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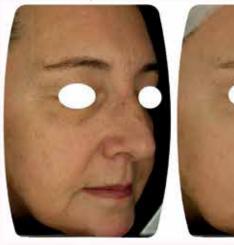




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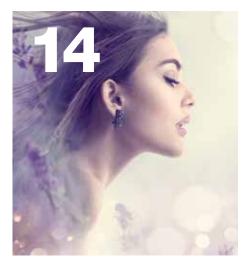
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meet the team...



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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.





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

stands out on the shelves within this highly competitive market.

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

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.

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 coauthoring the book 'All About Kids' Skin — The Essential Guide' published by ABC Books



It occurs to me that eventually everyone becomes a dinosaur.

Baby Boomers, I'm looking at you (us)!
Millennials, stop reading now (unless
you're an over-achiever who owns a
relevant brand!)

The price we all pay for enjoying living on this planet is the inexorable march to a time when things don't work quite as well as they used to! A quick walk to the shops becomes an afternoon adventure involving a bottle of water, some comfortable shoes and a mobile phone just in case an Uber is required for the return trip!

Don't get me started on the quest for an uninterrupted 8 hours sleep!

All the experts you consult, such as Doctors, Physiotherapists, lawyers, police, etc all seem to be younger than your kids and barely out of nappies.

And then there's the gradual reduction in your ability to perceive your surroundings. People don't seem to speak as clearly, things don't taste the same, and (here's the central point of this article) writing seems to become smaller and smaller!

I don't know about you, but the fine print on anything to do with Personal Care and Cosmetics products seems to be designed for an airforce pilot with 20/20 vision! We live in an age when product information is as complete and all encompassing as it has ever been, just when a lot of the target audience, such as persons of a certain age keen to buy anti-aging products, are losing the ability to read the print!

Whatever your personal views on "Clean Beauty", "Natural Ingredients", "100% Organic", "Vegan" or whatever, there's not much point in offering products in these categories if the target customer can't read the claims, ingredients lists and use instructions!

The thing is, it's perfectly possible to use the available space on a bottle, jar and box to provide all of the above in print that the average dinosaur can read. It just takes some empathy for the customer and effort by the product owner/designer to ensure everyone can read the valuable information they are putting on the product and packaging.

Sure, regulations are changing, and the

amount of information legally required is increasingly putting pressure on the discretionary stuff. There are brands out there making it all work but plenty who aren't!

So, if you are a brand that targets a more "mature" segment of the Personal Care and Cosmetics market, have a think about how easy it is for your customers to experience your product, not just after they open it, but as soon as they pick it up and begin the process of deciding whether it's something they want and, hopefully, need!

I guarantee you will have millions of devoted customers!

Till then, please pass the magnifying glass!

Cheers,

Julian

(rapidly approaching dinosaur status!)

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'The more inventory a company has, the less likely they have what they need', said Taiichi Ohno the father of lean manufacturing which effectively then became the just in time (JIT) inventory system. Given the upheavals to the global supply chain of just about everything, I wonder what his thought process would have been to tackle today's problems.

Procurement has typically been a function measured by cost saving, not revenue assurance.

This past year has seen procurement centred around cost saving go out the window, in favour of doing whatever is necessary to secure supplies, in the most timely manner. Recognising that this can be an expensive exercise from expediting shipments (if you even can) to premium prices and increased shipping costs. This requires people from procurement, logistics and finance to come together to identify

key gaps to protect the manufacturer from such disruptive events.

Manufacturers and suppliers alike suffer when there is supply chain disruption. It presents an interesting argument for manufacturers to incorporate a disruption related metric into their evaluation of suppliers.

No doubt, businesses of significant size already have this factored, but it got me to thinking – what is an appropriate size to start doing this? A quick search on my own system showed we are handling some 600 individual raw materials – enough to convince me that at least some investment in better mapping our own supply networks would be worthwhile.

The importance of holding inventory for any manufacturer consists of

- 1. Reduce risk of non-ability to manufacture due to raw material shortages.
- 2. Smaller inventories require less capital

- to hold them, thus improving the company's liquidity.
- 3. Avoiding loss of sales due to not having SOH to manufacture.
- 4. Efficient production scheduling.
 Before covid, a JIT system worked well but this meant there were few buffers leaving little room to manoeuvre in instances where something went wrong, like a global pandemic!

New inventory management requires resilience and rapid pivoting. Manufacturers need as much visibility as possible into their stock holdings. No longer is a 'what happened yesterday will likely happen tomorrow' type scenario good enough for suppliers, manufactures or customers.

Manufacturers have limitations when selecting suppliers based on quality considerations, product specifications and other criterion. However, where possible diversifying the supplier network to include flexibility

and resilience, and those who can recover operation capacity quickly after disruptions are now critical differentiators.

Prioritising data is a critical inventory management strategy. And this goes for us all – suppliers, manufacturers, testing facilities and brand owners.

Our focus must also include inventory accuracy. Unless stock on hand reports are detailed in real time, the potential of struggling to keep up with demand in some areas or having an oversupply of raw materials for goods that customers are no longer interested in is very real.

Changing consumer behaviours for example, a focus on Australian Made, a focus on Australian derived ingredients is creating a surge in demand and leading to forecasting errors, which could not have been foreseen prior to Covid. Notably there has also been a change in product mix and volumes.

In order to balance the new norm for lead times into production schedules manufacturers need to become experts in understanding their suppliers' capabilities and transportation issues.

Importantly, being able to adequately communicate this to clients, who's first reaction to delay is often disappointment, is key. In fact, managing client expectations around lead times now almost needs its very own job category!

Manufacturers also have issues around new requirements for health and safety, physical distancing when in the workplace, quarantine and managing staff fatigue.

Add in the financial challenges of balancing business priorities of the supply chain at a time when there is a strong focus on cost management and cash flow. Being able to respond effectively and quickly when a changing market breeds uncertainty and cash flow pressures are high – all while you have those 600 balls in the air at one time. This is the new world of order inventory management for manufacturers as I see it.

Procurement is now a function no longer only measured by cost saving, but definitely prioritises revenue assurance.



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.





As of 1 July 2020, everyone in the Australian cosmetics industry has had something to celebrate. The change comes as welcome news for those engaged in product manufacturing and distribution right through to beauty counter staff, assisting consumers first-hand in our major retailers. Although, many would have missed that the Australian Government ban on the use of new animal test data for cosmetics came into effect that day; unsurprisingly so, given that all attention back then was on the challenges of COVID-19.

Efforts to get the message out about this historic leap forward for animal welfare in Australia were greatly accelerated in early 2021: a major retailer and social media outreach program was launched in February by the National Retail Association (NRA), with support from the Australian Government and in collaboration with Accord.

Using their strong national retailer network, NRA engaged with and educated retailers on the ban. This outreach to retailers was accompanied by an extensive online consumer awareness information package.

In their visits to retailers, NRA Policy Project Manager Ms Ebony Johnson was struck by just how interested and positive their staff were about these developments.

'Most retailers we have seen are delighted that this ban is now in place and are grateful for the information clearly explaining its details to assist both their staff and customers', Ms Johnson said.

'An important part of the program has been reinforcing that cosmetics include much more than just makeup or skincare products. Our retailer resources, like the handy in-store postcards, highlight other important products that are also impacted, such as toothpaste and shampoo.

'And the outreach does not end with retailers. All aspects of our social media are public-facing and are driven by appealing and informative videos targeting all types of consumers of cosmetic products,' Ms Johnson said.

Noting that any legislation has complexities, the NRA has created a dedicated website explaining all key details: https://animalcosmetictestban.com.au/about/.

Accord has welcomed the NRA's



campaign, and the large social media audience it has tapped into has been hugely impressive says Mr Craig Brock, Accord Policy and Public Affairs Director.

'This level of awareness-raising provides an excellent platform for the coming launch of the Voluntary Industry Code to Support the Australian Ban on Testing Cosmetics on Animals.

'Work on this Code progressed well throughout 2020 and into 2021. Most pleasingly, Australia's peak animal welfare body, RSPCA Australia, engaged constructively with Accord throughout this process and they have helped to improve the Code.

'The Code will provide useful guidance to cosmetic industry businesses and interested consumers. Its focus is on valid product advertising claims related to animal testing, now that the Australian ban is in force.

'Feedback from across the industry and from other relevant organisations has been incorporated into the Code, which has been expertly drafted for clarity and rigour by our legal partners for this project, HWL Ebsworth Lawyers', Mr Brock said.

A launch of the Code is scheduled for the first half of 2021 and will be followed by industry awareness and training sessions.





Viewpoint

Are you missing out on your ideal lab-based role because you are INVISIBLE?

by Michelle Raymond

How many of the following statements apply to you?

- ☐ I work in the lab and rarely see anyone outside our lab team.
- ☐ I can't share my formulating success on my resume due to non-disclosure agreements.
- ☐ I don't go to industry events as the company budget doesn't stretch to cover whole team.
- ☐ I'm an introvert, shy, have social anxiety and get overwhelmed at big industry events.
- ☐ I am not included in supplier visits as I am a junior chemist.

If you can relate to multiple statements above – does this leave you feeling invisible?

Realistically, if people can't see you and they can't know about your great work, then how will you stand out in the industry?

Firstly, if you believe LinkedIn is only for those that are in sales roles and

doesn't apply to lab roles, I am going to challenge you to stop and rethink.

Before we go any further, these are some LinkedIn stats you should know -

87% of recruiters regularly use LinkedIn.

A study found that 122 million people received an interview through LinkedIn, with 35.5 million having been hired by a person they connected with on the site.

If a recruiter were searching the platform to recruit for your dream role, would they stop and look at your profile?

Chances are at one time you registered on the platform, filled in the bare minimum, and left it alone ever since.

Top 5 Tips for Updating Your LinkedIn Profile

- 1) Profile Photo there needs to be a recent professional photo.
- 2) Profile Banner often overlooked by

- scientists. It is your chance to stand out and be memorable. Use it.
- About let this reflect more about who you are and what you are looking for. Describe your ideal role and environment.
- 4) Experience make sure this is up to date.
- 5) Recommendations ask for five recommendations from colleagues, clients, or well-known industry peers.

It is possible to update your settings to let recruiters know you are open to new roles without it being public knowledge.

Selling yourself is one of the hardest things to do. Highly likely you will self-sabotage and undersell your skills and experience. If this sounds like you, then invest in yourself and get a LinkedIn profile written or reviewed by an industry expert.

LinkedIn is much more than an online resume.



It is an opportunity for you to create your professional brand.

A professional brand, also known as a personal brand, is a conscious and intentional effort to influence public perception of you. It must be authentic and is a great way to establish your position in the industry as an authority in your space.

Building a professional brand will elevate your credibility, attract employers of choice, and your ideal roles.

The path to building a professional brand is divided into - building connections and posting content consistently.

Top 3 Tips for Building LinkedIn Connections

- 1) Use personalised invites.
- 2) Target connections at the ideal employer.
- 3) If a connection request is accepted reach out and thank the person.

Did you know that only 1% of LinkedIn members create content and comment consistently on other posts?

90% of LinkedIn members will never interact but will log in every day to follow what is happening. 9% will interact infrequently.

By creating content, you will automatically rise into the top 1%! It is that easy.

You can create polls, share interesting articles/papers, create documents, dispel industry myths, or even acknowledge a colleague.

Top 5 Tips for Posting Content on LinkedIn

- 1) Include an eye-catching picture.
- 2) Start slowly. 2-3 times per week is more than enough.
- 3) Be you share what you find interesting.
- 4) Use Grammarly to give you confidence in what you have written.

5) Respond to all comments quickly.

If you are a consultant in the industry that is looking to grow your business all the above still applies. You can build using your personal LinkedIn profile or a LinkedIn Company Page.

Globally, there is a shortage of content creators and even more so in the personal care and cosmetic science space. There is a massive opportunity for scientists of all backgrounds to create a strong brand and stand out easily.

Time for you to step out from the shadows of the lab and share your thoughts and knowledge.

If posting content is too much for you in the beginning, start with liking or commenting on other people's posts. You will help to support them and show up in their networks also.

Being top of mind will pay off.

If you don't do it, someone else
reading this article will.

SUNSCREEN highlights by John Staton

How Much Sunscreen Testing is **Enough?**

I was recently asked "How often should my sunscreen product be retested". This is not an uncommon question and becomes more urgent when a consumer group investigator asks this after noting the age of a provided efficacy report.

A far as I can determine, there appears not to be any firm deadline for revalidation of SPF or other performance claims made for sunscreens. Even the current review of the Australian Regulatory Guidelines for Sunscreens [ARGS], due for finalisation mid this year, does not explicitly provide any direction on this on a routine timeline basis.

In a previous discussion I had with the TGA, way back when the AS/NZS 2604:2012 was being finalised, the opinion at that time was that after 10 years would be an expectation – although this suggestion was never put into regulation.

So, how do we approach this question? Firstly, consider that sitting over all types of sunscreens, be they primary or secondary, is the question of consumer protection legislation. In essence, this really nets back to the question of what would a reasonably expected by a purchaser. Let's take some examples of how this expectation might apply.

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Example 1: Pregnancy Test Kits.

Although these have an expiry date indicated, would a reasonable person be surprised if this expiry had not been revalidated for say 15 or 20 years?

Example 2: Electrical equipment in commercial use. Even though the power leads on the equipment we use in the lab or office has been Q.C. passed (as usually shown on a tag when purchased), it is a requirement that this be revalidated in a specified number of years, typically 2, 3 or 5.

Here then are considerations. Firstly, SPF testing is not considered to be Quality Control but is a measure of expected efficacy. SPF cannot be extrapolated directly from content of actives. Most products we purchase come with an "efficacy" expectation, which might be in terms of fitness for purpose. However, the idea that quality is defined as fitness for purpose should not be confused with quality control. In the case of a sunscreen, it is not entirely valid to argue our case on the basis that each batch is assayed and physically tested, stability tested and microbiologically intact and assume that that confirms efficacy.

Secondly, the guidance in the current ARGS (expected to be similar in the

new version) gives direction on the management of changes to products post Listing and market launch.

- a. Addition or deletion of an actives creates a new therapeutic good and SPF testing of this is explicit.
- b. Changes to the excipient combination, with the exception of fragrance or colour, also creates a new therapeutic good and SPF testing of this is explicit. However, there are other considerations which can severely impact of a sunscreens' efficacy.
- a. The substitution of a different grade of Zinc oxide or Titanium dioxide.
- b. Changes in method of manufacture, such as dispersion of inorganics.
- c. Substitution of emulsifiers, stabilisers and dispersing agents, particularly proprietary mixes, which have the same INCI name but can perform quite differently.

We, as cosmetic scientists, are usually the best qualified to recognise where revalidation of efficacy is advisable. The test costs, although significant, are still relatively inexpensive compared with product recall of one batch of non-performing product intended to protect our users.

Professional / Product / Personal Safety

What?... is Cosmetovigilance?



Recently, I've been doing quite a bit of this, but I didn't realise it had a name – or in fact that it was a known discipline/profession.

It all started when one of my favourite clients applied for a 'Non-Tox Award' and was knocked back because their preservative 'Phenoxyethanol'....was

"associated with allergic responses"

We all have opinions about 'safe' and 'unsafe preservatives', and other ingredients......but this one hit me for 6!

What had I missed?.... I'd heard about PHENOXYETHANOL being 'bad' because of 'ethanol', it being a glycol ether....possibly because it had both and x and a y in its name (I may have made that last one up)...but I'd not head about allergies and this ingredient!

I had conducted a full safety assessment on their entire product range; what I now know is called Cosmetovigilance; that is a strategic, scientific search for any and all possible known adverse events associated with the product and any of its ingredient, alone and/or in certain combinations.

The concept comes from the medicines industry....it's designed to

ensure that manufacturers stay alert for possible emerging issues with their products and their ingredients, so that they continue to provide safe products to consumers.

In this case the product was a nappy cream that contained ~40% natural oils and waxes, ~25% water, ~20% zinc oxide, a couple of emollients, a couple of emulsifiers, a perfume and preserved with phenoxyethanol, developed in 2013.

So how to?.....

STEP ONE – where are we?

1.1 Brand owner

- Have you had any compliant or issues with this product?
- Do you want to make any changes?
- How is the stability testing going?1.2 Manufacturer
- Have you had any complaints or issues with this or similar products?
- Could I please have the full formulation and a copy of the specifications for each of the ingredients?
- Have you made any changes / do you want to make any changes?



by Wendy Free

STEP TWO - What's new?

With all of this on hand, the process began by looking for anything that had changed since the product was launched....

One of the most useful resources identified was the 2014 COSMETIC INGREDIENT REVIEW CIR Resource Document <u>Dermal</u>
<u>Penetration</u>, Absorption, and other Considerations for Babies and Infants in

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Safety Assessments¹

I also looked at

 REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Amended by: of 30 November 2009on cosmetic products Commission Regulation (EU) 2019/1257 of 23 July 2019²

- IFR A 49th Amendment³ and
- SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)⁴ and
- a "newly published" text book
 Handbook of cosmeceutical excipients
 and their safeties Yu Heng Kwan, Yee
 Kei Tung, Jaspreet Singh Kochhar,
 Hairui Li, Ai-Ling Poh and Lifeng
 Kang 2014 ISBN 978-1-907568-53-4
- and thought about AICIS⁵....and the Poisons schedule⁶
 Also, I refreshed my memory on
- REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures and
- Resolution CM/ResAP(2012)1 on safety criteria for cosmetic products intended for infants⁷

STEP THREE – LOOKING for Problems

With these resources in my mind, I went 'looking for problems'; I wasn't trying to demonstrate that the product was 'safe' I was trying to demonstrate that there was 'no evidence' for any part of it being hazardous.

Most of you will, hopefully be familiar with the incredible free resource that is the CIR⁸ (Cosmetic Ingredient Review) and of course will be familiar with COSing⁹ and particularly the annexes that tell us what's prohibited, restricted and controlled in the EU in terms of ingredients. We're also all keeping an eye on the Canadian Hot list¹⁰ and can search particular ingredients and adverse effects via the FDA¹¹ and Canada¹²

From there for each ingredient I conducted a search using both PUBMED¹³ and Google Scholar using

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the INCI and terms like "adverse effects" and/or 'toxicology' and/or 'allergy' etc.

Searches were also conducted for generic version of the product type for example 'nappy' / 'diaper' / 'infant' / 'neonate' / 'baby' etc, and then looking for emerging or repeating themes. In this case I was particularly interested in both dermal uptake and/or longer term effects.

From Pediatric Dermatology. 2018;35:225-229

From 2004 to 2016, 166 total adverse events were reported to the FDA for baby products. Reports increased 750% in 2014-2016 over 2011-2013. The majority of this increase came from the categories of baby powder and diaper and baby wipes, with these two products accounting for 79% of all reports from 2014 to 2016. Baby powder increased to 52 reports in 2014-2016 from one report in the 3 prior years, and diaper and baby wipes increased from 42 reports in 2014-2016 from 3 in the 3 prior years.

A single baby wipe manufacturer accounted for 28 of 50 reports (56%), with at least three product subtypes listed......

Forty-six percent of these events (77/166) led to a health care system visit, including hospitalization (n = 7), emergency department visit (n = 8), and healthcare provider visit (n = 70). A serious outcome was reported in 48% of adverse events (80/166), including death (n = 4) and disability (n = 4).

The most common symptom category was rash (n = 65), followed by neoplasm (atypical cellular growth) (n = 48), other skin reaction (n = 23), eye reaction (n = 14), and other systemic reaction (n = 13). Figure 2 demonstrates a heat map associating product classes with symptom reports. Rash reports were associated most often with baby lotions and wipes. Neoplasms, specifically ovarian cancer, were most often reported with baby powders.

STEP Four – SORTING the real from the 'opinions'.

There is quite a good amount of real data out there BUT unfortunately many, many 'peer reviewed' publications¹⁴ have not yet considered that there are controls around ingredients such as perfumes and preservatives and *continue to sprout bunk*

about what to avoid.

"The average number of allergens in each product was 2.4 (95% CI, 2.05-2.51).

The most prevalent single allergen was cocamidopropyl betaine, found in 45 (24%) followed by propolis/beeswax in 35 (19%), phenoxyethanol in 33 (18%), tocopherol in 25 (13%), and DMDM hydantoin in 24 (13%)"¹⁵

Reading further, these people bought products from the local supermarkets and then ran the names through a computer programs; trusting the results for what was and what was not an allergen

Cosmetics and skin care products for neonates and infants are considered as "hypoallergenic", "tested" or "safe". Nevertheless, the prevalence of haptens in these products is a matter of concern, since allergic contact dermatitis in children is gaining an importance. We aimed to assess the prevalence of haptens in cosmetics designed for children younger than 1 year. To identify haptens, the components of the cosmetics listed on packaging were compared with substances from European baseline series, Cosmetics series and Fragrance series. Survey comprised 212 cosmetics among which 186 (87.7%) contained at least one hapten from reference lists. Altogether there were 41 different haptens found in cosmetics. Number of sensitizers per product ranged between 1-12 and, each product contained 2.51 haptens on average. The most abundant sensitizers were cocamidopropyl betaine, tocopherol, propylene glycol, fragrances, lanolin. Majority of products for children were labeled as hypoallergenic/dermatologically tested/safe for children etc. from which 85% contained haptens. This survey highlights the extent of presence of haptens in cosmetics for children under the first year of

Digging a bit deeper lead me to their <u>information resource</u>....a commercial organisation that states in part

What else is COCAMIDOPROPYL BETAINE called?

This chemical can be identified by different names, including:

CADG, Cocoyl amide propylbetaine, COCAMIDE DEA, Coconut Diethanolamide, Cocamidopropyl betaine, Disodium cocoamphodipropionate,

Cocamidopropyl dimethyl glycine, Cocoamphocarboxypropionate, OLEAMIDOPROPYL DIMETHYLAMINE,

Cocoamphodiproprionate, Coconut oil acid diethanolamide

And helpfully tells its clients to

"Google" it. The internet is an excellent source of ingredient information that can be searched by product, by company and by specific chemical.

I think I'll just leave that one there..... interestingly both the reports cited above were published as 'letter's to the editor' and thus not subject to peer-review.

Note: if you are interested in something that actually is COCAMIDOPROPYL BETAINE, CIR tells that it can contain impurities that are known sensitising but is generally safe for use when formulated to be non-irritating.

STEP Five – Brining it all together

After around 40 hours research; I was able to determined that the product was likely safe as used, as there was no credible evidence to the contrary, and was in particular pleased to quote both

- FDA's Screening of repeated dose toxicity data in safety evaluation reports of cosmetic ingredients issued by the Scientific Committee on Consumer Safety between 2009 and 2019¹⁷
- Scientific Committee on Consumer Safety SCCS OPINION ON Phenoxyethanol 2016

That indicated that there was sufficient data to indicate that when phenoxyethanol was used at 1% or less, (in leave on nappy products for infants¹⁸) the margin of safety was acceptable.

So back to the beginning – what did I miss?

In response to my enquiry, the paper was from 2008 and starts with "Allergy to cosmetics is common"

 Really it's not....over 12 years in the USA there were only 166 adverse events reported for baby products, and of those about 1/3 were for just one product! Let's do the math, in 2016 there were 3,941,109, babies born, so over the 12 years lets estimate that there were about 47 million babies, with 166 adverse events (reported); and keep in mind this IS they time when we had 'talc in our baby powder'; and many of those making reports were the adults who had been effected in their childhood; and

 Babies are perhaps the most vulnerable group to adverse effects

The paper then tells us that it was not actually phenoxyethanol that the patents reacted to but a premix containing Methyldibromoglutaronitrile/phenoxyethanol 2%;

- so a known formaldehyde releasing substance and a preservative used at double its reported safe level.....
- Also figuring on their list was Methylchloroisothiazolinone/ methylisothiazolinone at 100 ppm... so, not maybe quite the most reliable source of current toxicology information?

**

In Australia it is MANDATORY to report adverse events; see¹⁹; In EU se Resolution ResAP(2006)1on a vigilance system for undesirable effects of cosmetic products ("cosmetovigilance") in Europe in order to protect public health²⁰

Yours in health and happiness;

Mrs Wendy Free

 ${\it B.Sc~M.Tech~Mngt~MASM~MRACI~FAOQ} \\ {\it talktous@quality matterss a fety matters.} \\ {\it com.au}$

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Social Engineering – what is it?

Why do I need to be concerned about it?

Cyber-attacks in Australia continue to be on the rise.

And for the unsuspecting it can have devasting consequences

In fact, a report from the Australian Competition and Consumer Commission(ACCC) identified Australians lost over \$634 million over a recent 12 month period

Most cyber-attacks prime aim is to defraud and begin with a little-known term.

"Social Engineering"

One aspect of a Social engineering attack involves the Cybercriminal gaining access to your emails or a client/supplier emails.

They often sit and observe for weeks, the patterns of accounts payments, invoices and even terminology used between the two parties.

And when the time is right, they intercept an invoice or payment due and change the bank account details on the invoice.

Sometimes, they even invent a bogus invoice.

An unsuspecting payment officer makes payments to these accounts which is in fact a clearing account for the Cyber criminals.

As soon as the payment has been cleared (A day or two), the money is transferred to an overseas account and once this occurs it is usually lost for ever.

How do these Cyber Criminals gain access??

Often it starts with an innocent click on an email attachment that looks like it is from a genuine source.

To help Australians identify threats, on the 30th of June 2020 the Australian Cyber Security Centre released a malicious cyber activity report.

In conjunction with this: -

The Government announced two key initiatives to help fight Cyber-crime in this country including reducing the likelihood of people being taken for a ride through being the victim of phishing emails:

1/ There will be a whopping \$1.35 billion Cyber Enhanced Situational

Awareness and Response (CESAR) package to boost protection and cyber resilience for all Australians. Under the Government's CESAR package, the ACSC will continue working with AFP and ACIC to enhance capabilities to prevent and disrupt cybercrime targeting Australia.

2/CESAR will also provide funding towards enhancing Report Cyber, improving the detection of widespread cybercrime campaigns and enabling the effective sharing of threat intelligence and cyber security advice to all Australians.

Whilst I cannot provide specific circumstances, we are aware of or assisted with several "Social Engineering" Claims

Example 1 /\$400,000 was paid out on legitimate invoices, where the bank account details had been changed on the incoming invoices.

Example 2 / \$275,000 was paid out on fake invoices from a known supplier. Again, Bank account details had been changed.

So to my Check list

- 1/ Be wary, very wary of opening emails & attachments from unknown senders.
- 2/ Be cautious of opening attachments from even known senders.
- Check the email address first for legitimacy.
- 3/Where you receive an email to change bank account details, or an invoice with different account details. Ring the supplier First.
- Tip 1 -Don't use the phone number contained in the email. Ring a known contact within the company to confirm.
- Tip 2 -Don't email the company, you may just be communicating with the Cyber Criminal.
- 3/ Make sure all your virus protection is up to date.
- 4/If you use an external IT service provider, ask them to do a security review and provide a report.



by James Gillard

And Last but not least consider Cyber Insurance.

Whilst the primary aim is to cover the monetary losses incurred should you experience a Cyber event, its most powerful aspect is having a

24/7 Cyber Emergency Assistance

A specialist team of IT, Accounting and Legal experts on call to guide & support your Business in your time of need.

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

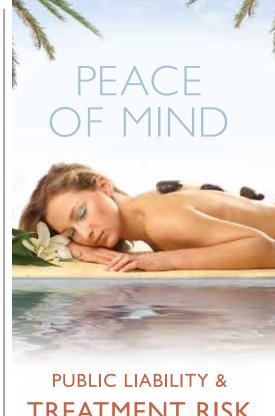
James Gillard

Managing Director





There is an old saying "A stich in time, saves nine"



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BANNING PLASTIC

New National Plastics Plan 2021 Sustainable Packaging



The Australian federal government launched a National Plastics Plan on the 4th of March 2021 to address ongoing concerns with plastics and the environment. In the plastic prevention plan they propose the following:

Work with industry to fast-track the phase out of polymer types in certain applications, and consider regulatory action should industry phase outs not be achieved:

• Phase out plastic compostable packaging products with additive fragmentable technology that do not meet relevant compostable standards (AS4736-2006, AS5810-2010 and EN13432) (July 2022)

- Phase out expanded polystyrene (EPS) from loose packaging fill and moulded packaging in consumer packaging (July 2022), and EPS food and beverage containers (December 2022)
- Phase out PVC packaging labels (December 2022)

The Australian government has also stated 4 national packaging targets by 2025 with two of them being:

- 100% of packaging being reusable, recyclable or compostable
- Phase out of problematic and unnecessary single-use plastic

At Weltrade Packaging, we have been working on this for the last 2-3 years.



by Steve Welsh

98.5% of all the packaging we supply is 100% recyclable ready.. NOW.

100% of the packaging we supply is either direct screen printed or has labels that meet the 2022 requirements already.

100% of Biodegradable options are Recyclable, Break Down in landfill, with NO microplastic traces.

100% of our bioplastic solutions are Recyclable and lower the carbon footprint of the product.

100% Recycled plastic can be applied in the majority of our PET jar and bottle lines.

The new National Plastics Plan is addressing the 2.5million tonnes of plastic waste created by Australian's made up of primarily single use packaging such as water bottles, coffee cups and straws.

Biodegradable v Compostable

The plan and standards also addresses claims made by some that products are compostable, these generally use fragmentable or oxo-degradable processes leaving micro plastics in the ecosystem for hundreds of years. We welcome this initiative!

In our industry a package needs to retain liquid or maintain efficacy with oxygen, this will involve a layer that can not breakdown in compost as compost needs moisture to break down unless it contains one of the methods above.

Our Biodegradable process relies on the internationally recognised biodegradable standard ASTM D5526. We have tested our packaging in independent laboratories in the USA. The results clearly demonstrated that over time the packaging will fully biodegrade in landfill. The testing guidelines measure the gasses not weight loss, the catalyst is the enzymatic breakdown of the polymer through microbial activity that result in anaerobic and aerobic environments. Therefore the packaging is designed to breakdown in standard landfill environments leaving behind only soil and gas and zero micro

plastics.

Our material breakdown process is different to the oxo-degradable that has been around for some time. In the Oxo-degradable process, it is more mechanical and that breaks the packaging down into pieces.

Anything sustainable for the packaging industry is a good thing. The more government support for more recycling and supporting doing the right thing is what governments should do.

Visit ur sustainability pages on WeltradePackaging.com.au for more technical information and data or give our team a call 07 5597 0102.

(Ref: National Plastic Plan)



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The **Who** and **What** about your **TECHNICAL COMMITTEE**

By Pam Jones

Have you ever wondered about the ASCC Technical Committee and what they do? Who is currently serving on this Committee, and why do they dedicate their spare time to our society? When and where do they meet? If you know extraordinarily little about the T.C. members, perhaps I can give you a summary so that you may consider joining and supporting your industry when our AGM comes around in September.

What does the Technical Committee do, and when and where do they meet?

The ASCC Technical Committee is a voluntary body of technical members of the ASCC, which acts as the scientific advisory Committee for members' benefit. They meet formally five-six times per year and communicate regularly by email/telephone/conference calls. They report to the ASCC Council, and you may access information generated by the Committee on the ASCC web site.

Below is an outline of the nature and scope of the T.C. activities. The Committee may take up any technical/

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scientific aspect which may impinge upon the cosmetics/personal care industry.

- Regulatory input/comment/
 participate in the review/drafting of
 ISO Standards and AUS/NZ standards
 and recommendations on matters that
 impact the industry such as AICIS,
 TGA, and other proposed regulations
 (e.g., Microbeads, Animal Testing,
 Cosmetic Labelling etc.)
- <u>Sunscreens</u> Australia was the frontrunner in sunscreen testing.
 The ASCC plays a significant role in updating the ISO and Australian standard on Sunscreens.
- Position Papers, Position Statements

 these are prepared for specific topics
 present the position of the ASCC
 clearly and scientifically, to inform & educate both members of the ASCC
 and the public at large.
- <u>Journal</u> the T.C. is responsible for classifying and approving conference papers from the ASCC Conference and some external conferences and magazines. Articles are then published in *The Science of Beauty* within the

- section identified as Technical and bearing the ASCC logo.
- 'Hot Issues' are addressed such as Sustainability/RSPO, Claim Substantiation, Sunscreens and Vitamin D, Natural/Organic.
- The T.C. liaises with other relevant bodies such as ACCORD in mutual concern areas (e.g., certain regulatory areas).

Who is currently on the ASCC Technical Committee, and why do they volunteer their time.



Ranelle Anderson
Chairman of the Technical Committee
Technical Manager at Ausmetix Pty. Ltd.

- 15 years' experience in pharmaceutical and cosmetic formulation, analytical testing, internal auditing, manufacturing (GMP and TGA) and quality assurance
- I am experienced in developing innovative high-end skincare, dermatological products, sunscreens, personal care, and hair care.
- I am familiar with ACO, Cosmos and global regulations.
- Member of Ban Cosmetic Testing on Animals Implementation Advisory Group

"Volunteering on the T.C. provides a chance for me to build on existing knowledge, develop new skills and give back to the ASCC as a volunteer member.

Joan Chiu



Technical Business Manager Personal Care. IMCD Australia

- I have worked in the industry for 15 years.
- I have experience in formulations and product development.
- A trainer for natural cosmetics and cosmeceutical brands

"I want to contribute to the industry and the society; given my background, the technical Committee seemed to be the obvious choice. I want to help spread technical knowledge and help and support newcomers to the industry."



Dhanushka (Danny) Hettiarachchi Product Manager, Quintis Sandalwood

• I have been working with the natural products industry for 17 years.

- I represent the ASCC at the International Standards Organisation/ Standards Australia's Committee on essential oils.
- Adjunct academic at University of Western Australia and Edith Cowan University
- State expert witness on sandalwood.
 "I took an interest in joining the Technical
 Committee for their work towards the
 progress of cosmetic sciences in Australia. I
 find it is my utmost pleasure to work with
 my fellow committee members, a dedicated
 knowledge bank of experts in diverse branches
 of cosmetic science."



Yvette Ishac

R&D Manager. Care Manufacture Pty. Ltd.

- I have more than 20 years of experience in the development and formulation of Personal Care and Pharmaceutical Products.
- I have extensive knowledge of worldwide Cosmetics regulatory standards.
- Member of Standards Australia Committee CS-042 for Sunscreen.

• Previously, member of the

Technical Committee for Cosmetics in the Egyptian Organization for Standardization and Quality "I am gaining great experience by being a member of the Technical Committee. This allows me to stay abreast of advances in my area of expertise and assist others' professional education. Technical Committee makes a great difference in the Cosmetics industry! This helps all members play a role in maintaining the Cosmetics industry in Australia up to the highest level of technical & regulatory expertise to match worldwide standards for the industry."



Pam Jones

Technical Editor

Director PCA Consulting.

- I have worked for more than 40 years in the Fragrance, Personal and Home Care industries.
- I am familiar with all aspects of the Asian market, working in Singapore for seven years and Hong Kong for six years.
- I have worked in Q.C., R&D, Sales, Marketing and Business Management. "I joined the Technical Committee to give back to the industry that helped make me a career overseas. I am passionate about passing on all knowledge that I have gained through my overseas work to tomorrow's upcoming Cosmetic Chemists."



Paul Kent.

Technical and Product Manager at Avenir Ingredients Pty. Ltd.

- I have more than 20 years of experience in cosmetic and pharmaceutical R&D.
- I have spent more than ten years of experience in the natural skincare market.
- I am experienced in natural formulations, sunscreens, product innovation, scale-up, vendor management and clinical trial design.

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"In 2020, I joined the ASCC-TC, seeing it a great opportunity to learn from the vast experience on the T.C. and contribute some of the knowledge I have gained over 20 years back to the industry. Producing position papers on 'hot topics', contributing to calls for industry feedback from government departments or NGO's. My goal is to have ASCC-TC recognised as the place to go when you need information on a complex technical topic relating to cosmetic science."



Nick Urquhart.

Secretary of the Technical Committee Director Nauchem Services.

- Involved in the industry for over 40 years mostly in a development function and more recently operating as a private consultant for the last 12 years.
- I am one of the ASCC representatives on the Standards Aust. Committee CS-042 Sunscreen Agents.
- Previously represented the society on the TGA ARGOM-09 Project Team (Australian

Regulatory Guidelines for OTC Medicines).

- I am a founding member of Monash University's Bachelor of Pharmaceutical Science Industry Advisory Group.
- Chairman of the IFSCC 2009 Conference Steering Committee. "My main reason for joining the T.C. lies in attempting to give something back to the industry that has provided a livelihood throughout my working life. But it's not entirely unselfish; I have benefitted from the enjoyment gained from the many good friends and acquaintances I have made over the years."

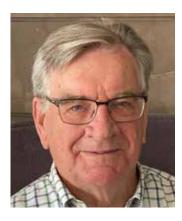


John Staton.

Scientific Director at SciPharm Pty Ltd

- I have been involved in the cosmetic/personal care industries for 55 years.
- My background is in product development, and for the last 23 years, I have specialised in sunscreens.
- I am representing Australia on the ISO Technical Committee TC 217 - Cosmetics Working Group 7 -Sunscreens.

"ASCC has always been a promoter of the science of cosmetics, particularly in Australia. We need to have recognition in the industry and at the government level. Having an active Technical Committee has ensured that we are in the loop with any issues impacting the science and the regulation of cosmetics and personal care product development and manufacture."



John Warby.

Retired. Active on many scientific committees.

- Working life in pharmaceuticals /biotechnology (28+ years) I then worked for 12 years in the Cosmetics industry, most recently as Regional Technical Manager.'
- I am a member and held positions in the following.

- o RACI Pharmaceutical Science Group
 - o Pharmaceutical Science Group
 - o University of NSW Chemistry

"I have always believed that as professionals, we have a responsibility to contribute to the development of members by participating actively in areas of our expertise. The specific instance of the ASCC Technical Committee has a long history of devoting considerable time and effort to address a wide range of technical and regulatory issues and assess scientific papers submitted for publication in our Journal. The work covers national and international elements as well as having been cited in a major legal judgment.



Maile Zauber.

Vice-Chairman of the Technical Committee Industry Group Manager. Carst & Walker

- Initially from South Africa and involved in the cosmetics industry since 1998.
- I am experienced in QC., R&D, sales, Technical Marketing & Development.
- Member of the 2021 conference committee

"I joined the Technical Committee for the love of it. Part of it is giving back, but at the same time using the opportunity to learn."

Let your youth

Lubrizol Life Science – Beauty (LLS Beauty) introduces LapagylTM advanced botanical ingredient, an oil-based extract from the South American lapacho tree that promises to slow aging of facial skin.

LapagylTM advanced botanical ingredient is an oil-based lapacho bark extract that promotes a slower aging process and an increased skin longevity, which leads to a radiant, younger and improved appearance.

As we age, the telomeres that protect our skin cell chromosomes shorten, which causes cellular senescence and skin aging. This botanical ingredient works by helping to delay the shortening of telomeres which forestalls the signs of aging skin.

In vivo testing demonstrated its efficacy. In a clinical test of 30 female volunteers, the subjects used a cream containing 3% ingredient on half their face and a placebo cream on the other half twice a day for 28 days. The depth of crow's feet wrinkles decreased 21.6% while skin radiance and moisturization increased, 24.4% and 17.9%, respectively.

Visibly improved overall appearance A test with 2% LapagylTM advanced botanical ingredient showed

improvement in the firmness of the upper eyelid and reduced eyelid drooping.

The source of this wonderful

ingredient is the lapacho tree, the national tree of Paraguay. It was known as the "tree of life" by the Incas, who revered it for its healing properties. LLS Beauty obtains the bark from a 100% women-owned family company that works closely with small producers and growers. The supplier also provided baby lapacho trees to farmers to plant them for future growth while supporting reforestation. The extraction process itself is sustainable and the ingredient is COSMOS approved and of 100% natural origin content.

Aging can't be stopped, but the outward signs of it can be slowed. LapagylTM advanced botanical ingredient will let users retain their youthful looks longer by delaying the onset of the appearance of aging.

LapagylTM advanced botanical ingredient is ideal for use in daily skin care products, in oil-based formulations for complete care of mature skin or as part of a natural cosmetic formulation with the aim to improve skin longevity. To learn more, click here.

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.

28 days

0 days





27



Assure+ Leaves Formulation Space For Creativity

Assure+ from A S Harrison & Co and EverCare is a natural SPF and UVA performance booster. Its secret lies in its efficiency – only 0.25% is required to achieve SPF50+ in Zinc only formulations. Compared with synthetic boosters, Assure+ is an economical solution that leaves plenty of room in your formulation to be creative.

What Makes Assure+ so special?

Assure+ is a Pongamol extract – a naturally derived ingredient with an ecofriendly extraction process. It is TGA and COSMOS approved and is one of the only NATURAL SPF boosters on the market. It is a natural antioxidant and demonstrates both UVB and UVA boosting.

You can gain 10 points of SPF with only 0.25% Assure+ in your Zinc formulation making it one of the most economical, natural SPF boosters available.

Let's Talk about Pongamol

Pongamia Pinnata Seed Extract is an extract of the seeds of Pongamia pinnata (L.), Fabaceae (Australia INCI:

Assure+ Boosts SPF and UVA



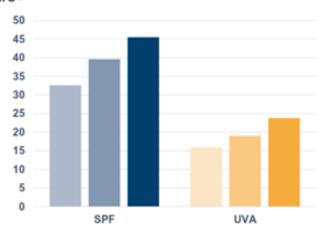
Cream Base SPF 30 Formulation

20% Zano 10 Plus with and without 0.10% Assure+

	Zano 10 Plus (20%)	Zano 10P + 0.10% Assure+	Zano 10P + 0.25% Assure+
SPF	32.6	39.6	45.5
UVA-PF	15.9	19	23.8
UVA-PF/SPF	0.49	0.48	0.52
Critic A	371	372	374

In vitro - non-ISO-24443

28





Pongamol). The Pongamia species is globally abundant. Other names for this oil include honge oil, kanuga oil, karanja oil, and pungai oil.

Pongamia (Millettia pinnata), formerly known as Pongamia pinnata, is a tree/shrub with a broad distribution from India, through central and south-eastern Asia, Indonesia and into northern Australia. The Queensland Herbarium currently considers pongamia native to northern Australia (Queensland and the Northern Territory).

The seeds of pongamia are rich in oil, which might be a new source of 'biofuel'. Research and field trials to assess the species' capacity to produce biofuel are currently underway in Queensland and the Northern Territory. https://www.daf.qld.gov.au/__data/assets/pdf_file/0003/67575/IPA-Pongamia-Risk-Assessment.pdf

Typically, the plant starts yielding pods from the fifth year on with the yields increasing each year until it stabilises around the tenth year.

WHO IS EverCare?

Previously part of the Umicore group, EverCare developed an in-house technology to produce ultra-fine zinc oxide 20 years ago. Still today, EverCare is exclusively active in the production

of zinc oxide (mostly for personal care applications). This focus allowed them to develop expertise over the years in terms of product knowledge and quality control and also in terms of the formulation expertise and regulatory support they offer to their customers.

Today, EverCare is recognised as one of the leaders in the field of UV protection supplying their Zano® and Xperse® ranges to most of the major brands worldwide. Their business philosophy to remain the leaders in their industry by putting the client's developments first is well summarised by their 3 keywords: Innovate, Enable, Protect.



THE POSITIVE REEF INITIATIVE

Even though Corals are one of the most important ecosystems on the planet, they are disappearing at an alarming rate. While scientists agree that the major contributor to coral reef bleaching events is due to rising temperatures of sea water, there is continued interest in understanding the direct impact humans have on local coral reefs. Of particular attention has been the environmental

impact of UV filters used in sunscreen ingredients, especially for coral reef tourist locations.

Concern over sunscreen pollution and its potential impact on coral reefs, particularly in high-traffic tourist areas, has led to legislation that prohibits the use of particular UV filters that are thought to contribute to coral reef bleaching.

Through the Positive Reef Initiative, EverCare intends to actively contribute to influencing coral reef restoration. EverCare's commitment is to offer ingredients that allow for the creation of reef-friendly sun care products, while at the same time making a positive contribution to stop coral reef damage and promote its restoration.

The Positive Reef Initiative is committed to helping consumers make informed decisions on their sunscreen purchases, to researching and restoring coral reef populations, and reducing our global carbon footprint to reduce our impact on climate change which affects coral reef habitats. With increased awareness of the impact of sunscreen on coral reefs, consumers are not only looking for natural, reef-safe ingredients for their sun care products, they are also looking for brands committed to protecting the environment.

You can find information on the Positive Reef Initiative at:

https://www.linkedin.com/showcase/ positive-reef-initiative/ https://www.instagram.com/ positivereefinitiative/?hl=fr https://www.facebook.com/Positive-Reef-Initiative-130063771817959/

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

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A 2020 VISION

Technical Considerations to achieve complete Clean Beauty for your product of the future

Part I.

by Ric Williams

Cosmepeutics International Pty Ltd

Clean Beauty is a modern multifaceted concept, in product development and presentation, that brings together many aspects that have been in development over the last decade.

These multi-faceted components are;

- 1. Formulations, this means focusing on the 12 Principles of Green Chemistry, using ingredients that are Safe to use and Good for you, and don't use anything that you know is not. Clean Beauty products contain essentially natural (but also nature identical or naturally derived) ingredients obtained through ethical sourcing, with responsible (non-animal) safety assessments.
- 2. Sustainability as it is also about being environmentally conscious. Embracing more chemical materials and packaging from sustainable sources, and using packaging materials that have a minimal effect on the environment, where possible.
- 3. Employing low energy processing or energy saving techniques reducing your carbon footprint that may affect climate change by protection of the natural environment. This also is a means of Cost Savings usually ignored.
- 4. Over-riding Transparency in that you are open and honest, presenting your product, particularly with Claims as to what your product does (ignoring negative comments about

others). This provides the consumer with Confidence and Trust in your company and products.

Recent changes have appeared in the advent of the concept of "Clean Beauty".

Most importantly it is a positive set of claims; not negative claims.

However, what I see in marketing this concept is, one (or maybe two) of these components being addressed and still the "Clean Beauty" claim is used.

It is usual that only the one (or maybe two) components are adhered to because the sponsor does not have a clear idea of what they all mean. This paper tries to rectify that by defining the four components in a technical approach, so marketers and management can see what is required, and how they can utilise this to promote their products.

Let's be assured that all components need to be applied before this concept becomes real.

Now for the technical parts of the concept;

1. Formulations

1.Non-Harmful Ingredients / Cruelty Free

Over-riding consideration is to use raw materials that have a low toxicity profile. If the material has a higher toxicity profile then it must be used at a level below its toxicity threshold. In research for this paper, I have read many articles written by the likes of the lobby group EWG and well-meaning bloggers that rely on others "research" whether it be right or wrong, proliferating, in most cases, the incorrect or biased information coming from these sources that have misinterpreted information or have biased views based on ulterior motives (usually to please those providing their funding or promoting their own brands as better by denigrating others).

A classic article of this type is "The "Toxic 20" - Meet the Ingredients a Green Cosmetic Chemist Would Never Use". written by Victoria Hoff, Byrdie Updated Jan 23, 2020[1], with an opening statement "You've heard of the "dirty dozen," but how about the "toxic 20?" When it comes to our beauty products, it might seem as though the list of ingredients to avoid is growing longer by the minute—but that's only because experts and consumers alike are wising up to the impact of their ingredient labels." This article relies heavily on EWG articles and contains information that is usually based on Material Safety Data Sheets (with the material tested at 100%) and not on the material tested in the product at normal use levels.

Countering this are articles such as "What the Research Says About 10 Controversial Cosmetics Ingredients",

Beauty, May 14, 2018 by Tara Haelle[2], which attempts to counteract the wild incorrect information, with real science.

Unfortunately, there are three problems with this second type of article,

- 1. The consumer will still have a feeling of suspicion about the materials mentioned due to the larger volume of articles denigrating them as opposed to those debunking the incorrect information. Distrust of someone in a white coat also pervades here.
- The sad fact that bad press sells more magazines than good press, apart from those with articles about the royal family, of course.
- 3. There is also a pervading thread on the internet that states "If you cannot pronounce it then it must be bad". Here you must take time to explain to the consumer, possibly via your website or a leaflet supplied with the product, what the material is, where and how the ingredient is sourced. This also applies to where claims are made that materials are "ethically" sourced. Note; "Ethical sourcing" includes sustainability, fair trade and being environmentally responsible.

I have spoken before about the European Union (EU) Regulation on Common Criteria for Cosmetic Claims (655/2013), and the European Commission's (EC) report on Article 20 of the EU Cosmetics Regulation[3] in relationto the common criteria for cosmetic claims, has raised concerns over free-from and hypoallergenic claims.

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

These attempts to limit the "Free-from ..." claims but only in product advertising. There is no restriction on these info-mercial articles saying the same thing.

I say, believe the science!

On the positive side you should look towards the 12 Principles of Green Chemistry as guidelines in your formulations. The twelve principles of green chemistry are:[4]

While these are designed for the manufacture of the raw materials used in our industry, highlighted in blue are where these

can apply to the last stage of manufacturing cosmetic products.

1. Prevention.

Prioritise the prevention of waste, rather than cleaning and treating waste after it has been created. Plan ahead to minimise waste at every step.

Plan to make enough to fill the order with no excess, and this involves packaging as well as product.

Use efficient mixing equipment and storage vessels where minimal residue is left after the batch has been completed.

2. Atom economy.

Reduce waste at the molecular level by maximising the number of atoms from all reagents that are incorporated into the final product. Use atom economy to evaluate reaction efficiency.

Minimise side phases or the use of evaporative solvents where possible.

3.Less hazardous chemical syntheses.

Design chemical reactions and synthetic routes to be as safe as possible. Consider the hazards of all substances handled during te reaction, including waste.

Ensure that hazardous chemical syntheses are not occurring in your batch, eg the formation of Nitrosamines (reaction of a secondary amine with an amide). You will need a chemist to advise you about such adverse processes.

4. Designing safer chemicals.

Minimise toxicity directly by molecular design. Predict and evaluate aspects such as physical properties, toxicity and environmental fate throughout the design process.

See the section below under "So what can be used?"

When designing products try to use materials that are readily biodegradable and avoid those that are not biodegradable.

When designing products try to use materials that are safe in use and avoid those that are not safe when handling the pure material.

5. Safer solvents and auxiliaries.

Choose the safest solvent available for any given step. Minimise the total amount of solvents and auxillary substances used, as these make up a large percentage of the total waste created.

Ensure that the raw materials you use do not contain hazardous solvents or preservatives (eg With the INCI material Carbomer – varieties such as Carbopol 934 or 940 are made with benzene solvent while Carbopol 974 or 980 are made with a safer

solvent). If they do consult with the supplier if less harmful versions can be obtained.

6.Design for energy efficiency.

Choose the least energy-intensive chemical route. Avoid heating and cooling, as well as pressurised and vacuum conditions (ie ambient temperature & pressure are optimal).

See below Section 3. Low Energy Processing / Energy Saving Techniques

7. Use of renewable feedstocks.

Whenever it is practical to do so, renewable feedstocks or raw materials are preferable to non-renewable ones.

Ensure your purchasing obtains raw materials that are sourced from renewable feedstocks, where possible. This can be achieved by setting appropriate QA Specifications for such materials.

8. Reduce derivatives.

Unnecessary generation of derivatives—such as the use of protecting groups—should be minimized or avoided if possible; such steps require additional reagents and may generate additional waste.

9. Catalysis.

Catalytic reagents that can be used in small quantities to repeat a reaction are superior to stoichiometric reagents (ones that are consumed in a reaction). Catalysts will help increase selectivity, minimise waste and reduce reaction times and energy demands.

10. Design for degradation.

Chemical products should be designed so that they do not pollute the environment; when their function is complete, they should break down into non-harmful products that are not toxic, bioaccumulative or environmentally persistent.

When designing products try to use materials that are readily biodegradable and avoid those that are not biodegradable.

11. Real-time analysis for pollution prevention.

Analytical methodologies need to be further developed to permit real-time, in-process monitoring and control before hazardous substances form.

Monitor all batches to ensure that the process is as efficient as possible and that it continues to remain efficient and non-hazardous.

12. Inherently safer chemistry for accident prevention.

Whenever possible, the process itself, the substances in a process, and the forms of those substances, should be chosen to minimize risks such as explosions, fires, and accidental releases.

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When designing products try to use materials that are safe in use and avoid those that are not safe when handling the pure material.

Non-Animal Derived Ingredients

As animal-derived materials are restricted if you are using a "Cruelty-free" claim, the only materials in this category are where no animal is harmed in sourcing. Obvious materials are Beeswax, Propolis and Honey, Milk/Yoghurt and Algae derived materials.

Vegetarian and Vegan Ingredients

Obviously Vegetarian and Vegan materials would be acceptable, however the two factors which restrict their use are Cost and Availability.

So what can be used[5]?

Notwithstanding that there are the various differences (within classifications) under certified organic standards around the world, I will endeavour to outline what can be used and those that are of limited use (usually where there is no suitable alternative), plus those that should be avoided.

If I have neglected any material it is not for reason of malice but reasons of lack of space and lack of knowledge. For this I apologise.

Solvents / Carriers

Suggested ingredients;

1 Purified water. Water used should be of a standard of purity agreed with the certification body. The minimum requirement is for the water to be;

Total Microbial Load

less than 100cfu/ml

Heavy Metals

less than 0.1 ppm

Conductivity

Subject to product type, in that, products with added salts need not have an upper limit for conductivity but products where salts are not required the standard should be less than $5.1~\mu S.cm-1~@~25oC.$

- 2 Organic alcohol. Legally required denaturants may be used, though the certification body will require details.
- 3 Organic glycerine and 1,3 Propanediol.
- 4 Organic (vegetable derived) oils.

Ingredients with Limits;

1 Other solvents of organic origin. **Undesired ingredients**;

- 1 Solvents derived from petroleum products
- 2 Ethoxylated or propoxylated solvents
- 3 Denatured alcohols where the

- denaturant is not approved as certified organic
- 4 Synthetic Esters and Ethers
- 5 Phthalates

Surfactants (detergents/emulsifiers)

Suggested ingredients;

- 1 Soaps (vegetable/organic origin only) eg. Sodium Palm Kernalate, Sodium Olivate
- 2 Anionic Surfactants derived from
 Fatty Alcohols without Sulfation eg.
 Sodium Stearoyl Glutamate, Sodium
 Cocoyl Glutamate, Sodium Stearoyl
 Lactylate, Sodium Lauroyl Lactylate,
 Sodium Cocoamphoacetate, Fatty
 Acid Sulfosuccinates, Fatty Acid
 Isethionates, Acyl Sarcosinates, Methyl
 Acyl Taurides
- 3 Glyceryl Esters of Fatty Acids eg. Glyceryl Mono Stearate, Glyceryl Di Stearate,
- 4 Alkylpolyglucosides eg. Decyl Glucoside, Lauryl Glucoside,
- 5 Alkylglucosides eg. Cetearyl Glucoside, Sucrose Cocoate, Sucrose Stearate
- 6 Alkylbetaines eg. Coco Betaine, Cocoamidopropyl Betaine
- 7 Condensation products eg. Brassicyl Isoleucinate Esylate, Cetearyl Olivate, Sorbitan Olivate, Cocoyl Proline, Glyceryl Laurate, Polyglyceryl-2 Dipolyhydroxystearate
- 8 Protein Derived Anionics eg. Cetearyl Wheat Straw Glycosides, Potassium Palmitoyl Hydrolyzed Wheat Protein, Potassium Lauroyl Wheat Amino Acids
- 9 Cationics eg. Cocodimonium Hydroxypropyl Hydrolyzed Wheat Protein (where "hydroxypropyl" component, is from "natural" sources), PCA Ethyl Cocoyl Arginate
- 10 Nonionics eg. Fatty Isopropanolamides, Sorbitan Esters,
- 11 Lecithin and Lecithin derivatives
- 12 Inulin and Inulin derivatives

Ingredients with Limits;

Nonionics eg. Fatty
 Monoethanolamides (with low DEA content),

Undesired ingredients;

- 1 Alkyl Sulphates eg. Sodium Lauryl Sulfate, and Ammonium Lauryl Sulfate (only because of bad publicity). I have seen where Sodium Coco Sulfate is approved but how is this so when the Coco part contains 50-55% Lauryl. Possible Greenwashing.
- 2 Alkyl Benzene Sulfonates eg. Sodium Alkene Benzene Sulfonate
- 3 Alkyl Ether Sulphates eg. Sodium

- Laureth Sulphate, Ammonium Laureth Sulphate
- 4 Polysorbates eg. Polysorbate 20
- 5 Ethoxylated Nonionics eg. Laureth-8, Ceteareth-20, PEG-400
- 6 Ethanolamides eg. Fatty
 Diethanolamides (with high DEA
 Content), Fatty Monoethanolamides
 (with high DEA Content)

Emollients, Oils, Waxes

Suggested ingredients;

- 1 Oils, Butters and Waxes of vegetable origin.
- 2 Emollients derived from natural sources but modified by chemical processes (eg esterification). These should have a good toxilogical profile.
- 3 Purified petrochemical products (eg Mineral Oil, Petrolatum and Paraffin Wax).

Ingredients with Limits;

1. Organic oil products of animal origin.

Undesired ingredients;

1 Non-organic products of animal origin.

Salts and Mined minerals, when they are essential to the nature of the product

Suggested ingredients;

- 1 Montmorillonite, Zeolite and Kaolin clays.
- 2 Chalks.
- 3 Sand.
- 4 Salts.
- 5 Pumice
- 6 Zinc Oxide and Titanium Dioxide
- 7 Sodium Bicarbonate and Sodium Carbonate

These should be used whole and non-modified, though washing; steam cleaning; ultra heat treatment and other mechanical cleaning and drying methods are permitted.

Undesired ingredients;

- 1 Salts of Heavy Metals (including Lead, Mercury, Chromium),
- 2 Alumina
- 3 Talc

Viscosity modifiers and thickeners:

Suggested ingredients;

- 1 Plant derived gums eg. Guar Gum, Xanthan Gum, Sclerotium Gum, Accacia Gum, Carrageenan
- 2 Cellulose and Cellulose Derivatives where cellulose and starch "derivatives" do not include ethoxylated or propoxylated side chains
- 3 Starch, Dextrin and derivatives
- 4 Montmorillonite and kaolin clays.

Ingredients with Limits;

- 1 Acrylates and acrylate derivatives
- 2 Carbomers

Anti-microbial agents:

One must consider that a preservative is added to a product to kill a living organism (ie Bacteria, Mold or Yeast. If they do not do this then they would not be effective preservatives.

Preservatives are there to help the product overcome the incidental introduction of microbial contamination during processing and use, and when used correctly, with the judicious choice of preservative types, and at appropriate levels (recommended levels below threshold toxicity levels), they will prevent incidental contamination of products, and do not impact on the safety of cosmetics; during use. One overriding consideration is that preservatives are not designed to render the product sterile, or compensate for unhygienic manufacturing methods or inadequate packaging, hence levels should be kept to an effective minimum.

Suggested ingredients;

- 1 Sorbic, Benzoic acid and their salts eg. Potassium Sorbate and Sodium Benzoate.
- 2 Essential Oils, essential oil isolates or extracts that may be intrinsically modified, with preserving activity. 'Intrinsically modified' means simple physical or chemical modification that does not materially alter the active ingredients. This includes Phenylethyl Alcohol from organic sources.
- 3 Modified Amino Acids and natural ingredients that have anti-microbial action eg. Ethyl Lauroyl Arginate, Leuconostoc/Radish Root Ferment Filtrate.
- 4 Other "natural" sourced preservatives.

 Ingredients with Limits;
- 1 Phenoxyethanol.
- 2 Lactoperoxidase.
- 3 Phenylethyl Alcohol (from synthetic sources).
- 4 Silver compounds
- 5 EthylHexyl Glycerin
- 6 Organic sourced glycols eg. Caprylyl Glycol
- 7 Caprylhydroxamic Acid
- 8 Benzyl Alcohol.
- 9 Naticide (due to its solvent content) **Undesired ingredients**;
- 1 Para-Hydroxybenzoates (parabens)
- 2 Formaldehyde and formaldehyde releasing compounds, Quaternium 15, DMDM Hydantoin, Sodium Hydroxymethyl Glycinate, Imidazolidinyl Urea and Diazolidinyl

Urea compounds

- 3 Phenol and phenol derivatives
- 4 Chlorine, Bromine and Iodine based antimicrobials
- 5 Trichlorohydroxy Di-Phenyl Ether (Triclosan) due to it being "bio-accumulative".

NB; I must point out here that, in my opinion, these materials are not harmful when used at approved levels, but should be eliminated due to the bad press these materials receive, causing "commercial suicide" if you use them.

I have found that you cannot convince most consumers because of the widespread misinformation that you find on the internet. See the picture captioned "RECOGNISED EXPERTS OVER TIME", above.

Anti-oxidants:

Suggested ingredients;

1 Vitamins

Mixed Tocopherols (Natural Vitamin E), Ascorbic acid (Vitamin C), Retinyl Palmitate (Vitamin A), Niacinamide (Vitamin B3),

2 Antioxidant Nutrients:

beta-carotene, mixed carotenes, Coenzyme Q10, selenium, zinc, bioflavonoids, cysteine & methionine (sulphur-containing amino acids), Lycopene.

3 Antioxidant Herbs:

Artichoke, Bilberry, Ginger, Ginkgo, Grape seed extract (pycnogenols), green tea, hawthorne, milk thistle, olive leaf, Rosemary, St. John's Wort, turmeric.

4 Other Antioxidants:

Resveratrol, Melatonin, Alpha Lipoic Acid, Acetyl-L-Carnitine.

5 Dimethylmethoxy Chromanol (0.01-0.05%)

Restricted ingredients;

1 Sodium Metabisulfite

Undesired ingredients;

- 1 Butylated Hydroxytoluene (BHT)
- 2 Butylated Hydroxy Anisole (BHA)

Fragrances

Suggested ingredients;

- 1 Fragrances components of organic origin.
- 2 Essential Oils of organic origin.

Undesired ingredients;

- 1 Fragrances components of non-organic origin.
- 2 Synthetic Solvents
- 3 Fragrances containing Phthalates

Colours

Suggested ingredients;

- 1 Colour components of organic origin.
- 2 Titanium Dioxide, Zinc Oxide and Manganese Oxide, and mixtures of these

Undesired ingredients;

- 1 Colour components of non-organic origin.
- 2 Colures based on heavy metals.

Humectants

Suggested ingredients;

- 1 Glycerin (from vegetable origin),
- 2 Sorbitol and other sugars from natural sources,
 - 3 Urea (from vegetable origin),
- 4 1,3 Propanediol (eg Zemea, from vegetable origin)
- 5 Proteins and protein hydrolysates from vegetable origin,
- 6 Salts of Pyrrolidone Carboxylic Acid (PCA),
 - 7 Sodium Lactate

Undesired ingredients;

1 Impure Propylene Glycol from petroleum sources.

Acids

Suggested ingredients;

- 1 Alpha Hydroxy (Fruit) Acids (Glycolic Acid, Lactic Acid, Citric Acid, Salicylic Acid, etc) from natural sources
 - 2 Ascorbic acid
 - 3 Azelaic Acid
- 4 Buffers based on organic compounds

Ingredients with Limits;

- 1 Mineral Acids
- 2 Salicylic Acid from synthetic sources

Undesired ingredients;

1 Strong acids with a pH less than 2.

Alkailis

Suggested ingredients;

- 1 Sodium Hydroxide
- 2 Buffers based on organic compounds or salts

Ingredients with Limits;

- 1 Isopropanolamine and Monoethanolamine (with no or low level of Diethanolamine)
- 2 Tertiary Amines (eg Triethanolamine 99% (with no or low level of Diethanolamine))
- 3 Other organic amine derivatives

Undesired ingredients;

- 1 Diethanolamine
- 2 Triethanolamine 85% (with high level of Diethanolamine)
- 3 Strong alkalis with a pH greater than

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Sequestering Agents

Suggested ingredients;

- 1 Ascorbic Acid.
- 2 Dicarboxylic acids
- 3 Plant derivatives with Sequestering action eg. Sodium Phytate

Undesired ingredients;

1 EthyleneDiamineTetraacetic Acid and its salts (EDTA)

Other Materials

Suggested ingredients;

- 1 Abrasive materials of vegetable origin, such as cellulose, ground nut shells, bamboo, luffa and the like, for exfoliation.
- 2 Active ingredients obtained from natural (plant, animal, mineral) sources and not substantially chemically modified for use. If they are dissolved in solvents these solvents must comply with the restrictions listed under "Solvents".

Ingredients with Limits;

- 1 Abrasive materials of aquatic origin, such as chitin and mother of pearl, for exfoliation.
- 2 These category 1 Restricted materials include organic raw material(s) which may undergo a chemical reaction to form compounds that act as functional or active ingredients in a product, where these ingredients comply with the toxicity and biodegradeability criteria and have documented evidence that they are derived from predominantly natural sources. One example is emollient esters.
- 3 These category 3 Restricted materials include non-organic agricultural ingredients not listed above only where it can be demonstrated that the ingredient is not available as organic in sufficient quantity or quality.
- 4 Salts, Fillers and binders only if it can be demonstrated that they are necessary for the proper functioning of the product.
- 5 Organic products of animal origin.

Undesired ingredients;

- 1 Petrochemicals and other synthetic substances as ingredients in their own right.
- 2 Non-organic products of animal origin.
- 3 Impure fatty chain source material of petrochemical origin.
- 4 Tale
- 5 Plastics (eg Abrasive beads)

2. Organic Formulations

Obviously, the number of combinations and permutations is so large I cannot go into all the options

for formulations here, however, it can be generally said that where you are using a material that is prohibited you should switch to a material from the permitted class, in order to claim a status of "Organic". When you are using a material from the Restricted class you can continue to use this but there should be a justifiable situation that exists where the material cannot be substituted. Otherwise Restricted items should be replaced with a material from the permitted class.

3. Non-Organic Formulations

Natural = Safe Synthetic = Harmful

The term "Natural", used in today's advertising, infers that the material or product is safer than a synthetic chemical. In many cases, this cannot be further from the truth. Some natural materials are safe, but many may be quite hazardous or even fatal if incorrectly or inappropriately used.

In extreme cases, Formaldehyde is a natural preservative, Natural Pyrethrin is extremely hazardous whereas Synthetic Pyrethrin has been modified to remove the components hazardous to humans, Vitamin A can be hazardous in concentrations as high as 0.5%, Bee Venom, Temple Viper venom, and other toxins used as anti-wrinkle ingredients can cause immune deficiency if overused, and almost all the pure essential oils we use, are considered poisons by government regulatory authorities — the list goes on.

The corollary is also false – it is a fact that many synthetic chemicals used in cosmetics are amongst the safest (with respect to toxicology, skin irritation or allergic reactions) as they have been scientifically engineered to be so, also, undergoing some of the most stringent testing – something a lot of natural ingredients have not. Synthetic oils being perfect examples of safe cosmetic ingredients.

Many sponsors, today, continue to manufacture products with synthetic materials, and there should be no problem with this, given correct information is provided.

The Australian Competition and Consumer Commission (ACCC) has an (enforceable) regulation that no product on the Australian market should be unsafe for its intended use. Under the Australian Consumer Law (ACL), Commonwealth, state and territory ministers can regulate consumer goods

and product-related services by issuing safety warning notices, banning products on a temporary or permanent basis, imposing mandatory safety standards or issuing a compulsory recall notice to suppliers.

Under the ACL, suppliers of consumer goods and related services are required to report deaths, serious injuries or illnesses associated with consumer goods. This requirement is known as mandatory reporting.

All participants in the supply chain of a consumer good are required to comply with the reporting requirement. This includes a retailer, dealer, hirer, distributor, installer, repairer, importer, manufacturer and/or exporter of the consumer goods in question.

Similarly, all participants in the supply chain for product related services linked to the goods that are associated with the death, injury or illness are required to report the incident. This could include installers and service technicians.

A supplier is required to submit a report within two days of becoming aware of a reportable incident. Suppliers can do this using the ACCC's online form, which is available on the Product Safety Australia website[6].

from

https://www.accc.gov.au/business/ treating-customers-fairly/product-safety

Taking note of the above from Australian Consumer Law (ACL), sponsors should take precautions to ensure that their product IS safe for its intended use and this may mean conducting skin irritation testing such as the Repeat Insult Patch Test, or similar testing. If this is done then talk about it – tell the consumer that you have done this and got good results – be Transparent!

4. Formulation variations

More is not always better.

This may be a self-evident statement, in that many ingredients should not be used above recommended levels, as they may be irritant at high levels. Emulsifiers, used at high levels, can disrupt the micelles and cause instability in the emulsion.

Skin creams that are developed for cold/wet climates are generally heavy creams and when used in hot climates will feel greasy, "heavy" and leave the skin hot, prickly and "suffocated".

Hair conditioners when containing too much conditioning additives will leave the hair dull and greasy.

Vitamins work but your body will only use what it can and the remainder is generally excreted. Has anyone taken "MultiVitamin" capsules and wondered why their urine is a bright yellow? This is the excess vitamins, particularly B2, which your body cannot absorb. In fact, Vitamin A can be toxic at high levels (0.50% being the highest I can recommend).

I once was asked by a doctor to develop a 20% Retinol treatment. Horrified at this I tried to explain that this would be irritant, to say the least. When I asked him why, he replied that a doctor down the road had a 10% Retinol treatment and he wanted to be twice as good. How can you answer that without getting angry? Limiting levels of ingredients to those that are proven effective, rather than be twice as good as your opposition will prove beneficial in the long run.

Waterless Cosmetics

I have seen the latest "trend" (?) in some people proposing formulating

waterless cosmetics, eg "Formulating on Trend: Waterless Cosmetics, Cosmetics & Toiletries, December 20, 2019 Author Kelly Dobos, Sun Chemical, Parsippany, NJ"[7], although this may be a false positive as consumers generally do not like products which will be thick/greasy or dry application (eg dry shampoos). There have been some positives such as beard oil rather than shaving creams, but generally consumers do not like waterless creams (ie ointments) and products such as dry shampoos were discontinued many years ago, as technology of water-based products improved.

To be continued in part II...

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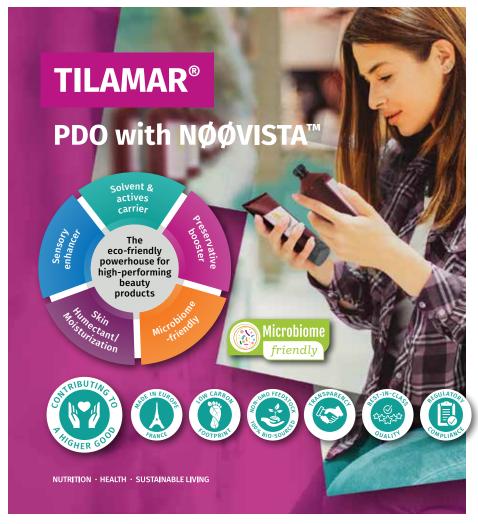
on Common Criteria for Cosmetic Claims (655/2013), and the European Commission's (EC) report on Article 20 of the EU Cosmetics Regulation in relation to the common criteria for cosmetic claims, has raised concerns over freefrom and hypoallergenic claims.

The EC Technical Document on Cosmetic Product Claims was updated in July 2017 to include Annexes that address claims of the free-from nature (Annex III) and the claim hypoallergenic (Annex IV). Annexes I and II (published in 2013)

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New cosmetic active complex to protect and repair against damages related to exposomeinduced oxidative stress.

Hortense Mallard, INABATA France/ PHARMASYNTHESE,

INABATA France/ PHARMASYNTHESE

Abstract

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Half of worldwide population lives in cities and is daily exposed to urban pollution, consequently pollution has become a public health crisis. By 2030, urban population will reach 60% and up to 70% by 2050. The high levels of air pollutants are not limited to China or India anymore as western capitals like Paris and London often exceed the World Health Organization alert levels. Indeed, it is 90% of those citizens that are exposed to higher levels of air pollutant; particles PM10 & 2,5; than the World Health Organization limits. (1) Nowadays a growing number of scientific and epidemiological studies have demonstrated that human exposure to environmental stress is associated with premature skin aging and hyper pigmentation. (2) The deleterious effect of those stress might be amplified with each other, when combined they form to the prooxidant smog also qualified as EXPOSOME. (3) The first epidemiological study was conducted on elderly Caucasian women, and showed that exposure to traffic related Particles Matter (PM2.5-PM10) contributes to skin aging. (2) More studies were performed to provide further evidence for that pollution can accelerate skin aging. (4, 5, 6). Not only wrinkle formation but also pigmentation spots appearance could be linked with pollution exposure (2). While the underlying mechanism of action of pollution in skin is not clearly defined, there is strong evidence implicating the generation of Reactive Oxygen Species (ROS) and subsequent state of oxidative stress in all layers of the skin. (5,7,8,9,10,11,12) According to those discoveries, it seems that protecting skin from Exposome-induced oxidative stress is the best way to delay skin ageing.

1 Introduction

A stress-protection rare amino-acid from the sea

Deep oceans are hostile environments, cold, dark and poorly oxygenated. However, many living organisms evolved to live under these conditions, developing special abilities that have allowed them to survive. Strombine, a rare amino-acid found in many organisms such as sponges, sand worms, oysters, gastropods seamed to play an essential role in case of environmental stress. In marine invertebrate such as mussels, Mytilus edulis, Strombine

accumulation was identified as a metabolic stress marker (13). Data suggest that a high concentration of Strombine contributes to regulating osmotic pressure in tissues (14). A newly developed Strombine derivative compound will act at a cellular level to prevent and repair the harmful effects of stress.

Moringa extract the pollution shield

The Moringa tree is native from India, from southern Himalayas valleys. It is known as the miracle tree or tree of life, thanks to its countless benefits on health, and has been used for centuries in traditional medicine. Traditionally, Moringa seeds were know, in topic application, for their antibiotic and antiinflammatory proper- ties. However recently, seeds were found to be the best natural coagulant discovered so far, and a solution to replace aluminum sulfate in drinking water treatment. They can decrease water turbidity and depollute it from heavy metals. (15) These heavy metal depollution properties are carried by water extractible lectins from seed. (16, 17) Further researches have shown that the extract of Moringa seeds can clear water from 60 to 90% of Cadmium. Lead, Copper, Zinc, Nickel, Arsenic and

STEMPROTECT is a new way to address exposome stress, combining the pollution shield properties of the Moringa extract with the protective effect of the rare amino-acid derivative against oxidative stress

2 Efficacy tests

2.1 In-vitro efficacy screening

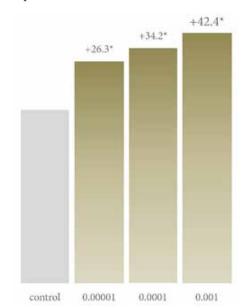
Gene activation screening was performed on cell cultures of fibroblasts and keratinocytes to identify potential activity of our newly developed aminoacid.

Three main efficacy trends emerged

- Stress protection: antioxidant, anti-inflammatory
- Anti-ageing: tissue adhesion, dermis stimulation and cell longevity
- Cell regeneration: stem cells vitality

2.2 In-vitro stem cells protection against UV-induced oxidative stress assay

Our skin is the reserve of several adult stem cells. They are essential to renew epidermis and dermis layer but also to ensure proper wound healing and skin repair in case of environmental assault.



Graph 1: stem cells survival rate under oxidative stress (Percentage versus control / p<0.05)

Data in graph 1 show that the new Strombine derivative amino-acid can protect epidermal stem cells from oxidative stress in a dosedependent way, respectively +26.3%* at a dose of 0.00001%, +34.2%* at a dose of 0.0001 and 42.4%* at a dose

Skin ageing is mainly driven by external stress exposure while intrinsic ageing (genetic predisposition) as a way smaller impact. This is due to high vulnerability of stem cells to the Exposome stress, which will lose their ability to selfrenew or differentiate. Indeed, stem cell aging is a process in which stem cells progressively lose their ability and their functionality, succumbing to senescence or apoptosis. Unresolved oxidative stress and concomitant oxidative damages of cellular macromolecules including DNA, proteins, lipids, and carbohydrates have been recognized to contribute to stem cell aging. (21) It is important to protect this pool of skin stem cells against oxidative stress to restore a better cellturnover and to fight skin ageing.

Protocol: Human keratinocytes were obtained from a 51 years old woman donor. Cells were cultivated at 37°C in a humid atmosphere and 5% CO2. The culture was then enriched into stem cells using Goodell method. (22) After enrichment, cells were incubated for 24h without (control) or with an increasing concentration of the amino-acid (0.00001, 0.0001 and 0.001% v/v). Then UVB irradiation was applied (30 mJ/cm²) or not (control). Finally, cells were incubated again with the amino-acid for 13 days. At the end of the incubation, cell viability assay was performed (dosage of intracellular phosphatase activity) [49]. All conditions were tested in triplicate (n=3).

2.3 Ex-vivo Skin regeneration assay

The skin thins progressively over adult life at a rate that accelerates with age. Epidermal thickness decreases about 6.4%

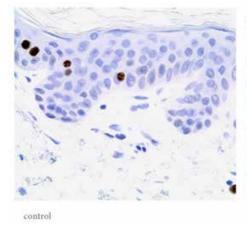
per decade and even faster in women. This is due to a lower keratinocyte cells number as well as a slower cell turnover. (23) The phenomenon is even increased in case of oxidative stress as the high level of ROS will induce premature cell senescence resulting in a growth arrest of cells. (24) With external assaults and build-up of oxidative stress, there is an accumulation of senescent cells in skin, with an irreversible arrest of proliferation and an incapacity to divide. (25) Ki-67 is used as a marker of cell proliferation (26, 27).

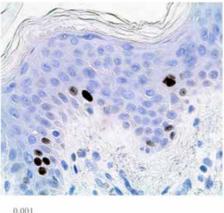
Data obtained from the ex-vivo assay show that the new Strombine derivative amino-acid, at a low dosage (0.001%), can stimulate epidermal cell renewal (+37,1%*), even under oxidative stress, thus promoting cell renewal and epidermis turnover.

Protocol: Skin biopsies were obtained from woman donor of 44 years old. They were incubated over 24 hours at 37°C in a humid atmosphere and 5% CO2, without (control) or with an increasing concentration of the aminoacid (0.00001, 0.0001 and 0.001% v/v, diluted at 10% in DMSO and added to the culture medium). At the end of the incubation period, explants were fixated in paraffin and sliced twice using microtome. Cell division was assessed using a specific immunostaining of Ki67 protein. Positive cells we counted on 5 different microscopic fields randomly chosen on the 2 different cuts.

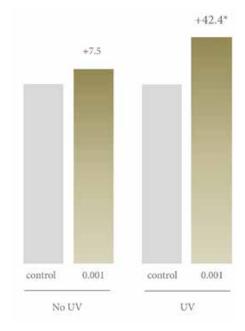
2.4 In vitro DNA repair assay

Activation of PARP is one of the early DNA damages responses among other DNA sensing and repair molecules.





Picture 1: Ki67 specific immunostaining in skin biopsies



Graph 2: Levels of PARP Activity in keratinocytes (percentage versus control / p<0.05)

Data in graph 2 show that the new Strombine derivative amino-acid (at 0.01%) can stimulate DNA repair mechanism increasing PARP activity (+42.4%*), only in case of oxidative stress.

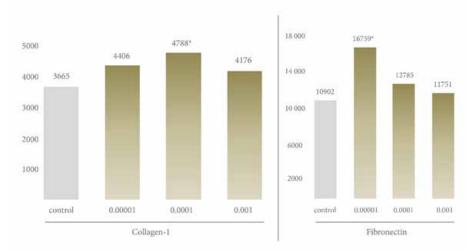
PARP constitute a family of cell signaling enzymes that have emerged as critical regulatory components of the immediate cellular response to DNA damage. They play a key role in maintaining genome integrity through modulation of multiple cellular responses (including base excision repair, necrosis and apoptosis) in the face of oxidative stress. (28)

Protocol: keratinocytes were cultured at 37°C in a humid atmosphere and 5% CO2, when confluences was reached, on batch was exposed to UVB irradiation (200 mJ/cm²), then incubated without (control) or with an increasing concentration of amino-acid (0.00001, 0.0001 and 0.001% v/v, prediluted at 10% in DMSO and added to the culture medium). At the end of the incubation period, PARP activity was quantified. Second batch was performed the same way without UVB irradiation. All conditions were tested in triplicate (n=3).

2.5 In-vitro and ex-vivo anti-ageing efficacy

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Dermal epidermal junction (DEJ) is an acellular region of the skin that separates the epidermis and the dermis. It makes the link between basal layer



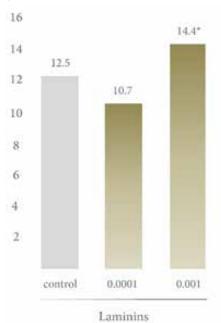
Graph 3 & 4: Levels of Pro-collagen-I and Fibronectin in culture medium (ng/ml/p<0.05) Data in graphs 3 and 4 show that the new Strombine derivative amino-acid can reinforce dermal epidermal junction thus increasing the level of fibronectin (16759 ng/ml*, +54%) and to stimulate collagen synthesis (4788 ng/ml*, +42%)

of the epidermis and extracellular matrix (collagen) of the dermis thanks to molecular anchors. Laminins and fibronectin are the most important anchor proteins composition the junction. The DEJ plays fundamentals roles in skin such as mechanical support for the adhesion of the epidermis to the dermis. Or control of basal keratinocytes polarity and their migration and structural organization in the epidermis. The most reproducible structural change in skin aging is DEJ flattening with a reduction in its proteins content. This results in a decrease of connections between layers, a less resistance to shearing forces and an increased vulnerability to insults. The smaller surface area between the two layers also reduce communications and cellular supply of nutrients and oxygen between the dermis and epidermis. Flattening is associated with decreased rate for keratinocytes proliferation, and increased potential dermo-epidermal separation, thus facilitating wrinkle formation. (29, 30, 31, 32, 33)

Protocol: Skin biopsies were obtained from woman donor of 44 years old. They were incubated over 48h at 37°C in a humid atmosphere and 5% CO2, without (control) or with an increasing concentration of the amino-acid (0.00001, 0.0001 and 0.001% v/v, pre-diluted at 10% in DMSO and added to the culture medium). At the end of the incubation period, dosage of pro-collagen I and

fibronectin were performed in culture medium.

Results are expressed in ng of protein by mL of medium.



Graph 5: Levels of Laminins in culture medium (ng/µg of total proteins/ p<0.05)

Data in graph 5 show that the new Strombine derivative amino-acid can reinforce dermal epidermal junction increasing the level of Laminins (+14.4%*)

Protocol: Cells from woman donor were incubated at 37°C in a humid atmosphere and 5% CO2, when confluence was reached, they were incubated for 96 hours without (control) or with an increasing concentration of aminoacid (0.001, 0.01 and 0.1% v/v, pre-diluted at 10% in DMSO and added to the culture medium). At the end of the incubation period, dosage of total laminins in the cell media were performed. Results are expressed in ng of laminins by µg of total proteins. All conditions were tested in triplicate (n=3).

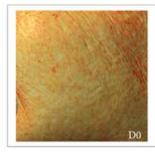
2.6 Clinical study: improvement of skin radiance

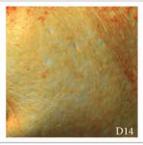


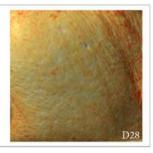




Picture 2: Image obtained, before and after 14 and 28 days, of twice daily application of a serum containing STEMPROTECT (2%).







Picture 2: Image obtained, before and after 14 and 28 days, of twice daily application of a serum containing STEMPROTECT (2%).

Data obtained from ANTERA 3D® measures show that STEMPROTECT, at 2% in a serum, can increase Individual Typology Angle (ITA) by up to 8%, after only two weeks of product application on the face.

Protocol: 22 healthy women volunteers with Caucasian skin type. Each volunteer applied a formulation containing 2% STEMPROTECT for 28 days, twice daily. Before the study started, and then after 14 and 28 days, ITA skin measurements were taken using a ANTERA 3D® from Miravex, photographs were taken in triplicate, using Trichoscan® Smart from Tricolog, under room temperature and humidity-controlled conditions.

3 Conclusion:

The combined activities of the Moringa extract and the newly discovered Strombine derivative aminoacid confers to STEMPROTECT the ability to fight exposome-induced oxidative in stress in skin. The protection of stem cells, the DNA repair properties and DEJ rejuvenation gives to this innovative active ingredient the ability to fight skin ageing drastically improving look and skin radiance.

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