the safety of cosmetic product, but Reach is still requiring animal testing for the purposes of industrial safety and yet we still have new chemicals coming out of Europe.

This duopoly is common throughout the world including the proposed NICNAS regulations to be introduced in July 2019. That is, we will still require various animal based tests to prove human (industrial) and environmental safety before the chemical (or product with a new chemical) is imported into Australia.

Nanoparticles

Another interesting addition to the new AICIS Regulations is with respect to Nanoparticles;

Part 7 of the proposal is a categorisation of industrial chemicals introduced at the nano-scale. It presents options for the properties of nano-scale chemicals that should be used as criteria to define the chemicals that require pre-introduction assessment.

“Organic” Claims

In September 2017, the International Organization for Standardization (ISO) officially released Part 2 (ISO 16128-2:2017) of the guideline covering the technical definitions and criteria for natural and organic cosmetic ingredients and products. Part 1 (ISO 16128-1:2016) was issued in February 2016, and now with this second part complete a producer can

now freely use this guideline. This has not yet been adopted in Australia with the current Australian Standard (AS6000) being developed for foods, totally inadequate for cosmetics.

As an international standard on the definition of marketing claims like “Natural” and “Organic” is needed, industry experts and professionals generally agree as it helps the claims gain a science-based backing, reduces the potential for greenwashing and is likely to gain consumer trust as a result.

Is the Law an “Ass”

A – Moroccan Argan Oil vs Aldi

<https://www.smh.com.au/business/consumer-affairs/aldis-moroccan-argan-oil-hair-products-claims-misleading-federal-court-20170906-gybsb6.html>

I have had discussions with the lawyers (and others) regarding the recent court decision in the Aldi vs Moroccan Oil case.

There are rumours out there, that the entire case of Moroccan Oil vs Aldi was reversed, and this is not the case.

1. The first (original) court decision re trade mark use was not challenged or reversed.

2. The original court finding that Aldi was false and misleading in that they used “Pixie Dust” levels of active and claimed that this did something was NOT challenged or reversed.

Therefore, claims despite the use of “Pixie Dust” levels of active can still have an adverse legal precedent if again challenged in a court of law.

3. The third decision in the original case, where Aldi were found to be false and misleading in that they called the product “natural” when there was less than a reasonable amount of natural ingredients, was the only decision that was challenged and reversed.

Unfortunately, as this does not appear to affect Moroccan Oil’s market, they (and hence the lawyers) will not appeal the reversal.

B – A company behind popular baby shampoos and body washes has been fined, by ACCC, for making misleading claims that its products are organic.

<https://www.accc.gov.au/media-release/accc-targets-misleading-organic-claims>

They have been fined for describing some baby products including a “natural” baby bath and body wash as organic.

The sponsor described its Natural Baby bath and body wash, baby shampoo and baby moisturiser as pure, natural and organic, but the products contain two synthetic chemical preservatives.

The Australian Competition and Consumer Commission issued the company three infringement notices over the alleged false or misleading claim.

While companies do not legally need organic certification to label their products ‘organic’, ACCC Commissioner Sarah Court said businesses must make sure they are not misleading

or deceiving customers with that description.

“Businesses making organic claims must be able to substantiate those claims,” she said.

The commissioner said the ACCC was concerned about what a consumer would understand when they looked at the label of a product.

“Organic is a premium claim, designed to tell consumers ‘this is organic’, and often attracts a premium price,” Ms Court said.

“We were concerned that the use of the word organic says to a consumer, at a minimum, this is an organic product and this doesn’t contain any chemicals.

“In these products, there were a couple of synthetic chemicals, and that is sufficient to say this representation is misleading.”

The products contain the preservatives sodium hydroxymethyl glycinate and phenoxyethanol, which are considered safe and commonly used in cosmetics and skin care products.

Ms Court said the infringement notices issued, over the baby products, did not mean the products were not safe to use.

“This is not about saying this product dangerous at all,” she said.

“Companies that want to use descriptors like organic or free-range need to make sure their products generally conform to what consumers understand that to mean.

“We think to consumers that means it doesn’t contain synthetic chemicals.”

Well is the law an “ass”?

Firstly, how does the ACCC come to this decision which is contrary to the guidelines set out by ISO 16128 and all known “organic” certifying bodies, which allow minor quantities of inorganic or synthetic materials.

Secondly, how does the industry reconcile the court decision re the denial of “organic” claims for Skin Naturals yet enforce the decision to allow bastardisation of “natural” claims in the case of the Aldi Protane Moroccan Argan Oil products.

What are “Free from ...” Claims?[9]

These are marketing claims such as;
Sodium Lauryl Sulfate (SLS) Free
Sodium Laureth Sulfate (SLES) Free
Silicone Free
Cocoamidopropyl Betaine Free
PVP/PVA Free
Methylisothiazolinone (MIT) Free
Polyethylene Glycol Free
Propylene Glycol Free
Parabens Free
Mineral Oil Free
Phthalates Free
Formaldehyde Free
No Harsh Synthetics

No Harsh Preservatives
 Sulfates Free
 Alcohol Free
 No Animal Products/Derivatives
 Not Tested on Animals
 No Animal was Harmed ...
 Gluten Free
 Palm Oil Free
 Allergens Free
 No Synthetic Fragrances
 No Rainforest was destroyed ...
or the most absurd, Chemical Free

Please note that the first fourteen on the above list all came from the label of one product.

A quote from Colin Sanders is way better than I could put it;

“... I think the chemists understand very well. The use of free from claims is one of the more blatant examples of using chemophobia to sell products, and in the process demonise chemicals. If you are a chemist this is a pretty horrific thing to do. It is not surprising that some of us react very emotionally. You are hitting at some of our most deep-seated values. ...”

A less antagonistic alternative to “Free from ...” claims is;

Clean Beauty

With respect to **Formulations**, this means focusing on ingredients that are good for you and don't use anything that you know to be harmful. Being vegan is important. Vegan eating and vegan beauty is huge in Australia. What people are putting into their body is equally important to what they're putting on it. It is also a holistic approach, so it's not just about what you're putting on your skin, but how much water you're having, how much sleep you're getting, and what types of food you're eating. It's the combination of all that to achieve healthy skin.

It includes **Sustainability** as it is also about being environmentally conscious.

Many brands are now embracing more sustainable raw materials and packaging. Given the increase in landfill waste, in packaging, use recyclable materials where possible.

It is also about environmentally conscious with **low energy processing** or **energy saving techniques**, being an important plus.

It requires **Transparency** in that you are open and honest in presenting your product.

Remember 59 percent of millennials read the back of a label before making a purchase, so we're talking to an educated(?) consumer.

It is not quite the same as “Free from ...” claims in that “Clean Beauty” stresses the positives not the negatives. At the end of the day it's about what the product can deliver, so let's get some honesty out there and tell the consumer how good your product is rather than say how bad your opposition is!

Part A – Regulations – Asian Regulations for Claims and Advertising

In general, Asian countries also follow the PIC/S Code (with local variations) for their regulations. I will not go into each of these as there have been other eminent speakers handle this, however there are some specific clauses in Asia, with respect to claims and advertising regulations. Clauses with particular interest are;

China

For cosmetics imported to China for the first time, Chinese importer needs to provide the following documents when applying for an inspection from CIQ:

1. **A self-declaration letter stating that the imported cosmetic product complies with relevant Chinese laws and the normal use of the product will not cause any harm to human health;**
2. Product formula;
3. Hygiene license or record-keeping certificate;
4. For cosmetics exempted from hygiene license or record-keeping requirement, the following documents are required:
 - a) Safety Evaluation Report issued by the qualified institutions for substances of potential safety risks; and
 - b) Documentation that permits the production and distribution of the imported cosmetics in the country of production or a Certificate of Country of Origin;
5. **Sample labels in Chinese, product labels in the original language and the translated text in Chinese;**
6. **Information on the product name, volume/weight, specifications, country of origin, batch number, expiry date (production date and shelf life), target market, and information about packaging company;**
7. Other documentation required by AQSIQ (the General Administration of Quality Supervision, Inspection and Quarantine).

South Korea

Advertising

Importers and manufacturers can have claims provided that the claim of activity of functional ingredients can be substantiated. Claims along with supporting evidence must be submitted to the Korean Ministry of Health, Welfare and Family Affairs before approval is given.

Labeling

For imported cosmetics, a Korean label must be placed over the original label on secondary packaging. Labeling requirements for importers include: retail price, country of origin, importer, importer address, batch codes and date of manufacture.

The Korean Ministry of Food and Drug Safety (MFDS) has released the revised rules for labelling and advertising of cosmetics, which took effect from 1 Mar 2014 and initially

apply to products that are manufactured and imported for the first time.

The rules mainly put forward requirements for contents on labels or packages, instructions for use and advertisements, and outline claims that are prohibited and permissible to be used for different types of products. For imported cosmetic labelled and promoted in foreign languages, companies need to amend the labeling information accordingly and prevent labels from being damaged or falling off during circulation.

Taiwan

Article 24

No obscene, immoral, false or exaggerate advertisement may be published or publicized in newspapers, publications, advertising leaflets, or on broadcasting, slides, motion pictures, television and other mass communication media for promoting the sale of cosmetics.

Before publicizing or advertising any cosmetic product, the manufacturer or dealer thereof shall first submit to the central, municipal or county/city competent health authorities for its approval all the text, pictures and/or oral statements contained therein; and shall subsequently present the approval letter or certificate to the mass communication institutions concerned for their examination. For the cosmetic advertisements which have been approved by the central, municipal or county/city competent health authorities in accordance with the provisions of the preceding Paragraph, the approval letter or certificate so issued shall be valid for period of one year.

ASEAN Countries

ARTICLE 4

Ingredient Listings

Member States shall adopt the **Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC** including the latest amendments.

ARTICLE 6

Labelling

Member States shall take all necessary measures to ensure that cosmetic products may be marketed only if product label is in full compliance with the ASEAN Cosmetic Labeling Requirements appearing as Appendix II and the information required thereunder, shall be in legible and visible lettering.

ARTICLE 7

Product Claims

1. Member States shall take all necessary measures to ensure that product claims of cosmetic products comply with the ASEAN Cosmetic Claims Guideline, appearing as Appendix III. In general, product claims shall be subjected to national control.
2. As a general rule, **claimed benefits of a cosmetic product shall be justified by substantial evidence and/or by the cosmetic formulation or preparation**

itself. The company or person responsible for placing the cosmetic product in the market **will be allowed to use their own scientifically accepted protocols or designs** in generating the technical or clinical data provided there is justification why such design is used.

ARTICLE 11

Special Cases

Member State may provisionally prohibit the marketing of a cosmetic product in its territory or subject it to special conditions, if the Member State finds out that on the basis of a substantiated justification, the cosmetic product, although complying with the requirements of the Directive, represents a hazard to health or **for reasons specific to religious or cultural sensitivity**. Certain product claims may be permitted or prohibited in accordance with national requirements. Furthermore, the Member State for reasons related to its local organization and laws, may designate a specific competent authority and subject to a different control, a specific cosmetic product which comply with the requirements of this Directive and Annexes thereto. It shall immediately inform the other Member States with a copy to the ASEAN Secretariat stating the grounds for its decision.

Europe

The European Union (EU) Regulation on Common Criteria for Cosmetic Claims (655/2013), and the **European Commission's (EC) report on Article 20 of the EU Cosmetics Regulation in relation to the common criteria for cosmetic claims**, has raised concerns over *free-from* and *hypoallergenic* claims.

The EC Technical Document on Cosmetic Product Claims was updated in July 2017 to include Annexes that address claims of the free-from nature (Annex III) and the claim hypoallergenic (Annex IV). Annexes I and II (published in 2013) are already being applied, and the new elements of the EC guidance included in Annexes III and IV are applicable as of July 1, 2019.

Type of 'Free from' claim	Status	Reasoning
'Free from' + ingredient prohibited by the EU Cosmetics Regulation	⊗	E.g. 'Heavy metals free' Claims which convey the idea that a product has a specific benefit when this benefit is mere compliance with minimum legal requirements shall not be allowed.
'Free from' + ingredient or ingredients category that are present in the product	⊗	E.g. 'Free from formaldehyde' (if the product contains formaldehyde releasers) If it is claimed on the product that it [does not] contain[s] a specific ingredient, the ingredient shall be deliberately [absent] present.
'Free from' + ingredient not supposed to be present in the product	⊗	E.g. 'Preservative free' (if the product is a fine fragrance containing high amounts of alcohol or bath salts, not expected to contain preservatives) Claims shall not attribute to the product concerned specific characteristics if similar products possess the same characteristics.
'Free from allergenic / sensitizing substances'	⊗	A complete absence of the risk of an allergic reaction cannot be guaranteed and the product should not give the impression that it does. "Free from" claims or claims with similar meaning should not be allowed when they imply guaranteed properties of the product, based on the absence of (an) ingredient(s), which cannot be given.
'Free from' + ingredients category (e.g. fragrance, preservative, colorant)	OK/ ⊗	E.g. 'Preservative free' is wrong if the product contains an ingredient, not in the official list of preservatives (Annex V) but having antimicrobial properties. E.g. 'Fragrance free' is wrong if the product contains an ingredient that exerts a perfuming function, regardless of its other possible functions in the product. <u>This claim is acceptable except if the product contains an ingredient having properties of this ingredients family as a side function.</u>
'Free from' + an ingredient or an ingredients family that are legally used	⊗	E.g. 'Parabens free' Claims for cosmetic products shall be objective and shall not denigrate the competitors, nor shall they denigrate ingredients legally used.
'Free from' claims that allow an informed choice to a specific target group or groups of end users	OK	E.g. 'Free from alcohol' in a mouthwash intended as a family product. E.g. 'Free from animal-derived ingredients' in Vegan products. Claims are an integral part of products and shall contain information allowing the average end user to make an informed choice.

Annex IV: 'Hypoallergenic' claim

The claim "hypoallergenic" can only be used in cases, where the cosmetic product has been designed to minimize its allergenic potential. Evidence to support the claim must be available by verifying and confirming a very low allergenic potential of the product through scientifically robust and statistically reliable data (for example reviewing post-marketing surveillance data, etc.).

A product claiming to be 'hypoallergenic' will not contain known allergens or allergens precursors.

Part B – Considerations of Substantiation of Cosmetic Claims [6]

1. Benefits should be delivered in line with reasonable consumer expectations;
2. Overall impression of the consumer should be in context of product presentation or advertising;
3. Influence of "Puffery" on the impact of claims;
4. Claims of a cosmetic should be supported by information on the finished product itself, and/or its ingredients, and/or on combinations of ingredients;
5. Claims should be supported by sound, relevant and clear evidence based on generally accepted data, experimental studies (instrumental/biochemical methods, sensory evaluations, studies without using human subjects) and consumer evaluations;

Evidence might consist of one or a combination of these categories as appropriate.

Part B – Four Principles for Building Effective Claim Support Packages [6]

1. Start from the claim to design the test.
Start with the question; "What would you like to claim?" and follow this by;
"What is the best method to prove this claim?"
2. Know the physiology/biochemistry of the area you are testing.
Start with the question; "What is changing?"
3. Know the measuring principles of the equipment or test methodology that could be used in your study.
Start with the question; "How do I measure the change?"
4. Know the study design and the impact of statistics including bio-statistics. Start with the question; "Can I prove it changed?"

Part B – Types of Cosmetic Claims [6]**1. Physico-Chemical Characteristics.**

This type of claim mentions the aesthetic appearance of the product.

eg. "Smooth, creamy, luxuriance."

In this case the claim is based purely on the subjective, emotive responses of the user.

To test this panel test is most appropriate.

2. Chemical Analysis.

This type of claim specifies the active component(s).

eg. "Contains 15% Vitamin C."

In this case the claim is drawn directly from the formulation, substantiated by simple analysis of the product.

3. Product Performance.

This type of claim conveys how the product performs.

eg. "Will reduce the appearance of fine lines."

This is the case where strong evidence from clinical trials,

conducted by reputable companies trained in this area, are required. Statistics require a large number of people will be tested, particularly where small differences are to be detected.

4. Customer Preference.

This type of claim uses consumer panels or testimonials. eg. “9 out of 10 women who use this notice an improvement.”

Again panel tests, consumer panels or clinical trials with questions probing subjective issues are generally used here.

5. Emotive Claims.

This type of claim says nothing about the product but refer to the consumer.

eg. “Because I’m worth it” – L’Oréal.

No trials will generate this claim as it is totally encompassed by the term “puffery”.

6. Single Ingredient Claims.

This type of claim implies the activity of the ingredient is maintained in the product in which it is incorporated. This is sometimes softened by the phrase “helps”, “aids” or similar modifiers.

In this case a double-blind cross-over trial versus a placebo is the most common test method.

7. Product Claims.

This type of claim implies that the product, as a whole, delivers the effect.

This is sometimes softened by the phrase “helps”, “aids” or similar modifiers.

eg. “Our newest Product X with our exclusive “Lift Complex” revitalizes mid-life skin.”

Another form of this type of claim is where the claim uses “pass marks” that are hard to quantify,

eg. The words “revitalizes”, “softens”, “protects”, etc.; or the concepts such as “cell youthfulness”, “work in synergy”, “gently removes”, etc.; are sufficiently obscure or based on subjectivity to also be in this category.

eg. Most anti-wrinkle products using multiple peptide technology in a moisturising base cream.

In this case evidence must be generated on the complete product itself and what do you use as a comparison? Obviously, you cannot produce a placebo so it must be tested by itself – without comparison. The selection of the methodology is critical and should involve some form of clinical trial using specifically designed test methods with before and after evaluations providing statistically significant difference in results that will prove the claim.

Variations

“According to Callaghan¹⁰, there are nine general types of cosmetic claims:

1. **Ingredient**—Describes the properties of individual

ingredients (i.e., “aloe vera and allantoin for a soothing effect”);

2. **Performance** — Measures a product’s effects (i.e., “reduces fine lines”);

3. **Lifestyle** — Plays upon consumer lives and preferences, and needs to be qualified (i.e., “natural goodness,” or “skin fitness for men”);

4. **Sensory/Aesthetic** — Claims that consumers can feel or sense (i.e., “minty fresh”);

5. **Endorsement** — Professional, positive opinions on a product’s effects, however, be wary of blogger, celebrity, etc., endorsements;

6. **“Fluffy”/Empty** — Platitudes to appeal to consumer emotions (i.e., “pure bliss,” or “because you’re worth it”);

7. **Negative** — Includes free-from claims (i.e., “does not contain silicones” or “chemical-free”);

8. **Medical, Drug and Borderline** — Claims to treat or prevent “skin diseases” and are not permitted (i.e., “anti-inflammatory” or “heals dermatitis, eczema”); and

9. **Photographic** — These say everything without saying anything (i.e., a “natural” product showcased in a botanical photograph).

Digital Claims

Cosmetic claims are unavoidable; they exist not only on cosmetic packaging, but also on TV, in public transportation, in magazines and on the internet.

“You just cannot get away from them – [cosmetic claims] are everywhere,” noted Callaghan.

Callaghan asserted that their presence online does not promote the product transparency that many consumers believe—as “the internet is the most unpoliced selling place of cosmetics,” it is the one place where claims can be made that would otherwise be disallowed.”

A Neilson Report’s top 10 most credible claims¹¹ are:

1. Vitamin E
2. Aloe
3. Plant-based
4. Retinol/Vitamin A
5. Coconut Oil
6. Green Tea
7. Free-from Harsh Chemicals
8. Chamomile
9. Hypoallergenic
10. Avocado

Meanwhile, the 10 least credible are:

1. Turmeric
2. “Maraju”
3. Crystal-infused
4. Oxygen
5. Hemp oil and CBD
6. Pearls
7. Silicone-free

8. Fragrance-free
9. Petrochemicals-free
10. Sulfate-free

Consumer Trials – Single Product [6]

Where a product claim is made (eg “Our newest Product X revitalizes mid-life skin.”) you have no placebo to compare the product to, as the product, without the product, is nothing.

In this case each consumer in the trial is given one sample and asked to trial it for a specified period of time, then asked to answer a series of questions or undergo a series of clinical tests. The results are then tabulated.

Consumer Trials – Two Products [6]

Paired Comparison Test

This test compares the performance or properties of one sample versus another. That is, is A better than B?

Consumers are given two products (A and B) and asked to try both under normal conditions of use. After use they are asked which is better for the characteristics of interest.

Triangle (Difference) Test

Three samples are given to a consumer, where two are identical (marked differently of course) and the third is different (it may be the control or the test product). The two identical products provide a test control and the different sample provides the ability of the consumer to determine if there is any difference. All three samples must be identical in presentation (packaging, colour, odour, consistency, etc.) in order to avoid any bias.

This test asks the consumer to pick the one product that is different from the other two.

Dual Standard (Difference) Test

This involves four samples (two controls and two test samples). The consumer is given a control product and a test product (identified as such), then given the remaining test and control product (unidentified) and asked which is the same as the control and which is the same as the test product. Again all samples must be identical in presentation (packaging, colour, odour, consistency, etc.) in order to avoid any bias.

Dual/trio (Difference) Test

The consumer is given three samples two of which are controls and one is a test sample. One control sample is identified and the consumer asked to identify the status of the other two.

Multiple (Difference) Test or the “A not A” Test

Consumers are given a control sample and a test sample, then asked to identify each sample from a set of mixed test and control samples.

Double Blind Cross-over Test

Each consumer is given one sample and asked to trial it for a specified period of time, then asked to answer a series of questions or undergo a series of clinical tests. After this time, they are given the alternate sample and asked to test for the same period (and same methodology), then asked to answer a series of questions or undergo a series of clinical tests. The results are then compared.

This test is much longer in execution, more expensive and may be subject to dropouts, variations in lifestyle of the consumer, or environmental conditions.

Note; These “two-product” tests are only applicable for an ingredient claim and not a product claim (as mentioned earlier) or where a placebo, that must be identical in presentation (packaging, colour, odour, consistency, etc.) in order to avoid any bias, cannot be obtained.

Best of Luck!

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- 11 The Least Credible Claims in Skin Care Cosmetics & Toiletries Newsletter December 19, 2018 Author; Brooke Schleeauf From www.nielsen.com.
- 12 Regulation EU No 655/2013
- 13 European Commission “Technical document on cosmetic claims” <http://ec.europa.eu/docsroom/documents/24847>

Appendix 1

Compliance actions by the TGA

The TGA uses a staged risk-management approach to compliance that attempts to identify entities at risk of unintentional or deliberate non-compliance and enable the development of appropriate strategies to prevent non-compliance.

Regulatory compliance framework

The TGA employs a combination of monitoring strategies to support its compliance program

Compliance undertaking

A person (including a company) who believes they have, or are likely to have breached an offence or civil penalty provision in the TGA legislation, can apply to enter into a written undertaking as an alternative to court action being commenced by the TGA

Court action

Outcomes of court action by the TGA

Cancellations

Following a review by the TGA, therapeutic goods that are not compliant with the legislation can be cancelled from the ARTG

Suspensions

Following a review by the TGA, therapeutic goods that are not compliant with the legislation can be suspended from the ARTG

Advertising directions notices

An advertiser may be directed by the Secretary of the Department of Health to take steps to address non-compliant advertising

Complaints about advertising

Outcomes of investigations into complaints about therapeutic goods advertising directed to consumers which have been referred to the TGA by the Complaints Resolution Panel for follow-up action

Advertising: Sanctions and penalties by the TGA

The TGA has the power to use a range of compliance and enforcement tools to address non-compliant advertising of therapeutic goods. Advertisements must comply with the requirements outlined in the Therapeutic Goods Act 1989 (the Act) and the Therapeutic Goods Advertising Code (the Code).

Compliance and enforcement tools

These tools range in seriousness depending on a number of factors, including the nature of the breach, the advertiser's attitude towards compliance, history of non-compliance and potential risk to the public. Compliance and enforcement action can be taken whether the advertisement was brought to our attention through a formal complaint or by other means.

Note: there are multiple references to 'penalty units'. As of 1 July 2017, the value of a penalty unit is \$210. This amount may increase on 1 July 2018. The value of a penalty unit is listed in the Crimes Act 1914.

Some of the tools available to the TGA include:

Referral

The TGA may refer any practice concerns to state or territory health departments and/or the Australian Health Practitioner Regulatory Agency.

Warning letter

The advertiser will be asked to amend the advertising to ensure compliance with the relevant therapeutic goods advertising requirements and respond to the TGA within a specified timeframe.

The TGA will confirm that the advertising has been made compliant and may take further compliance action where the advertiser has failed to address compliance issues identified in the warning letter.

Substantiation notice (under S.42DR)

Substantiation notices may be used to request information to establish the person responsible for an advertisement or to obtain information to substantiate claims made in an advertisement.

On receipt of a substantiation notice from the TGA, the recipient will need to provide the information requested.

If an advertiser fails to comply with a substantiation notice, the TGA may publish a warning notice under section 42DY or prosecute the advertiser under section 42DS, which carries a maximum penalty of 500 penalty units (in 2017-18, this is \$105,000). The provision of false or misleading information in response to a substantiation notice can also be prosecuted with a maximum penalty of 1000 penalty units and/or 12 months imprisonment. The TGA may also pursue civil action for the provision of false or misleading information (section 42DT).

Direction (under S.42DV)

The advertiser may be directed by the Secretary of the Department of Health to take steps to address non-compliant advertising and/or retract or correct the advertising.

Failure to comply with a direction may result in criminal prosecution or civil proceedings (see below).

Directions will be published on the TGA website.

An advertiser can request a review of a direction issued under s.42DV.

Public warning notice (under Section 42DY)

Where the TGA suspects that there has been a breach of the legislation in relation to the advertising of the therapeutic goods, a public written notice can be issued to the public containing a warning about the advertised goods, provided it is satisfied that it is in the public interest to do so.

The TGA can also issue a public warning notice if an advertiser has failed to comply with a substantiation notice and it is in the public interest to do so.

Infringement notice (under Section 42YK for failing to comply with Section 42DL or Section 42DM)

Infringement notices will have a maximum 12 penalty units* for an individual or 60 penalty units* for an incorporated body for non-compliant advertising.

In 2017-18, this will result in fines of \$2,520 for an individual and \$12,600 for an incorporated body.

Multiple infringement notices can be issued, depending on the number of non-compliances identified.

The advertiser will need to address the non-compliant advertising that resulted in the infringement notice in order to avoid future criminal or civil proceedings.

Enforceable undertakings (under Section 42YL)

Instead of pursuing court action, the TGA may accept the offer of an enforceable undertaking from an advertiser who believes they have, or are likely to have, breached an offence or civil penalty provision in the TGA legislation.

If the TGA accepts the undertaking, the advertiser is bound by the terms agreed to in the undertaking.

The terms of the undertaking may include mandatory training of staff employed by the advertiser and steps needed to ensure compliance of any future advertising.

A breach of the terms can result in the matter being referred to the Federal Court where orders can be made under Section 42YL(5) of the Act.

Criminal prosecution (under Section 42DL, 42DM and 42DW)

If convicted by a court for advertising non-compliance (including failure to comply with a direction from the Secretary), it can impose penalties of:

Imprisonment for 5 years or 4,000 penalty units*, or both, where the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Imprisonment for 12 months or 1,000 penalty units*, or both.

100 penalty units* for strict liability offences (where intent does not need to be demonstrated).

Offences by corporations can also attract a 5x multiplier.

Multiple advertising offences may be pursued. There is also provision for continuing offences (i.e. increased penalties for each day of non-compliance following notification of compliance issues).

Appendix 2

European Commission “Technical document on cosmetic claims”

<http://ec.europa.eu/docsroom/documents/24847>

ANNEX I : Common criteria for claims used in relation to cosmetic products

ANNEX II : Best practice for claim substantiation evidence

ANNEX III : Free from claims

ANNEX IV : Hypoallergenic claims

Formulator's Forum

Continued from page 38

Eugenol
Hydroxycitronellal
Iso Eugenol
Amyl Cinnamyl Alcohol
Benzyl Salicylate
Cinnamal (Cinnamic Aldehyde)
Coumarin
Geraniol
Hydroxymethyl Pentyl Cyclohexene Carboxaldehyde (Lylal)
Anisyl Alcohol (Anise Alcohol)
Benzyl Cinnamate
Farnesol
2-(Tert-Butyl Propionalde) (Lilial)

Linalool
Benzyl Benzoate
Citronellol
Hexyl Cinnamic Aldehyde (Hexyl Cinnamal)
D-Limonene
Methyl Heptene Carbonate
3-Methyl-4-(2,6,6 Trimethyl-2-Cyclohexene-1-Yl)-3-Buten-2-One
Oak Moss Extract (Evernia prunastri)
Tree Moss Extract (Evernia furfuracea)

Thanks for your attention.

Next Issue – Biodegradation

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