the science of beauty

Vol 9 No 5

April/May 2020

Mother Nature – Helping Hands

Oleosomes (Hydresia® SF2) provide an all-natural "difference you can feel" in alcohol-based hand sanitisers.

- ✓ Alcohol-based products can be used to significantly reduce the microbial population on the skin.
- ✓ Alcohol can be drying to the skin and repetitive use can cause cracking, redness and skin irritation.
- ✓ Consumers have observed a marked improvement in skin moisturisation, when comparing Oleosome-based alcohol sanitisers to the market leading alcohol moisturising sanitiser*.

*Blinded Consumer Panel Study

Oleosomes Hand Sanitiser vs. market leading alcohol moisturising sanitiser (30 people - 20 females and 10 males)
Conclusion – Oleosomes hand sanitisers (at 6%, 8% or 12.5%) are preferred over the market leading sanitiser.

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Proven Delivery System

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Refer to our article **"Mother Nature Helping Hands"** in this issue.
Learn more about the A S Harrison & Co range of personal care ingredients –
Contact us for more details, starting formulations and samples.

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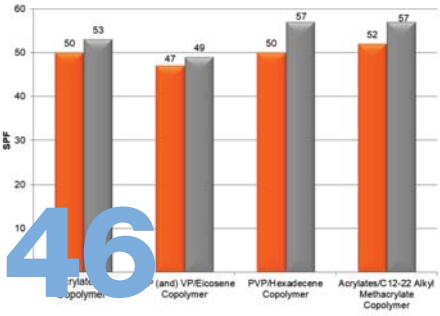

ASCC

ASCC 2020 VISION

FOR A CLEAN AND SUSTAINABLE FUTURE

ASCC 2020 Conference

Important update!

Affiliated with the IFSCC

The ASCC understands that it is a difficult time for us all in the wake of the COVID-19 pandemic and subsequent disruptions to the global landscape in the last few months. As a result of the rapidly changing situation and overall uncertainty the world is facing the ASCC has been monitoring the situation as it develops and how it will impact not only our members but also the industry and society as a whole.

The ASCC takes the health and safety of everyone involved with our industry and affiliated industries extremely seriously whether they are ASCC members or not. I am sure that many of you are concerned for the ongoing situation and how this will impact currently planned ASCC events and activities.

We would like to therefore announce that the 52nd Annual ASCC Conference scheduled to be held 19-21 May 2020 has been **rescheduled to 16-18 November 2020**. The ASCC Council and 2020 Conference Organising Committee has been working extremely hard to ensure the continuation of this event albeit at a later date than initially planned. This decision has been made to ensure the safety and wellbeing of all delegates/ exhibitors/ speakers etc. in what is a difficult time. We are certain that the rescheduled date will ensure a successful and well attended conference still proceeds this year.

In terms of the impact this will have for those delegates already registered and sponsors/ exhibitors already signed up to attend.

- All registrations for the conference received so far will be transferred to the new dates without any issue.
- All exhibitors/ sponsors will be transferred (as of now) to the new date without any changes. If you have any questions regarding your exhibition/sponsorship, please contact us immediately.
- All hotel accommodation bookings made directly with Ozaccom will need to be adjusted to the new dates. Please allow the ASCC and Ozaccom some time to facilitate this change and we will make a notification regarding how this will be done shortly.
- Registration will remain open.

This is an unprecedented and rapidly changing situation that the Organising Committee and Council are constantly working on and reviewing, we will provide more answers and directions as we work with our partners on how we manage the change, we ask for your patience and understanding. We would like to assure you that the rescheduled date of 16-18 November 2020 will not change.

The ASCC Council and Conference Organising Committee would like to express their thanks to everyone for their patience and calm so far. This is an extremely uncertain time for us all and we wish everyone and their families to remain safe and healthy. As has always been the case the industry will continue to work together to ensure we all come out of this on the other side.

Many thanks to our premium sponsors!

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Matthew *Martens*
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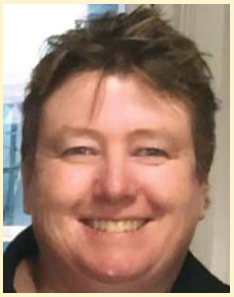
meet the team...

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.

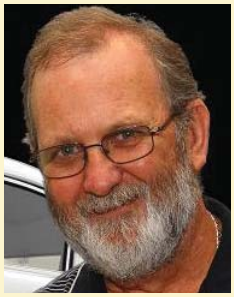
JULIAN JONES, the founder and Managing Director of ikonsulting Pty/Ltd, is Passionate about the Personal Care Industry in Australia and Globally.
Julian has been an active member of the ASCC for over thirty years. During this time he has served as President and Chairman of the Victorian Chapter of the 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.

together everyone adds more!

by Julian Jones

Never has it been truer than today, that "Alone we can do so little, together we can do so much" (Helen Keller, date unknown).

As a brand or service industry business owner, you will probably have assembled a team of people to grow your sales and expand your business to look after your clients better. Most of us started as individual entrepreneurs with an idea for a product range or a new service that filled a gap in the market and/or provided a better solution than was previously available.

Initially, we try to do everything – both to keep costs down, but also because we believe we can do it all better than anyone else! When you are successful, the inevitable day comes when you realise that you need help! And so starts the challenging job of recruiting and managing a team.

The traditional way of doing this is, of course, through hiring people, training them and leveraging their time and skills to grow your business. This has worked well for a long time and for many businesses, still does. Creating a well-managed team in a welcoming work environment is a proven way to build a bigger, successful company. Structuring the management of that team will evolve over time and should result in ongoing success.

Recently we have seen the rise of the "virtual" business where most functions are outsourced and staff numbers are kept to a minimum. Does this mean it is easier to manage this kind of business from a team perspective? The answer is yes – and no!

While you may not have a staff directly employed by your business, you certainly have a team of people working to build your success. This team requires management to ensure everyone is heading in the same direction and aligned with the goals that you as the business owner identify. Third party suppliers and outsourced solution providers can be very efficient at assisting you and your business, but they need to understand what it is you, as the owner, want to achieve. Clearly describing your plans and expectations up front and on an ongoing basis helps to make this happen.

I have found some amazing people as I have grown my business and I enjoy working with them every day! We communicate regularly and seek each other's wisdom and guidance as equals rather than in the more traditional model where employees tend to look to management/owners for leadership and guidance. I think this at the core of all well run and managed businesses.

Dick Smith, Australian entrepreneur, once said, "I realised I was good at putting in systems, asking advice, copying others, surrounding myself with capable people...all of those simple formulas that you need to run a business." If you, as the owner see your team as a source of solutions, ideas and expertise in areas where you lack them, they will become very invested in your success for more than just the income you represent to them.

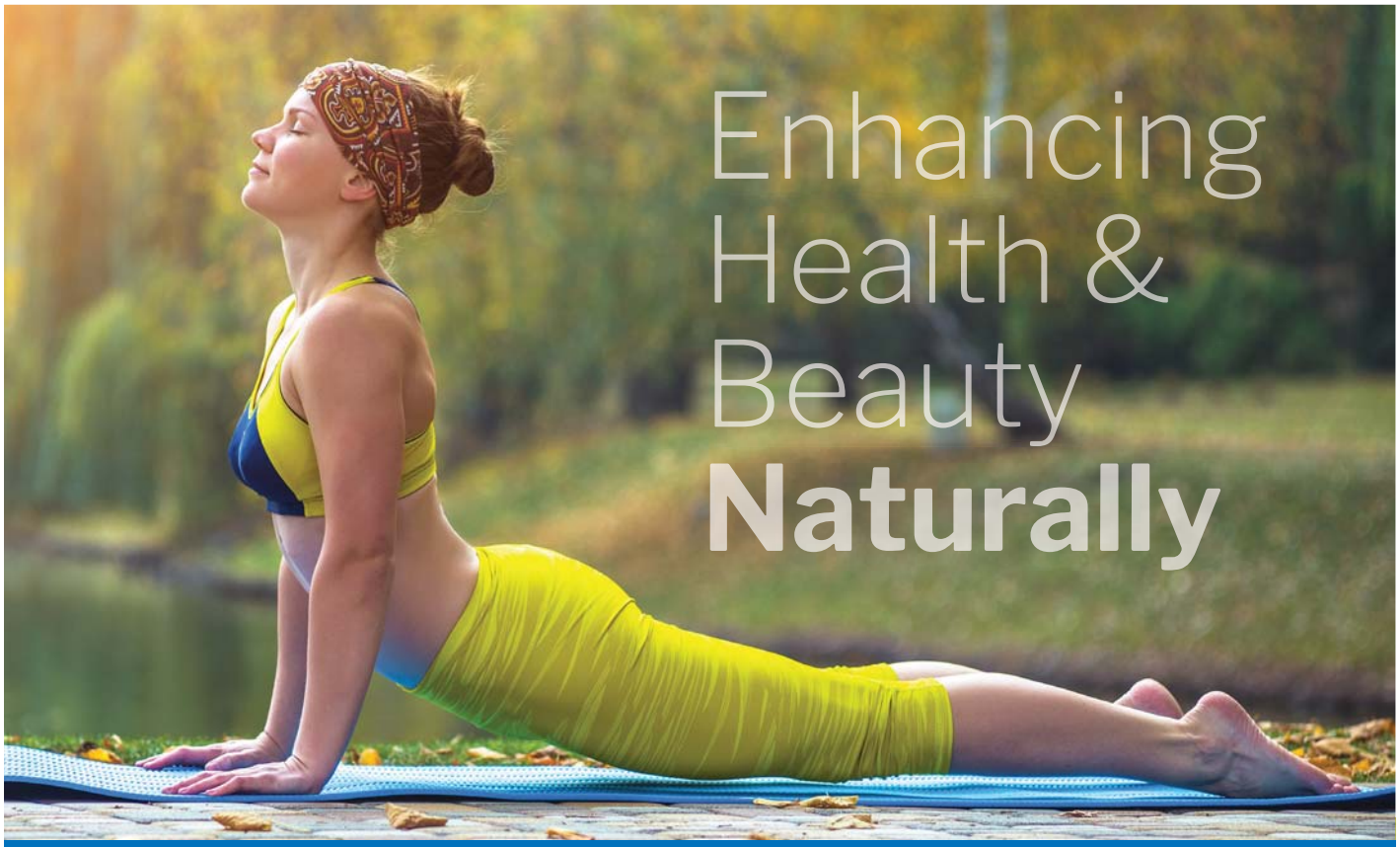
I see this form of collaboration as the best form of Teamwork – where Together Everyone Adds More to your business.

That's got to be a good thing, right?!

Till next time, stay safe and healthy.

Till next time – cheers,

Julian



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52nd Annual ASCC Conference

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Making sure your Cosmetics Business Insurance is on target

Consider these questions.

- I buy my insurance direct from an Insurer, so why I do I need an Insurance Broker?
- What should my scorecard look like when considering an Insurance Broker?
- What should be most important for my business? Is it simply price or is it the breadth of cover that protects me?
- What are my expectations of the service I expect from my chosen Broker (short & long term)?

Please take a minute to now consider the following.

1 *Finding a qualified Broker. A qualified Broker should not only be one who is authorised to operate as a Professional Insurance Broker. Qualified should also mean Qualified to help you with your insurance needs based on the number of years' experience they have in certain Industries, such as the Cosmetics Industry.*

by James Gillard

Insurance Made Easy (IME) have over 20 years' experience in helping Businesses in the Cosmetics & Complementary Health Industries. Our relationship with insurers is strong and our chosen insurers understand your Industry and how it operates, what the risks are, how to reduce the risk through insurance covers in place, etc.

2 *The depth of your business relationship with your Broker is also highly important. It must be fluid, not just that they meet with you or contact you prior to your insurance renewal. Your business can shift and change during the year and so your risk profile can alter. Consequently, your insurance needs may change.*

At IME we take this part of our relationship with our clients and your Business activity very seriously and stay close to our client's needs. Likewise, our relationship with insurers is also important to us. These insurers specialise in the chosen Industry and this builds a strong understanding of the specific industry requirements. Whether it be. Sponsor/ Brand holder, materials supplier, contract manufacturer, finished product manufacturer, Wholesaler, Distributor, Retailer, Warehousing, Regulatory Affairs Consultants, etc. An Insurance Broker's ability to recognise and understand these processes you are actively involved in ensures a head start in your relationship with your Broker.

3 *Find an Insurance Broker who can provide you with the right range of insurance products and with payment options aligned to your budget.*

At IME we take the view that we need to know your Business as well as you do to align your Business Risks with the right type of insurance products. A tailor-made insurance solution is our aim each time and this also includes suitable payment options.

4 *Is your Insurance Broker in the know?* Find out if they are.

- *Members of the National Insurance Brokers Association (NIBA) who are the peak body in the insurance industry for Brokers*
- *Are they members of an insurance broker group such as Steadfast? This type of membership provides peace of mind for you knowing the insurance broker has the strength of a large organisation behind them*
- *Are they actively involved in your Industry?*

At IME we have a long-term relationship with the Complementary Medicines Association, we attend their conferences and are represented with a trade table for enquiries. This opens the opportunity for us to meet members of the Industry each year and at all levels. We are also a member of the Australian Society of Cosmetic Chemists.

5 *Claims Management and your Insurance Broker.*
The claims process and service you receive is integral to choosing your Broker. Having the right representation from your Broker relieves much of the anxiety at the time of a claim.
At IME Brokers we are your advocate and take the role of assisting you with the claims process with the insurer as well as monitoring your claim until finalisation.

In Summary

Using an Insurance Broker will save you time and money because they can provide you with expert knowledge, advice, and negotiate competitive premiums on your behalf.

Given IME's credentials outlined above and our passion to help educate Businesses in the Complementary Health & Cosmetics Industry ,we can also help you with your own insurance needs.

Here to help you

If you are unsure about your current insurance coverage and need a professional advisor to review your policy or risk, and to discuss your own individual circumstances, please contact me on m. 0418341260 or Philip Watson m. 0423791368 to assist you with any insurance enquiry you may have.

James Gillard
Managing Director
Insurance Made Easy Brokers

coronavirus

impact on the packaging industry

by Steve Welsh

It is scary to think that just a few months ago no one knew what the coronavirus was, two months ago we were watching the outbreak in China and how it was affecting their economy and now, a global pandemic with borders shut worldwide, markets crashing and panic erupting throughout society.

At the time of writing this article, the latest regulations have implemented strict measurements regarding social distancing. Restaurants and cafes are limited to takeaway only, clubs/pubs/gyms/cinemas are closed, sports are postponed and there cannot be groups of more than 100 people indoors. The advice is changing daily and it's very likely by the time you are reading this article they could have changed again.

As you may have been noticing, resources have been very limited throughout supermarkets and pharmacies. Everything from toilet paper, masks, meat and hand sanitisers, everyday consumers are finding it very hard to buy necessity products due to the increase of demand. This increase of demand, has led to strict purchasing limits to help allow everyone a fair share of these goods. However, the constant demand for all this stock is pushing pressure on suppliers to be able to meet these needs.

For us in the packaging industry we have never been more busy, we are receiving countless of enquiries everyday for immediate supply of bottles and closures, mainly for hand sanitisers. The quantities that customers are requesting are in the hundreds of thousands and we have now got to the point where our lead time for production & delivery has hit the 8 week mark. With the current advice from medical experts, this virus is here to stay for at least 6 months to a year, so we expect the demand for hand sanitser bottles to remain the same during this time and we will be offering made to order bottles and closures as an alternative option.

Another issue that Australians are now facing, which is impacting the economy, is the value of the AUD is at an all time low for 20+ years. A large part of our business is importing packaging from our offshore factories and supplying to brands throughout Australia. This drop of the AUD has increased the price of packaging, due to import of materials which has ultimately led to consumers now paying more for goods than what they were previously. At Weltrade we mitigate the risk for our clients through setting pricing based on the market and holding that pricing until the goods are supplied. It is ensuring that planning is more important than ever and that you deal with a packaging supplier that can deliver on their promises in terms of quality and timing. To fix a problem down the track is a major heartache.

Finally during these uncertain times, more than ever it is comforting that you are working with a team of packaging professionals both in Australia and on the ground in China to get the best service possible, as well as to make sure what you receive is what you expected.

We are continuing to support all our clients everyday and offering them solutions to their packaging requirements, so that they can get to the marketplace as soon as possible. On behalf of all the Weltrade Packaging team we hope you stay safe and healthy during this pandemic and if you would like to discuss anything further, please do not hesitate to get in touch with us. You can reach us on 07 5597 0102 or email us on info@weltradepackaging.com.au.

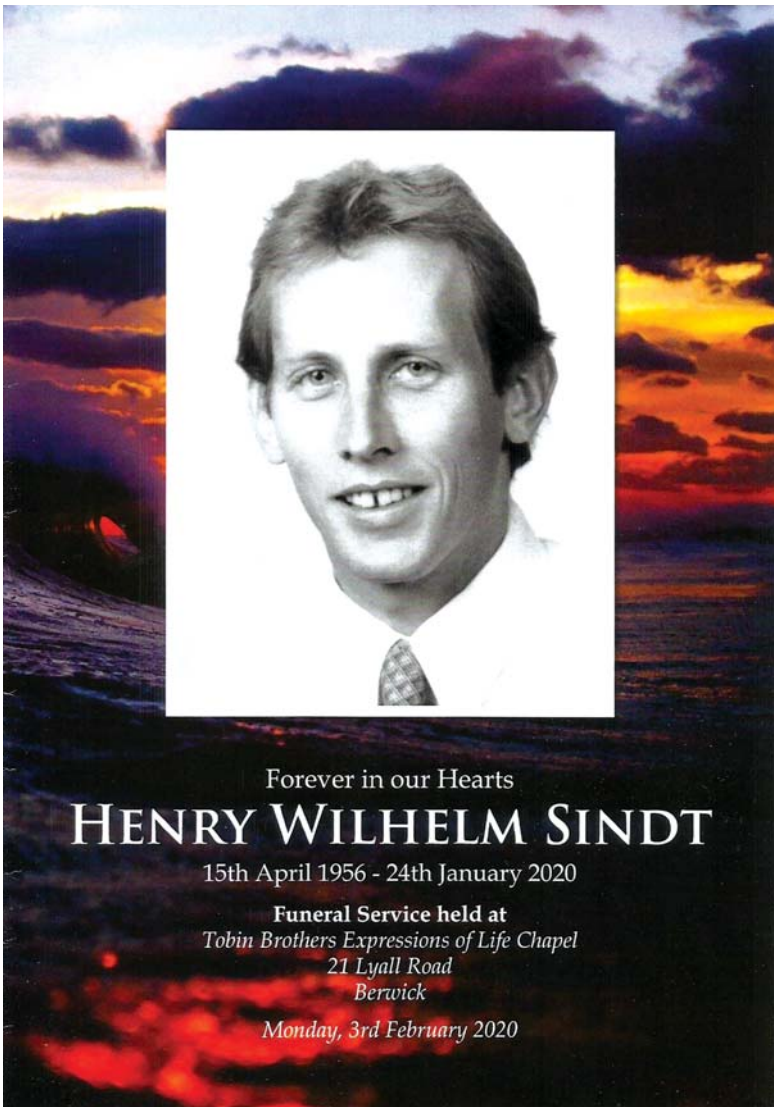
Regards, **Steve Welsh**

Vale to Henry Sindt

I first met Henry in the late 1980's, he was at FD&O and I had just come off a few years at BBA, so we could readily talk his, even back then, favourite subject – fragrances, at a reasonably technical level. Henry had an easy-going way about him, his quirky sense of humour notwithstanding. His jokes and quips weren't always as funny as he thought, but he never failed to have a chuckle himself on telling them. Initially, meetings were just that – although after a year or three of Henry dropping by with the latest Dragoco Report, the usual 15-20 minutes easily stretched into an hour before we knew it.

Conferences were where our friendship ultimately really developed. Back in those days there was always the 'free' Saturday afternoon, either spent exploring the local area, be that a bushwalk, a browse through the local township, a walk along the beach, or perhaps spent in the lounge bar or near the pool, or even better at a bar near the pool.

Eventually our 'meetings' became more of a friendly catch-up at my local coffee shop, perhaps three or four times a year, so much so that when I ordered my morning coffee and mentioned Henry would be dropping by, they would be ready to bring out his pot of English Breakfast as soon as he arrived. Amongst the very first subjects Henry would bring up would be updates on the two 'girls' in his life. Which sports identity Jeanette was currently treating or something about Letitia's latest exploits on the volleyball court, and eventually her initial forays into modelling.



He never changed, even with all he was going through and latterly our 'meetings' as such, were via the phone, and as always, Henry wouldn't let you off the phone easily. I can't finish up without conveying a story told by his nephew, how, during one of his hospital visits to see uncle Henry, there was an elderly patient with a walking frame very slowly passing by the door, Henry simply called out 'Show off'.

Goodbye my friend, I'll certainly miss you.

Nicholas Urquhart.

First off – Jake's words

Farewell Comrade – the past month has found me searching and often fumbling to find the right words to put down on paper.

Curiosity is a condition of the living, something which Henry had a youthful abundance of. It allowed him to make deeper and more meaningful connections with people of all walks of life. He was always so interested in all aspects of those lives he touched, seemingly sharing the joy of everyone's triumphs, and just as likely to help support in moments of failure.

Whilst Henry's optimism was legendary, it was his sense of humour which drew me towards him. Customer meetings with Henry usually left us in stiches with his dry sense of humour, whilst nearly always running overtime. He really defined the term "great partnership" in business both with his colleagues and his customers.

After 30 years with Symrise Henry undeniably left his mark, and he will always be part of our family.

Take care my friend, see you on the other side.

Jake McDonald

Division Manager
Scent & Care
Oceania

And, from Kate Bird

Henry developed the most amazing long-term friendships with many of his customers. He was so very highly regarded by everyone that he has worked with, combining his vast knowledge of the fragrance industry with his love for a chat – and we all know he loved a chat!

One thing that really stood out to me about Henry was his amazing ability to turn everything in to a positive, no matter what the situation. This became so evident through his illness – he was always able to see the positive side of things, even though he was going through the most intense challenges. Sometimes it was even easy to forget, for a second, what he was going through. That to us, is so very inspiring and spoke truths about his strength of character.

He'd frequently narrate over the phone while he was typing out an email, right down to the sign off at the end and joked he was doing his 'talking book' thing. You couldn't cut it short, he would just keep going until he reached the end.

Rest easy Henry…and in words he would frequently offer in challenging times… "it's all good comrade", "she'll be right mate".

Kate Bird

Fragrance Development
Account Manager
Scent & Care

cosmetic testing overview

by Emanuela Elia

In Australia, testing on cosmetic products is mostly not mandatory. However, there are many reasons why cosmetic products in Australia and overseas undergo a number of tests and clinical trials:

- To obtain safety and efficacy data during the product development phase
- To ensure quality
- To be able to differentiate their product (i.e. competitive advantage)

The aim of this article is to touch briefly on the most popular cosmetics tests available:

In vitro tests for finished products and raw material

- Toxicology tests for ingredients
- In vitro tolerance tests for finished products
- In vitro sensitization tests
- In vitro efficacy
  - Antioxidant/anti free radical activity
  - Whitening activity
  - 'Soothing activity'
  - Cell renewal
  - Collagen synthesis
  - 'Healing activity'
- Endocrine disruptors

Microbiology studies

- Challenge tests (i.e. demonstrate the antimicrobial activity effectiveness of the preservative system of your cosmetic product before its launch)
- Quality control
- Stability studies
- Microbiological efficacy

In vivo and *in vitro* sun care products tests – exception based on TGA regulation

The TGA regulates some sunscreens as therapeutic goods in Australia. Primary sunscreens (products used primarily for protection from UV radiation, SPF 4 or more) and moisturisers containing sunscreen with SPF greater than 15 fall under this category (i.e. they are not cosmetic products). Only approved ingredients can be included in sunscreens, and each of these ingredients has been assessed for safety. The TGA requires the efficacy of each sunscreen product to be tested to determine the sun protection factor (SPF), which is printed on the label. Therefore, for most sunscreen products some level of testing is mandatory.

Although *in vitro* testing can be extremely valuable in the product development process, when we talk about "claims substantiation" we primarily need to refer to *in vivo* clinical tests, as these are the tests that commonly provide the evidence needed to support product efficacy and safety claims.

Cosmetic claims have been defined as "any product information in public domain regarding content, nature, effect, properties or efficacy etc. From a marketing prospective they are designed to drive consumer interest by stating product features".

The most common claims are:

Product Performance claims
"reduces the appearance of wrinkles "

Ingredient based claims
"contains glycerine to hydrate the skin"

Sensory claims
"the skin feels soft"

At some point of the product and brand development process becomes important to have a claims plan for certain products. Marketers need to identify product claims that meet the interest and expectations of consumers in the desired market(s) and match this with their research. Here are some examples of tests that might be necessary to support products claims:

In vivo tolerance and efficacy clinical tests

- Dermatological safety tests
- Efficacy tests
  - Objective measurements (highest level of scientific evidence)
    - Trans-epidermal Water Loss (TEWL)
    - Skin pH
    - Moisturising effect
    - Soothing
    - Skin radiance
    - Skin oiliness
    - Anti-acne
    - Anti-ageing
    - Anti-wrinkle
    - Skin firmness
    - Immediate smoothing
    - Dark circles & Eye puffiness
    - Hyperpigmentation
    - Matt & Shine
    - Cleansing
    - Hair & Scalp
    - Scars and stretchmarks
    - Etc.
  - Clinical grading/Expert assessment
  - Before and After clinical photography (supporting visual evidence)
  - Consumer studies (subjective assessment)

Advertising Cosmetic Products

Attention! The definition of "cosmetic" is important. Cosmetic claims must meet the definition of cosmetic product e.g. "reduces the appearance of wrinkles". If the claim meets therapeutics definition i.e. "eliminates wrinkles" the product will be regulated as a therapeutic product.

In Australia, advertising of cosmetic products is regulated by the Australian Consumer Law (ACL) and enforced by the Australian Competition and Consumer Commission (ACCC). The ACCC states that: "It is unlawful for a business to make false or misleading representations about goods or services when supplying, offering to supply, or promoting those goods or services".

Therefore, to be lawful claims must refer to:

1 ESTABLISHED EVIDENCE when effects are obvious, evidence based on published reports, previous studies, publicly available information or product formulation details. This means that **brand owners might not need to conduct more testing** (i.e. contains glycerine to hydrate the skin)
2 FURTHER EVIDENCE TO SUPPORT ESTABLISHED EVIDENCE when more detailed evidence is required to prove a particular aspect of the claim. In this case, **brand owners might need to conduct more testing** (i.e. hydrates the skin for 72 hours)
3 SCIENTIFIC/TECHNOLOGICAL DEVELOPMENT when the claim refers to a break-through formulation, a novel ingredient, or a benefit that is totally new. If this is the case, **brand owners will certainly need to conduct more testing** (i.e. new product reduces appearance of wrinkles by X%).

Essentially, marketers have two options:
1 making small changes to the claim to accommodate the level of evidence they are prepared to support
2 conducting a test to create extra value for the product

Sometimes testing is conducted in certain countries so importers/exporters can meet regulatory requirements. Also, to prove actual efficacy in the country the products are sold. Sometimes the decision is simply based on specific research centre capabilities. Other times it is due to seasonality (some skin care studies are best conducted in winter).

Conclusion

Tough competition drives cosmetic brands to focus more on product development and marketing.
Product testing is a way for cosmetic companies to invest in their potential competitiveness in both areas. However, can small/medium cosmetic companies afford testing?

In Australia we are fortunate to have an 'R&D TAX Incentive'. This is a government initiative, which offers generous benefits to companies conducting product testing in Australia. The Incentive for eligible core R&D activities or supporting R&D activities is a 43.5% refundable tax offset if the turnover of the Australian entity is less than $20 million per annum OR a 38.5% non-refundable tax offset for all other eligible entities (information correct at the time of writing).

As safe and effective products together with good marketing are vital for cosmetic brands, understating the testing available for cosmetic products becomes essential. This overview of the different types of cosmetic tests aims to provide just that. Research service providers and cosmetic companies are encouraged to work together to strive for quality and success of cosmetic products.

References

https://www.ideatestsgroup.com/

https://www.business.gov.au/assistance/research-and-development-tax-incentive

has your contract manufacturer caught the corona virus?

or is at least feeling the affects of it …

by Michelle Kane

A few factors come into play here, but the answer is probably yes to some extent. Whilst headlines highlight delays in new iPhones, the possibility of shortages in (the favourite) diet soft drink, the International Monetary Fund advising of an adverse scenario for the global economy and panic buying of toilet paper, there is also potential pain for SME contract manufacturers in Australia.

The reality is that all contract manufacturers need raw materials, packaging, operational testing facilities, PPE and the ability to service equipment to continue to be able to manufacture. With the shutdown of the world's second biggest economy, and significant others now grinding to a halt, there is little doubt we are all feeling a little pain in some or multiple of these areas.

Large manufacturers who can insulate risk with significant stock holdings and companies with negative net debt will no doubt find the path ahead somewhat easier. For many smaller contract manufacturers though, the waters are a little murkier.

Packaging is starting to be a real problem. Yes, China is reopening factories, but the delays have seen contract manufacturers here already run out of packaging. Alternate options are not quickly available for any 'non standard' bottle or tube. To change requires new label designs, new tube artwork, new boxes for example adding cost and a host of compliance paperwork issues at the very least. The complexity of a simple change becomes manifestly more difficult. The factories in many parts of China have reopened, but with great demand further delays are inevitable.

And no point getting on any high horse about manufacturers not supporting local suppliers – the reality is that like most manufacturing sectors in Australia, successive Australian governments over many years have not supported local industry to retain intellectual property or be competitively priced in the market. Many contract manufacturers do their best to buy local where they can, but the unfortunate reality is it's not always possible or viable.

Upgraded quarantine practices at Australian ports are causing delays of containers, even those that have not originated from any of the Covid 19 hotspots. Inside those containers are the raw materials we need to keep manufacturing. At the time of writing just to get a booking with quarantine was experiencing delays of 3 to 4 weeks. Plus shipping lines are adding additional costs.

Equipment maintenance usually requires spare parts and where do they come from? You guessed it, usually China, Germany, Japan, Korea or Italy. I'll share a couple of personal examples. Our tube production has decreased as one machine waits for spare parts. What is normally a 3 or 4 day turnaround is now weeks. We had also ordered a

major piece of equipment for a specific job to meet strict dead lines (which have now long since past). It was meant to ship the week the virus broke out and as such still sits in a foreign country due to the delays in securing bookings on ships. And yes, thankfully we still made the deadline, but only because we were resourceful.

All have heard of the dusk mask panic buying I'm sure, but what of other laboratory consumables? Government facilities are definitely checking stocks of consumables and testing media. Without certain media some pharmaceutical and personal care testing can not be done. Without it product potentially can not be released for sale.

With all of these restrictions the consequences are manufacturers are having to reevaluate staff levels, work with new cash flow scenarios and generally be more cautious.

There are of course some manufacturers who will benefit, antibacterial product manufacturers being one such group, and such challenges often drive innovation within the industry which leads to positive outcomes. Procurement people may be shaking their heads, but I also sense a spring in their step when they find a solution through new and different channels, opening new doors.

Whilst the world waits for this to be over, fingers crossed contract manufacturers can be resourceful enough to survive these potentially tough times. Support your local manufacturers people! Always loving a good conspiracy theory, I'm off to stock up on tonic water ☺

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.

IFSCC 2019 Conference in Milan

IFSCC 2019 Conference in Milan with the following organising committee. (From the left.) Mika Tanaka, *Hospitality Committee;* Fumiaki Iwase, *Vice-Chair, Public Relation Committee;* Kaoru Suganuma, *Chair, Public Relation Committee;* Yoshikuni Yamamoto, *Chair, Hospitality Committee;* Yoichi Shimatani, *President of the Organizing Committee;* Masumi Kurasawa, *Public Relation Committee*

a look at the Society of Cosmetic Chemists of Japan

by Pam Jones

This month we look at the Society of Cosmetic Chemists of Japan. SCCJ has a considerable membership over 1900 members. The group aim is to encourage advancement in cosmetics and related technologies, both domestic and worldwide. They hold their AGM in May each year to plan their following year's activities. These activities include a Research Symposium in July and November 2020, seminars in September and February 2020, lectures as well as tours. You may remember I mentioned in the last column that the Japanese society had been working with the Taiwan Society for one of their exchanges. They also publish journals with the latest papers, mainly in Japanese in March, June, September and December. Some good news is the committee currently has an English version of their website under construction.

Mr Shimatani from Shiseido Co., Ltd. the President of SCCJ and Mr Ikeda from Shiseido Co., Ltd. who is the Secretary-General of SCCJ, as well as all members of the SCCJ, are looking forward to hosting the IFSCC Congress in Yokohama. They expect more than 550 papers and 2000 participants for this event. At the end of April, they will notify all successful applications for paper and poster presentations, and at the end of March they will send out the 3rd announcement (I have attached in this article) regarding the information to register for the event.

Distinguished lecturers such as Dr Yoshinori Ohsumi of the Ohsumi Frontier Science Foundation and Nobel prize winner in 2016 for Physiology or Medicine will open the programme on October 20th, 2020.

What's HOT in Japan

Snow Beauty Mirror

Panasonic and Kose are experimenting at Maison Kose, a new specialty shop located in Ginza, Tokyo. The store opened in December 2019.

The web site states "Just sit in front of the mirror and analyse your skin condition. The Snow Mirror will instantly digitise and display your skin condition(see photo attached) A non-contact sensor embedded in the mirror detects the skin surface and subsurface conditions. It detects wrinkles, scoring lines, pores and skin colour as well as hidden spots that are invisible to the eye, with the same precision as medical equipment. Based on digital counselling and analysis results, we will recommend the best products."

3rd Announcement

Distinguished Lecturer

Mr. Yoshinori Ohsumi, Ph.D.
Ohsumi Frontier Science Foundation, The Nobel Prize in Physiology or Medicine 2016

Invited Lecturers

Prof. Hee Young Kang, M.D., Ph.D. (Dept. of Dermatology, Ajou University School of Medicine, Korea)
Prof. Emi K. Nishimura, M.D., Ph.D. (Dept. of Stem Cell Biology, Medical Research Institute, Tokyo Medical and Dental University, Japan)
Dir. Dai Kitamoto, Ph.D. (Research Institute for Sustainable Chemistry, AIST, Japan)
Prof. Kouichi Asakura, Ph.D. (Dept. of Applied Chemistry, Faculty of Science and Technology, Keio University, Japan)
Prof. Hiroaki Kitano, Ph.D. (President of The Systems Biology Institute / Okinawa Inst. of Science and Technology Graduate University, Japan)

Program at a Glance

Time	Tuesday, October 20	Wednesday, October 21		Thursday, October 22		Friday, October 23	
AM	Registration	Invited Lectures	Poster Session Exhibiton	Invited Lectures	Poster Session Exhibiton	Invited Lecture	Poster Session Exhibiton
		Oral Sessions		Oral Sessions		Oral Sessions	
		Break		Break		Break	
		Oral Sessions		Oral Sessions		Oral Sessions	
PM		Lunch	Free Discussion	Lunch	Free Discussion	Lunch	Free Discussion
		Oral Sessions	Poster Session Exhibition	Oral Sessions	Poster Session Exhibition	Oral Sessions	–
		Break		Break			
		Oral Sessions		Oral Sessions		–	
	Opening Ceremony	–	–	–	–		
	Distinguished Lecture						
Evening	Welcome Reception	Social Event		–		Closing Gala Banquet	

Session Categories

1. Cutting Edge Life Science
- Skin & hair Biology
- Influence of external environment on skin & hair
- Safety / alternative methods
- Microbiome

2. Future Formulation and Function
- Formulation technology (including emulsification-, powder-, dispersion-, and surface modification-technologies)
- Skin care
- Sun care
- Color cosmetics
- Hair care
- Fragrance, packaging, and cosmetic devices
- Processing technology
- Advancement of analytical technologies

3. Novel Concepts
- Sensory / psychology research
- Consumer research
- Big data / IoT / AI
- Regulations
- Sustainability
- Innovative, breakthrough concepts
- Others

Registration Fees

	Early Bird Registration	Regular Registration	On-site Registration
	Sept 26, 2019-May 31, 2020	June 1-Aug 31, 2020	October 20-23, 2020
IFSCC Member	110,000 JPY	130,000 JPY	150,000 JPY
Non-Member	140,000 JPY	160,000 JPY	180,000 JPY
Accompanying Person	60,000 JPY	80,000 JPY	100,000 JPY
Student	20,000 JPY		

*tax-exempt

Ms Mai Aoki Secretariat of the IFSCC Congress 2020 Yokohama is available for any of our members who may have a question about the congress. ifscc2020@convention.co.jp

Kao Curél Deep Moisture Spray for the Entire Body

To be launched in April 2020 and priced at USD18.50, the new moisturizing spray is for dry and sensitive skin. It claims a micro moisture formula that allows the active ingredient ceramide to deeply penetrate the skin and soften and moisturize with one spray.

Shiseido MAQUillAGE
Dramatic gelly compact

This gel compact launched in November 2019. The packaging states "A jelly consistency foundation that adheres to the skin and provides a glow and natural finish. It includes a puff that fits perfectly on the skin and lasts for 13 hours according to data results collected by Shiseido. It claims a finish without oiliness and excess sebum that causes the makeup to move, fade or appear dull."

*My thanks to Mr Kobayashi

Cargill Beauty
Unleashing Nature
Sustainably

System 1.0

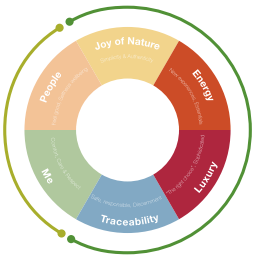
For Skin Care - Face & Body

Re-inventing GreenEthic formulations

To better understand the current & future GreenEthic consumer expectations, we conducted several consumer studies. 6 consumer profiles were identified.

Current GreenEthic consumers:

- Positive impact on planet/people
- People responsibility

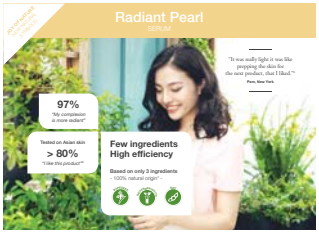


Future GreenEthic consumers

- No negative impact on planet/people
- Brand responsibility

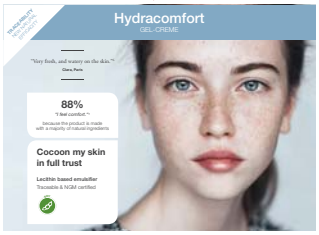
A system is composed of a Core formulation made of 3 ingredients...
... to achieve products that are Safe, Simple, Versatile, Affordable, Nature-derived & Sustainable

Our System 1.0 for Skin Care is composed of:

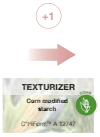


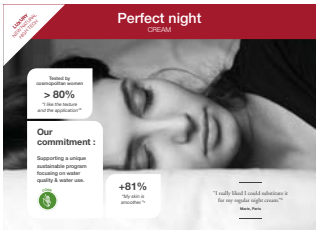
Light and fast penetrating serum designed for Asian skin

Easy to apply serum thank to good spreadability

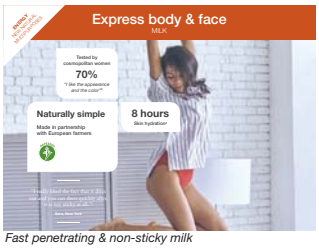


Light gel-cream texture for a velvet skin feel

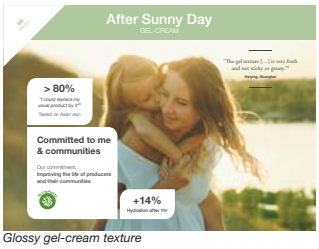




Rich cream with cushion effect



Fast penetrating & non-sticky milk



Glossy gel-cream texture

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Cargill®

Seascalp™

biomarine ingredient gets to the root of healthy, beautiful hair

Lubrizol Life Science – Beauty (LLS Beauty) has launched its first active ingredient for hair, leveraging Lipotec™ Active Ingredients expertise to deliver a one-of-a-kind consumer solution for scalp care. Seascalp™ biomarine ingredient is proven to minimize the accumulation of sebaceous lipids and strengthen the skin barrier function for a healthy scalp with less itchiness, greasiness and inflammation.

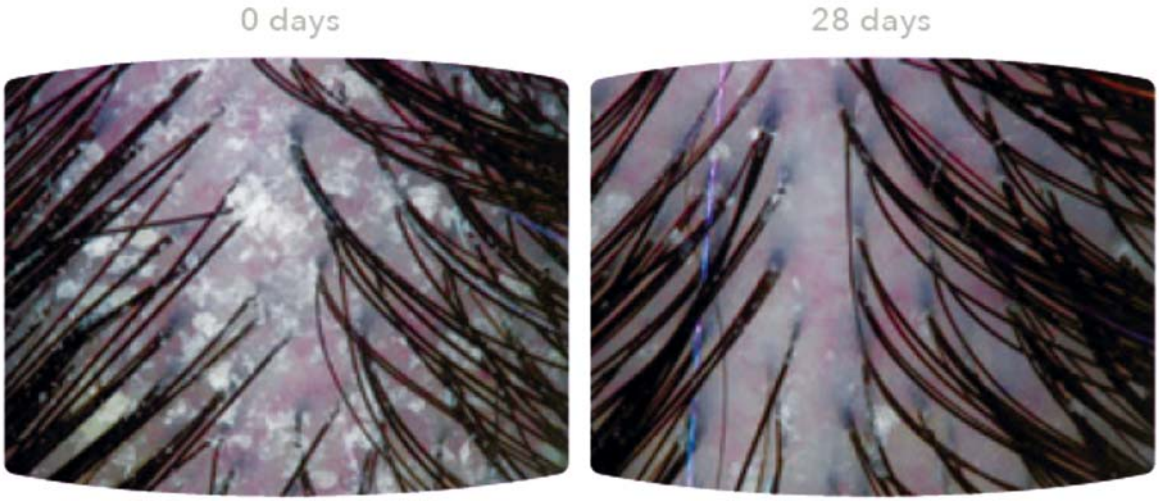
Beautiful hair begins at the scalp, but when it gets out of balance, producing high levels of sebum and triggering skin inflammation and barrier dysfunction, people are more prone to experience scalp discomfort.

Seascalp™ biomarine ingredient is a biotechnological solution ideal for a daily hair care routine to soothe the scalp and minimize the presence of flakes while preventing its reappearance.

Research has shown the efficacy of the leave-on formulation. In an in vivo study, a group of men and women with dandruff applied either a serum with 3% Seascalp™ biomarine ingredient or a placebo serum once every two days for 28 days. At the end of the study, the visible presence of flakes was reduced 40.5%, greasiness was minimized by 26.7% and participants reported enhanced scalp comfort.

In another study, men and women with dandruff applied a 3% Seascalp™ biomarine ingredient serum on their scalps once a day for 28 days. After the application ended, benefits in helping manage inflammation-prone scalps were seen for two additional weeks, reducing inflammation reoccurrence and providing extended scalp protection and comfort.

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.



Reduction of flakes

Vitality Bottled

Botanical essences, herbs and oils are woven into our collective DNA, our cultural heritage, fears, hopes and dreams.

While it is misleading to suggest that any particular essential oil or extract can save us from a global pandemic, cure cancer or maintain our youthful looks way past their natural end point, it is equally misleading to dismiss the role that oils play both in grounding us and in making life feel worthwhile and joyful.

Seeking comfort in nature, in the back-to-basics simplicity of things, is a human impulse that strengthens during times of uncertainty and change.

New Directions was built on this impulse, this desire to celebrate the vitality of the natural world and apply that life force to business.

Our business journey started Twenty-Five year ago when the purchase of a single drum of Citronella oil catapulted us into a whole new world of possibilities.

While this year has challenged us all in ways that were unimaginable just weeks ago, experience has taught us that turning our attention to nature is always a worthwhile investment.

Feeling inspired to start your business journey? Our social networks are buzzing right now with free information, ingredient inspiration, new product ideas and packaging innovation. Join us today and take your first step to a more balanced, calm and beautiful tomorrow.

NEW DIRECTIONS AUSTRALIA

sunscreen highlights

by John Staton

Enough **SED**?

Worth a look on the ARPANSA website is a fairly recent addition of a chart which records the predicted dose of UV compared with hour by hour actual intensity over each day [Fig 1].

https://www.arpansa.gov.au/our-services/monitoring/ultraviolet-radiation-monitoring/ultraviolet-radiation-dose

The hour of day is plotted against UV dose in Standard Erythemal Dose "SED" units (1). SED is not a commonly used term but is standardised value which is independent of skin type, important for the understanding of the value of the SPF unit. In effect, 1 SPF unit is equal to 2 SEDs for a light skin colour (Fitzpatrick Type I). An SPF 50 is thus the equivalent of 100 SED for this low melanin skin type. As can be seen from the chart, in peak summer conditions the higher end of the daily dose experienced in Australia is around 74 SEDs (Darwin Jan). This converts back to the equivalent of 74/2 = 37 SPF units for a full day of sunlight exposure.

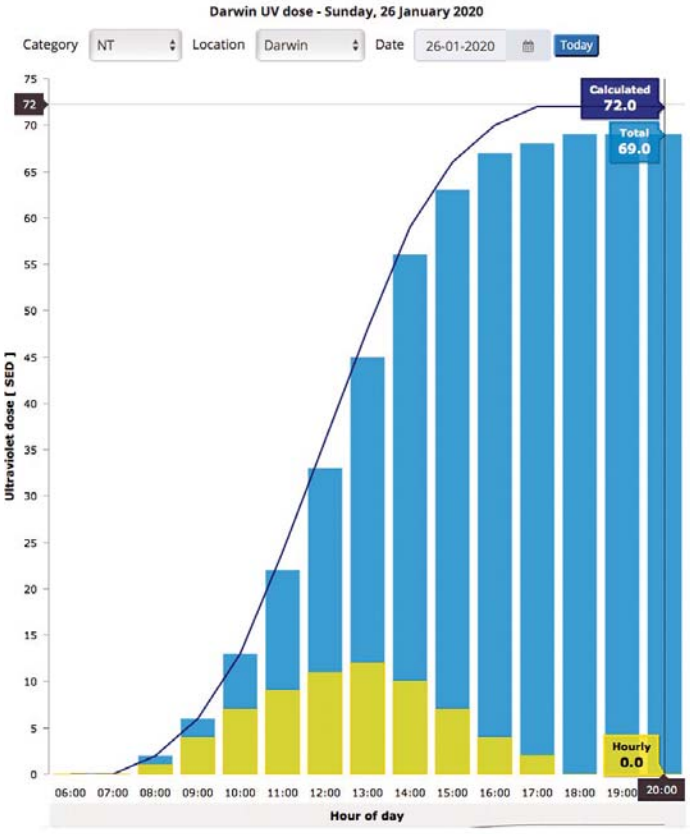


Fig 1. ARPANSA UV Dose Chart example – Darwin, Australia 26th Jan 2020.

The important take home is that, whilst we constantly try to educate consumers to apply sunscreens at a rate close to the 2 mg/sq cm needed for SPF tests, the reality is that there is still very good protection achieved from an SPF 50 sunscreen at around half that application rate – in effect all day.

Note that this calculation does not take into account reflected light, such as from water and assumes reapplication over the day in order to compensate for wash or wipe off.

Whilst this does not suggest that one should stay for extended periods in the full summer tropical sun or that reapplication is not necessary, it does give some sort of logical support to the claimed efficacy of SPF 50 or SPF 50+ sunscreens. Open the ARPANSA link and have a play with the charts. You will find them for all major cities of Australia and the slide control allows tracing of the effect of dose accumulation through any given day.

Reference

1. BL Diffey Bl,. Jansen CT, Urbach F. **The standard erythema dose: a new photobiological concept** Photodermatology …, Sept 1997 https://doi.org/10.1111/j.1600-0781.1997.tb00110.x

John Staton - Scientific Director : Solar Eurofins Cosmetics and Personal Care

- Sunscreen Testing
- UVA Testing
- Chemistry
- Stability Testing
- In-Vitro Tests
- Clinical Studies
- Hair Testing
- Consumer Research

Dermatest has recently joined the Eurofins testing group. With over 45 years experience in cosmetics and 27 laboratories worldwide, serving the cosmetic industry and in continuous expansion. This dynamic resource allows us to offer an even broader scope of testing and development services.

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www.dermatest.com.au
https://www.eurofins.com/cosmetics/

Mother Nature Helping Hands

by Aaron Lorch

Let's explore an actually natural ingredient and how it can help your products – including hand sanitisers. We know how everyone is, rightfully, washing and sanitising their hands these days. We also know the damage a lot of washing and sanitising can cause to the skin barrier. However, these two factors are seemingly at odds, because a broken skin barrier is more susceptible to infection (yes, COVID-19 enters the body via the respiratory system, and yet it's not the only thing we're protecting against).

Hydresia® SF2 is a truly natural emulsifier providing powerful skin hydration and an active-delivery system, that can also be used as a drop-in deep moisturising additive for hand wash and hand sanitiser formulations. Needless to say, it ticks the palm-free, vegan, non-GMO, PEG-free, COSMOS certified boxes also. It's about as "free from" as you can get, while still conferring real performance and a gorgeous skin feel.

Actually Natural?

Personal Care is a funny industry. We have these labels for things like "100% natural" even though they don't occur in nature. There is a vast array of 100% natural emulsifiers available now, yet only a handful of these are actually natural.

Hydresia® SF2 is the oleosome component of Safflower seeds, isolated in aqueous dispersions, in a chemical-free, green manufacturing process. Oleosomes are a complex structure, comprising of plant oils and vitamin E, encased in phospholipids and held together by an oleosin protein coating. It is a natural storehouse of energy, used by the seeds to fuel germination. And it's totally stable in high concentrations of alcohol. We're going beyond oil with natural authenticity and real performance.

Helping Hands

There's a debate about what kind of chopping board is most hygienic for use in your kitchen: plastic or wood. Wood is naturally more porous than plastic, yet plastic scores much more easily from a knife. The real answer: the safest chopping board is an undamaged one. A rough surface harbours more bacteria than a smooth one.

It's widely known that excessively washing and sanitising one's hands can lead to further skin damage. Ethanol is an

excellent solvent and surfactants are designed to pick up oil. They're doing their job when they damage our hands. Yet this is exactly the process we need to go through during a global pandemic.

So why not help your customer's hands by giving back some natural plant oils and Vitamin E? We have samples of an alcohol hand-sanitiser in the office that uses Hydresia® SF2 and it actually feels marvellous on the hands. This will mitigate damage caused to hands by using such harsh products along with helping the repair of already damaged hands.

How to…

Using the Hydresia® SF2, in a hand sanitiser, is actually simple. Drop it into your existing formulation, removing the balance of water (not the alcohol). Both the immediate feel, the rub-out and moisturisation with dramatically improve. It can be used in a similar way with surfactant systems. The rub-out will break down the oleosomes, releasing all the natural oils and Vitamin E onto your hands.

Others love this as a cold-process emulsifier that can hold 3x its weight in oil, including oil-soluble actives. Likewise, there are studies showing its efficacy as a means of delivering actives into the skin. It's texture as an emulsifier is very light, yet luxurious. Depending on any additional rheology modifiers you may choose from, you can formulate a variety of product formats: from simple lotions to wonderful 'whipped' cream textures. It works with colour, sun, skin and hair products too.

Closing

With the Coronavirus wreaking havoc around the globe, a lot of us are in a position now where we can lend a helping hand, by helping hands. Hydresia® SF2 makes that easy for us to do, with an actually natural product that delivers amazing performance.

Feel free to get in contact with myself and the team at A S Harrison & Co for a hand with samples at email performanceingredients.ash@harrison.com.au or call us on +61 (0)2 8978 1016

What's Hot / What's not?

three forlorn and forgotten aspects of cosmetics

by Wendy Free

Nitroso-what's?

Lost in the world of paper-based science, well-before we were worried about 'chemicals' and 'natural' there was a safety issue, a serious safety issue, that's recently re-emerged in the medicines world – *so look out cosmetics*, you're probably next.

The rules and regulations world-wide do detail the probation and limitation of these substances but, up until very recently (ie ~18 months ago) there was NO capability in Australia to have products tested for these highly toxic and genuinely carcinogen impurities and by-products.

If you delve deep enough into the ASCC web page (1980 position paper) you can find excellent technical guidance[1] on this issue and SCCS also provides some guidance[1]; but for here and now let's try to keep it in layman's terms.

Nitrosamines are highly carcinogenic. They can be (and are) present in air, water, food, natural and synthetic products, in some jurisdictions' concentrations of greater than 50 ppb (ie 0.05 mg/L) are prohibited, in other there is a TOTAL prohibition; that is NONE are permitted.

In general nitrosamines form spontaneously in low pH, aqueous solutions where there are nitrites or nitrates present together with amines.

- Sources of Nitrites/nitrates include natural plant materials, air, water etc
- Sources of Amines can potentially include amino acids (proteins), TEA, DEA, betaines, etc

(do you get the picture?)

There are some very potent drivers of the 'spontaneous' reaction between these substances, that is to say some ingredients are much more susceptible to nitrosamine formation than others.

- Primary amines like TEA are MUCH faster at making nitrosamines than other types of amines
- Secondary amines take longer to form into Nitrosamines (but maybe these few hours are not really relevant when you have a shelf life of several years?), however these nitrosamines tend to be more chemically stable and, more carcinogenic.
- Tertiary and Quaternary amines can react, over extended periods of time, under the right conditions too.

When formulating or considering safety (& stability), PLEASE think about the potential for Nitrosamines to form, and what you might be able to do to help slow or stop this.

Ideally one would invariably avoid the relevant starting materials, but that's really not possible every time.

There after we should be OBLIGATED to think about ingredient PURITY, and here I mean FREEDOM from impurities, *the very opposite of 'natural and organic!'* If our starting materials contain the minimum amounts of nitrosamines to start with, and they also have minimal nitrates / nitrites and low trace mineral content, the problem is already half solved.

From there a prudent formulator will AVOID unnecessary amines, especially of the more reactive kind.

For example, adjusting the pH with TEA is just pouring trouble into your beautiful product, please don't do this.

Also, please think carefully about what preservatives you are using, some of them are quite good players in this dirty game. Once you have high quality, nicely pure, chemically unreactive ingredients, perhaps think about adding some of the substances that help to prevent nitrosamines from forming; (I know you're just going to throw them in at the end but we can try!).

Some of these finishing touches can include antioxidants (Nitrosamines form in the water phase so you NEED water soluble antioxidants) and CAREFULLY selected chelating agents (noting that some antioxidants are themselves amines, so they potentially add to rather than reduce the problem); the literature reports that ascorbic acid (Vitamin C) is especially good at reducing the formation of nitrosamines … so you might need to think about how you're going to add enough of this acid, to keep the solution stable, and at a pH above that where the nitrosamines preferentially form… (no wonder we stopped worrying about this – it's kind of too hard!) … But your client and our consumers ARE relying on the safety of cosmetic products so please do bring yourself and your team up to speed on *nitro-se-what's-its*.

Ps ....Cannabis and Hemp

RULE 1 – if it's NOT cold pressed hemp seed oil / low THC hemp fiber it **is ILLEGAL in cosmetics**.

Question – "But what about if there is no CBD and no THC?"

Answer – See rule 1.

OK I know you don't believe me, please let me take you through it.

In Australia and in MOST of the world trade in *Cannabis sativa* is illegal and/or very much restricted, even when there is NO THC and/or NO CBD.

ASIDE: In some Asian countries ANY form of Cannabis including cold pressed hemp seed oil is an AUTOMATIC death penalty – do you REALLY want to be responsible for that? *PLEASE THINK ABOUT this – one of your customers could be executed for taking their (your) body butter on holiday! Talk about a costly marketing claim.*

In Australia, there are at least 3 legislative instruments that prohibit the use of Cannabis sativa in cosmetics; except when it's cold pressed hemp seed oil, lets walk through them shall we?

SUSMP[2]

SUSMP relates to supply, packaging and labelling.

- This legislative instrument SPECIFICALLY excludes foods
- This legislative instrument DOES include cosmetics and essentially all other non-food uses.

Schedule 9

- pertains to **Prohibited Substance** – *Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.*
- Includes CANNABIS (including seeds, extracts, resins, and the plant and any part of the plant when packed or prepared), **except**:
  a) when separately specified in these Schedules; (this only allows Prescription only medicines of specific types) or
  b) processed hemp fibre containing 0.1 per cent or less of tetrahydrocannabinols and hemp fibre products manufactured from such fibre; or
  c) **when in hemp seed oil* for purposes other than internal human use** containing 50 mg/kg or less of cannabinoids, including 20 mg/kg or less of tetrahydrocannabinols, **when labelled with either of the following warning statements: i) Not for internal use;** or ii) Not to be taken.

* *"Hemp seed oil" means the oil obtained by cold expression from the ripened fruits (seeds) of Cannabis sativa.*

So – in cosmetics anything other than cold pressed hemp seed oil or low THC fiber is a PROHIBITED SUBSTANCE

Customs Prohibited Imports Regulations 1956[3]

This regulation pertains to IMPORT, supply, and includes label statements.

(1A) This regulation applies to publications and any other goods, that:

(e) promote or incite the misuse of a drug specified in Schedule 4; or

Schedule 4 of the regulation includes, as item 35. **"Cannabis, including extracts and tinctures of cannabis"**

Please note that it says NOTHING about CBD, THC, if its Cannabis, an extract or tincture it's prohibited…

But what about…

Customs (Prohibited Imports) (Importation of Hemp Seeds and Hemp Derived Products) Approval 2018[4]

(Yes; I was hoping you'd ask about that one…)

This legislative instrument uses the same definition of 'drug' as does Customs (Prohibited Imports) Regulations 1956; that is… an item included in Schedule 4 of those regulations; that includes item 35. **"Cannabis, including extracts and tinctures of cannabis"** is prohibited unless specifically except…

This instrument does allow for the importation of a range exempt Cannabis derived materials, but they ARE very limited, and specifically include

(a) hulled hemp seeds; (not permitted by SUSMP – so that's a no in cosmetics, but possible yes for food)

(b) hemp seed meal; (not permitted by SUSMP – so that's a no in cosmetics, but possible yes for food)

(c) hemp fibre; (conditionally allowed by SUSMP)

(d) hemp seed oil if:
  (i) the total cannabidiol content of the oil is 75 mg/kg or less; and
  (ii) the total tetrahydrocannabinol content of the oil is 50 mg/kg or less;

(e) a product that contains or consists of hulled hemp seeds, or that contains ingredients extracted or derived from hemp seeds, if:
  (i) the product does not contain another drug; and
  (ii) the product does not contain any

other parts (including unhulled hemp seeds) of, or extracts from parts (except hemp seeds) of, a plant of the genus Cannabis; and
(iii) the total cannabidiol content of the product is 75 mg/kg or less; and
(iv) the total tetrahydrocannabinol content of the product is 50 mg/kg or less.
(but again, not permitted by SUSMP – so that's a no in cosmetics)

If you wanted you could also look at the requirements of the Office of Drug Control and the obligations in regards to export of these products…or invest several years petitioning each of the relevant authorities…or you could wait for someone else to do this…I guess it all depends on how strongly you want that marketing claim.

Ps … CITES[5]

Most of us are very conscious of animal ingredients, animal testing and cosmetics, but few of us really considered endangered plants.

There are rules about the illegal trade of many plant (and animal species) but somehow these don't always get transferred into our everyday considerations. (Except in relation to Orangutans and Palm oil – nice to have an exception, all be it rather indirect)

It's actually very easy to find out what is and is not included on the **Convention on the International Trade in Endangered Species of Wild Fauna and flora** => There's a list[6,7]

And it does include

- EXTRACTS: *Any substance obtained directly from plant material by physical or chemical means regardless of the manufacturing process. An extract may be solid (e.g. crystals, resin, fine or coarse particles), semi- solid (e.g. gums, waxes) or liquid (e.g. solutions, tinctures, oil and essential oils). AND*
- POWDERS: *A dry, solid substance in the form of fine or coarse particles. AND*
- Finished products packaged and ready for retail trade; *Products, shipped singly or in bulk, requiring no further processing, packaged, labelled for final use or the retail trade in a state fit for being sold to or used by the general public.*

The list is divided into 3 parts,

- Appendix I – lists the species that are the most endangered among CITES-listed animals and plants
- Appendix II – lists species that are not necessarily now threatened with extinction but that may become so unless trade is closely controlled.
- Appendix III- is a list of species included at the request of a Party that already regulates trade in the species and that needs the cooperation of other countries to prevent unsustainable or illegal exploitation

Australian for example might find it quite incredible to learn that prickly pear (Opuntia sp.) makes the list in A1 and A2 (depending on the specific species and origin); a wide range of other 'cosmetic ingredients' also feature (many as wild harvested *rather than cultivated*) including Aloe, Snowdrop, many species of Euphoria, … and more.

So perhaps before you consider including that super-exotic active from Albania, deepest Africa or Antarctica, CHECK to see if its endangered, and thus trade restricted?

It's up to all of us to keep on top of what's real, where ever we can. As always you are more than welcome to contact me obligation free on any matter,

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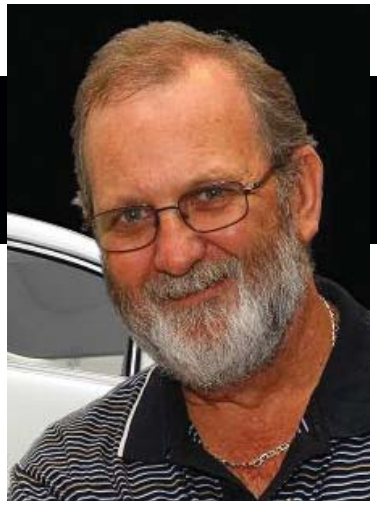

Part 51 –

by Ric Williams

Pollution, its effects on skin and hair and what can cosmetics do to help

The most recent trend in cosmetic development is the development of ingredients and products that protect us from environmental pollution in developed countries.

Reference 1 states "More than 80% of consumers worldwide think skin absorbs pollution from the air. Pollution, dirt and chemicals from vehicle emissions, plants, factories, cigarette smoke, etc., are seen by consumers as the second largest cause of skin, scalp and hair problems across the globe; the first is lack of sleep. In some countries, e.g., Russia and China, air pollution is considered a predominant cause of hair and skin problems—even more than sun exposure. Those most sensitive to dust and dirt are consumers in Brazil, Mexico, Pakistan and India, followed by Russia and China."

Definition

Pollution can be defined as *"the contamination of the atmospheric, surface or water environment (indoor or outdoor) by any chemical, physical or biological agent that modifies the natural characteristics of that environment, or pollution can take the form of energy, such as noise, heat or light. Pollutants, the components of pollution, can be either foreign substances/energies or naturally occurring contaminants. Pollution is often classed as point source or nonpoint source pollution."*

As you can see this definition is fairly broad and will involve many agents that are "chemical, physical or biological" we should be concerned with.

The outdoor environment can be affected by streams full of toxic chemicals from industrial processes, rivers overloaded with nutrients from farms, trash blowing away from landfills, city skies covered in smog. Even landscapes that appear pristine can experience the effects of pollution sources located hundreds or thousands of miles away.

Household pollutants are contaminants that are released during the use of various products in daily life. Studies indicate that indoor air quality is far worse than that outdoors because homes, for energy efficiency, are made somewhat airtight. Moreover, household pollutants are trapped in houses causing further deterioration of indoor air quality.

Hazardous household products fall into six broad categories: household cleaners, paints and solvents, lawn and garden care, automotive products, pool chemicals, and health and beauty aids. Many commonly used household products in these

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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.

categories release toxic chemicals.

The indoor environment in any building is a result of the interaction between the site, climate, building system (original design and later modifications in the structure and mechanical systems), construction techniques, contaminant sources (building materials and furnishings, moisture, processes, outdoor sources and activities within the building, such as everyday kitchen products, faulty boilers, open fires, fly sprays and even air fresheners), and building occupants. All contribute to poor indoor air quality.

Forms of Pollution

The major forms of pollution are listed below along with the particular contaminant relevant to each of them:

Air pollution: the release of chemicals and particulates into the atmosphere.

Common gaseous pollutants include carbon monoxide, sulfur dioxide (SO2), chlorofluorocarbons (CFCs) and nitrogen oxides (NO2) produced by industry and motor vehicles, and polyaromatic hydrocarbons (PAH).

Photochemical ozone and smog are created as nitrogen oxides and hydrocarbons react to sunlight.

Particulate Matter, or fine dust is characterized by their micrometre size PM10 to PM2.5.

Heavy Metals (lead, mercury, cadmium, etc.).

Volatile organic compounds (VOCs).

I might throw in here a trade secret about the aerosol industry. They have succeeded in a slight deception. Consumers think they are good for eliminating those nasty ozone layer destroying CFC's, however, what they have mostly replaced the CFC's with are Greenhouse Gases, and the consumer doesn't say anything. Strange.

Water pollution, by the discharge of wastewater from commercial and industrial waste (intentionally or through spills) into surface waters; discharges of untreated domestic sewage, and chemical contaminants, such as chlorine, from treated sewage; release of waste and contaminants into surface runoff flowing to surface waters (including urban runoff and agricultural runoff, which may contain chemical fertilizers and pesticides); waste disposal and leaching into groundwater; eutrophication and littering.

Light pollution: the most common forms are Ultra-Violet Light, Infra-Red Light and Blue-Light (Mobile Phones, Computers and Televisions), but also includes light trespass, over-illumination and astronomical interference.

Microbial contamination: Microbiological contamination refers to the non-intended or accidental introduction of

infectious material like bacteria, yeast, mould, fungi, virus, prions, protozoa or their toxins and by-products from water, soil, air, etc. and decomposing organic matter.

Radioactive contamination, resulting from 20th century activities in atomic physics, such as nuclear power generation and nuclear weapons research, manufacture and deployment. Chernobyl and Three Mile Island have not helped either.

Given those definitions, in cosmetic science, it is the Air, Water, Light and Microbial that we are most concerned with, although Radioactive contamination could also be considered. These sources include (from Ref 2);

Sources Outside Building – Contaminated outdoor air

Pollen, dust, fungal spores
Industrial pollutants
General vehicle exhaust
Soil gases (CSG, Methane from landfills)
Animal gases (eg Methane and other Greenhouse gases))

Emissions from nearby sources

Exhaust from vehicles on nearby roads or in parking lots, or garages
Loading docks
Odours from dumpsters
Re-entrained (drawn back into the building) exhaust from the building itself or from neighbouring Buildings
Unsanitary debris near the outdoor air intake

Soil gas

Leakage from underground fuel tanks
Contaminants from previous uses of the site (e.g., landfills)
Pesticides

Moisture or standing water promoting excess microbial growth

Rooftops after rainfall
Attics
Basements
Rising damp on walls
Un-ventilated Laundries, Toilets and Bathrooms

Equipment – Ventilation systems

Dust or dirt in ductwork or other components
Microbiological growth in drip pans, humidifiers, ductwork, coils
Improper use of biocides, sealants, and/ or cleaning compounds
Improper venting of combustion products
Refrigerant leakage

Equipment – Other systems

Emissions from office equipment (volatile organic compounds, ozone)
Supplies (solvents, toners, ammonia)
Emissions from shops, labs, cleaning processes

Elevator motors and other mechanical systems

Human Activities – Personal activities

Smoking
Cooking
Body odour
Pet odour

Human Activities – Housekeeping activities

Cleaning materials and procedures
Emissions from stored supplies or trash
Use of pesticides and deodorizers
Airborne dust or dirt (e.g., circulated by sweeping and vacuuming)

Maintenance activities

Microorganisms in mist from improperly maintained cooling towers
Airborne dust or dirt
Volatile organic compounds from use of paint, caulk, adhesives, and other products
Pesticides from pest control activities
Emissions from stored supplies

Building Components and Furnishings – Locations that produce or collect dust or fibres

Textured surfaces such as carpeting, curtains, and other textiles
Open shelving
Old or deteriorated furnishings
Materials containing damaged asbestos

Unsanitary conditions and water damage

Microbiological growth on or in soiled or water-damaged furnishings
Microbiological growth in areas of surface condensation
Standing water from clogged or poorly designed drains
Dry traps that allow the passage of sewer gas

Chemicals released from building components, furnishings or chemicals in the home

Volatile organic compounds or
Inorganic compounds

Other Sources – Accidental events

Spills of water or other liquids
Microbiological growth due to flooding or to leaks from roofs, piping
Fire damage (soot, PCBs from electrical equipment, odours)

Special use areas and mixed use buildings

Smoking lounges
Laboratories
Print shops, art rooms
Exercise rooms
Beauty salons

Food preparation areas

Redecorating/renovation/repair activities

Emissions from new furnishings

Dust and fibers from demolition

Odors and volatile organic and inorganic compounds from paint, caulk, adhesives

Microbiologicals released from demolition or renovation activities

Indoor air often contains a variety of contaminants at concentrations that are far below any standards or guidelines for occupational exposure. Given our present knowledge, it is difficult to relate complaints of specific health effects to exposures to specific pollutant concentrations, especially since the significant exposures may be to low levels of pollutant mixtures.

Effects of Pollution

From Ref 3,

"The scientific principles of pollution were explained by Prof. Jean Krutmann, Ph.D., from Leibniz Research Institute for Environmental Medicine (Germany). He discussed traffic-related pollution in megacities like Beijing in China, Los Angeles in the United States, and Rome and London in Europe. His research into the effect of air pollution on elderly women in Germany showed a higher occurrence of pigmented spot formation on the cheeks with increasing soot concentrations.

Collaborative projects in China reported not only exposure to particulate matter (PM), but also to nitric oxide correlated with pigmentation. These gene/environment interactions involve arylhydrocarbon receptors (AHR) activated by polyaromatic hydrocarbons (PAH). Women with high genetic risk scores developed 52% more lentigines on their cheeks compared with low risk-score participants."

Reference 4 quotes Dr Maria Coronado as saying "Air pollutants such as heavy metals, PM and gas pollutants such as SO2, NO2 and PAH are believed to settle on the scalp and hair causing irritation and hair's cuticle damage. Apparently, these contaminants can also migrate through the hair follicle conduit, causing oxidative stress, excessive sebum creation, redness, itching, dandruff, oily scalp, and hair loss. In addition, pollution might also cause faster colour fading."

A more alarming suggestion comes from Ref 5.

"… Thousands more people than previously thought are dying each year from the effect of poor air quality, including pollutants from everyday objects and appliances in their homes, the landmark new report is to claim.

The report warns that at least 40,000 deaths a year can be linked to the effect of air pollution, with thousands more deaths across Europe.

But while the danger of outdoor air pollution has been well documented in recent years, the report will highlight the dangers from the secret killers in our homes, schools and workplaces.

It will warn that everyday kitchen products, faulty boilers, open fires, fly sprays and even air fresheners, contribute to poor indoor air quality.

According to the report "indoor air pollution may have caused or contributed to 99,000 deaths annually in Europe". …"

A product brochure from Solabia "Glycofilm Pollustop V2" states "in short – Build a pollution barrier to maintain skin health and beauty!

According to cutaneous biology fundamentals, the skin, and in particular the outer stratum corneum layer, are physiologically programmed to play the role of protective barrier between the body and its environment. In addition to the damage caused to skin by UVs, the atmospheric pollutants in our daily environment must also be considered as a major source of cutaneous stress. During the past few years, changes in lifestyles and increasing urbanization worldwide have amplified the risk. Skin cells, their lipid and protein components and their DNA are major targets for pollutants that generate oxidation and inflammation, even though the way they do this has not yet been clearly identified. Premature aging, acne, irritable and sensitive skin, atopic dermatitis and eczema, dry skin, redness and itching are some of the consequences related to pollution. …

How deeply pollutants are absorbed in skin depends on their

nature, as well as on the condition of the outer epidermis. Unfortunately, the protective possibilities of this layer are not unlimited. Prolonged, repetitive exposure to high levels of pollutants overwhelms the skin's natural defence capabilities, causing the barrier to weaken and damage to spread. In the mid-term, biologically stimulating the skin's natural defences, including the antioxidant barrier, and optimizing regeneration of the barrier function are a key strategy to protect against pollution.

Another product brochure from Solabia "Solashield V6" states, Underestimated for a long time, the pollutants which constitute our daily, inside and outside environment, are today at the heart of preoccupations because of a direct link to the public health issues. On the first line, skin cells, their lipid and protein components but also their DNA are the targets of pollutants, generators of oxidation and inflammation. Pollution causes alterations in skin radiance, being asphyxiated due to the accumulation of particles, and in skin integrity. Dry skin, reactive and sensitive skin, acne and more particularly premature and accelerated aging are the consequences known for the pollution.

However these references seem to be only scratching the surface and many more effects would need to be considered.

What should a cosmetic product do?

I have seen many products and articles regarding a products protection from pollution, but …what pollution? Based on the above, there are many things that can be done and a product should specify which pollutant(s) it is protecting from.

A product file from Sederma regarding CityStem lists the requirements as;

- Protect skin cells from the penetration of pollutants,
- Remove and neutralise of toxic oxidant species,
- Strengthen of the skin barrier,
- Repair cell metabolism.

A simple solution would be to put an impenetrable barrier on the skin and hair, however this will also prevent skin from "breathing" or removal of sweat or sebum, plus being uncomfortable and unappealing.

However when considering all the potential contaminants it seems that no one product can do this without being over-stacked with actives and hence expensive. So, let's consider the main contaminants we can assist with, ie.

Air pollution

Antioxidants can be used to minimise free radical formation (from SO2, NO2 and peroxides) and there are many that could be used. These include natural actives such as Vitamin C, Vitamin E (natural Tocopherol only), Resveratrol, Alpha Lipoic Acid, Rosemary extract or a plethora of available antioxidant materials that are available from raw material suppliers.

Volatile organic compounds (VOCs) and polyaromatic hydrocarbons (PAH) are a little more difficult to counteract and here, my view, is to provide some absorbent material that will stay on the surface of the skin (or hair).

Film formers or absorbent powders such as Clay, Zeolite or Zinc Oxide/Titanium Oxide may work.

Film formers may also work with particulate matter and heavy metals can be absorbed by mineral matricies such as Zeolite or neutralised by sequestering agents (EDTA or Sodium Phytate).

Water pollution

Anions such as Chlorine or Fluorine can be counteracted by incorporating a salt such as Sodium Thiosulfate or an absorbent polymer such as PVP.

However, water may be contaminated with many more toxic chemicals that we would find difficult to counteract. These would include faecal matter, pesticides and industrial/household chemicals, too many to have one panacea.

Microbial contamination

This is relatively simple to prevent and that is to use a preservative system (using multiple components) that is not only broad spectrum but used at its maximum recommended level. The use of "antiseptic" ingredients could also be considered if that is a main claim in your product profile. Antibacterials can work however most are not used for long enough to be truly effective, also some will build microbial resistance if overused. Alcoholic Sanitisers and Essential Oils seems to resist this problem. It is also suggested that simple soap and warm water is very effective to wash off contaminants, with the alkalinity of real soap also disrupting the viability of microbes on the skin.

Light pollution,

Protection from UV light is fairly well established but protecting from Blue Light and Infra-Red light is a little less defined. At this stage, a physical barrier such as Zinc Oxide and/or Titanium Dioxide would be recommended.

Otherwise, all you can do is to include one or more of the active components (suggested by raw material suppliers) that mitigate the effects of light pollution.

Radioactive contamination,

I am not suggesting that we include anti-cancer drugs in cosmetics but there is a lot of anecdotal evidence that;

1. Supplementing with nascent iodine may help counteract the effects of radioactive Iodine.
2. Potassium Orotate can prevent the accumulation of Cesium-137.
3. Calcium and Magnesium can decontaminate a form of nuclear waste known as Strontium 90.
4. Studies show that DMSO actively detoxifies and protects the body from the effects of harmful radiation.
5. There are many types of clays that bond to nuclear waste from the body. Others include Kaolin, Red Clay, Bentonite, Fuller's Earth, Montmorillonite. French Green Clay is

another absorptive clay shown to possess the ability to rid radiation, toxic metals and chemical residues from the human body.

⋆ Zeolites can attach themselves to and remove nuclear waste from the cellular level.
Note; Nuclear waste is typically "cleaned" or "stored" in the environment by mixing it with Zeolite clay and packing it underground.

6. Studies show that charcoal possesses the unique ability to neutralize radiation, and that 10 grams of charcoal can neutralize up to 7 grams of toxic material.
7. Papain is a cysteine hydrolase extracted from papaya fruit known for its ability to reduce toxicants. In one laboratory study on rats, it was found that half of rats supplementing with papain could survive a lethal amount of radiation, whereas control rats did not survive.
8. Initial evidence suggests that bee pollen may significantly lower the negative side effects of radiation exposure, in particular that of radium, x-rays and cobalt-60 radiotherapy.

So, what do we do next – simple – decide on what you want to protect against.

Hopefully that is *not one product suits all*), because, if it is, then good luck trying to include all the actives you will need to incorporate into the one product.

Should it be a spray (not an aerosol), a cream, a liquid or something you swallow?

Should we have one product for outdoors and one for indoors, even though there are common contaminants in both?

Should we have one product for each of the contaminant classes eg. Air, Water, Light, Microbial and Radiation sources (or do we have those now, in some form or another)?

These questions, my friends, is for someone far more erudite than me, although if left in the hands of a marketing person we may not only have one product suits all but will (not may) be asked to include more items to protect against – a common occurrence that is the fear of all cosmetic scientists.

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Antimicrobial testing: what do the results mean?

by Kevin Roden

Abstract

Tests designed to determine the antimicrobial efficacy of a product, such as a preservative in a cosmetic, a sanitiser in a household cleaner, or even a disinfectant, have set pass requirements. These often specify minimum log reductions or % kill to meet the requirements of the test. This paper will discuss how these tests are conducted, what these terms mean, how they are calculated and how changes in the method used for the testing may lead to variations in the results achieved.

The paper will also cover changes to the Laboratory Accreditation Standard, ISO 17025, with regards to Measurement of Uncertainty and Statements of Conformity and what impact these changes may have on certificates of analysis issued for Preservative Efficacy Testing.

Antimicrobial Testing: What do the results mean?

When any product is formulated with antimicrobial active substances, such as preservatives or biocides, both referred to as biocides in this paper, there may be interactions between the biocide and the product or container. The biocide may be lost due to partitioning into the oil phase or micelles, interaction with other ingredients, absorption onto the closure or container or adsorption onto solid particles. This may be further compromised by the biocide converting to an inactive form due to a pH effect or it may be degraded by the storage temperature or other factors.

These factors may reduce the level of biocide available leaving only the aqueous phase residual concentration to be effective to control microbial growth.

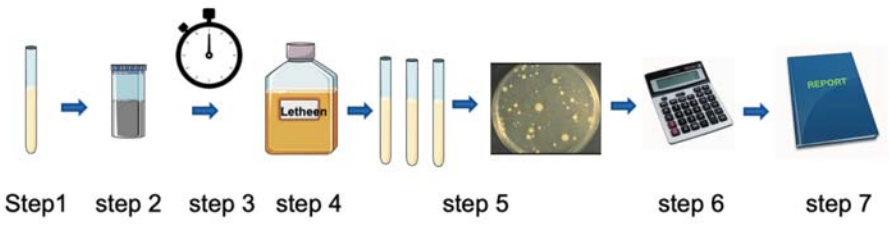
It is difficult to determine the aqueous phase residual concentration by chemical analysis as extraction techniques may recover bound, absorbed or adsorbed active and give false high results. Microbiological testing is a convenient way to determine the amount of active material available in the water phase, as this is where microorganisms are found and where the biocide needs to be to provide good antimicrobial efficacy.

Table 1 Steps in Antimicrobial testing

Step	Procedure
1	Prepare the test organisms
2	Add test organisms to the product under test
3	Allow a desired contact period
4	Neutralise the antimicrobial
5	Determine survivors
6	Calculate Log reduction or % kill
7	Report the results

Testing for disinfectant/sanitiser efficacy requires microbiological testing to ensure that in use concentrations are effective as biocides may experience the same loss of activity issues outlined above and may also be affected by the environment that they are used in where organic or other soiling may reduce their effectiveness.

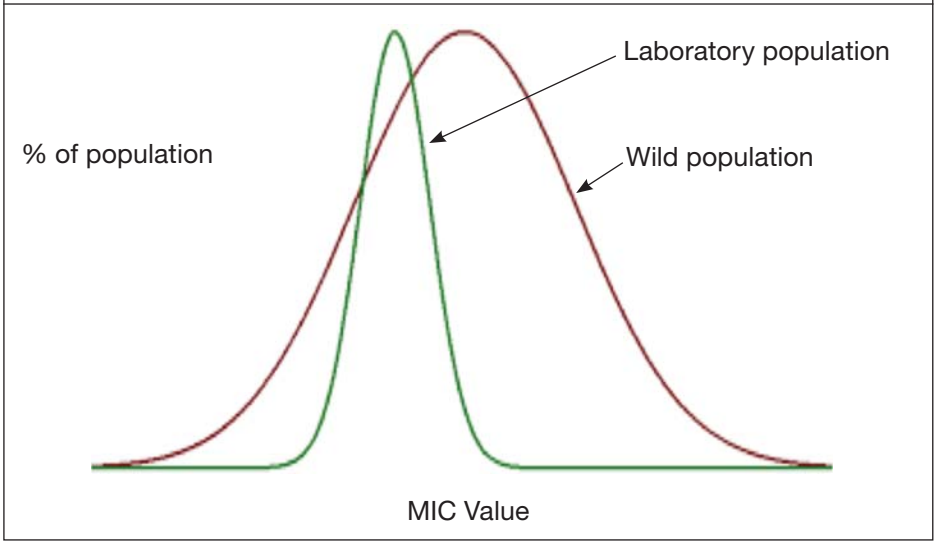
Diagram 1. Steps in Antimicrobial Testing



Microbiological Testing for antimicrobial activity always follows a simple pattern as shown in Table 1 and Diagram 1. Once an appropriate test method is selected all tests follow the same basic format.

Although the basic procedure is fairly simple to conduct, variations in the procedure can result in significant changes to the results achieved. Published standard test methods usually specify the steps to be taken to ensure reproducibility of the results. Possible variations in all steps from 1 – 6 may affect the results obtained and what they actually mean.

Diagram 2. Variation in MIC values for laboratory vs wild strain organisms



Step 1: Preparation of the test organism.

The test organism plays an obvious and critical role in the test outcome. The species of microorganisms used in the test must be selected on the basis that they are realistic, that is, that they would need to be controlled by the material under test. Cosmetic preservatives are tested with a selection of organisms to cover the range of Gram positive and Gram negative bacteria as well as a yeast and a mould. The species selected have either been isolated from infected cosmetics or are expected to be placed into cosmetics during production or by the consumer. Likewise, the bacteria selected to test antibacterial hand wash, typically St. aureus and E. coli or a Klebsiella sp., are selected on the basis that they are either skin or gut commensals and would expect to be encountered on hands.

All microorganisms exhibit an intrinsic tolerance to biocides and it is the naturally chromosomal controlled property or adaption of an organism. This may be expressed by a number of factors, including morphology, biofilm formation, nutritional starvation or growth rate control.

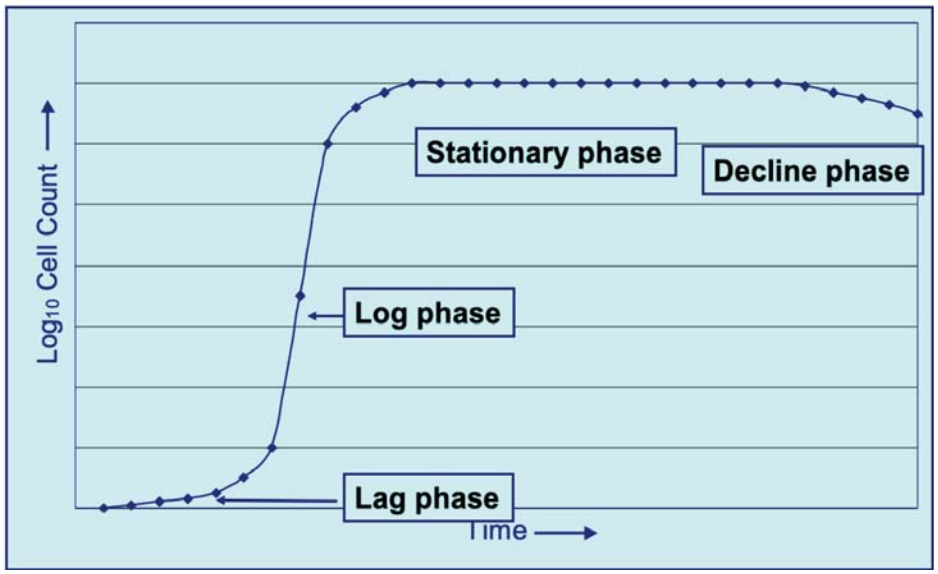
Bacteria are divided into two groups: Gram positive and Gram negative, based on the ability of a dye to bind to the cells. Gram negative bacteria possess an additional outer membrane, which stops the dye binding to the cell and often makes them tolerant to higher concentrations of biocide than Gram positive bacteria. The outer membrane acts as a further permeability barrier to entry of biocides, many of which must penetrate the cell membranes to reach their targets within the cytoplasm of the cell.

Pseudomonads are commonly more tolerant to biocides than most other microorganisms. They have been found to have differences in their outer membrane permeability of up to 400 times that of other Gram negative organisms, making it more difficult for biocides to enter. [1,2]

The strain chosen is not as important, provided the same strain is used by all laboratories conducting the test as variability in susceptibility occurs across any population. The maintenance of cultures is paramount in keeping the culture homogeneous in this respect. Continuous subculturing with inherent mutation/variation can result in a culture that behaves quite differently to the parent stock and care must be taken to minimise passage numbers or generations away from the original culture held in a reference collection.

Natural variation that occurs across generations results in offspring with varying tolerance to biocides. Obviously, the more generations the greater the potential for variations to occur. If factory isolates known to express tolerance to the biocide are a concern then they should be used in addition to or in place off the usual culture collection organism. Special care must be taken to ensure the tolerance is not lost by the cultured organisms as this

Diagram 3. Bacterial Growth Curve



can rapidly occur when passaging with no selective pressure to maintain the tolerance is allowed. It must also be considered that the use of these special organisms in conducting tests will require higher levels of biocides to pass the test requirements than that required by usual test organisms.

The effect of this variation in the population may affect test results. A population with a wide variation in the Minimal Inhibitory Concentration (MIC), as represented in diagram 2, against a biocide will likely show a result with a fast initial kill due the higher number of cells showing a low MIC value followed by a slower and less complete kill due to the number of more tolerant organisms. In contrast a population that has a narrow variation on MIC values will likely show slower initial action followed by a rapid and complete kill.

The growth phase of the culture also determines the tolerance to biocides. The growth curve shown as diagram 3 shows the 4 phases of growth of any population. Test organisms are usually prepared in either log (exponential growth) or stationary phase; determined by the age of the culture. Standard Test methods usually stipulate the period of incubation of a test culture to ensure it is in the appropriate growth phase. Cultured bacterial cells supplied with excess nutrients grow quickly during exponential growth phase. Once there is a shortage of nutrients or excess of waste products, the culture enters stationary and then decline phases. Bacteria respond to the starvation stress with growth rate reduction and induction of defense mechanisms [3, 4]. As a result, they may become more tolerant to biocides.

Cultures in exponential growth are actively metabolising and are therefore more susceptible to the effect of biocides due to increased free radical production from interference with normal metabolism. Bacteria usually become more resistant to environmental stress during slowing down of growth. This has been seen in both steady state and batch growth of cells and by comparing mid exponential with stationary phase growth large differences in efficacy have been demonstrated. The most tolerant cells are those in decline phase. While only viable cells will be counted to determine the initial cell concentration, the population may contain up to ten times the number of dead cells than viable cells. The dead cells will undergo lysis and release cell debris and intact enzyme systems that may interfere with the efficacy of the biocide.[3]

Test cultures may be prepared by growing them in a liquid medium or on a solid agar. Cells grown in liquid media have been shown to be hardier and less susceptible to antimicrobial attack than those washed from solid agar surfaces.

Almost all test methods include a requirement for the number of cells to be included in the inoculum along with how they are prepared. Cells grown in liquid medium or washed from solid agar require diluting to the required concentration. The dilution of the cells may result in a carryover of nutrients into the inoculum, particularly from liquid cultures. This may be removed by centrifuging and resuspending the cells in a non-nutrient solution, such as isotonic saline. Other test methods require the cells to be diluted in nutrient broth [5] or even a 1:500 dilution of nutrient broth. [6] These variations result in different supply of necessary nutrients to the cells to support growth and they may also inhibit the biocide under test.

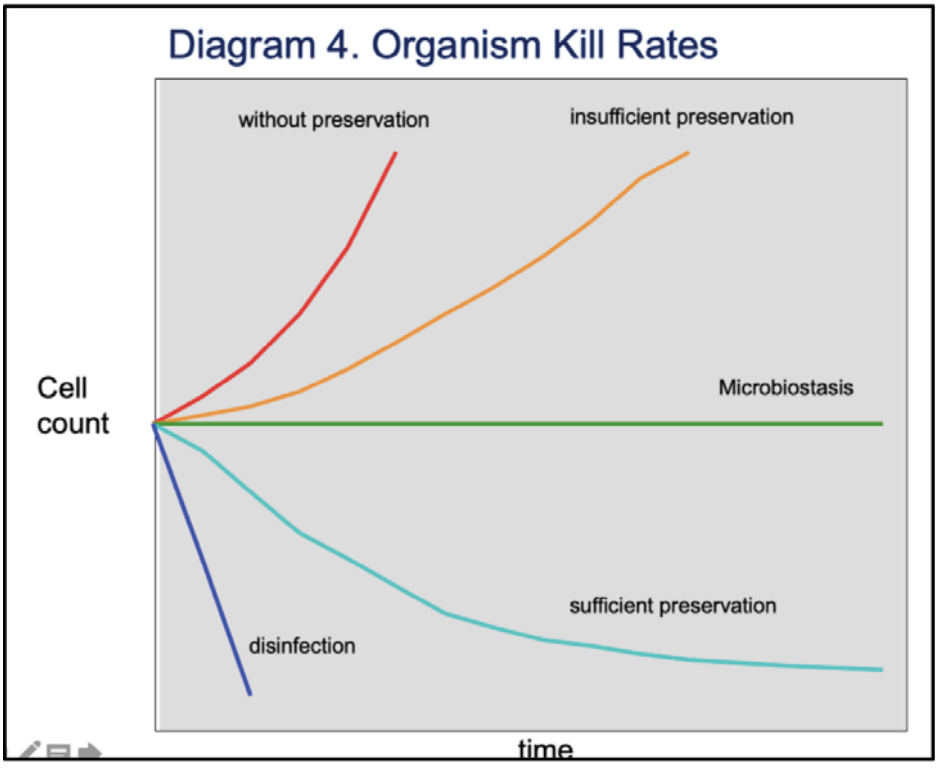
The number of cells included in the inoculum is critical to the test result and will be further discussed later in this paper.

Step 2. Add test organisms to the sample under test

The inoculum may vary in volume, placement and method of addition. The volume of inoculum added may affect the efficacy by diluting the test material if too much or repeated inoculations are conducted. The inoculum may be dripped in or onto a test samples, sprayed on and then mixed or left on the surface, all may affect the final outcome.

Step 3. Allow a desired contact period.

The contact time of the microorganisms with the test material must be realistic and sensible. Disinfectant tests typically allow 5 – 8 minutes contact while preservative efficacy tests allow days and weeks to see an effect. These times reflect actual in use periods. Tests for antibacterial hand wash are typically conducted using 30 seconds and 5 minutes contact. Results



for 5 minutes contact are often reported and are entirely unrealistic if the hand wash is to be rinsed off. However, if it is a leave on product, it may be a reasonable time. The standards for antibacterial surfaces and textiles utilise a 24hour contact period [5, 7] which may be totally inappropriate, such as for medical staff uniforms or antimicrobial cutting boards while acceptable for antibacterial socks or underwear that just need to stop growth rather than kill any organisms.

Step 4. Neutralise the active.

All antimicrobial tests require that the effect of the antimicrobial agent must be neutralised or stopped following the required contact time so that surviving organisms can be recovered. If this does not occur, the killing effect on cells may be allowed to continue well past the required contact time and may even inhibit growth of surviving organisms resulting in incorrect test results. If available, a neutraliser specific for the antimicrobial is used, such as sodium thiosulphate for chlorinated water. Otherwise general neutralisers, including Lecithin and Tweens are used in varying concentrations. A list of examples of neutralisers is included in Annex C of ISO 119320:2019 [8. If it is not possible to neutralise the biocide then dilution of the test solution may be used. It is usual to find the result where no organisms are recovered reported as <10cfu/mL due to at least a 1:10 dilution in neutraliser. If this cannot be validated, then a result of <100cfu/mL is often seen indicating further dilution to 1:100 was necessary. It is usually considered that if a 1:1000 dilution is required to validate the neutraliser system, then the test product is antimicrobial.

All antimicrobial tests require that the neutraliser is validated to ensure a correct result has been achieved.

Step 5. Determine survivors

The enumeration method of surviving organisms may also affect the test result. The diluent and agar type chosen may influence recovery as surviving organisms may have been sub lethally injured. Agars with lower nutrient value, such as plate count agar (PCA) or synthetic agars like R2A, has been found to give better recovery than a high nutrient agar such as Tryptone Soya Agar (TSA) and the choice of agar used may affect the results obtained [9]. Counts conducted using the spread plate technique, spreading the inoculum over the surface of pre-poured agar plates, have been claimed to give a higher recovery than pour plates, where molten agar is poured onto the recovered organisms and mixed, due to less chance of heat stress on the surviving organisms. The counter argument is that pour plates give an additional dilution step thereby improving recovery of surviving organisms. Pour plates also have an increased sensitivity over spread plates due to a higher volume of inoculum into the plates.

Step 6. Calculate log reduction or % kill

Some methods require a log reduction, almost always determined as a common logarithm or log base 10 ($\log_{10}$) such as Pharmacopeia Preservative Efficacy Tests, while others require % kill to be reported, as is usually the case for antimicrobial cleaners and disinfectants. The two methods use the same data but with different calculation methods. The $\log_{10}$ reduction compares the number of organisms surviving against the original number added while the % kill compares the number of organisms killed against the original number added. The calculation methods are shown in table 2.

There is a direct correlation between $\log_{10}$ reduction and % kill as shown by the data in Table 3.

Step 7. Report the results

Test methods generally require a number of factors be met to ensure the test is valid. These will include such things as the correct number of organisms in the challenge, the validity of the neutraliser and the survival and recovery of the test organisms from untreated control samples.

If these requirements are met a report can be prepared showing the calculated results. If the method contains pass criteria these can be compared to the results achieved and a statement of compliance with the test method can be made, such as "The sample tested meets Criteria A of the BP Efficacy of Antimicrobial Preservation". If, however, the test method contains no pass criteria the decision on what constitutes a pass is to be made between interested parties, making a compliance statement difficult. Laboratories accredited to ISO 17025 [ISO 17025 – 15 General Requirements for the competence of testing and calibration laboratories [10] are required to calculate uncertainty of measurements for all analysis conducted. This can be calculated but is not generally taken into account when reporting antimicrobial

Table 2. Calculation of Log Reduction and % Kill

Method	Calculation	Expressed as
Log reduction (R)	$R = \log_{10}(Ni \div Nx)$ $= \log_{10} Ni - \log_{10} Nx$	Number, e.g. 2
% kill	% = (Ni– Nx)/Ni * 100 = (number killed/number added) * 100	%, e.g. 99.9%
Ni: Number of microorganisms at time 0 Nx: Number of microorganisms at time x in the product		

Table 3. Comparison of Log reduction and % kill

Initial (Ni)	Recovered (Nx)	Killed (Ni – Nx)	Log reduction (log Ni-log Nx)	% kill [(Ni-Nx)/Nij*100
5,000,000	500,000	4,500,000	1	90
5,000,000	50,000	4,950,000	2	99
5,000,000	5,000	4,995,000	3	99.9
5,000,000	500	4,999,500	4	99.99
5,000,000	50	4,999,950	5	99.999
5,000,000	10	4,999,990	5.6989	99.9998

efficiency tests unless specifically requested. However, the 2017 version of the standard requires that measurement of uncertainty be taken into account when making compliance statements and only permits them if

i) the measurement results fall within the specification limits by an amount at least equivalent to the uncertainty of measurement; or

ii)the measurement results fall within the specification limits and the uncertainty of measurement is within the maximum permissible uncertainty prescribed in the specification; or

iii) the test specification defines the compliance decision rule to be used and the measurement results meet the specified criteria; or

iv) the customer and facility have agreed to a compliance decision rule.

Laboratories may not make a statement of conformity based on an agreement with the customer (iv above) if the report is for the purpose of regulatory compliance. So, if the test report is part of the development or quality assurance process, a compliance statement may be made with no reference to measurement of uncertainty. But, if the report will be used to meet regulatory compliance, then either the uncertainty for each measurement must be calculated and used to determine if the results meet the requirements set out above, or no compliance statement may be included on the report.

What do the test reports mean?

The best way is to look at a number of test procedures and see what the results actually mean.

Personal Care Products

Preservative Efficacy Tests (PET) may be conducted to a number of standards. They require that a range of defined micro-organisms are added to the sample under test and the sample is assayed at required times for surviving organisms. There are defined outcomes set for a reduction in the number of surviving organisms with time. The tests are designed to be reproducible and comparable and they gauge the effectiveness of the preservative system to control representative species. Their end points do not specify product sterility of the challenged product and they do not simulate in-use conditions or effects of packaging and as such only form part of the safety testing of a product. Clearly the test procedure meets the information given above. Pass criteria require minimum reductions in the number of surviving organisms calculated as log reductions. The required reductions for various Standard Test Methods are shown in Table 4.

Table 4. Acceptance criteria

Test Method	Log reduction of surviving organisms	
	Bacteria	Moulds & Yeast
USP	≥2 by 14 days and no increase thereafter	No increase in count throughout test
BP/EP option A	≥2 by 2 days and ≥3 by 7 days No increase thereafter	≥2 after 14 days and No increase thereafter
BP/EP option B	≥3 by 14 days No increase thereafter	≥1 after 14 days and No increase thereafter
CTFA (PCPC)	>3 by 7 days and no increase thereafter	≥1 after 7 days and No increase thereafter
CTPA	≥3 by 2 days and no increase thereafter	≥2 after 14 days and No increase thereafter
ISO 11930 Criteria A	≥3 by 7 days and no increase thereafter	Yeast: ≥1 after 7 days and no increase thereafter Mould: no increase at day 14 and ≥1 after 28 days
ISO 11930 Criteria A	≥3 by 14 days and no increase thereafter	Yeast: ≥1 after 14 days and no increase thereafter Mould: no increase in count throughout the test

Standard PET test tests require inoculating separate samples of the product under test once with individual organisms and measuring the number of surviving organisms at defined times. This method was developed for assessing preservatives in pharmaceuticals rather than cosmetics but differences in pack sizes, period after opening and use patterns lead to questions as to whether the procedure is still the most applicable. The use of single organisms rather than mixtures is at odds with in use challenges where mixtures of organisms are more likely to be encountered and mixed organisms may assist each other in surviving or colonising a product. It is also unlikely that a product will only be challenged on one occasion soon after manufacture. The sources of microorganisms include the raw materials, production and filling equipment, packaging and the long term use by consumers. Loss of the preservative added to a product may occur quickly, due to incorrect pH or temperature exposure during production, or more slowly due to migration into the oil phase or micelles. Challenging the product several times may show whether there is adequate protection if these problems occur.

Standard development procedures should include repeating the preservative efficacy test at the completion of the shelf life period for products stored in the final retail container, but also modifying the test to include additional inoculations or the use of mixed pools of test organisms may be considered to provide a more realistic challenge to the preservative system. The final protocol should take into account the potential susceptibility of the product to become contaminated as outlined in Annex A of ISO 29621 [11].

The Therapeutics Goods Administration (TGA) has released two relevant documents, Microbiological requirements for medicines (TGO 100) [12] and Microbiological quality of prescription and over-the-counter medicines [13]. These documents set out the TGA requirements that an aqueous

multiuse product must comply with the BP or European Pharmacopoeia (EP) unless it is a liquid oral antacid which must comply with the USP. The test data must be for product in its immediate container for market, stored in accordance with label storage conditions at the beginning and end of the proposed closed shelf life.

Sterile multiuse medicines, such as eye drops, must have data for shelf life after opening consisting of one of the following:

i) PET test with repeated microbial inoculations

ii) PET results on containers after simulated in-use

iii) sterility test results after simulated in-use

iv) microbiology tests results on part used containers after the full open shelf life.

The above requirements for non-sterile products would apply to sunscreens as they are therapeutic products in Australia.

The requirements for $\log_{10}$ reduction indicate that the difficulty in passing the preservative efficacy test can be ranked as BP, ISO 11930 and finally the USP. The BP and ISO methods require the same reduction at 7 days while the BP also requires significant reduction after 2 days contact. The additional contact period required by the BP (2 days) can make it difficult for products preserved with multifunction actives or preservative boosters, commonly referred to as non-preservative preservatives, as they are often slower acting than traditional preservative actives.

The inoculum concentration is stipulated in test methods but includes a range in the numbers or organisms allowed. All tests listed in Table 5 allow an initial concentration load of 105.0 – 106.0 cfu/mL or g of the test sample. Data in Table 6 shows that the initial inoculum concentration determines the number of organisms that need to be killed to meet the required log reduction, with significantly more organisms needed to be killed to meet the test requirements if the inoculum concentration is towards the upper allowed limit.

The data from Table 6 highlights the issue with log reductions in that it shows the variation between the number of organisms added and the number surviving while giving no information on the numbers involved. As there is a tenfold variation in the number of bacteria allowed in the inoculum concentration, there is a corresponding tenfold variation in the number of bacteria required to be killed to pass the test to the same reduction criteria.

Table 5 Reduction criteria ($\log_{10}$) for bacteria for different test methods

Test Method	2 days	7 days	14 days	21 days	28 days
BP Criteria A	2	3	3	3	3
BP Criteria B	-	-	3	3	3
USP	-	-	2	2	2
ISO 11930 Criteria A	-	3	3	3	3
Iso 11930 Criteria B	-	2.3	2.6	2.8	2.9

Table 6 Log reduction required vs number of bacteria killed

Innoculation level	Log Reduction	Reduction	Bacteria killed
Lower limit ($10^{5.0}$)	2 log reduction at 2 days	100,000 to 1,000	99,000 ($10^{4.99}$)
	3 log reduction at 7 days	100,000 to 100	99,900 ($10^{5.6}$)
Upper limit ($10^{6.0}$)	2 log reduction 2 days	1,000,000 to 10,000	990,000 ($10^{5.99}$)
	2 log reduction 7 days	1,000,000 to 1,000	999,000 ($10^{6.0}$)

Diagram 6. Product labels with Antimicrobial claims.

Antimicrobial Cleaning Products

Tests conducted on antibacterial household cleaners or sanitisers often indicate their "strength" by promoting their germ-killing power with claims on their labels including the % bacterial kill. Diagram 6 show label pictures of a disinfectant which kills 99.99% of germs along with a bathroom cleaning wipe and a washing detergent able to kill 99.9% of germs or odour causing bacteria. The test method for the disinfectants is mandated by the Therapeutic Goods Authority (TGA) under TGO 104 Standard for Disinfectants and Sanitary Products which recently replaced the long standing TGO 54 Standard for Disinfectants and Sterilants.[14] The TGO 104 requires that all disinfectants have to meet the same standard to be labelled as disinfectants, depending on which class of disinfectant they are labelled as. However, antimicrobial cleaning products do not.

The use of 'kills 99.9% of germs" or its many variants is commonly used in advertising and on labels. A search of the internet shows that consumers are confused by what this claim actually means. The two most common apparent ideas are that the missing 0.1% or 0.01% is either the superbugs developed by the use of the products, or the legal escape window to allow manufacturers to avoid litigation when someone using the

products develops an infection.

ACSPA, now known as ACCORD, released a document in 2002 titled "Code of Practice for Household and Commercial Cleaning Products Claiming Antibacterial Action". [15] This document was prepared in conjunction with the TGA and sets out minimum requirements to comply with when making antibacterial claims. It is based on the theory that consumers expect products labelled as antibacterial to kill bacteria when used as directed. The code requires that the product under test is either tested to the method set out in TGO 54 or other microbiological in vitro tests achieving a 3 $\log_{10}$ kill using Staphylococcus aureus and Escherichia coli and an in-use test showing a statistically significant antimicrobial performance over and above an appropriate control.

While there are limits on label claims they may make, as stipulated by the TGA, [16] including that the use of "antibacterial action" is covered by an industry code, such as the ACCORD code mentioned above, no test methods are stipulated to determine how the % kill rates are achieved. Data presented in Table 7 comparing log reduction and % kill against the inoculum count clearly shows that a 3 log reduction, or 99.9% kill, can be achieved by killing anywhere from as few as 100 organisms to 9,990,000 organisms, all dependant on the initial inoculum count. Throw in using early exponential growth cultures, long contact times, poor inactivation, plates poured with hot agar, dodgy calculations and you can get almost any result you require.

Table 7. Log reduction and % kill vs initial inoculum count

Inoculum Count (cfu/mL)	2 log reduction 99% kill		3 log reduction 99.9% kill	
	survived	killed	survived	killed
10,000,000 (10^7)	100,000	9,900,000	10,000	9,990,000
1,000,000 (10^6)	10,000	990,000	1,000	999,000
100,000 (10^5)	1,000	99,000	100	99,900
10,000 (10^4)	100	9,900	10	9,990
1,000 (10^3)	10	990	1	999
100 (10^2)	1	99	0	100

Table 8. Results of Tests on Antimicrobial socks to AATCC Method 100

Sample		*Staphylococcus aureus* ATCC 6538P		*Klebsiella pneumoniae* ATCC 4352	
		CFU/sample	R value	*CFU/sample*	R value
Business sock	A 24hr	<100	3	<100	3
	B 0hr	1.2×10^5		1.2×10^5	
Work sock	A 24hr	6.4×10^5	0	4.1×10^4	0
	B 0hr	1.3×10^5		6.1×10^4	
Ankle sock	A 24hr	1.3×10^7	-2	1.9×10^7	-2
	B 0hr	1.3×10^5		1.1×10^5	
Untreated Control	A 24hr	1.2×10^7	N/A	8.2×10^7	N/A
	C 0hr	1.1×10^5		1.0×10^5	
Inoculum count		1.3×10^5		1.1×10^5	

Antibacterial Textiles

Antibacterial textiles are also available either promoted to protect users from contamination or to extend the use of clothes between washing, particularly sportswear. There are several methods for testing these claims, the most appropriate being the AATCC Test Method 100-2012 Antibacterial Finishes on Textile Materials, Assessment of. [5]

This method involves inoculating treated textile samples with St. aureus and Klebsiella pneumoniae and determining the number of surviving organisms after 24h contact. The log reduction is determined, but no pass requirement is set, it is up to interested parties to agree an acceptable result. The method requires that the test organisms are diluted in a nutrient broth when preparing the inoculum. An untreated control is also inoculated, and test organisms are required to show significant growth over the 24h test period.

The results shown in Table 8 are for different sock types. The R value is equivalent to $\log_{10}$ reduction and a negative result indicates growth of the organisms over the test period. The socks all include an antimicrobial thread at various concentrations and in different blends with other fabrics. The results for each sock type tested have implications for the effectiveness of the different blends trialled.

What do they really mean?

The Preservative Effectiveness Test methods are generally consistent provided a standard method is used and if conducted correctly they will indicate if a sample under test has sufficient preservative available in the water phase to protect the finished product from microbial contamination. However, poor hygiene practices allowing growth of organisms in the process equipment and especially the development of biofilms, changes in the formulation, in particular the fragrance, or quality of raw materials or packaging may render the results invalid.

Incorrect maintenance of the test organisms, introducing variations to the inoculum preparation, including media type, growth phase and inoculum numbers may have a huge effect on the result achieved, failing a good preservative system or passing a poor one.

As for antimicrobial claims on cleaning products and household items and textiles, the quality of the results is dependent on the test method used and the quality of the testing conducted. Interpretation of the results needs to be done with respect to the test method involved to ensure relevant organisms and contact periods have been used in the planning of the test and determining

what reduction is really necessary to show that the product or article is either sufficiently preserved, that is, protected from microbial spoilage or that the antimicrobial product can actually meet the claims that the consumer expects.

The results for the socks tested shown in table 8 give very different results. All were for socks claimed to have antimicrobial effect allowing the socks to be reworn without washing. In use tests had shown the business sock could be worn for two months with no smell, the work sock for 1 month and the ankle sock for 1 week. The microbiological results were quite different from each other but mirrored the in-use tests for effectiveness. The results for the business sock would be sufficient to produce textiles blends able to self-sterilise, the work sock blend for textiles to self-protect and the ankle sock blend would not be recommended as an antimicrobial blend.

Results for antibacterial cleaning products may be tested to a recognised standard but if this is not revealed it is extremely difficult to tell what label claims actually mean. It is possibly safe to assume that reputable companies are using reputable test methods, but this is not the case for all products on the market.

Conclusion

There are many antimicrobial products available on the market including all products containing a preservative and those containing biocides that claim antimicrobial properties. There are many tests available to determine the efficacy of these. However, the particular test method utilised and variations introduced into these method by the testing laboratory may have a huge impact on the result obtained and therefore, the conclusions that can be drawn from those results.

An assessment of the method used, the initial inoculum concentration and contact times are the minimum variants that need to be included in determining if log reduction or % killed numbers quoted actually indicate a true antimicrobial effect for the product.

And, you always need to consider when you see a 99.9% kill: what happened to that 0.1% that got away and what is their significance?

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

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

Table 1 SPF 50+ Emulsion Sunscreen System

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

A: Acrylates copolymer
B: PVP (and) VP/Eicosene Copolymer-
C: PVP/Hexadecene Copolymer- Ganex V216 (ashland)
D: Acrylates/C12-22 Alkyl Methacrylate Copolymer- Allianz OPT (ashland)

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

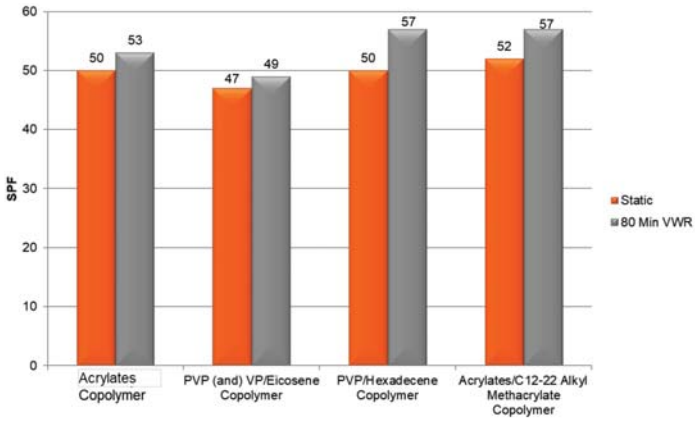
Supplied as a liquid aqueous emulsion, the new acrylates film forming copolymer is easily dispersed in the water phase of oil-in-water emulsions. The polymer can either be added into the water phase prior to forming the emulsion or post added after the emulsion is formed. It requires no heat or neutralization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

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

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

Rub resistance test was done via applying the sunscreen films onto a glass plate, let it dry out, then rinse for 1min to check the loss weight% of the sunscreen film. Test data suggest that addition of 1% this acrylate copolymer will help to retain ~82% of the sunscreen film. It's superior than addition of 1% PVP

Figure 1 Invo SPF and Water Resistance testing



(and) VP/Eicosene Copolymer, PVP/Hexadecene Copolymer and Acrylates/C12-22 Alkyl Methacrylate Copolymer

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

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

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

Reference

1 Department of Health and Human Services; Food and Drug Administration; Center for Drug Evaluation and Research (CDER). Labelling and effectiveness testing; sunscreen drug products for over-the-counter human use. Fed. Regist. 2011, 76, 35620–35665.

Table 2 Aesthetic panel testing result

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

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

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