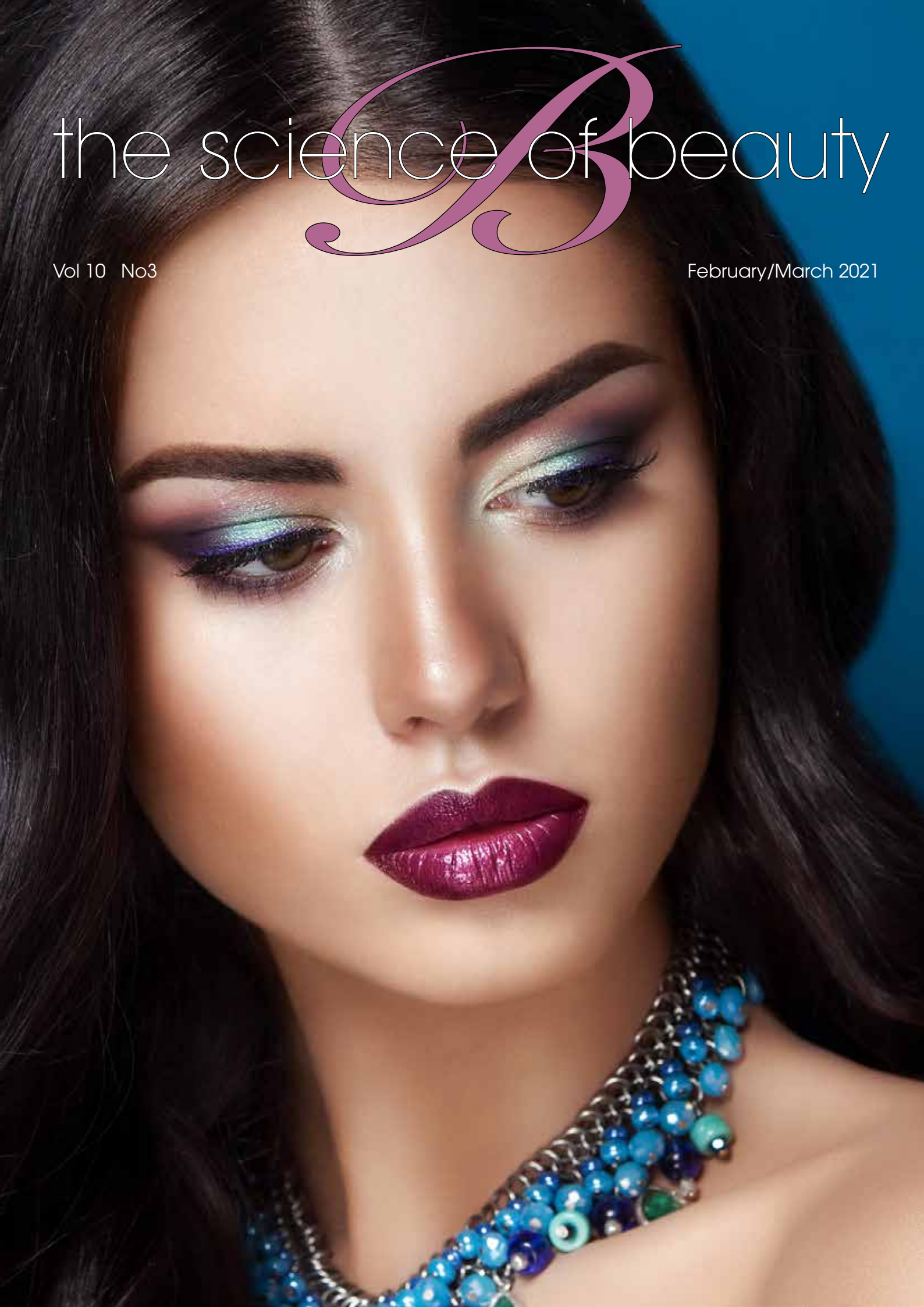
the science of beauty

Vol 10 No3

February/March 2021



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contents

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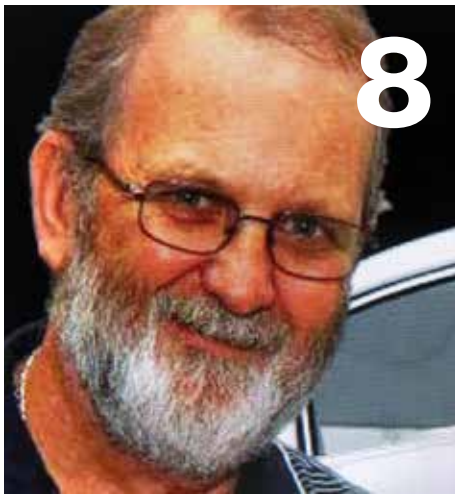

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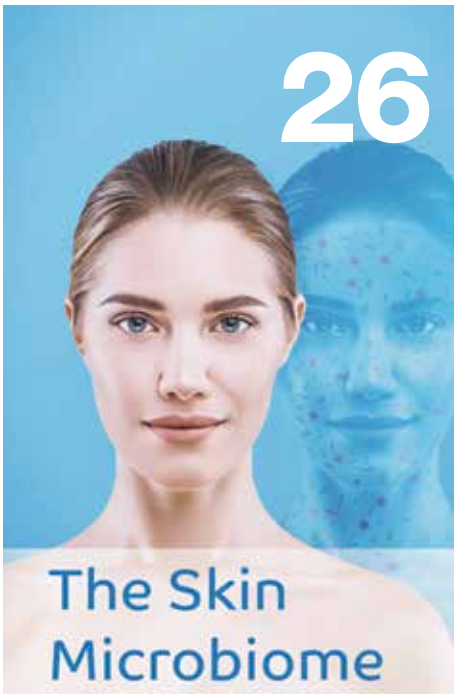

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meet the team...

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.

MICHELLE KANE is the managing director of PharmaScope Pty Ltd, a privately owned contract manufacturer established in 2004. Michelle has over 30 years experience in the pharmaceutical and personal care industry, being involved at many levels from procurement, product development, manufacturing, financial management and staff training and development, to name a few... Being based on the West Coast always brings the added challenge of seeking niche product development solutions and working creatively to achieve manufacturing outcomes in a competitive marketplace for our clients global demands.

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 furphies.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.

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.

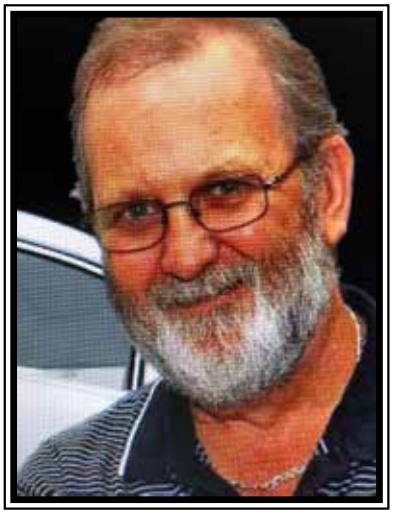
STEVE WELSH is a cosmetic packaging specialist with over 20 years experience across all mediums of packaging. As the director of Weltrade Packaging, Steve leads a team of designers, technicians, printers and supply chain professionals. To ensure the best exposure of your beauty, skincare or cosmetics 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.

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 Pharmaceutics). 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.

VALE

Ric Williams



There are few who have made such a contribution to our Society over many, many years. Several Technical Committee members have known Ric for more than 25 years and worked with him on many occasions on Conference Committees, Technical Committee, NSW Chapter Committee as well as various other areas including preparing submissions to Government on regulatory matters.

Ric had a broad ranging background in Technical and Operational areas of the personal care/cosmetics industry. Employed by multinationals and a range of smaller companies. In the last several decades he held senior technical positions as well as operating his own technical consultancy business - Cosmepeutics International Pty Ltd – since 1995

The cosmetics industry was not just an occupation but a passion – the time and commitment evidenced by professional activities as an educator, regular presenter at Conferences, and the longs-tanding series of articles 'formulators' forum' in our Journal, to cover just some of the key aspects.

You knew where you stood with Ric – no confusion about what he viewed as important and what might be an appropriate path to follow. If you had a different view, it would be considered – not always agreed with, but invariably open to reasoned debate.

We shall miss the contribution, the cut and thrust of debate and all the good times over so many years as well as honesty, optimism, authenticity, and meeting every challenge head-on no matter the difficulty.

The following summarises his many activities and professional life.

Tertiary Qualifications

- Bachelor of Science (Pure & Applied Chemistry) - UNSW
- Diploma of Environmental Studies - Macquarie University

The Australian Society of Cosmetic Chemists (ASCC)

- Full Member since 1982
- Awarded Fellowship -2014
- Life Member - 2019

Chapter Activities

New South Wales Chapter

- Committee Member: 1983 - 1985, 1994, 1997 - 1999

South Australian Branch

- Secretary: 1985 - 1993

Technical Committee

- Member: 1984 - 2016, 2017 -
- Chairperson: 1997 - 1999, 2018 - 2019

ASCC Council

- Member: 1986-1994, 1997-2002, 2018 -
- Parliamentarian: 1988-1990, 1997- 2002, 2018 -
- Vice-President: 1990-1992
- Registrar: 1992-1994
- Treasurer: 1997-1998

ASCC National Conference

- Convener 1989

IFSCC International Congress 1996 - Sydney, Steering Committee

- Member: 1988 - 1996
- Scientific Committee Vice-Chairperson: 1994 -1996
- Lecture Program/Speaker Coordinator: 1994 -1996

Position Papers

- The Use and Safety of Hydroxy Acids (Alpha Hydroxy Acids, Beta Hydroxy Acids and Alpha Keto Acids) in Cosmetics. *September 2005*
- Preservatives Used in Personal Care Products. September 2010, *Revised January 2018*
- Cosmetics and the Use of Animal Testing. *July 2015*
- Environmental Pollution of Cosmetic (and other) Plastics in Waterways. *March 2016*

Submissions prepared on behalf of the ASCC

- Productivity Commission 2008, Chemicals and Plastics Regulation, Draft Research ReportCanberra. *April 2008*
- ASCC Submission to Australian Government Productivity Commission on Chemical Industry. *July 2008*
- ASCC Submission to Standards Australia on Draft Standard for Organic and Biodynamic Products. *September 2008*
- ASCC Submissions to Federal Parliamentary Labour Party, Federal Parliamentary Liberal Party and Federal Parliamentary Greens Party on "Animal Testing of Cosmetics" in Australia *2014 –2016*

Key Publications

- Author of the 'formulator's forum', initially in 'Cosmetics, Aerosols & Toiletries' and then in 'The Science of Beauty' - totalling over 50 articles in the series.

ASCC Conference Papers

- Nine papers authored & presented 1989 - 2019

Ric also authored and presented at related organisations including International Aromatherapy and Aromatic Medicine Association, Association of Professional Aestheticians of Australia, Pharmacy Guild Conference.

Messages from Ric's Colleagues

A very sad day, not just for Ric's family but for his many friends and colleagues.

There are few who have made such a contribution to our Society over many, many years. I have known Ric for more than 35 years and worked with him on many occasions on Conference Committees, Technical Committee, NSW Chapter Committee as well as various other areas including preparing submissions to Government on regulatory matters.

The cosmetics industry was not just an occupation but a passion – the time and commitment evidenced by professional activities as an educator, regular presenter at Conferences, and the long standing series of articles 'formulators' forum' in our journal, to cover just some of the key aspects

You knew where you stood with Ric – no confusion about what he viewed as important and what might be an appropriate path to follow. If you had a different view, it would be considered – not always agreed with, but invariably open to reasoned debate.

I shall miss the contribution, the cut and thrust of debate and all the good times over so many years.

John Warby

I don't think anyone in the industry knew Ric better than you John and your comments are spot on!

He will be hugely missed.

Julian Jones

What a shock and we will all miss Ric, such a sad time.

Ric was very active on the technical committee and his place there will be missed. He also had a few ongoing projects both for the technical committee and conference that I would like to run by the tech committee on how these can be completed and dedicated to him.

Ranelle Anderson

Indeed a sad day for all of us and my thoughts are with Ric's family and friends. His untimely demise will be felt by all of us in ASCC and the industry, especially at TC. Ric will be missed but always remembered for his dedication and contribution for cosmetics sciences in Australia.

Danny Hettiarachchi

Very few of this caliber.

A true gentleman in work and friendship.

Marie Toyne

Other positive words about Ric that come to mind are his honesty, optimism, authenticity, and meeting every challenge head-on no matter the difficulty.

I find it very hard to believe what has happened. I cannot believe that we will never see him again and listen to his passionate views and beliefs.

I feel privileged to have known him and called him my friend. I will remember him, a man with a fighting spirit who went above and beyond for a cause that many would have abandoned.

Pam Jones

I had the pleasure of sitting on a discussion panel in Adelaide with Ric Williams and Stephen Morris about the virtues of RSPO and sustainable palm oil. Needless to say it was a great experience and one that could have gone on for hours.

Sharon Morse

The loss of Ric is very sad. He was a very knowledgeable person and I will miss our occasional chats. I spent an hour with him In Fremantle and remember it clearly.

Stephen Morris

I have known Ric for over 30 years. In that time, when I first started publishing the magazine for the ASCC, he always supported me with information I needed about people or the industry as a whole.

He wrote over 50 articles for the magazine under his Formulator's Forum section which was very popular and I received many requests for copies of his articles. I was glad when the magazine went on to the website so I could direct the enquiries there. Apart from his regular articles he wrote many technical papers for the magazine as well.

Ric was very passionate about the industry he loved. I always enjoyed his debates with other members of the ASCC when he would stand his ground knowing he was right and most times he was.

On a personal note. Over the thirty plus years we have become friends and I always looked forward to meeting up with Ric at the annual conference. I will miss him this year. I will also miss the irregular phone calls when he kept me updated on Desley and the family especially his grandchildren whom he adored.

Rest in Peace my friend

Joy Harrison

The Most Powerful *Marketing* Force in the Universe!

by Julian Jones

As 2020 disappears in the rearview mirror - and hopefully falls into a deep ravine - I've been thinking about what makes a really good brand and product. In our very crowded industry everyone is trying to stand out, offer a unique selling point or benefit and become successful.

During my 37 years working in the Cosmetics and Personal Care space, I've seen hundreds of new brands and thousands of new products launch - some successfully and many less so. In thinking about the possible reasons why some win and some fail it occurs to me that, ultimately, it comes down to the consumer perception of the brand and product. No matter how much hype is generated by marketing campaigns, the consumer usually forms their own opinion about a brand or product and, I would suggest, it comes down to honesty.

An honest brand or product delivers on its promise, simple as that, but also very complicated to achieve! Consumer perceptions vary widely based on education, use experience and yes, advertising. It has been said before that it is relatively easy to get a consumer to try a new product but much more important to keep them coming back for more!

I would suggest that the reason a consumer continues to buy a brand and product is a great experience from the first time, convincing them to keep buying and even better referring others to try the brand/product, too. It used to be based on word of mouth, but these days more likely social media comments and influencers.

So what does an honest brand or product look like?

There are many things to get right so that your brand/product is honest.

1. Packaging

Does the packaging honestly portray the actual product? Is the size in keeping with the actual contents? Does the weight reflect the volume? When it's unwrapped to the actual bottle/jar/tube, etc will the consumer feel they have got what they expected? Much of this is legally mandated but you would be surprised how many products push the envelope!

2. Labelling

Does the primary and secondary (if any) labelling maintain a consistent message? Are the claims being made fair, accurate and verified? Can the text be read without using a magnifying glass (especially the ingredients list!)?

3. Formulation - this is a big one in our industry!

Are the active ingredients used to justify the benefit claims used at the correct levels to actually deliver on the promises? Your customer won't know till they've tried the product - but they sure will once they have! This is a major one to get absolutely right if you want to have your customers come back for more and recommend you as an honest brand to others.

4. Pricing

I know you think this should be number one for honesty but actually pricing is only a part of a much bigger picture, which is value.

Honest value is what consumers want to see. If a product is relatively expensive but can justify the price because of higher quality packaging, benefits, consumer

experience, then it is honest.

If the product is priced low, then most consumers will accept a lower level of experience from it, provided it is still suitable for purpose.

What consumers won't accept is a product that promises the world but delivers a very average or, even bad experience.

This is the key point: when you are creating, manufacturing, marketing and selling a product the resulting consumer experience must be in line with what you promise, what they expect and what they actually get!

Line up all the variables into a completely honest package and you will enjoy great success.

Drop the ball on any of them or, worst still, deliberately mislead your customers and the outcome is a foregone conclusion!

May the Force Be With You in 2021!

Till next time…

Cheers,

Julian

BUILDING A BRAND BY STANDING OUT FROM THE CROWD:

Not as easy as you might think!

Cosmetics have the advantage of giving consumers a sense of empowerment over their appearance, the freedom of choice, and the ability to experiment without too much damage to our skin and budget. Due to their large range of applications and relative ease of production, cosmetic consumers are spoiled for choice and any one product can easily be drowned out amongst the noise of their competitors.

With many brands both old and new, the competition has never been fiercer. Embarking on the journey of creating new cosmetics is not as easy as mixing a couple of good ingredients together with some advertising! Many brand owners out there will agree. In fact, with time and experience, everyone realises the significant impact of all other business aspects, from formulation to product testing, insurance, marketing, social media, distribution, and more. The truth is that for brands to succeed, it requires an incredible amount of time, resources, money, and luck. And even this will not ensure your success.

How exactly then is one to stand out to consumers? The first step is to identify the type of consumer you wish to target. Think to yourself the myriad of behaviours that could result in a sale. Some heavily value brand loyalty, staying with their favourite brand over a number of years. Others may go with whatever catches their interest at the time of purchase, and more still might follow certain trends (natural, targeted treatments, multifunctional). Use of a certain product might spark an embrace of the philosophy, rationale, and story

by Emanuela Elia

behind the brand. But at the same time, an unhappy or bored consumer may change their and move on to something else – and rightfully so!

Regardless of your target market, once identified you will want to utilise strategies that speak to them and align with their values. A common mistake is to adhere to a strategy that appeals to you, when you should really be thinking about reception from your target market. Detailed here are some general strategies regarding this process.

Be original

How many times have you visited a cosmetic brand website and read: "These products have been developed because such and such had tried EVERYTHING and nothing worked, so he/she decided to create their own products that really works!"

Or

"Our products are the are 100% vegan, organic, natural, clean, pure, non-toxic, botanical ingredient etc. with no nasty chemicals."

Regardless of the accuracy of these statements, it is a fact that consumers tend to tune out when they hear or read the same thing over and over. It is probably fair to say that consumers deserve a bit more elaboration in an inventive way on what truly differentiate a certain product from other similar products in the market if they are to make the switch.

Be sure of what you are saying

Another common theme among products is their supposed focus on "ditching the chemicals". The naturalness of a chemical has no bearing on how harmful it is, and yet we find claims that "chemicals that are found in skincare and household products can disrupt hormones and cause abnormal cell growth and range in effects like causing eczema, premature ageing, fertility problems, and even cancer." As members of the Society of Cosmetic Chemists I believe that more should be done to address the issue of spreading misinformation so blatantly on public website.

Be knowledgeable or engage with professionals

It is also important to choose ingredients that have an abundance of studies behind them to support their efficacy or at least one robust clinical trial. Ideally, studies should also be repeated from time to time to establish whether the efficacy can be confirmed under different experimental conditions and for different populations. Unfortunately, some raw materials come with data from very small or poorly designed studies. Although the graphs and images focus on great visual impact, it's important to thoroughly understand if the data is reliable and interpreted correctly. Indeed, a key element of a good scientific study is the accuracy of the statistical analysis and whether the correct analysis was applied. It is recommended that either you or your employees have a good understanding of some basic statistical principles. This will no doubt come in handy when both brand owners and their cosmetic chemists attempt to identify materials to invest in for their cosmetic range.

Be realistic

Sometimes brand owners are tempted to use in the one product ingredients targeted for different effects, in the hope that the final result will be a product that is effective in all areas. Though some ingredients might have been tested through clinical trials and shown to be effective for one or two use cases, it is unlikely that combining different effective ingredients will produce a cumulative effect. In fact, unless otherwise proven through independent clinical trials on the final product, mixing the different ingredient is likely to significantly dampen or even change the overall effect. Brand owners are encouraged to discuss this with their cosmetic scientist.

Be honest

Legitimately, brand owners want to introduce to the market a product like no other, that their client would want to go back to because of their evident virtues. That is virtues, with an emphasis on the plural, because one product is apparently meant to do it all!

Most commonly, a variety of products have been introduced to target simultaneously a number of skin ageing signs such as:

- Wrinkles
- Pigmentation
- Enlarged Pores
- Dehydration
- Loss of Elasticity
- And more

However, when it comes to proving the efficacy of such products in fulfilling all those different tasks, the undertaking can turn out to be quite challenging. There are a number of individual active ingredients that have been proven to have extensive cosmetic benefits (e.g. retinol, niacinamide, ascorbic acid etc) and even those results can vary widely between people. However, there are many other ingredients where there is a lack of reliable data.

In Australia, we are incredibly lucky to have the opportunity to set up our own business quite easily and explore viable opportunities. The cosmetic industry more than others is very accepting of different visions, trends and (real or alleged) innovations. This allow many brands to find their space in the market for as long as there are enough consumers receptive to their message and willing to support them in their journey. Especially during this pandemic, we want to show our support and appreciation to the many brand owners out there that are contributing to the overall success of the industry. Good luck, and may the best prevail!

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.

Here's to Shackleton

by Michelle Kane

Recently I was lucky enough to take a flight over Antarctica (let's face it, there are very few flight options currently available, and after a year I am going a little stir crazy with no air time). As I stared out the window in amazement, it got me to thinking more about this industry's awareness of what is happening in the coldest place on earth right now - and why it is crucially important to every single one of us.

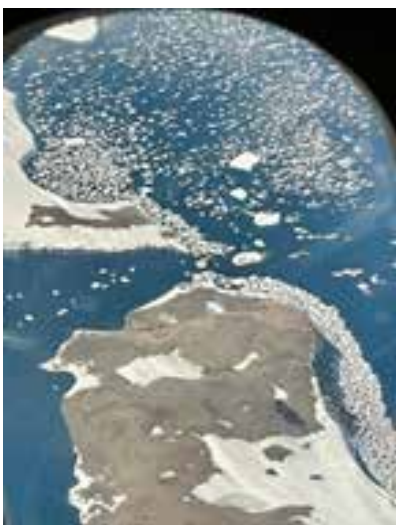
Today's explorations in the seventh continent are focused on the fields of science, climate and conservation, all of which are playing a pivotal role in our understanding of the planet.

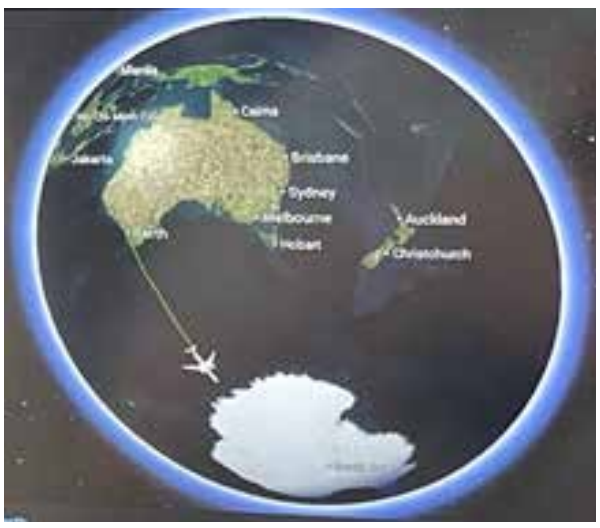
As the scientists on board the flight explained, we are realising what we learn from the frozen continent today will be paramount in fighting climate change in the future.

Manufacturing is a resource intensive industry. Trying to address this from the point of view of a small manufacturer can be daunting – where to start, how to start, and can we actually make a difference are just some of the many questions. Of course, even the smallest manufactuer can make a difference but it requires an openness to learning, perhaps a change in mindset, and a preparedness to invest financially for the longer term.

There is no single common definition of sustainable manufacturing, but the US Department of Commerce summarizes it as "The creation of manufactured products that use processes that minimize negative environmental impacts, conserve energy and natural resources, are safe for employees, communities and consumers and are economically sound".

So purely from a manufacturing operations point of view our focus of late has been on our energy intensity and consumption (including the renewable portion), water consumption, and any environmental





emissions.

Our client base is more and more interested in recycled and recyclability of packaging, what percentage of the ingredients are based on renewable resources, waterless formats and ingredients with green credentials.

Sustainable manufacturing is now at the forefront of creating manufacturing value. Back in 2011 the global market for low carbon products was estimated at US$ 5 Trillion dollars. I can only image what that figure is ten years on. As at the end of June 2019, Australia had issued $15.6 milion in green bonds with more than 400 green infrastructure investment projects in the pipeline, according to the climate bonds initiative, ranking us 13th in the world for expenditure.

Retailers and brands are demanding that suppliers respond to green consumers. Walmart were one of the first to apply a worldwide sustainability index to over 100,000 global suppliers in order to give their customers clear environmental and social rating for every product it sells.

A Harvard Business School study looked at financial analytics and companies with a visible reputation for environmental sustainability had a higher financial value.

Cutting energy bills by 20%, which most of us can do with a relatively small outlay, could equate to as much as a 5% increase in overall profits for a manufacturer.

Young workers value sustainable workplaces, a 2010 survey showed that 96% of 18–45-year-olds wanted their employer and workplace to be environmentally friendly, or at least environmentally aware.

As Shackleton said himself, 'It's in our nature to explore, to reach out into the unknown. The only true failure would be not to explore at all. I'm on board with him – lets explore what more all of us within this industry can do to make sure future generations can keep reaching out into the unknown.

Antarctica is both critical and wonderfully compelling, just by the way.

MICHELLE KANE is the managing director of PharmaScope Pty Ltd, a privately owned contract manufacturer established in 2004. Michelle has over 30 years experience in the pharmaceutical and personal care industry, being involved at many levels from procurement, product development, manufacturing, financial management and staff training and development, to name a few... Being based on the West Coast always brings the added challenge of seeking niche product development solutions and working creatively to achieve manufacturing outcomes in a competitive marketplace for our clients global demands.

Ocean Plastic Packaging

by Steve Welsh

Just like that, we are in a new year. 2021, I bet we are all hoping it to be different to the unexpected year of 2020. The whole world has been affected in different ways and the packaging industry was no different.

Amongst the craziness of 2020, at Weltrade Packaging we were still trying to push the boundaries on sustainability, what we can do differently and how we can offer more packaging solutions to our customers. If you have been following us, you would have known that environmentally friendly packaging is one of our major focuses. We currently have options for Biodegradable, Sugarcane Bioplastic and Recycled Plastic packaging material amongst our range of bottles, jars and tubes.

We are proud to announce here first at Science of Beauty, that we can now offer Ocean Plastic material in our cosmetic tubes. The ocean plastic is transformed from used fishing nets, ropes and rigid plastic, into a high quality recycled raw material. The Ocean Plastic tubes are made to order and can be custom coloured and printed, with options for silk screen printing, offset printing and hot stamping. We have the ability to make the tube with up to 50% Ocean Plastic material, the colouring of the plastic tube will be dark/yellow and will have spots throughout the tube body. This is to be expected, as we are using a large range of different ocean waste, the colouring helps the brand tell their story.

So we can assist you with your packaging that will not only serve its primary purpose to keep your product safe but also, that it has been recovered from the oceans or waste sources that would have ended up in landfill or has a super low carbon footprint or that will break down in landfill BUT also still be recycled in the normal recycling process.

From a business perspective, we have seen many of our clients adopt sustainable packaging into their product range and have seen increases of over 40% in their sales. Consumers are now demanding a change in packaging and as a brand if you are not offering a sustainable solution it may be detrimental to future sales, as well as the potential risk of not adhering to future packaging laws and regulations.

You may have seen a recent case where a hair care brand made an announcement that they could not guarantee their packaging was actually ocean waste when they had been marketing as that for over twelve months. At Weltrade Packaging we guarantee we won't release new sustainable options without a thorough testing process to substantiate our claims for you and make sure we have certifications to back it up.

To learn more, simply reach out via email, phone, zoom or in person, if there is a question you need answered or if you are looking to implement sustainable packaging into your cosmetic brand please do not hesitate to get in touch with one of our team members.

Reach us at 07 5597 0102 or info@weltradepackaging.com.au

The Liability of not having Product Liability Insurance

In this series of editorials for 2021 we look at commercial insurances that are important to your Business risk profile. In this edition we cover Product Liability Insurance.

by James Gillard

In this series of editorials for 2021 we look at commercial insurances that are important to your Business risk profile. In this edition we cover Product Liability Insurance.

If you are a Business involved with

- Importing or Exporting raw materials or fully manufactured product
- Manufacturing
- Wholesaling
- Retailing

You should have Tailored Product Liability insurance in place which will be encompassed with your Public Liability Insurance Policy.

Whilst you might not be the direct manufacturer of the product because you import from overseas and sell online, under Australian Consumer Law, you are deemed to be the Manufacturer. Therefore, you can still have a lawsuit made against you for injury caused by your product.

An example, a skin reaction to a person's face with potential long-lasting impacts or scaring. Our photo above depicts such a possible incident of this occurring.

When I apply for Insurance cover

It is an insurance requirement to ensure all the relevant details about your Business is collected when applying for Public & Product Liability Insurance so insurers can properly assess your risk and in doing so consider offering terms. Therefore, it is necessary for a detailed proposal form to be completed by you with all the correct attachments.

The following information is usually requested and collected when you are completing an Insurance Proposal Form for Product Liability Insurance.

Some of the Essential Information that will be required

- Number of Years operating Business Name, ABN, and website address.
- The period of insurance from start to end date for the policy.
- Your limits of Insurance Indemnity/ Sum Insured.

$5 million, $10 million or $20 million cover are the usual options.

- Your Business turnover in the last 12 months and your estimate next 12 months.
- A detailed description of your Business Practises (includes what you are, a Manufacturer, Wholesaler, Retailer, any Associated Industry).
- List of Products manufactured and/ or distributed by you (you will be required to describe the type of different products manufactured/ handled or distributed and/or the type of service you undertake for others)
- Evidence of your Quality Control procedures in place (examples of processes you have documented & employ, product certifications such as TGA, ISO & Australian standards)

This is a key component of insurer assessment.

- If importing products from overseas you would be asked to list which countries by which products. Any packaging details (who undertakes this), what the imported raw materials are & the overseas or Australian basis you source raw material from.
- Breakdowns also of your products by State and/or Overseas a percentage of your total turnover is attained. In terms of any exports overseas you would be asked to detail the value of Exports and which country you are exporting to.
- If your products are subject to the regulations of the Therapeutic Good Act (1989) the insurer may want to know what percentage of your goods are sold over the counter, or which ones must be prescribed by a Medical Practitioner.

There will be many other questions, that will require detailed information and will be specific to your business. Given our vast experience, we will guide you through to ensure essential information for insurers will be captured.

In our next editorial we will outline what details are required when you apply for Product Recall Insurance.

One call to Insurance Made Easy -Insurance Brokers

If you would like to learn more about Product Liability Insurance, you can contact our friendly team at IME Insurance Brokers.

We provide professional service and personal assistance when we discuss what your individual circumstances are.

You can contact us by calling our office on **1800 641 260.**

sunscreen highlights

by John Staton

The Rise and Fall of Homosalate?

The EUs Scientific Committee on Consumer Safety (1) has recently released an opinion report with conclusion 1 stating "On the basis of safety assessment of Homosalate, and considering the concerns related to potential endocrine disrupting properties, the SCCS has concluded that Homosalate is not safe when used as a UV-filter in cosmetic products at concentrations of up to 10%".

Conclusion 2 of the same document recommends that Homosalate be permitted as an ingredient in cosmetics at no more than 1.4%, due to concerns that it behaves as an endocrine disrupter. As this low concentration is not practical for sunscreens, this may well see the end of this active for this use.

Early sunscreen products originating back in the 1920s such as the brands was Skol® and Coppertone® relied on Salicylates such as Benzyl salicylate and Homomenthyl Salicyate (Homosalate). At best, the SPF of these early products would have been no more than 8 to 10, given that Homosalate on its own provides a yield of only around 0.5 SPF units per percentage content. For example, the FDA SPF reference formula, known in previous editions of ISO 24444 as "P7", provides SPF 4 from 8% content. Of course, at that time, tanning was promoted as the claim and not protection, so that the products no doubt permitted significant UV light penetration as well as providing maybe some local analgesic effect to soothe the burn, courtesy of the salicylates.

We moved to SPF 15 formulations around the late 1960s and began to shift focus from tanning to protection around that time, although products such as Reef® Suntan Oil still suggested a tanning use. Here is when cocktails of actives were appearing as the limit of each single active meant that more than one was needed for efficacy. When the Australian sunscreen standard was first drafted, an upper limit of SPF 15 was set for claim as the concern was that higher SPF would encourage longer time in the sun. Homosalate, at permissible limits of 10% in most markets and up to 15% in USA, Aust, Canada and Mercosur (South America), could not achieve this alone and more multi-active formulations appeared.

I do not know if it was demand or innovation that moved us to even "stronger" SPF 30, but certainly it was generally necessary to now add even more actives to the original formulations and include some UVA absorber, since this contributes upwards of 15% to SPF protection as well as providing broad spectrum protection, now mandatory.

Despite its lower efficiency, Homosalate continues to have wide support at an active in a market now dominated by SPF 50 and SPF 50+. Wikipedia (2) states that Homosalate is "Contained in 45% of U.S. sunscreens". A quick check of TGA Listed sunscreens (3) on sale in Australia shows that a massive 348 include Homosalate.

Given the usage numbers indicated above, the impact of the possible deletion of this active will be significant. If the FDA moves on this, then it further reduces even now limited options for Sunscreen actives.

Already busy clinical test labs will no doubt see a rush of reformulations for SPF testing. As Homosalate also serves as a useful solvent for solid sunscreen actives, simple substitution is unlikely to be an option for those impacted.

References

1. Scientific Committee on Consumer Safety SCCS OPINION on Homosalate

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_244.pdf

2. https://en.wikipedia.org/wiki/Homosalate

3. Australian Register of Therapeutic Goods (ARTG)

https://www.eds.tga.gov.au

LUBRIZOL LIFE SCIENCE

Lubrizol's Eco-Conscious Beauty Portfolio

Products built on company's Five Pillars of Sustainability

Eco-Conscious Beauty, from Lubrizol Life Science – Beauty (LLS Beauty), is a portfolio of nature-based formulations that will allow customers to bring to market products that meet the public demand for cleaner and more responsible personal care.

The Eco-Conscious Beauty formulations are created on the foundation of the following five pillars identified as standard criteria when it comes to sustainable beauty:

- Nature-based ingredients – More than just using ingredients from nature, this requires supply chain transparency to ensure they are ethically and responsibly sourced.
- Minimalistic labels – Shorter, simpler ingredient labels to let consumers feel more confident about what's in the product and what isn't.
- Biodegradability – Consumers want to know what happens with the product after it goes down the drain. Substantiated claims of biodegradation and non-ecotoxicity reassure consumers that they can use wash-off products with confidence.
- Responsible formulations – Developing formulations that require less energy and raw materials and that generate less waste during production is an efficient way for customers to reduce their environmental footprint.
- Fair trade and social impact – Sustainability is not only about ingredients and their environmental impact. It also requires considering the influence of our activities on humankind. Ensuring fair and ethical working conditions as well as empowering disadvantaged communities allows a sustainable supply chain and creates a positive social impact.

The Eco-Conscious Beauty portfolio, which includes a wide range of products for skin care, hair care and skin cleansing, is made possible by LLS-Beauty's expertise in formulating and its extensive library of active ingredients. Combined with their market knowledge and consumer insights, it allows them to further the goals of sustainability.

Today's consumers demand high performance and insist on minimizing environmental impact. Eco-Conscious Beauty allows our customers to easily and responsibly deliver the products the marketplace wants with the confidence that they are doing their part to support sustainability. That message will resonate with consumers.

To learn more about the Conscious Beauty collection, visit Lubrizol.com/beauty.

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.

What?...is that?

by Wendy Free

For regular readers, you may recall that last time we considered impurities. This time I'd like to talk about ingredients; the actual things you are putting in your products and onto the market.

Summer usually seems to be a particularly interesting time for "challenging opportunities" and this year was no different…but I digress.

With the change-over from NICNAS to AICIS (can we call it "ache-ies"?) there appears to be an opportunity for some people leap across to the very last step in classifying their ingredients, kind of forgetting that there are a whole heap of hurdles that need to be addressed before we can tick off 'human health', 'environmental risk' and 'introduction category'…. (If you're not clear here please go back to the issue before last…).

So If you are certain that……

(1) Your ingredients is not part of the Customs (Prohibited Imports) Regulations 1956;
for example

- Natural and manufactured growth hormones, or
- an aphrodisiac such yohimbine, or
- an ozone depleting substance, or
- included in the Chemical Weapons convention such as Ricin

(Guess which one of these I've seen recently!?)

(2) Your product is NOT the product of genetic modification and thus subject to Gene Technology (Inclusion on the GMO Register) Determination (No. 1) 2020

Then it's time to progress to the poisons standard.

(NB this is general advice only DO NOT rely on it – lots of things have been simplified)

About the poisons standard.

This is where you find out what the legal limit of use of that essential oil, preservative, quat, surfactant its……it is a legislative instrument, which means unarguably the law and you can't 'justify you way out of it'. (You can however apply to have it changed = time and $$$$, and a very convincing argument).

The poison's standard is not a universe scale of toxicity; it's been designed, and redesigned and tinkered with over many, many iterations to attempt to apply a uniform set of controls on the packaging, labelling, record keeping, possession, advertising and supply of substances that have the potential to cause harm to people and animals.

Poisons which are packed and sold solely for industrial or manufacturing, use are exempt from **all labelling** requirements (covered by Workplace health and safety laws) but they are NOT exempt from laws pertaining to their use in manufactured items, laws pertaining to possession, supply, advertising etc.

Let's start by looking at the basics of how the 'schedules' work, noting that the vast majority of legislative instruments

have 'schedules' or lists and that these are DIFFERENT across the various instruments; we're ONLY talking "poisons schedules" here. The (above/below/aside?) table provides a summary.

Important to note:

- The poisons standard CAN and DOES apply to traces and impurities that may be present in natural and other starting materials. "It is important to remember that a Schedule entry includes preparations containing the poison in any concentration and all salts and derivatives of the poison unless it specifically states otherwise"
- It doesn't JUST apply to the specific substance names (unless stated) "Classification of a substance as a derivative of a scheduled poison relies on a balanced consideration of factors to decide if a substance has a similar nature (e.g. structurally, pharmacologically, and toxicologically) to a scheduled poison or is readily converted (either physically or chemically) to a scheduled poison".
- The poisons standard uses its own special chemical language; it doesn't stick to INCI, AAN or even include CAS! and

Substances can be included or excluded based on % or purpose.

How and where does it apply?

"Cosmetics" are NOT permitted to contain any substances to which schedules 2, 3, 4 or 8 apply; and I'd very strongly suggest NOT including anything included in schedules 7, 9 or 10 for what I hope is obvious reasons?

Importantly for the cosmetics industry is that pertaining to possession, advertising and distribution.

Say for example you are considering a new herbal extract from the Australian Native "White Cedar"? Advertising, possession and/or distribution of **Melia azedarach** (S10 - Substances of such danger to health as to warrant prohibition of sale, supply and use) is probably going to get you in very big trouble.

There after it applies to % used and purpose use.

- Vitamin A can only be used at a maximum of 1% before it becomes PRESCRIPTION ONLY and Any growth hormones / yohimbine are PRESCRIPTION ONLY above 10 ppm (after you've chose to ignore the prohibited import)
- Many essential oils, surfactants and quats have % / use limitations too.
- Additionally COMPONENTS of natural and chemical substances also have limits…..

Thereafter packaging and particularly labelling can be prescribed…..

While the labelling of WORKPLACE substances is required to comply with Workplace health and safety regulations, the labelling of products for consumer use is required to comply with the Poison Standard. But here it becomes complicated; say you sell shampoo in 120 mL, 250 mL and 1L bottles; and the 1L bottles are labelled FOR PROFESSIONAL USE ONLY? In practice and especially in this case I'd advise that your 1L bottle label's comply with BOTH requirements, as well all know that they're often available for retail sale.

Sometimes, your label just needs a PHRASE added such as "IF IN EYES WASH OUT IMMEDIATELY WITH WATER" (> 5% and <30% AMMONIUM COCOYL ISETHIONATE in rinse off cosmetic formulations) to avoid that big nasty **POISON** word in very large front at the very top front of your bottles, as well as a whole heap of other controls; Other time you'll need to limit the quantity (to 125mL or less) AND include a flow restrictor AND a child resistant cap and KEEP OUT OF REACH OF CHILDREN; and NOT TO BE TAKEN; in the case of >25% eucalypts oil.

So, back to **What?**...is that?

Know that you've assured yourself that NOTHING in your product; ie no colour, fragrance component, constituent named or otherwise is in your ingredient or in your formulated product is affected by SUSMP or other high level legislative instruments, you can THEN start to look at "ache-ies compliance.

Yours in the ever-increasing complexity of our unique regulatory system…

Wendy
Mrs Wendy Free B.Sc M.Tech Mngt MASM MRACI FAOQ
talktous@qualitymatterssafetymatters.com.au

QUIZ for those that feel inclined…

1. BISMUTH COMPOUNDS for cosmetic use, are

a. Dangerous Poisons (S7)
b. Allowed as Bismuth Citrate in hair colourants at <3%
c. Allowed as bismuth oxychloride.
d. Not restricted so long as they're not in BENZIDINE-BASED AZO DYES

2. BORAX is

a. limited to 0.35% for therapeutic topical use
b. Limited to less than 1% boron in cosmetics
c. unlimited in hand cleaning preparations
d. all of the above.

3. Which is NOT included in the poisons schedule?

a. TRIETHANOLAMINE
b. CAMPHOR
c. EUGENOL
d. CLARY SAGE OIL

4. The Poisons Standard does NOT apply to

a. Foods
b. Natural extracts and substances
c. Goods used for manufacturing or industrial use
d. Free samples

5. Which preservative is NOT scheduled?

a. Natamycin
b. Sodium Benzoate
c. Formaldehyde
d. Phenoxyethanol

Alternate Preservation Systems – Driven by Change

By A S Harrison & Co

The interest in alternative preservation continues to be strong - alternative preservation is a method of using multifunctional ingredients with antimicrobial properties as a preservation system instead of using traditional preservatives like parabens, isothiazolinones, or phenoxyethanol. In response, INOLEX has expanded its alternative preservation portfolio with the addition of **Lexgard® Natural MHG MB** to its **Lexgard®** Series.

Lexgard® Natural MHG MB is a versatile, 100% natural, sustainably sourced alternative preservation.

Traditional approaches to preservation are increasingly undesirable due to negative consumer perception and concerns over health and safety. The growth in alternative preservation products has been the result of a drive by conscious consumers.

INOLEX Alternative Preservation Systems employ Hurdle Technology, which allows for the use of multifunctional components or aspects of the formulations as hurdles for microbes to collectively prevent contamination. These components and formulation factors can include membrane disruptors, organic acids, chelating agents, and pH.

By using this strategy, formulators can use combinations of milder ingredients and other formulation factors instead of traditional preservatives that consumers

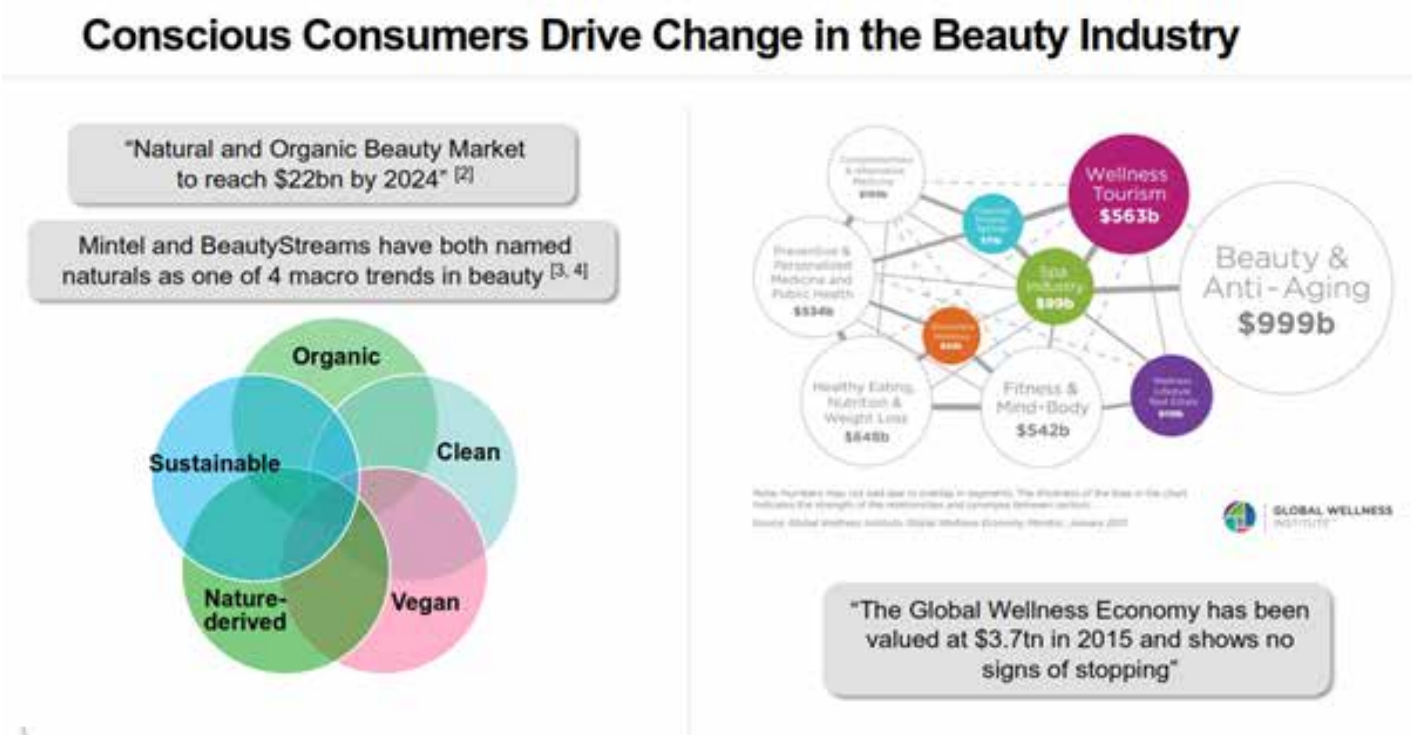


Figure 1: Conscious Consumers Drive Change in the Beauty Industry

are seeking to avoid. Success of this strategy also requires the use of Good Manufacturing Principles (GMP) in combination with the formulation approach to preservation.

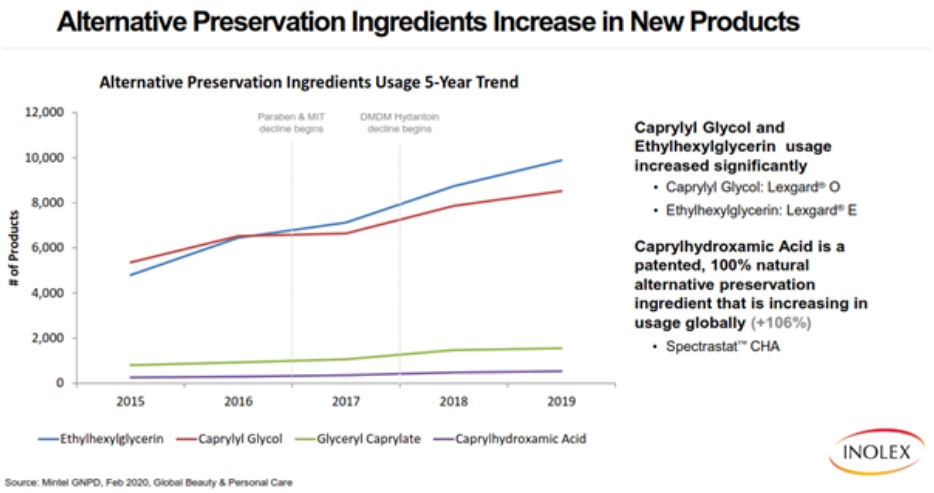
The Hurdle Technology approach rethinks traditional preservation. Instead of using one powerful preservative, multiple barriers to microbial growth (or "hurdles"), can be established to keep microorganisms in check.

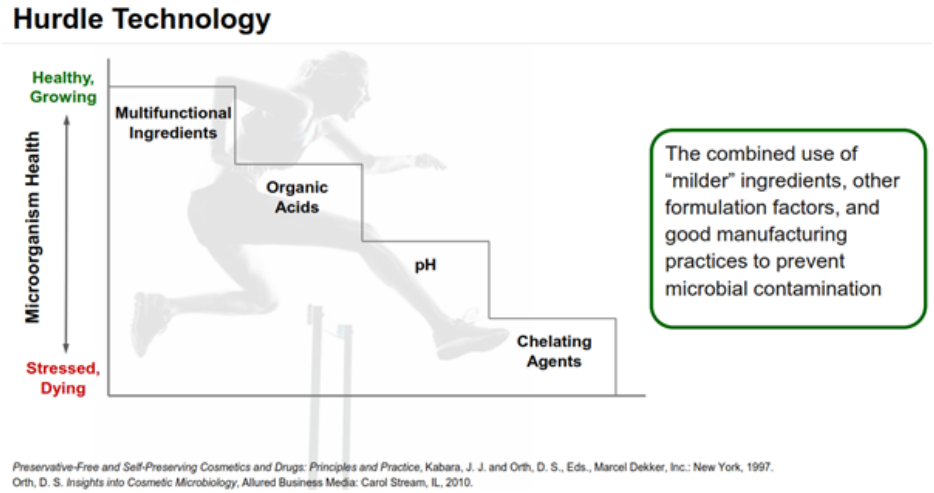
Good Manufacturing Practices (GMPs) are a critical element of hurdle technology/alternative preservation.

- Clean, well-maintained facilities
- Validated cleaning and sanitisation SOPs
- Micro-free purified water systems
- Micro specs and testing on all incoming raw materials
- Clean, protective packaging
- Validation of preservative efficacy throughout scale-up and accelerated stability testing
- Micro content testing on all manufactured lots
- NEW Lexgard® Natural MHG MB
- NEW multi-benefit innovation
- 100% Natural
- Sustainably sourced castor and RSPO MB palm feedstocks
- Glycol-free
- Cold processable

Shield & Protect:

Protects formulations from microbial growth. Preservative Efficacy Test (PET) results show a strong efficacy against bacteria in emulsions, cleansers, and wipes formulations. Methylheptylglyerin is part of the alternative preservation class of chemistries called Medium Chain Terminal Diols (MCTDs). MCTDs are important components of any preservation approach because they help to boost the efficacy of traditional and alternative preservation ingredients. Lexgard® Natural MHG MB gives this efficacy boost with the added benefit of being 100% natural, cold processable and glycol free.





Lexgard® Natural MHG MB as an Alternative Preservation Component

Lexgard® Natural MHG MB protects formulations from microbial growth across formulation types.

Natural Lotion

Use level & pH	0.5 – 1.5% (w/w) @ pH 5.0		1.0 – 1.5% (w/w) @ pH 6.5	
Microorganism	Bacteria[3]	Yeast[3]	Bacteria[3]	Yeast[3]
Microorganism[1] Log_{10} Count	Day 2: <1.00	Day 2: <1.00	Day 2: 3.15 (g+); <1.00 (g-) Day 7: <1.00	Day 2: <1.00
Log Reduction	5 log	4 log	Day 2: 3 log (g+); 5 log (g-) Day 7: 5 log	4 log
Industry Pass Criteria Met	PCPC | EP-A[2] | USP51		PCPC | EP-A[2] | USP51	

Sunscreen

Use level & pH	1.0 – 1.5% @ pH 5.0		1.0 – 1.5% (w/w) @ pH 6.5	
Microorganism	Bacteria[3]	Yeast[3]	Bacteria[3]	Yeast[3]
Microorganism[1] Log_{10} Count	Day 2: <1.00	Day 2: <1.00	Day 2: <1.00	Day 2: <1.00
Log Reduction	5 log	4 log	5 log	4 log
Industry Pass Criteria Met	PCPC | EP-A[2] | USP51		PCPC | EP-A[2] | USP51	

Natural Shampoo

Use level & pH	1.0 – 1.5% (w/w) @ pH 5.0		1.0 – 1.5% (w/w) @ pH 6.5	
Microorganism	Bacteria[3]	Yeast[3]	Bacteria[3]	Yeast[3]
Microorganism Log_{10} Count[1]	Day 2: <1.00	Day 2: <1.00	Day 28: >5.00	Day 2: <1.00
Log Reduction	5 log	4 log	Ineffective	4 log
Industry Pass Criteria Met	PCPC | EP-A[2] | USP51		Does not meet pass criteria	

Wipes Juice

Use level & pH	1.0 – 1.5% (w/w) @ pH 5.0		1.0 – 1.5% (w/w) @ pH 6.5	
Microorganism	Bacteria[3]	Yeast[3]	Bacteria[3]	Yeast[3]
Microorganism Log_{10} Count[1]	Day 2: <1.00	Day 2: <1.00	Day 2: <1.00	Day 2: <1.00
Log Reduction	5 log	4 log	5 log	4 log
Industry Pass Criteria Met	PCPC | EP-A[2] | USP51		PCPC | EP-A[2] | USP51	

Footnotes

1. Microorganism Log_{10} Count (CFU/g) and Log Reduction reported for lowest recommended Use Level indicated in table. Higher use levels may result in greater log reductions.
2. Industry Pass Criteria Met are defined based on the lowest recommended Use Level indicated in the table. Criteria are only representative of results for Bacteria and Yeast. Meeting the referenced criteria is contingent on inclusion of a mold control agent in the formulation.
3. Bacteria: *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa*; Yeast: *Candida albicans*
- Full Preservative Efficacy Test formulations and results provided upon request

Lexgard® Natural MHG MB controls odor in deodorants, naturally.

MIC and Preservative Efficacy Test (PET) results show a strong efficacy against bacteria in formulation.

Lexgard® Natural MHG MB inhibited bacteria proliferation in formulation as indicated by the Day 2 log reduction in *Staphylococcus aureus* at a low use level near approximate skin pH. *Staphylococcus aureus* (gram+ bacteria) was used as a proxy microorganism for *Staphylococcus hominis*. A natural lotion is used as a proxy for deodorant creams or sticks.

Staphylococcus hominis is the gram+ bacteria in the underarm area that is responsible for excreting the malodor-causing thioalcohol.[1]

Natural Lotion

Use level & pH	0.5% (w/w) @ pH 5.0
Inoculum Level	6.04
Day 2	<1.00

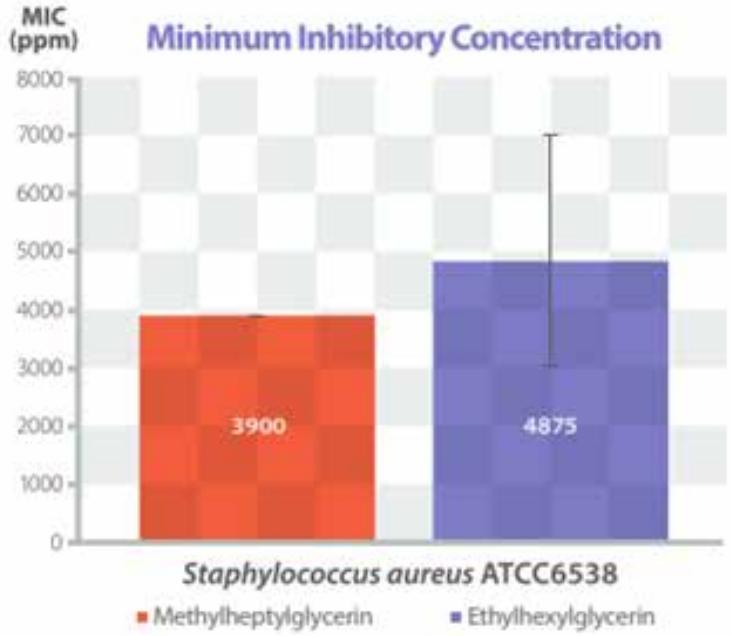
1. Minhas et al. eLife 2018;7:e34995. DOI: https://doi.org/10.7554/eLife.34995

Natural Odour control:

Controls odour in deodorants, naturally. MIC and by preventing growth of odour-causing bacteria. Added benefit of delivering efficacy from a 100% natural ingredient. Preservative Efficacy Test (PET) results show a strong efficacy against bacteria in formulations. Based on the chemistry of Methylheptylglyerin we know it is bacteriostatic, meaning that it prevents growth or proliferation of bacteria, but it is not bacterial – it does not "kill". That is critical in a deodorant (or natural deodorant) application where you want to preserve the skin's microbiome and at the same time prevent odour development. Lexgard® Natural MHG MB is compatible with other microbial control agents common in deodorants and has the added benefit of delivering efficacy from a 100% natural ingredient.

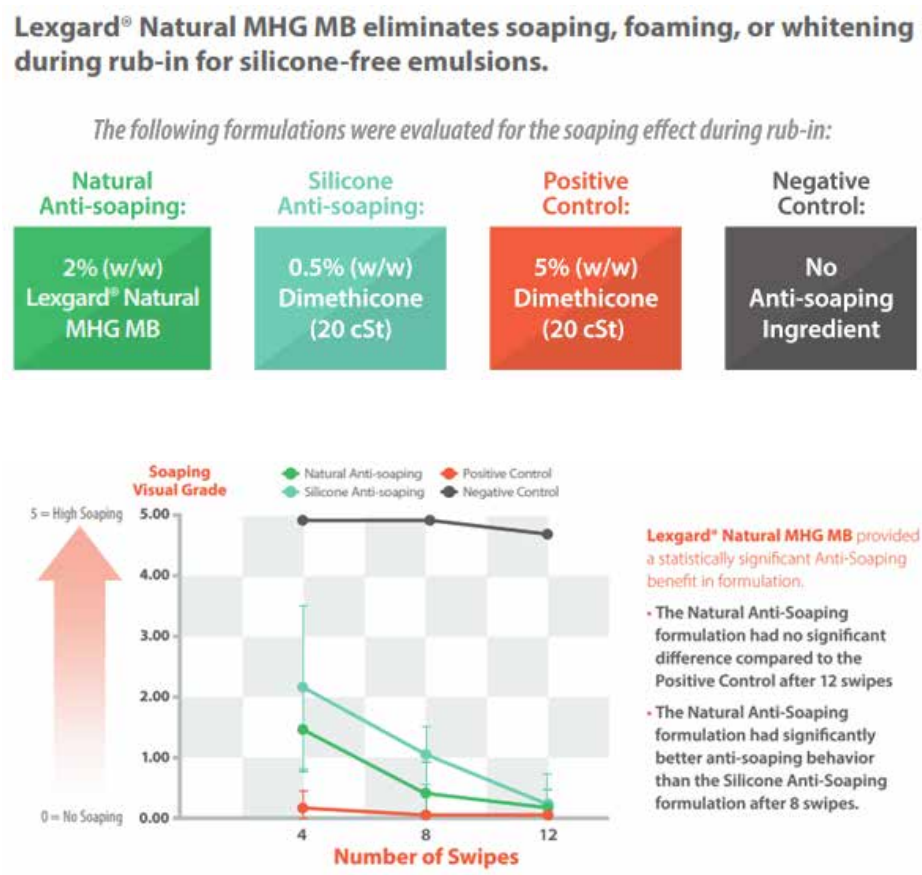
Natural Anti-Soaping Emulsions:

Helps minimise or eliminate soaping or foaming during rub-in of silicone-free emulsions. Technically it would eliminate soaping in silicone-containing emulsions but silicone (e.g. dimethicone) does that too. The real formulation challenge starts when you need to remove silicones to create Clean or Natural formulations, or simply



Lexgard® Natural MHG MB inhibited bacteria proliferation at a low concentration (MIC = 3900 ppm). The Minimum Inhibitory Concentration (MIC) value was evaluated for Methylheptylglycerin as a secondary indication of the expected effect against gram+ bacteria. *Staphylococcus aureus* (gram+ bacteria) was again used as a proxy microorganism for *Staphylococcus hominis*. Ethylhexylglycerin was used as the control. A lower MIC correlates to inhibition of microbial growth at a lower in-use concentration.

- **Methylheptylglycerin is a 100% biobased methyl-branched C8 glyceryl ether**
- **Ethylhexylglycerin is a petro-based ethyl-branched C8 glyceryl ether**



because your target consumer wants silicone-free. Often when silicones are replaced with other emollients for the silicone-like sensory benefit, the soaping or foaming problem emerges. Adding Lexgard® Natural MHG MB minimises the foaming. It is highly compatible with emulsion formulations giving the benefit of anti-soaping without the need for further reformulation and increasing the natural content of your formulation at the same time.

INOLEX's Alternative Preservation portfolio includes individual ingredients and complete systems that work with your formulations' microbial growth "hurdles" to provide broad spectrum antimicrobial control.

Feel free to get in contact with the team at A S Harrison & Co for a hand with samples, formulations, and other suggestions: call us on +61 (0)2 8978 1000 or email performanceingredients.ash@harrison.com.au

schülke

What does healthy skin depend on?
A balanced skin microbiome.

The skin is colonized by billions of microorganisms. The skin microbiota also called skin flora is the microbial community in a specific environment. Microbiome are all genes from a microbial community which is highly individual and body site specific. Microbiome is dependent on temperature, moisture, nutrients, pH and other physical and chemical skin parameters.

Healthy skin usually has a balanced microbiome with a high diversity of microorganisms. Diversity is the relative distribution of the species. The more different species occur indicate the higher the diversity. A balanced microbiome contributes to skin health and vice versa.

Patients with atopic dermatitis have a disturbed skin barrier. They show an unbalanced microbiome with high Staphylococcus aureus occurrence which indicate low diversity. There is a clear correlation between an unbalanced microbiome and certain skin diseases. Therefore, a balanced microbiome

should be protected!

Will preservatives affect the skin microbiome? in vivo microbiome study with euxyl® PE 9010.

After searching different database, we found that microbiome related claims such as prebiotics and probiotics are used even with preservatives and multi-functionals. schülke did a in vivo study with euxyl® PE 9010 to investigate the influence on the skin microbiome.

in vivo microbiome study set up

- 23 test persons
- Subjects with healthy skin in the test area (inner forearm)
- 2 times daily application (one baseline untreated; another baseline treated with cream containing euxyl® PE 9010)
- Biodiversity comparison after 3 weeks

Analysis process of the microbiome

- Microbiome sampling
- DNA extraction
- Identification of micro-organisms
- Relative abundance to describe microbiome composition

in vivo microbiome study results relative abundances

- Individual differences between test persons are visible
- Hardly variances between baseline and after 3 weeks
- Main Groups are Firmicutes (e.g. Staphylococcus) Actinobacteria (e.g. Corynebacterium, Micrococcus) and Proteobacteria (e.g. Moraxella)

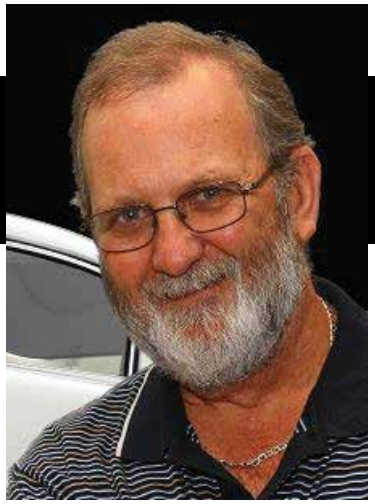
in vivo microbiome study conclusion

- euxyl® PE 9010 respects the individual microbiome
- euxyl® PE 9010 does not influence the individual diversity of the microbiome
- euxyl® PE 9010 is suitable for use in combination with microbiome influencing actives and formulations with a microbiome claim, as it does not affect the microbiome

Antimicrobials and the microbiome conclusion

According to the test results, euxyl®

PE 9010 has no negative impact on the microbiome. Multiple formulation ingredients of the formulation will most likely have more impact. A holistic approach is crucial for the development of a microbiome formulation!



Part 54 –

by Ric Williams

Blue Light and its Effects on Skin

Sunlight, at an effective temperature of 5,780 kelvins, is composed of nearly thermal-spectrum radiation that is slightly more than half infrared. At zenith, sunlight provides an irradiance of just over 1 kilowatts per square meter at sea level. Of this energy, 527 watts is infrared radiation, 445 watts is visible light, and 32 watts is ultraviolet radiation ("Reference Solar Spectral Irradiance: Air Mass 1.5". Retrieved 2009-11-12).

UVR

The sun gives off ultraviolet (UV) radiation that we divide into categories based on the wavelength.

UV radiation (UVR) that reaches the Earth's surface can be divided into UV-B (290-320 nm) and UV-A (320-400 nm). UV-A can be further subdivided into UV-A I, or far UV-A (340-400 nm), and UV-A II, or near UV-A (320-340 nm).

Visible Light

An extract from the conclusion in the paper published in Journal of Investigative Dermatology (2012) 132, 1901–1907; doi:10.1038/jid.2011.476; published online 9 February 2012, titled ; Irradiation of Skin with Visible Light Induces Reactive Oxygen Species and Matrix-Degrading Enzymes

By Frank Liebel, Simarna Kaur, Eduardo Ruvolo, Nikiforos Kollias and Michael D Southall; states "the approximate depth for penetration of visible light (400–700 nm) in a fair-skinned Caucasian individual was estimated to be between 90 and 750 μm, compared with a depth of 1.5–90 μm for UVR (Anderson and Parrish, 1981). Thus, even though visible light photons are less energetic than UV photons (and only thought to produce heat), due to the deeper dermal penetration visible light may still have a substantial effect on skin. Taken together, these results demonstrate that visible light exposure can induce

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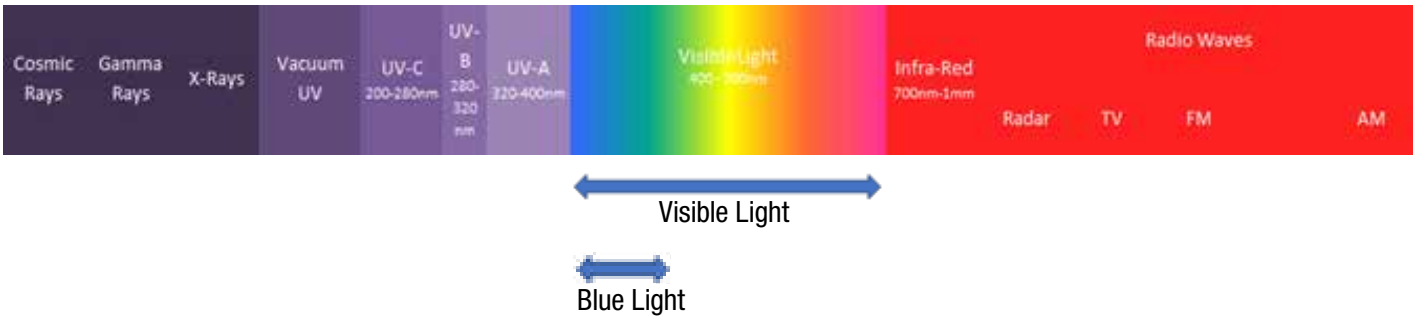
This column is intended not only as an education tool for non-technical people or beginners in our industry, but as a forum for those wishing to enlighten all about recent technology advances and new ideas. I hope experienced scientists will also contribute to this ideal and if you wish to do so please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



Reactive Oxygen Species (Free Radicals), which can lead to the release of proinflammatory cytokines and MMPs in the skin, similar to the effects of UV, and therefore visible light may contribute to the signs of premature aging in the skin."

Blue light is a range of the visible light spectrum, defined as having a wavelength between 400–495 nm (2.8 ev – 3.4 ev). This short wavelength means that blue light is a type of high-energy visible light with effects similar to low energy UVA light.

What's new about blue light?

Blue light has been around longer than we have - it's a natural part of sunlight. So why the sudden interest now?

Because blue light has come indoors. Today, blue light is also emitted by electrical and electronic devices such as smartphones, tablets, computers, TVs and even the humble light bulb. The intensity of blue light emitted by screens can reach 80% of the intensity of a blue sky. And the amount of time we spend in front of a screen is increasing rapidly. In Europe it's already around three hours, while in the USA and Japan it's currently more than four hours a day. And that's only an average

Blue light sources are becoming increasingly common in today's environment. Exposure to blue light comes from a variety of technologies including computers, televisions, and lights. Much of the exposure arises from light emitting diodes (LEDs). Today, many white LEDs are produced by pairing a blue LED with a lower-energy phosphor, thereby creating solid-state light (SSL). This is often considered "the next generation of illumination" as SSL technology dramatically reduces energy resource requirements.[1]

Increasingly, people are exposed to blue light via everyday technology. The 2015 Pew Research Center study found that 68% of U.S. adults own a smartphone and 45% own a tablet. The study also found that levels of technology ownership vary by age; 86% of Americans 18-29 and 83% of those 30-49 own smartphones.[2] Younger Americans also use high rates of blue light technologies. The survey of Common Sense Media in 2013 also demonstrated that 72% of children age 0–8 years old used mobile devices for watching videos and playing games.[3] Moreover, 93% of teens owned a computer or had access to one at home.[4] In contrast, computer ownership rates are lower for older Americans.[2]

Ref 5

Research on how blue light affects your skin is ongoing, but what dermatologists know so far doesn't look good. One small, peer-reviewed study of the effects of blue light on the skin, published in the Journal of Investigative Dermatology in 2010, found that exposing skin to the amount of blue light we get from the sun caused more pigment, redness, and swelling than when the same person's skin was exposed to comparable levels of UVA rays.

Blue light plays a critical role in maintaining good health, as it regulates our body's circadian rhythm.

The effects were only observed in people with darker skin tones, but the researchers noted that pigmentation also lasted longer. "This study absolutely makes us realize that blue light produces visible skin change, including redness and pigmentation," Loretta Ciraldo, a board-certified dermatologist in Miami and co-founder of Dr. Loretta skin care, tells Allure.

Another (very small) study published in Oxidative Medicine and Cellular Longevity, suggested that exposure to blue light might stimulate the production of free radicals in skin, which can accelerate the appearance of aging.

The bottom line? The blue light effect on skin needs more research before we can draw any solid conclusions, though early evidence seems to suggest it has the potential to be damaging.

Ref 6 - Conclusion

Human skin has been exposed to different levels of light since the creation of life. Interestingly, over the past decades, due to consequences of modern life, humans are not exposed to adequate levels of natural light during the day but are overexposed to relatively high levels of artificial light at night. Exposure to light emitted from electronic devices on human skin cells, even in case of short exposures, can increase the generation of reactive oxygen species. Skin is a major target of oxidative stress and the link between aging and oxidative stress is well documented. Especially, extrinsic skin aging can be caused by oxidative stress. Moreover, LEDs are among the main available digital camera photoflashes. Although, there are numerous advantages for the use of LEDs over Xenon flashes, the peak spectral intensity of LEDs lies in the blue region. Current data show that exposure to blue light can lead to

different levels of damage in human eyes and skin. Changing the spectral output of LED-based smartphones' flashes can be introduced as an effective method for reducing the adverse health effects associated with exposure to blue light.

Ref 7 - Abstract

Phototherapy with visible light is gaining interest in dermatological practice. Theoretically, blue light could induce biological effects comparable to ultraviolet A (UVA) radiation. To study the effects of blue light on normal skin in terms of photodamage, skin ageing and melanogenesis. Eight healthy volunteers were included and irradiation with visible blue light was given on five consecutive days. Skin biopsies were analysed with respect to photodamage (p53, vacuolization, sunburn cells), skin ageing (elastosis, MMP-1) and melanogenesis (Melan-A). No inflammatory cells and sunburn cells were visible before or after irradiation. A significant increase in the perinuclear vacuolization of keratinocytes was demonstrated during treatment (P=0.02) with a tendency towards significance after cessation of treatment (P=0.09). No significant change in p53 expression was seen. Signs of elastosis and changes in MMP-1 expression were absent. Minimal clinical hyperpigmentation of the irradiated skin was confirmed histologically with a significant increase in Melan-A-positive cells (P=0.03). Visible blue light, as given in the present study, does not cause deoxyribonucleic acid damage or early photo-ageing. The biological effects of blue light on normal skin are transient melanogenesis and inexplicable vacuolization without resulting apoptosis. In conclusion, the (short-term) use of visible blue light in dermatological practice is safe.

Ref 8 - Blue Light Effects

The human eye detects solar energy within the visible spectrum. Of this, blue light, also referred to as high energy visible (HEV) light, has a shorter and higher energy wavelength that is potentially harmful to the skin. It also has several positive and even therapeutic uses. Early morning sunlight contains higher proportions of blue light, which to early humans in their natural surroundings, served useful to wake them and energize their brains. Consequently, blue light has been used to help depression. This is the basis for full-spectrum, high intensity lighting for the treatment of seasonal affective disorder.

Blue light also has antibacterial properties, so it can be used for treating infections such as acne, thanks to its lethal effects on the bacterium Propionibacterium acnes. In-office blue light treatments lasting approximately 20 min are often used for acne treatment. There are also blue light devices for at-home treatment. These short blue light treatments, even if applied for five consecutive days, do not damage skin DNA and do not cause early photoaging.

The harmful effects of blue light appear to relate to prolonged exposure—especially to personal devices including cell phones and computers. Fluorescent bulbs emit blue light as well. Unlike ancient human ancestors living in the natural world, only about 40% of our blue light exposure comes from the sun. The remainder originates from our personal devices.

Furthermore, recent studies have shown that blue light penetrates skin deeply and can negatively impact all layers. In particular, it has been shown to produce oxidative stress in skin, contributing to free radical damage as well as premature photodamage, hyperpigmentation, inflammation and decreases in immunity. Beyond the skin, blue light, being visible, also penetrates the eye and falls on the retina, and a clear relationship has been established between the high energy exposure of blue light and the development of blindness from age-related macular degeneration. In addition, the retina's exposure to blue light can affect the brain and disrupt sleep. This may be related to decreased melatonin production or other unknown effects.Disp

Notwithstanding, millennial consumers in the United States check their phones an average of 157 times each day, compared with older adults who do so 30 times a day. Similarly, worldwide, people in most countries are exposed to an average of four additional hours of artificial blue light per day.

Prevention can use:

a. UV-filter(s) such as the newly introduced Biscotriazole to block blue light, or
b. Physical blockers such as Microfine Titanium Dioxide or Zinc Oxide, or
c. a new freshwater microalgae bioactive in the name of Scenedesmus rubescens Extract which stimulates skin's own defence.

Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (Bisoctrizole)

Bisoctrizole is a hybrid type sun blocking agent acting as both chemical and physical sunscreen. It covers both UVA and UVB range, but also tails off into the Blue Light region. Wavelengths covered: about 280-450 nm; peak protection at 303 nm and 358 nm Furthermore, it does not degrade under sunlight and is not significantly absorbed into the skin. It appears highly compatible with many other common sun blocking agents. Overall, it appears to have a good safety profile, even though current safety data are insufficient and long-term human safety studies are lacking.

Zinc Oxide

Zinc oxide is a mineral that provides complete UVB/UVA protection, mainly by reflection, has anti-inflammatory properties, and is considered a safe sunscreen ingredient. Zinc oxide is the only FDA approved sunscreen for use on children under 6 months of age. However, the regular form of zinc oxide leaves a strong white residue on the skin. To create a clear skin product rather than one that leaves a white residue, zinc oxide is now made in micro-size particles.

Like titanium dioxide, microsized or ultrafine grades of this ingredient have been developed, offering some of the same advantages and disadvantages described above, including the ability to provide more full-spectrum protection. Zinc oxide is less whitening in this form than titanium dioxide and provides better Blue Light protection.

Titanium Dioxide

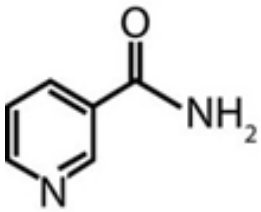
A pigment (found naturally) that reflects UV, Visible and InfraRed light in its standard form (Rutile mineral) but when micronised has very good reflection and absorption properties while being transparent on the skin (ie it does not absorb in the visible range). It has decreasing absorption of visible light (ie greater transparency) as the micronised particles become smaller unfortunately the UV absorption oes not increase that much (unlike Zinc Oxide) and relies mostly on reflection for its protection. This ingredient can be classified as a broad-spectrum agent.

The ideal sunscreen agent would be chemically inert, safe, and absorb or reflect through the full UV spectrum and into the Visible light spectrum. Titanium dioxide meets these criteria limited only by aesthetics. By decreasing the particle size of this pigment to microsize or ultrafine grades, thereby making it less visible on the skin surface, some of these advantages could be used.

Despite advances in the technology, formulating products with this ingredient that do not whiten the skin secondary to pigment residue is difficult. Adding other pigments that simulate flesh tones may partially camouflage this effect. The net effect may be that the user is inclined to use less of the product (a light application), effectively lowering the SPF. Hybrid products that use a combination of chemical UV absorbers with inorganic particulate sunscreens may represent a practical compromise.

Scenedesmus rubescens Extract PEPHA®-AGE (DSM)

DSM researchers have identified the potential of the freshwater algae Scenedesmus rubescens to stimulate skin's own defense against the negative impact of blue light protecting the skin barrier, capturing the free radicals and boosting the collagen synthesis. New outstanding in-vivo study results showed PEPHA®-AGE reduces immediately and strongly the skin hyper pigmentation and irritation after blue light exposure and restore an even skin tone.



Post treatment can include

Vitamin B3 (Niacinamide)

Niacinamide is one of the two principal forms of vitamin B3 (nicotinic acid is the other). Niacinamide serves as a precursor of NADH and NADPH, which are co-enzymes (facilitators of enzymatic reactions) essential for numerous metabolic pathways. In particular, these co-enzymes play a key role in metabolism of glucose, cellular energy production, synthesis of lipids and so forth. The levels of NADH / NADPH decrease with age, and topical niacinamide appears to reverse the decline.

Niacinamide also appears to have some antioxidant and anti-inflammatory properties. Furthermore, niacinamide is stable, safe and well tolerated in topical formulations even at relatively high concentrations.

All of the above suggests that niacinamide, theoretically, may be useful in skin rejuvenation and some skin conditions. These conditions include Rosacea and acne vulgaris. In particular Nicotinamide has demonstrated the ability to block the inflammatory actions of iodides known to precipitate or exacerbate inflammatory acne.

Associate Professor Diona Damian of the University of Sydney also reports that "Nicotinamide, or vitamin B3, prevents damage from both UVA and UVB radiation by protecting the immune system, and could be added to a sunscreen." With the concern over Blue Light, adding this to a sunscreen could assist with protection from UV right through Visible light (Blue light in particular).

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Sea grape as beneficial green macroalga for fighting skin aging

by Liliane PELLEGRINI, Max PELLEGRINI, Aurélie ZAMBONI

GELYMA, France

The diversity of life remains one of the most striking aspects of our blue planet. It is estimated that about 195,000 Eukaryotes species are catalogued in Oceans and more than 2,200,000 are predicted. These data include Animalia, Chromista, Fungi, Plantae and Protozoa without any precise mention for microalgae and macroalgae.[1]

Nowadays, algae are classified in four kingdoms: Cyanobacteria, Plantae, Chromista and Protozoa.[2] Among them, macroalgae constitutes an exceptional reservoir of innovative molecules for cosmetic purposes due to the important algal biodiversity throughout the world. They may bring numerous bioactive compounds incorporated in a wide range of products like creams, lotions and shampoons among others.

The major cosmetic applications relative to macroalgae concerns mainly Phaeophyceae (brown species), occasionally Rhodophyceae (red species) and more exceptionaly Chlorophyceae (green species). However Chlorophyta includes nearly 4,600 species and probably even more remain to be discovered as mentioned in several studies[2-3].

Consequently this group of green macroalgae remains to explore to source new bio-based products and applications. Some species showed interesting purposes for cosmetics, especially (1) the antioxidant potential of the extracts prepared from *Ulva pertusa, Enteromorpha linza* and *Bryopsis plumosa4, or* also from *Enteromorpha compressa, Enteromorpha intestinalis, Ulva fasciata, Ulva lactuca, Chaetomorpha antennina5*, (2) the powerful anti-inflammatory effect of *Codium fragile6* or (3) the oligosaccharides prepared from the polysaccharide ulvan of *Ulva* species[7].

One of the most frequent cosmetic concerns is skin aging, a complex inevitable process of human life, resulting from both intrinsic or genetically programmed ageing that occurs with time and extrinsic ageing caused by environmental factors. Intrinsic and extrinsic ageing of the skin follow different pathways but alone or associated, these processes induce numerous external signs of skin ageing that occur at the levels of epidermis, dermis and the dermal-epidermal junction.

Many research approaches have been put forward to fight skin ageing and defy such manifestations. These ways include prevention against external environment (sun, pollution…), activation of cell regeneration and strengthening the extracellular matrix (collagen and elastin).

In this study, the green seaweed *Caulerpa lentillifera* was investigated for its *in vitro, ex vivo* and *in vivo* potentials to work as skin anti-aging agent.

Caulerpa lentillifera is known as sea grape or "umi-budo" in Japan, "lato, lato-bilog, ar-arosep" in the Philippines and "Rong Nho" in Vietnam. It is one of the algal delicacies eaten by Okinawans, the inhabitants of the Japanese island Okinawa renowned for their longevity. It is appreciated for its nutritional value and also for its refreshing taste and succulent texture.[8] In some Asian places, especially in Japan, Philippines, Malaysia and Indonesia, the popping sensation when the little grains are chewed is very popular. For that reason, this alga is also called "green caviar": caviar-like seaweed pods that pop in the mouth just like the famous fish eggs. It is also used in Traditional Asian medicine.

Material and methods

The complex studied named OKINACEA® (Sea grape) contains water (65%), *Caulerpa lentillifera* extract (31%) and hydrolyzed rice bran protein (4%). It is safe for cosmetic applications following

the results of Patch – Het Cam – Ames and sensitizing potential testing.

INCI name is water (and) *Caulerpa lentillifera* extract (and) Hydrolyzed Rice Bran Protein

The thallus of *Caulerpa lentillifera* consists of horizontal irregularly branched stolons bearing numerous erect fronds which are densely covered by subspherical short ramelli. Each ramulus consists of a short stalk and a globose tip, 1-3 mm in diameter (Fig 1). The distinct constriction between the tip of the stalk and the base of the globose tip is a characteristic of this species (Fig 2).

Caulerpa lentillifera used for the manufacturing of this active came from controlled cultures in Asia.

Figure 1 : Morphology of the thallus of Caulerpa lentillifera (Sea grape)

Figure 2 : Magnification of stipitate ramelli with the presence of the constriction at the top of the stalk

In vitro study

The synthesis of procollagen 1 has been quantified on the supernatant of the cultures of normal human fibroblasts after 48 H cultivation in the presence of 2% active by using the kit "Procollagen type 1C-peptide (PIP) EIA Kit – ref. MK101 –TANAKA. The standard was vitamin C 50 µg/ml. – positive control). The total protein content was evaluated according to the bicinchoninic acid (BCA) method.

Ex vivo study and immunolabelling

All *ex vivo* studies have been performed on 24 skin explants obtained from an abdominal plastic surgery of a healthy Caucasian woman (53 years old). They are cultured in the specific survival explants medium BEM. 2 mg of a formulation (Carbopol gel) containing 2% of the active mixture were applied on the skin stripes at the following times: Day 0, Day 2, Day 5 and Day 7. The results are compared with untreated explants. Explants were taken off at D0 and D9. Each explant was cut into two parts: one half was fixed in ordinary Bouin solution for previous morphological analysis while the other half was frozen at -75°C for immunostaining.

Specific immunolabellings of collagen IV, laminin-5, GAGs and collagen I were performed on frozen cryostat cut tissues thanks to specific monoclonal antibodies and revealed by FITC (fluorescein isothiocyanate). Cells nuclei are then stained with propodium iodide. Optical observations have been performed by using a microscope Leica type DMLB equipped with a camera Olympus DP 72.

In vivo study

The *in vivo* study has been performed on 25 healthy women (age from 40 to 59). A formulation with OKINACEA® (5%) as a unique active ingredient has been applied twice a day for 28 days on crow's feet area. The measurement of the skin roughness and 3D pictures have been performed by fringes projection using a GFM PRIMOS® device.

Results and discussion

Results presented here after show that Sea grape was able to prevent some anti-ageing damages.

Sea grape strengthens the dermal epidermal junction (DEJ)

The DEJ serves various functions e.g. epidermal-dermal adherence, mechanical support for the epidermis. It also controls proliferation and differentiation of basal cells in the epidermis. It maintains the polarity of the epidermis ensuring the cohesion and exchanges between the two major skin compartments. The ageing of the skin comes with significant physiological changes to the skin, especially at the DEJ with possible disruption and loss of DEJ surface area that may lead to the increased fragility of skin and consequently the formation of wrinkles and sagging. According to a study of abdominal skin, the surface area of the DEJ decreases from 2.64 mm^2 in subjects aged 21 to 40 years and to 1.90 mm^2 in subjects aged 61 to 80 years.[9]

Therefore, early epidermal basement membrane care appears to be an effective approach to prevent skin ageing, to keep efficient nutrient exchanges and the rete-ridges as wavy as possible.

Sea grape is able to interact with two relevant protein structures of the DEJ: collagen IV and laminin V.

Overexpression of collagen IV

Collagen IV is involved especially to maintain a functional interface between the epidermis and the dermis and to provide a framework for other molecules. It is also important in the maintenance of mechanical stability. In sun-exposed skins, it has been noticed a significant diminution of collagen IV in

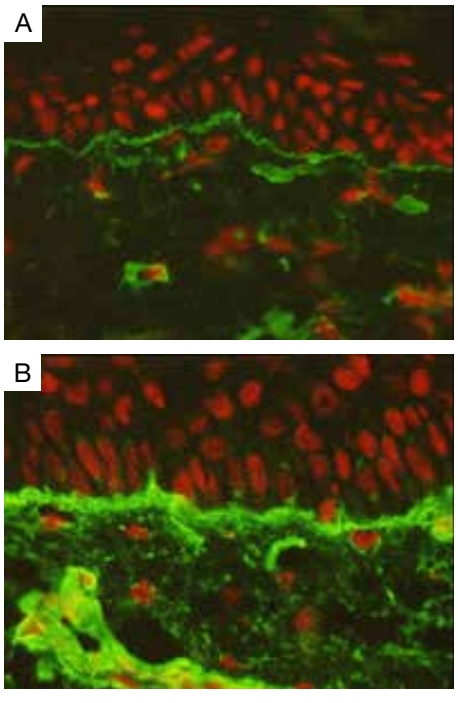

Figure 3 – Immunolabelling of collagen IV in human skin explants at Day 9.
A Control explants without any treatment The labelling appears as a scalloped band relatively clear and relatively regular along the DEJ.

B Treated explants with 2% Sea grape The marking is distinct and regular along the DEJ. It also appears in the basal keratinocytes.

the bottom of wrinkles compared to the flanks of wrinkles. This loss of collagen IV may affect the mechanical stability of the DEJ and contribute to wrinkle formation[10]. Therefore, to maintain or restore an optimum physiological state of the dermal-epidermal junction, it is imperative to have a means of increasing the amount of collagen IV therein.

Sea grape increases the synthesis of collagen IV (Fig. 3) and therefore helps to maintain an optimal physiological state at the interface between the dermis and the epidermis and to insure the stability of the DEJ.

Overexpression of laminin V

The major adhesive component of the dermal-epidermal junction is laminin V, an essential protein to bind epidermis to dermis. It plays a key role together with the basement membrane in cell communication, adhesion and skin regeneration. Its synthesis decreases in aged skin.[11-12] This causes a loss of contact between dermis and epidermis and results in a loss of elasticity and skin sagging. Therefore, the dermal-epidermal junction is also enhanced by substances that stimulate laminin V synthesis.

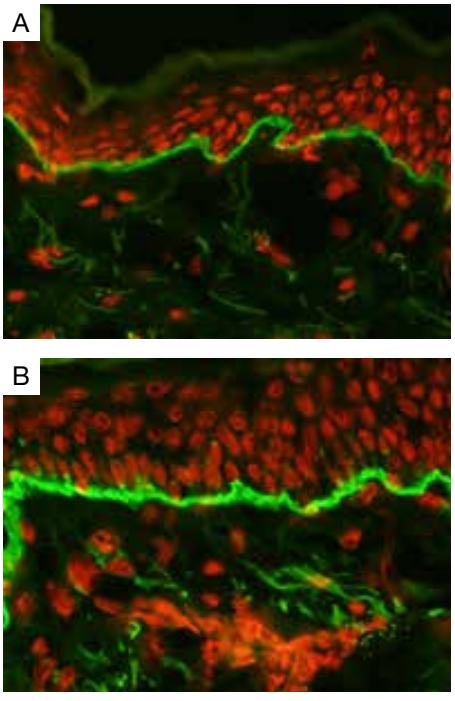

Figure 4 – Immunolabelling of laminin V in human skin explants at Day 9.

A Control explants without any treatment. The labelling appears as a scalloped band relatively clear and relatively regular along the DEJ.

B Treated explants with 2% Sea grape. The marking is distinct and regular along the DEJ. It also appears in the basal keratinocytes.

Figure 4 proves that the application of a gel with 2% Sea grape induces a noticeable over-expression of the laminin V in the DEJ and in the basal keratinocytes. Sea grape potentiates the production of laminin V and therefore contributes to maintain or repair normal epidermal basement membrane structure and its function.

By influencing the DEJ, Sea grape supports the good skin cell communication between the epidermis and dermis and guarantees its functionality and integrity.

Sea grape reinforces the dermal matrix

The dermis is a complex structure with dermal components surrounded by the extracellular matrix, composed of mucopolysaccharides (primarily hyaluronic acid), chondroïtin sulfates and glycoproteins. During skin ageing, dermal changes are significant in the cellular and extracellular matrix components. The dermis thins. Senescent fibroblast changes include an increase in matrix metalloproteinase expression and a decrease in its inhibitors.[13] The number of fibroblasts and their capacity decrease. New collagen production decreases and the dermal matrix declines. The dermis loses turgor due in part to a reduction of glycosaminoglycans synthesis. Elastic fibers also undergo important changes. Therefore, to counteract these dermal ageing signs, it is important to re-activate skin own production of matrix macromolecules, notably glycosaminoglycans (GAGs) in order to improve cutaneous tonicity and to reduce wrinkles and skin sagging.

Sea grape is able to improve the synthesis of major components of the dermis: GAGs and collagen I.

Stimulation of glycosaminoglycans (GAGs) synthesis

Glycosaminoglycans (GAGs) are involved in many of the cell processes occurring by means of molecular interactions in the cell surface. They also act as tissue organizers. Due to their high content in acid groups, they are osmotically active and attract water to maintain tissue hydration and turgor as well as the transport of nutritional material in the matrix. Moreover, GAGs are also involved in a variety of functions e.i. in the orientation and structural arrangement of other matrix constituents and in cell communication events. With age, significant reductions in the content of GAGs have been observed, that may lead to a reduction in water content and changes in skin thickness. As a consequence, the aged skin appears dried and wrinkled. GAGs are therefore becoming a new and original target in the treatment of skin ageing.

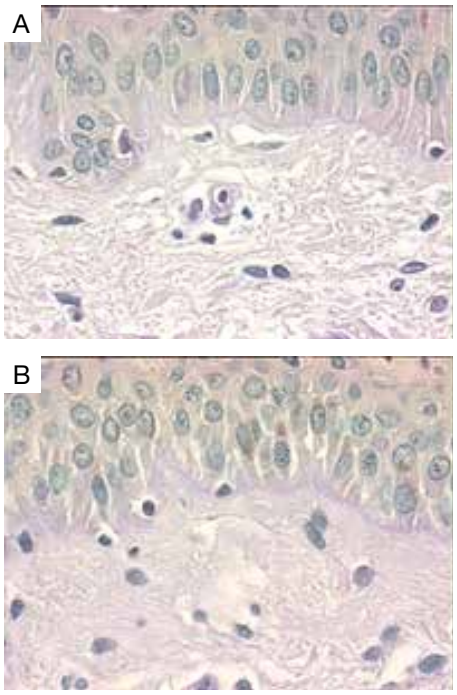

Figure 5 –Immunolabelling of GAGs in human skin explants at Day 9.

A Control explants without any treatment. GAGs present along the DEJ form a pink-violet band, regular and thin in the papillary dermis.

B Treated explants with 2% Sea grape. The pink-violet staining is regular and variously important.

The application of 2% Sea grape formulation after 9 days treatment induces an overexpression of GAGs along the DEJ (Fig. 5). Sea grape is able (1) to stimulate the biosynthesis of glycosaminoglycans (GAGs) and thus helps to improve skin moisturizing and (2) to replenish the skin volume.

Stimulation of collagen I synthesis

Collagen is a major structural protein of which fibers contribute to

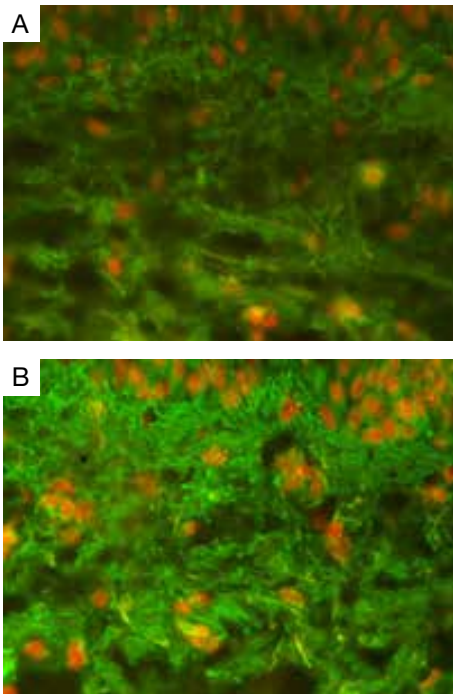

Figure 6 – Immunolabelling of collagen I in human skin explants at Day 9.

A Control explants without any treatment. The marking is very weak and less dense in the papillary dermis.

B Treated explants with 2% Sea grape. The marking is distinct with a network denser in the papillary dermis.

the elasticity and tonicity of the skin. It increases and continues to build up until about the age of 35 when the skin reaches the peak of its mechanical strength. After that, it begins to deteriorate and the skin become thinner and eventually saggy. With age, the secretion of collagen decreases linearly with a 29% loss in secretion ability between 19 to 68 years.[14] After damage, collagen biosynthesis remains at a level that is too low to allow mature skin to repair and to replace the collagen that has been lost. Therefore, the regulation of collagen synthesis can be potentially useful for cosmetics treatments.

So, the best ways to maintain a youthful, vital and healthy-looking appearance are to promote and protect collagen synthesis.

	PIP (ng/ml)	ng/ml/µg prot.	% stimulation
Control	288.2 ± 65.0	71.8 ± 13.9	
OKINACEAâ 0.5%	299.5 ± 31.7	108.2 ± 24.1 p = 0.007	51% **
OKINACEAâ 1 %	400.8 ± 54.7	103.5 ± 179 p = 0.005	44% **
OKINACEAâ 2 %	381.5 ± 38.9	107.9 ± 16.3 p = 0.002	50 % **
Vitamin C 50 µg/ml	487.7 ± 50.1	155.2 ± 19.1	116 % **

Figure 6 shows the action of Sea grape on the synthesis of collagen I. The percentage of the surface occupied by collagen I for the explants treated with OKINACEA® after 9 days treatment reaches significantly 118% compared to untreated explants at Day 9. Therefore, Sea grape is able to increase the synthesis of collagen and thus helps to restore youth appearance. This result has been confirmed by *in vitro* study.

Increase of the production of pro-collagen I

Collagen I is synthesized from a precursor molecule called "pro-collagen". The Type I pro-collagen is synthesized and secreted by fibroblasts which are specialized skin cells located in the dermis. It will form mature collagen which spontaneously assembles into thin collagen fibrils. Because pro-collagen I is a precursor molecule of mature collagen, its level reflects the level of the content of synthesized collagen I.[15]

Results, presented in the table here after, are obtained as a quantity (ng/ml) of pro-collagen I per quantity (ng/ml/µg prot.) of total proteins. ** $p < 0.01$ Student test.

At the different concentrations tested, Sea grape is able to stimulate highly significantly the synthesis of pro-collagen I by fibroblasts. With 0.5% active the increase reaches more than 50%. By activating both GAGs and collagen synthesis, Sea grape appears as a true restructuring agent.

Anti-aging effect of Sea grape – Clinical study

The first signs of ageing are seen in the skin of the face. The first areas affected are the eye corners where "crows' feet" appear. They start at the eye external angle, as fine cracks, then spread out to form a network of wrinkles.

Sea grape provides a significant reduction of 21% of the total roughness after only 28 days (Fig. 7).

Conclusions

With the increasing demand based on natural marine resource-derived agents for skin care applications, different kinds of macroalgae may be a promising source of agents with beneficial effects for skin health, especially skin ageing. Brown seaweeds are widely used, but other algal groups may offer a great potential for the cosmetics industry that is constantly

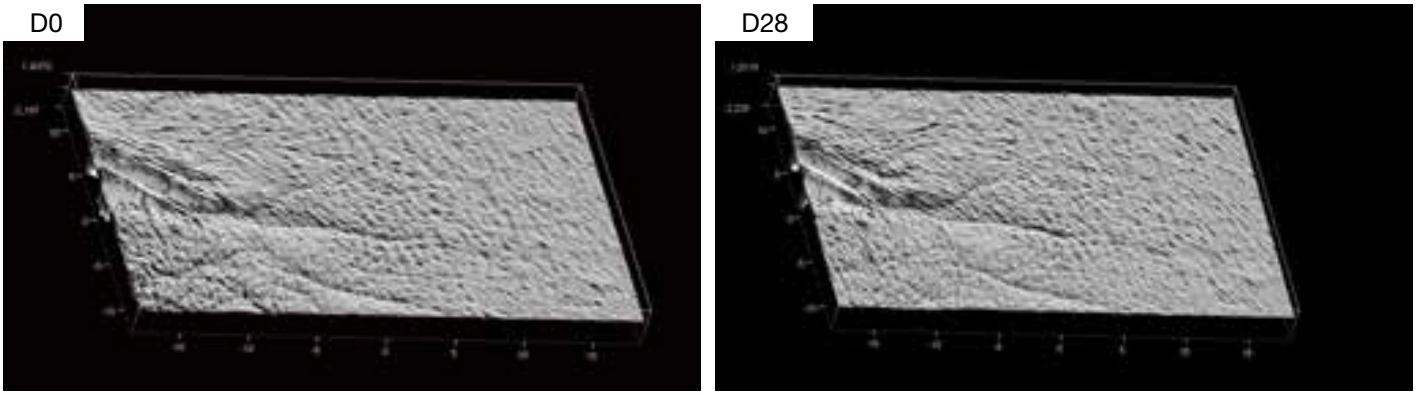

Figure 7: Evaluation of the efficacy of Sea grape on crows' feet

looking for innovation.

The present study is relative to a particular green macroalga *Caulerpa lentillifera*. Sea grape associated with Hydrolyzed Rice Bran proteins targets both the dermal-epidermal junction and the dermis. The product efficacy has been demonstrated by several *ex vivo, in vitro* and *in vivo* studies.

It offers the possibility to both (1) strengthen the DEJ functionality by stimulating both laminin-5 and collagen IV and therefore improving skin cohesion and increasing exchanges between the epidermis and dermis and (2) enrich and renew the extracellular matrix by increasing the synthesis of GAGs and collagen.

This finally contributes to improve the skin structure, to firm the skin and reduce the saggy skin and consequently to delay the major signs of skin ageing.

This product is ideal for anti-ageing face care, specific skin care for mature skin, repairing and restructuring skin care, firming body care with a recommended use level: 1% – 5%.

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Designing safety & claim support studies

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US - Eurofins CRL Cosmetic Testing

Nothing makes an R&D director happier than providing a validated sound scientific dossier to his/her marketing team on a technology or formulation that has gone through months, if not years, of development. From inception to market, there are endless meetings about progress, budgets, resource allocation and most of all, data generation. When you think about all of the time and energy you have spent on this one aspect of your pipeline, validating your work becomes paramount, so that it is universally accepted by not only the market place but by your management and investors as well. Ironically, this is the most crucial and usually the most expensive point of the project as a whole. What can you do to ensure that you are efficient in your success?

In order to properly validate your mechanism of action and support your claims, an outside lab is usually brought into the fray for good reason: you want an objective 3rd party verification of all you have done to this point. This will entail having all of your project management skills ready to go. This is akin to getting to the championship game in your favorite sport. The whole season now rides on how well you do in the next game or series. How do you position yourself for success? Below you will find some dos and don'ts that I have been faced with, both as a client and as a provider of clinical testing for personal care and cosmetic products.

Are you ready to test?

From the service side of the industry, I find that many clients come to the table thinking they are ready to test with a 3rd party laboratory. However, after the first meeting is over, they are usually going home with a todo list longer than the questions they had for me. So, ask yourself, are we ready to test? No matter your title or level of responsibility, you must build a team to answer this question. Having a team in place that represents all facets of the project, including where you have been and where you are going is the first step. Understanding how you landed on the functional claims, category and target consumer/customer are going to lay the foundation of what type of 3rd party lab you will need and what type of study design is warranted, as not all testing labs are created equal. All of your team members must bring their information and needs to the table to answer that question before you pick up the phone and ask for 3rd party commitment. Have a timeline built and map out the approval process commensurate with your company's policies. There are some companies that inherently have more red tape than others. Know and understand your internal process before bringing in outside counsel. This will certainly convey confidence and keep you in the driver's seat.

Represent your stakeholders

Having a good mix of representation on your team of R&D, marketing, operations, regulatory and sales

personnel, especially in the initial meetings with a 3rd party laboratory, will ensure that everyone's needs are accounted for and visible. This will also make for a much smoother utilization of data when it comes time to launch. Some of the best launches are the result of this synergy alone.

Communication

Gathering, moving and analyzing information is the norm in todays market place and is critical for success. It is imperative that the team you build have an open channel of communication within its team members and the lab when necessary. As the team leader/ project champion, you must know who your go-to people are. There are often cases of misplaced assumptions regarding who knows what, and who is responsible for deliverables and decisions. Many times I work with a project team looking to perform validation studies only to find that delays are imposed from executing as planned because the test materials are not available or not delivered on time to the testing facility. There are many reasons for this. Some examples include delays in release from QA, test materials that have not passed physical or chemical stability, last minute changes to the formulation design and for our international clients, test materials getting stuck in customs at the border. All of these issues can be mitigated with proper channels of information being open. If one person is the gate keeper of all the information, that person needs to have access to all facets of the project and to includes information that the team members possess. Establishing portals for information sharing, especially when collaborations exist over multiple time zones is something to also consider. At the end of the day, proper, concise and efficient communication is paramount to keeping all stakeholders informed and abreast of the status of your project.

Understand your goals

Have a holistic view of the expectations and goals. I always say to prospective clients, work your project backwards. Assuming that you get the best data possible, what will you say about it? Understanding the end game allows everyone to see the goal in the detail that is needed. Having a vague undefined goal is grounds for confusion, uncertainty and delays to market. Having the goal in mind is also crucial for developing the protocol to get you to the desired objective. One of the most common delays and unpredicted expenses companies incur are due to last minute protocol changes. These cause delays in final approvals, delays in recruiting the required subjects, and ultimately delays in study execution at the 3rd party lab. There is a high risk for decisions being made before final protocols are signed by not having your team review the protocols early on. This can lead to re-works, delays and loss of access to resources, equipment and personnel needed to perform the study.

Know your financial limitations

Budget, budget, budget, how many times have we all heard, we cannot do that, it is too expensive? Have a deliberate budget in mind when you are ready to validate claims. You can start off shooting for the stars but inevitably, you land back on Earth holding your budget in hand saying, we need a new plan. Match your needs within your budget. So many clients come to me with a beautiful study design only to realize that it is light years beyond what they budgeted for. Factors that drive price in any clinical study are of course the time and resources allocated by the lab; however, there are study design oversights that drive up study costs significantly. Having time points that can be managed Monday through Friday and within a regular work day reduces overtime commitment by the lab. Choosing technicians (or expert graders) to perform evaluations rather than MDs (where appropriate) is another way to save money. IRB cost, interim data requests, expedited reports and last-minute changes to the schedule once protocols are signed are huge drivers of cost, and many of these can be avoided with proper planning and good team building.

Focus on what you want to achieve

Validation of claims or target mechanism of action is in the eyes of the beholder. Keep in mind, in the personal care industry, consumer perception trumps all. If your technology/finished product does not deliver on consumer perceivable results, you most likely will not get a return customer and the market will quickly lose interest in your product. The good news is, consumer use studies are not that expensive. Know your consumer base, ask the right questions and provide the best use instructions possible. Many clients like to marry consumer use data with objective instrumental measures and/or expert grading. This is the trifecta of clinical study success. If you can show agreement with consumer perception, instrumental measures and expert assessment, you have a solid foundation for a bullet proof marketing campaign.

Understand your consumer

Consider the consumer experience when designing your study. Have you prepared use instructions that best represent how the product will be used? Do you have a mechanism in place to understand off indication use of your product? Factoring in these questions is critical to reduce the variation in consumer generated data. People in general are variable in their recollection of experiences. Having a way to reduce this through easy to read, easy to understand, and simple use instructions makes for a happy experience. Consumers/subjects evaluating a product will, when asked, provide valuable negative feedback as well. Ask for it, do not wait for it. It is better to understand the short comings of using your product before it hits the market. Is your product providing comfort and ease of use? If so, it will be viewed in a better light. Ask for diary comments, proof of use, have a hot line into the testing company for adverse event reporting. All of these provide subjects on your study with a positive experience which will ultimately be reflected in your data on product performance.

Translate your science and check regulatory requirements

Marketing should play an integral role as a cochampion of the validation process. They should be able to translate the science to consumer language which in turn should be converted to questions used for consumer perception studies. Marketing should also understand what the competition in their particular category is saying about similar products. Third party labs do not make marketing claims; they provide data to support them. Your marketing team should also have a hot line to a regulatory expert in the geographic regions of where you plan to sell your product. So much for world harmonization, the individual regulatory requirements worldwide are ever growing further apart and complex. Do not spend your valuable time and resources developing a technology only to find out you cannot sell it in your target region because of regulatory hurdles, restrictions on trade, and/or miss alignment with what is culturally acceptable.

Know your data

Finally, what to do with your data? Chances are, you may be in charge of getting a 3rd party laboratory to perform some validation or claim support studies but you do not remember the first thing about statistics. Your report comes back from the lab with P values and Z scores. Paragraphs about significant and non-significant data along with ANOVA analysis. What does all of this mean? Did you set up the study to have the data be understandable or are you counting on one of your science team members to make sense of it all? Is the data audited? So many times as a client, I have asked for the raw data to review and crunch myself to better understand the relationships. On the flip side, as a testing lab, I have had clients spend significant time and money on a study and not know what their data means or how to apply it back to the original objective of the study.

Conclusion

No matter how you get to your goal, always keep in mind the fundamentals. They are so easy to take for granted and in retrospect, the lack of attention to the fundamentals is the very reason why projects do not go as planned. So, build an effective and comprehensive team, know your budget limitation upfront, manage information in and out of the team efficiently, understand the expectations and stick to the plan. Understand the needs of your customers and translate the data in a way they understand. Last but not least, know your market and consumer front to back and translate data so that they both understand it to the point at which they come back for more.

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