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Message from the President

Covid 2019 has given us the chance to pause and reflect where we are. This pause has led many professionals to feel that this is the end of things. But if we ponder on this pause, we are bound to feel that in reality is it an end or a beginning? Is it an opportunity or a complete loss?

Although the beauty industry may be in a relatively stronger position than other consumer categories, 2020 will go down as perhaps, as the worst years in the history of the industry. But we should not lose the hope, as a lot of opportunities for the Cosmetic and Aroma segment is looming on the horizon, to make it big with proper quality and hygiene practices. Opportunities for Entrepreneurs and Businesses who can manage the field of 6 P's (Product, Price, Place Promotion, People and Performance) is sky high. Even before the pandemic, the definition of "beauty" was becoming more global and expansive, well-being and even during pandemic and even after it, this has not changed and hence, there is reason for hope.

Cosmetics and personal care are the most interesting and the most needed products in today's world. Even during Covid 19, cosmetics have been an integral part of the society with the status of essential category being given to products like hand wash, body washes, soaps, toothpastes etc. With increasing demand for products comes the increased demand for trained and educated persons in the field. Cosmetic chemistry's indepth knowledge is an important aspect in today's world especially with advancement of consumer demands and knowledge transparency available through internet portals. This breed of partially educated consumers has actually created the need for trained professionals and hence created a big job opportunity for those trained into this stream. Hence with changing regulations, changing technology and changing knowledge the need to hone our skills with extra education and technical knowledge is a must. Keeping this in mind we all should come together and gather our resources to take Indian Cosmetic Industry to the next level by utilizing the platform provided by ISCC to hone our skills and build up our strengths.

"Every crisis comes with an opportunity; Identify, Strategize, Execute the best you can".

Dr. Renuka Thergaonkar

ISCC Activities

March to November 2020

Although at ISCC we just finished hosting ISCC conference at HPCI 2020, the period of March to November has been the dullest and depressing period for the industry with India going in a lockdown from March end.

Our motto at Indian Society of Cosmetic Chemists is that not only we help you grow your network with industry professionals but also help you grow in terms of knowledge, experience and exposure. Keeping in view our motto, the society decided to go ahead towards taking the Cosmetic Industry to next platform and hence efforts were taken to arrange programs to benefit the members even during the lockdown. These efforts were further strengthened by our parent body IFSCC by conducting free webinars twice a month for the members in the most crucial months of April to November.

• ISCC in collaboration with FFDC Kannauj & KPMG successfully organized a webinar on "Harnessing Opportunities in difficulty of COVID-19 for Cosmetic & Aroma Industry" on 23rd May 2020. The Speakers for the webinar were Mr. Sanjeev Chawla – Director DC-MSME, Mr. S.V. Shukla - Principal Director FFDC and Dr. Renuka Thergaonkar - President ISCC. The theme of the seminar was to look at the opportunities posted by the impending pandemic and how to utilize these opportunities by the support of government schemes and support. The webinar was a huge success with 477 registered participants of which 326 attended the same. This webinar was attended by participants from India and other neighboring countries mostly students, industry persons and entrepreneurs.

- Your society also organized another Webinar in association with HPCI India titled "Changing Paradigm Trends in Cosmetic Industry post COVID" on Saturday 4th July 2020. The webinar had eminent speakers from the industry namely: Ms. Birgit Huber Deputy Director General IKW Germany; Mr. Nitin Sharma Business Head South Asia Clariant India; Mr. Manish Chaudhari Business Head Galaxy Surfactants and Dr. Renuka Thergaonkar President ISCC. The Webinar was moderated by Mr. Dilip Raghavan Chief Editor ,Color Publications. This webinar was attended by about 170 participants out of 340 registered participants. The webinar gave a glimpse about the new upcoming trends in the industry post Covid Era.
- This was followed by another webinar on "Sustainable and Green Cosmetics" on 24th November 2020. The webingr moderator Ms. Sandhya Chipalkatti very aptly moderated the session. The speakers comprised of eminent personalities from the industry namely Dr. Arunasiri Iddamalgoda, CED- Ichimaru Pharcos Co. Ltd, Japan; Dr. Hema Sharma-Dutta, Head-Personal Care, R & D Himalaya Drug Co; Mr. Shankar Prasad, Founder Director, Pureplay Skin Sciences Pvt Ltd and Ms. Pauline Raffaitin, Home & Personal Care, Business Unit Manager, Ecocert. This webinar was attended by about 100 participants out of 320 registered participants. The webinar gave in-depth information on Green and Sustainable cosmetics and how to formulate them and what are the various regulations pertaining to these products along with marketing challenges and opportunities for the ingredient and finished product industry.

FUTURE EVENTS:

Month	Program
December 2020	 Webinar in collaboration with OTAI on "Role of Surfactants in Hand & Surface Sanitisation in Personal & Home care segment" on 4th & 11th December 2020 Virtual seminar in collaboration with IHPCIA on "The Way Forward For The Next Decade For The Home And Personal Care Industry" on 5th& 6th December 2020
January 2021	Certificate course on Natural & Organic products & COSMOS Certification
February 2021	Certificate course on Basics in Cosmetics



Tocotrienol is more potent than tocopherols due to significant difference in their chemical structure.

The difference lies in the tail. The unsaturation (double - bond) in Tocotrienol makes it the more "aggressive" molecule; hence, more bioavailable.

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- Decreases pore size
- Effects skin tightening and nourishment
- Pigmentation reduction

... to the FORMULATION.

- Increases self life of products
- Improves Textures
- Enhances color intensity
- Protects product color





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Sustainable and Green: The New Cosmetics

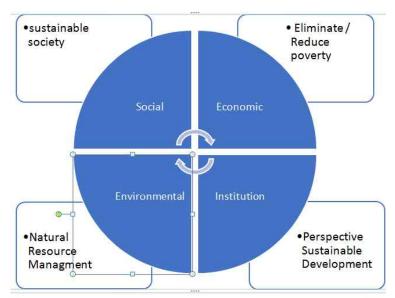
By Dr. Renuka Thergaonkar

We saw 2018 as a year of major change for the Indian beauty industry. Where in the industry moved towards not only establishing a new definition of cosmetics, but also towards the aspect that the cosmetics belongs very personally to the new age consumer through its innovative nature and sustainable approach. Beauty and wellness started converging. Consumers started looking up "wellness" label increasingly which became the new norm and more consumers demanding simple, comprehensive and transparent products. The resulting beauty wellness trend was defined as natural or organic products with a simple, comprehensive and transparent ingredient list targeted towards wellness of mind and body.

Then came Covid 19 the complete picture of Beauty industry changed the focus of people just shifted from Beauty to Wellbeing. Suddenly there was a spur of Hygiene products with emphasis on Wellbeing aspects. This trend is here to stay and more and more consumers will be looking for products emphasising on Wellbeing and using of natural ingredients. Consumers will be looking at environment friendly products that deliver health. This takes the onus on the formulators and raw material companies to supply Green and sustainable cosmetic products.

Sustainability is a way by which we can meet the needs of the present without compromising the ability of future generations to meet their own needs. Due to population explosion the natural resources are depleting and it is estimated that consumption of natural resources like water, greenhouse gases, minerals etc. will increase to 170% by 2040. This is a matter of concern and has led cosmetic companies to look at sustainability in social, economical and environmental aspects.

Sustainability requirements deals with proper use of resources, Increased literacy, Reduction in waste generation, Creating conventional and non conventional (herbal extraction, organic farming etc) resources. This requirement aims to create a New Normal -"sustainability for future" by reducing carbon footprints using science and technology approach. Today with this impact the consumers are expecting that the current formulas be converted to formulas with renewable materials using green ingredients.



But this is not simple as lot of inputs have to be extended towards the innovation and development of such products wherein companies can not only save money and improve productivity by reducing waste and inefficiencies but provide efficacious completely natural products to the consumers. As research impacts all aspects of the product innovation lifecycle—from adherence to new environmental regulations to the creation of greener products and services the emphasis should more be on it.

Simultaneously the importance of sustainability and provenance of materials to consumers, and the growing awareness and interest for vegan, organic and clean ingredients is increasing. Today the manufacturers have to ensure that they source materials ethically and continue to deliver products that perform at the right price. The importance of being transparent from ingredients to supply chain is an ever demanding task for brands in personal care.

Green materials are directly being corelated to Wellbeing and health. 75% of millennial and Gen Z consumers are believing now that natural skin care products are more effective. Ingredients are driven by environmental challenges and limited natural resources challenges. Hence more herbs, oils, herbasols are being used. Suddenly the spur of certified cosmetics with emphasis on natural has led to increased use of herbs like ashwagandha, basil etc in cosmetic products. So people are looking at Natural and Organic products with wellbeing emphasis on antibacterial, protecting properties. But on one end though these products are being used they are also worried about the environment and so Bio engineered raw materials are also coming up.

Pressing environmental issues have inspired some brands to explore other sustainable options especially "Environmental friendly bioengineered Raw materials". The latest wave of cosmetics are based on advanced research that includes the use of biotechnology-derived ingredients, genetic profiling for individual skin-care or nutritional regimes, stem-cellbased products and therapies to regenerate ageing tissues, or cell and tissue engineering for cosmetic purposes, Stem cells already exploring their potential for skin-care products rather now Growth proteins derived from specialized stemcell lines are being used. These specific proteins affect specific receptors in both fibroblasts and keratinocytes that increase the production of collagen. Engineered yeasts through a fermentation process to produce fragrance compounds. Squalane, the foundation of every product in its line, is made from renewable sugar cane using a patented process. Lab grown marine micro-organisms that secrete glycoproteins that stimulate collagen and elastin in skin, the beneficial molecules as are found at sea in a higher concentration.

Lab-born naturals resemble their traditional predecessors in form and function, they're not identical; in fact, in some cases, they've been designed to be stronger and more tolerable for the skin. In Lab developed ingredient, the impurities are removed, the potency is stabilized and you get the same efficacy, purity and stability with every batch. Biotech ingredients can also be engineered to be bioidentical to human structure, making them more effective than ingredients derived from both plant or animal sources.

Consumer awareness of biotechnology seems to have increased over the last decade, yet most consumers remain confused over the science and safety of these materials. There remains concern that these benefits come with a cost to the environment or increased risk to the consumer. Plants have been engineered to decrease pesticide and herbicide usage, protect against stressors, enhance yields and extend shelf life. Beyond the environmental benefits of decreased pesticide and herbicide application, consumers stand to benefit by development of crops with increased nutritional value, medicinal properties and aesthetic appeal.

Though this shift in the market is here to stay it has surely led to more demand from the formulators and cosmetic companies to create green and stable cosmetics with enhanced efficacy.

Polymeric Antimicrobials And Bacteriostats

By Partha Pratim Bhattacharyya - Consultant Cosmetic Chemist
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In this time of pandemic, it is very much relevant to have discussion on anti viral, antimicrobial and bacteriostats. Polymers are defined as the large molecule, built up by the repetition of small, simple chemical units. One aspect of sustainability is to enhance the sustainability of the human being who is the customer, by mitigating or eradicating the presence of harmful or perceived harmful ingredients. One subject of such perceived concern is the use of antimicrobial ingredients. Small-molecule preservatives are coming under increasing scrutiny, especially in Europe and polymeric antimicrobials are being investigated with the hope that they will function effectively in the product but will not permeate the skin barrier. There is an apparent dilemma here-because antimicrobials must be active biocides against living microorganisms but should not be harmful to humans, their animals, or their plants.

It has been argued that polymeric antimicrobials could be designed to be effective against a broad spectrum of harmful micro organisms, but the polymeric agent itself would be too big to penetrate the skin, and this would add an element of safety to the use of broad-spectrum antibacterials. geographically diverse group of researchers have approached this challenge by substituting polyethylenimine with alkaryl groups. The expectation is that, in addition to being less able to penetrate the skin, these materials would be more substantive to skin, which would provide antimicrobial protection for a longer duration and reduce the amount of these compounds that would be released to the environment. Moreover, functionalization with other functional groups could allow the solubility of the antimicrobial agent to be designed, and incorporation of several antimicrobial groups into one polymeric molecule could allow the formulation of "broad-spectrum antimicrobial cocktails" without the worry of the incompatibilities that are encountered when one tries to add more than one antimicrobial compound to a formulation. The polymeric antimicrobial approach is interesting and is one to be watched as it emerges to, hopefully, make our products even safer than the present exceptionally high level of safety.

In an interesting application, University of Florida researchers have pointed to silanols as antibacterial agents. The silanols are identified as trialkylsilanols, siloxanediols, and siloxanols. These all contain OH groups attached to a Si

atom. It is well known that such a bond is unstable with respect to condensation, which converts it to an Si-O-Si group. The latter group is the backbone of silicones, and this reaction is used to prepare silicones and also to drive solegel reactions. One way that the researchers overcome this inherent instability is to attach the silanols to polymers that contain hydroxyl groups to "silylated" polymers that release the silanols by hydrolysis "in situ" when the silylated polymer is applied to the appropriate substrate, such as topical application to the skin surface. The silylated polymers include polysaccharides, proteins, poly(alkylene glycol(s)), and amine and hydroxyl terminated polymers. It is also interesting that one embodiment is described in which the silanol is attached to filaments of, for example, cotton especially for use as dental floss.

Antimicrobial agents, such as silver, have been combined with a cross-linked hydrogel to create a hydrophilic polymer antimicrobial system that has potential application in the personal care industry, including cosmetics, skin treatment, diapers, and bandages.

Polymers with antimicrobial properties have been proclaimed. For example, chitosan is readily converted to 3trimethylammonium-2-hydroxypropyl-N-chitosan, Ncarboxy-methyl chitosan can be converted to an N',N"dimethylammoniumpropyl carbamoyl derivative and further modified by quaternization to produce a series of chitosanaminoamide quats. The antimicrobial activity of 3trimethylammonium-2-hydroxypropyl-N-chitosan against Escherichia coli, Staphylococcus aureus, and Pseudomonas aeruginosa was demonstrated using the minimum inhibitory concentration test. The derivative exhibited biocidal activity at least an order of magnitude higher than previously reported chitosan antimicrobial agents. Polyethylenenimine polymers have also been utilized as polymeric antimicrobial agents. For example, an antimicrobial polymer derived from polyethylenenimine was effective against pathogenic grampositive and gramnegative bacteria, yeasts and molds, and skin flora bacteria. Copolymers and derivatives of polyethylenimine with broad-spectrum antimicrobial properties are active against microbes on contact. It is believed that the large molecular size of these compounds enables them to resist removal from substrates and also prevents their ingress into the lower layers of skin of humans and animals.

Polymeric antimicrobials can also be effective against yeasts. Poly(methylmethacrylate covinylbenzoylchloride) and linear poly(chloroethylvinylether-co-vinylbenzoylchloride) are active against Candida albicans and Candida tropicalis.

The poly(methylmethacrylate-co-vinylbenzoylchloride) proved more active against both C. albicans and C. tropicalis because of its increased cytotoxicity on bacteria and its interference with the cell walls. Poly(chloroethylvinylether-co-vinylbenzoylchloride) also proved effective by increasing the permeability of yeast cell walls.

In this article the author has tried to present the glimpses of some of the researches in the contemporary world on polymeric antimicrobial and bacteriostats, which has relevancy in this pandemic situations. More over, polymeric antimicrobials are being introduced with the promise of product preservation without the worry of skin permeation, which is the key point of attraction to the author as a cosmetic chemist.

This article concluded by looking at the attempts of the industrial research to become good stewards of human, environment, and ecological safety.

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EasyTens® X1





EasyTens® X1 is a naturally-derived thickening agent for oils and is able to thicken a wide variety of natural oils such as such as sunflower, olive and rapeseed oil leading to transparent jellies. The following guideline is meant to assist in creating a successful formulation.

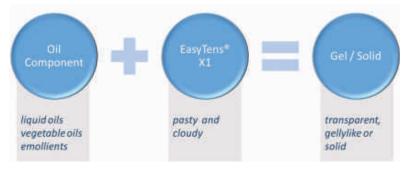
The appearance of **EasyTens® X1** is a waxy yellowish to brown solid. It might come with a foam layer on top which is chemically identical with the solid product. The product can be cut or scooped easily and melts between 50-60 ℃.

How to Formulate

HLB value Country of Origin Sustainability Natural Origin Index Bio-based Surfactant GHS Classification

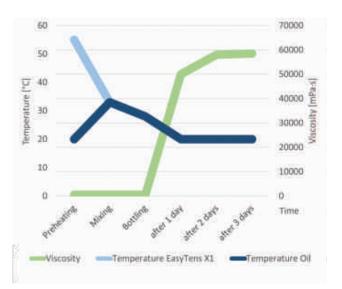
INCI Name

Polyglyceryl-4 Oleate (and) Sodium Caproyl/Lauroyl Lactylate approx. 9 Switzerland vegan, RSPO MB, 100 % renewable 1.0 according ISO 16128 category 1 according EN 17035 COSMOS approved not classsified according to the CLP regulation



In order to incorporate **EasyTens**® **X1** into the oil it is recommended to melt it at 50-60°C until it turns into a homogeneous liquid. Optionally it can be allowed to cool down again to approximately 35°C while stirring. The viscosity will increase but EasyTens® X1 will not completely solidify as long as shear forces are maintained. This allows for the use of rathr heat-sensitive ingredients to be incorporated as well.





Temperature dependency of the viscosity of preheated EasyTens® X1

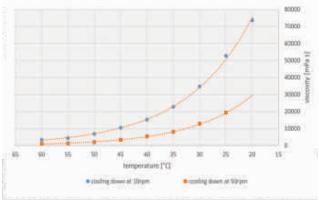


Figure 1: Dynamic viscosity of EasyTeas*XI at different temp tem 33 according to DW 53018

Dosage and Use

The typical dosage of EasyTens® X1 is between 10-20% of the final formulation depending on the desired hardness of the final product and on the overall composition of the formulation. Components that contain many polar functional groups typically tend to reduce the hardness of the final products. It is advised increase the concentration of EasyTens® X1 in such cases to make up for the loss in hardness.

In some cases concentrations below 10% can be considered but might lead to a slight loss of transparency of the formulation.

Due to the excellent emulsifying properties of EasyTens® X1 formulations containing more than 15% can be simply rinsed of with water leaving a smooth skin feel without stickiness or greasiness.



EasyTens® X1 10 - 20 % Oil 80 - 90 %

Max. 20 % of non-thickenable oils.

Lower Limit

approx. 5 % of EasyTens® X1 low viscosity, cloudiness at < 5 %

Upper Limit

no limitation

formulation gets sticky and gummy

Selection of the Main Oil Component

A list of suitable oils which are easily thickened by **EasyTens® X1** is given in the first column of table 1. The second column lists oils that have been found unsuitable as main oil component of a formulation but might still be incorporated as minor ingredient up to 20% for certain compounds (e.g. Isopropyl Myristate).



Suitable Unsuitable (thickenable) (non-thickenable) Sunflower Oil Castor Oil Olive Oil Silicon Oil Paraffinum Perliquidum Almond Oil Sesame Oil Hemp Oil Avocado Oil Isopropyl Myristate Isopropyl Palmitate Rapeseed Oil Caprylic / Capric Triglyceride Decyl Oleate Jojoba Oil Argan Oil Macadamia Oil Rosemary Oil Dicaprylyl Carbonate Squalane Coconut Oil* Hydrogenated Polyisobutene Octyldodecanol

Table 1: List of suitable and unsuitable oils

Note: This list is not intended to be exhaustive. Further unlisted oils can fall into either category.

*Coconut oil which usually appears as a butter falls in line with the other suitable oils by the addition of 20% EasyTens® X1 forming a transparent jelly. In the case of shea butter transparency was not achieved but a much smoother texture was observed.



Review on Cosmetics Product Testing: A Must for its Success

By Vinay Kumar Singh - Cosmetics Consultant

Product is successful when it sells in the market and brings profit and revenue for the manufacturer. For a successful product, quality is an important factor for consumer to accept it. In order to ascertain quality of a product, it must be tested on various parameters. Without testing the product, one can not be sure of its quality, safety and efficacy. Before any new product is put in the market, it must be thoroughly tested. Product testing program involves following:

- a) Stability Testing
- b) Safety testing
- c) Performance/Efficacy testing

Stability testing

Stability testing evaluates a product's ability to maintain its original aesthetic, physical and chemical characteristics under controlled conditions designed to accelerate aging. Such testing can provide an early indication of problems that may occur in formulations.

Why stability testing is done?

Stability data is useful as an "early warning system" that alerts a formulator about problems related to formulation, Package etc.

Such advance information can be helpful in many ways: -

- To guide the chemist during product development
- To ensure that the product will continue to be aesthetically acceptable to the consumer.
- To determine that the product will perform as intended and remain safe to use.
- To forewarn the manufacturer about problems which may occur after the consumer has purchased the product.
 Thus, stability testing gives us an idea of the future risks and provides us guidelines to lay down a foundation for evaluation of future problems.

When stability testing is done?

Stability testing is done:

- Whenever any new formulation is developed.
- Qualifying new raw material
- A modification in the formula
- A modification in manufacturing process
- Change in immediate packaging.

How Stability testing is done?

Stability testing involves:

includes following:

- Testing of formulation in initial stages of product development.
- Compatibility testing.
 Changes that occur in the product over a period of time

- a) Physical
 - Viscosity
 - Texture
 - Colour
 - Odour
 - Loss of Volatile constituents
 - Uptake of water
- b) Chemical
 - pH
 - Degradation of active constituents
 - Interaction between constituents

c) Microbiological Spoilage

Changes that occur in the container over a period of time includes following:

- Leakage
- Corrosion
- Stress cracking

To obtain the stability data in short time accelerated stability testing is done.

Accelerated stability testing involves exposure of the product to following parameters:

- ► Elevated temperature
- ► Elevated humidity
- ► Cycling tests
- ► Freeze-thaw tests
- ► Exposure to light
- ► Mechanical tests.

(1) Elevated temperature:

Storage at elevated temperature is critical, since the rate of chemical reaction roughly doubles for every ten degree increase in temperature. This test allows us to see certain problems much sooner than they would appear at room temperature. The drawback of this process is that, at high temperature we may be forcing reactions to occur that would not happen at all at lower temperatures.

The most common storage conditions includes 45°C, 54°C, 37°C, 35°C, room temperature, 4°C.

It is recommended to store enough sample to make all the observations required as per your specification.

At each checkpoint product should be checked for following parameters:

- a) Physical attributes such as colour, odour, viscosity etc.
- b) Microbial Challenge test for preservative efficacy
- c) Percentage of actives
- d) Functional attributes

(2) Elevated Humidity

Since many products are adversely affected by moisture, storage at elevated humidity normally forms part of stability tests

(3) Freeze – thaw tests

Subjecting a product to alternate freezing and thawing can be of value in indicating the tendency of liquid products to cloud or crystallize or the physical stability of creams or other liquid of creams or other liquid emulsions.

(4) Cycling tests

Tests under conditions that are periodically changed can impose greater stress on samples than storage under constant conditions. The following are suggested as generally useful cycling conditions.

- ► 37°C/80% r.h alternating 24 hourly with 20°C /ambient humidity.
- ► Mean maximum temperature
- ► Mean maximum humidity alternating 24 hourly with 20°C /ambient humidity.

(5) Exposure to sunlight

Where products are likely to be exposed to light in the market or in use, it is necessary to investigate the effect of such exposure. Mostly the effect of sunlight is seen as change in colour of the products.

(6) Mechanical tests

Vibration of samples can be useful in indicating whether demixing is likely to occur in powder or granular products; it can also serve as an indicator of emulsion stability. Clear definition of test objectives and careful planning of tests can yield the required information most efficiently and in the shortest time.

Compatibility testing goes hand in hand with stability testing. This test highlights the interaction between contents & the immediate container.

These interactions may be of following types:

- ► Sorption of constituents of the contents by the container.
- ▶ Leaching of constituents of the container into the contents.
- Adverse effects on the container such as corrosion.

Safety Testing

The cosmetic product regulation of the consumer protection Act says that all cosmetics & toiletries shall not harm their users. All the products must be formulated keeping in mind the safety of end-user.

Safety testing programme involves 3 tests: -

- 1) Microbiological Safety Tests
- 2) Toxicity Tests
- 3) Irritation and sensitization Tests.

(1) Microbiological Safety Tests

Bacteria, moulds and yeasts are everywhere. Most cosmetic products particularly those with a water content are potentially food and a growing place for micro-organisms. If they gain a foothold in a product they will quite likely spoil it and might even present a health hazard to the user.

- ▶ Because no one wants to keep refrigerated their cosmetics and use within 2 days of purchase like food, most cosmetic products will require the addition of preservative. Its function is to inhibit growth of micro-organisms in the product. It is therefore a poison, so its proportion in the product needs to be small as possible. One must ensure that the freshly manufactured product is as free from micro-organisms as possible. The preservative will have enough to do killing all those which gain entry during the use of the product from fingers, from lips and from left-off tops.
- ▶ Both raw materials & finished products are checked for microbial content. This is done by diluting a sample of known volume with diluent and using this to inoculate an agar jelly plate. This is incubated at 37°C for 48 hours. This incubation period is enough for each viable micro-organism to grow into a colony large enough to be seen and counted. From this count the number of viable micro-organisms in each cm³ of the product can be calculated. This is the total viable count or TVC. The aim should be a TVC of less than 10 per cm³.

A manufacturer not only wants to know if his products are of good microbiological quality but also that the preservatives he had added will be effective. To check this, Microbial Challenge test is performed.

(2) Toxicity Tests

A toxic substance is a poisonous substance. As far as possible, no toxic materials should be used in cosmetics. However there are certain materials which at a low

percentage are safe to use but at high conc. are toxic. Each countries legislation lays down maximum limits on the proportion of these materials.

For eg:- Formaldehyde in nail hardners: max-5%, Asbetos in talc is not allowed as it is carcinogenic, Boric acid in talcum powders: Max – 5% (Must state: ' not to be used for children under 3 years of age')

For cosmetic purpose it is essential to use materials of a suitable standard of purity. All raw materials intended for use in consumer products have been tested for potential toxicity. Batches of laboratory animals (rats) are given a dose of test substance in proportion to the level of the substances in the finished product to see if it causes death or harm. The results enable the legislation to state whether a material may be used freely or be tightly controlled or to be banned

(3) Irritation & Sensitization Testing

Allergic reactions- There are many substances which to the majority of the users are completely safe but to a few they produce allergies. These allergic reactions are of 2 types.

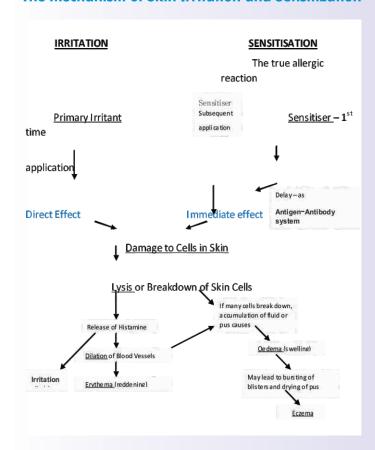
- * Primary Irritation & Sensitization
- * Irritants & sensitizers in cosmetics

Some known Irritants & sensitizers are quite widely used in cosmetics due to following reasons:-

- (1) Unavailability of safer alternative Eg: para-phenylene diamine & para-tolydene diamine in hair dyes. Thioglycollic acid in perm lotion.
- (2) a substance is so valuable as to make its use worth (the risk involved in it may adversely affect only very few people) Eg:- Lanolin It is an excellent emollient and replacement for sebum. Some people are allergic to it.

When a known irritant or sensitizer is included in a product, it must be stated on the label, together with any special instructions. For eg: - Contains phenylene diamine. Skintest advised. Discontinue use if irritation occurs. Do not use on broken skin etc.

The Mechanism of Skin Irritation and Sensitization



Testing for irritation and sensitization:-

- ► Patch Testing
- ► Photosensitivity
- ► Eye irritation testing
- ► Inhalation testing
- ▶ Acnegenicity
- ▶ Systemic effects

Patch Testing

This involves following steps

- 1. Preparing a patch test strip
- 2. Applying the samples to the patches
- 3. The patch test strip is placed on the arm or back for 48 hours.
- 4. The patches are removed after 48 hrs
- 5. The skin is inspected for signs of irritation, reddening, itching or blistering, etc.

The mechanism of irritation: -

An irritant substance cause following sequence of symptoms

- 1. Irritation itch or pain
- 2. Erythema reddening
- 3. Oedema Swelling, blistering
- 4. Eczema- blisters burst

The symptoms will depend on Conc. of irritant and Sensitivity of person's skin to it.

Photosensitivity

Some substances only produce adverse reactions when exposed to light. These are called as phototoxic or photo allergenic materials.

In this case also, patch test is carried out and the subject is exposed to UV radiation regularly throughout a 3-week period and again after 14 day rest period with one single exposure. They are then evaluated for allergic response. Any phototoxic effects generally appear within 24 hrs and subside after 72 hrs. The effects of phototoxic substances includes intense erythema, hyper pigmentation, sunburn, edema & blistering.

Eye Irritation Testing:

Draize Eye irritating test

Although cosmetic products aren't directly put in the eye, the potential for accidental contact with products such as make up, shampoo and skin creams is high. Just like the skin, the tissue of the eye can become inflamed when exposed to irritants, sensitizers or photosensitizers.

Inhalation Testing

When inhaled into the body, some compounds may cause internal damage or inhibit the respiratory system. Symptoms may include coughing, sneezing or burning. For this reason, any compound that might be used in an aerosol or particulate product should undergo inhalation safety tests. In this test, animals are exposed to the compound via inhalation at a certain conc. in the air. Mortality rates are then measured. This data will help in quantifying the usage of the compound.

Acne genecity

Certain cosmetic products can also cause acne. Researches have found that the external ear canal of an albino (New Zealand rabbit) is a good model for predicting a products acnegenecity.

The test product is applied to the rabbit's ear and observed for acne daily for 2 weeks. Then the product receives a qualitative rating for its acnegenic potential. Although the data obtained for acnegenecity from animal testing is helpful, it cannot replace human testing. In India, there is ban on animal testing thus all tests done on animal is replaced by In-Vitro testing.

Systemic Effects

Compounds used in cosmetic products must also be tested for systemic effects such as mutagenecity (the ability to damage DNA), carcinogenecity (ability to cause cancer) and teratogenecity (the ability to cause birth defects). These tests are long term and it continues for 2-3 yrs. The subjects are kept under observation for long term. One assumption about these tests is that, if an agent causes cancer, mutations or birth defects in animals, it is likely to cause the same problem in human beings.

INDIAN STANDARD: Note that in India, Animal testing is stopped thus one must follow IS 4011-Safety Evaluation Of Cosmetics.

Depending on the product, prior human participant studies may be carried out in order to confirm the safety of the cosmetics finished product and to evaluate its tolerance in humans. Any human testing must be scientifically justified, as unjustified testing is unethical. The test should be conducted on selected panel of human volunteers, using good clinical practices, under the supervision of Dermatologist, and/or Ophthalmologist and/or Paediatrician (depending on the nature of the evaluation).

Performance / Efficacy testing

Efficacy tests are essentially designed to show that a product performs the function for which it is intended, for example that a moisturizer 'moisturizes', a deodorant reduces or masks detectable body malodour, an antidandruff shampoo reduces visible dandruff scale, and so on. In order to establish a frame of reference for the evaluation of efficacy it is usual to include both positive and negative controls in a study. The positive control is often a leading marketed product with an established history of effective performance. The negative control, in the simplest case, would be the test formulation minus the active ingredient, a true placebo.

Alternatively, the efficacy test may be simple comparison of new versus old, such as the comparison of novel and conventional moisturizing agents in a standard moisture lotion base.

Whenever possible the efficacy tests should be run on a double-blind basis to avoid the risk of bias in the evaluation procedure. This involves providing test and control products in identical plain containers distinguished by code numbers so that test subjects and accessories are not aware which sample is which. The code is revealed on completion of the study. This has the advantage of ensuring a totally independent and unbiased result.

In addition to product efficacy, the feedback on perfume, colour and Packaging is also important as it is rightly said "The best quality product in the world is not good if it does not sell, and it will not sell if it does not look right, or if the pack does not appeal to the customers".







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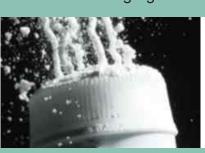


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