

Original Article

Sunscreen Products must Come under Regulatory Regulations and Adopt the More Safety Requirements and Information of a Cosmetics Product in India

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The purpose of the Regulatory requirements were to enable goods produced or marketed in one country to enter other participating countries by removing the barriers linked to standards, technical regulations and conformity assessment. Regulation of sunscreen, their safety and efficacy support still remain complex and insufficient. Any potential risk from a product should be assessed as part of product safety evaluation.

The regulated countries like US, EU and Australia having structured and detailed regulations about sunscreen products and have been published categorized instructions with specified limitations through their own authorities websites which are applicable for companies and consumers, In India, there are numerous websites which correlate with general requirements of products (pharma.- drugs, food and cosmetics) before and after commercializing into the market but for sunscreens need to launch websites (may add in CDSCO/BIS) with all mandatory information, instructions, guidelines and regulations and other safety related sections must be provided on the single portal for companies and consumers.

Key words: Sunscreen, SPF, Harmonisation, Regulatory requirements, Sunscreen regulations in India.

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1. INTRODUCTION

Sunscreen is a lotion, spray, gel or other topical product that absorbs or reflects some of the sun's ultraviolet (UV) radiation and thus helps protect against sunburn. Sunscreen was invented & first used in 1928, and the first major commercial product was brought to market in 1936, introduced by the founder of L'Oréal, French chemist Eugène Schueller. During the same period, Hamilton Sunscreen came to the Australian market in 1932, developed by chemist H. A. Milton Blake, Zinc oxide paste has also been popular for skin protection for thousands of years⁽¹⁾.

In United States, European countries and Australia, cosmetics manufacturers ensure product safety prior to marketing, list all ingredients on the product label

and comply with any restrictions that are established for cosmetic ingredients and products. Any potential risk from a product is assessed as part of its safety evaluation.

Many recent reports from Europe and other western countries have highlighted increasing cases of allergic and photo allergic reactions to sunscreen products. Almost 20% of photo allergic dermatitis or cosmetic allergy is attributed to sunscreen agents. Benzophenone-3 (BZ3) found in sunscreen moisturizers, lip balm and children's sunscreen has been reported to be very hazardous.

The increasing incidence of skin cancers and photo damaging effects caused by ultraviolet radiation has increased the use of sun screening agents, which have shown beneficial effects in reducing the symptoms

and reoccurrence of these problems. Many sunscreen compounds are in use, but their safety and efficacy are still in question. The USFDA, European Union and Australia have incorporated changes in their guidelines and on the websites to help consumers select products based on their sun protection factor and protection against ultraviolet radiation, whereas the Indian regulatory agency has not yet issued any special guidance and mandatory safety requirements on sunscreen agents, as they have classified under normal cosmetics only. In this study, mandatory requirements are discussed such as regulatory requirements of sunscreen products in India as well as provided the comparative study upon sunscreens/sun care products information in the main section or subsections of the health agencies websites, which must be available online (websites) and if regulated/stringent countries have been initiated the regulations related to sunscreens than India should also follow those regulations and guidelines. The all mandatory guidelines and regulations must be harmonized globally.

2. RESEARCH METHODOLOGY

Information was collected with regard to important regulations of sun care (sunscreen) products by regulatory authorities and Ministry of health through investigation of current guidelines which are available online for public health services. Further information with respect to regulatory requirements for sunscreen products specified by regulatory authorities of US, Europe, India, Australia and ASEAN countries were collected. A conceptual agenda was formulated containing general requirements for marketing approval of sunscreen products in India and all mandatory safety information must be available on the CDSCO (Ministry of health) websites for manufacturing companies and public. Finally, an attempt was made to put together the parameters and sequence of data required by regulatory authorities for development and marketing approval of sunscreen products. Regulated authorities want consumers to understand that not all sunscreens are created equal. Consumers should be “deeply concerned” they may

be being misled on sun protection claims from some of the most popular sunscreen brands.

Sunscreen:-Sunscreen also known as sunscreen, sunblock, suntan lotion, sunburn cream, sun cream or block out is a lotion, spray, gel or other topical product that absorbs or reflects some of the sun's ultraviolet (UV) radiation and thus helps protect against sunburn. Skin-lightening products have sunscreen to protect lightened skin because light skin is more susceptible to sun damage than darker skin. A number of sunscreens have tanning powder to help the skin to darken or tan; however, tanning powder does not provide protection from UV rays.

Multiple organic compounds are usually incorporated into chemical sunscreens to achieve protection against a range of the UV spectrum. Inorganic particulates may scatter the microparticles in the upper layers of skin, thereby increasing the optical pathway of photons, leading to absorption of more photons and enhancing the sun protection factor (SPF), resulting in high efficiency of the compound, the classification of sunscreens is shown in below figure:

Classification of sun screening agents

The sun works its black magic by emitting two kinds of harmful ultraviolet rays: UVA and UVB, UVA rays cause human skin to wrinkle and age faster (UVA = aging) UVA is subdivided into UVA1 and UVA2, which are simply UV rays in the same waveband but with differing wavelengths. UVA1 is believed to be less damaging than UVA2. While UVB rays cause human skin to tan and sunburn (UVB = burning). UVB rays are also responsible for the majority of skin cancers. Both UV rays work in conjunction and cause severe damage to your skin when it's overexposed to the sun. UV filters in sunscreens prevent this damage from happening by forming a protective layer on the skin⁽²⁾.

a) Sun Protection Factor:

SPF numbers measure how long a sunscreen will protect from burning compared to how quickly your skin turns red without sunscreen. For instance, if your skin starts burning 30 minutes after being out in the sun with no protection, a sunscreen with SPF 20 would prevent you from burning for 600 minutes (30

min x 20) or 10 hours. This, of course, is dependent on the sunscreen's stability and whether you correctly wear and re-apply

SPF is a measure of how well a sunscreen will protect skin from UVB rays, the kind of radiation that causes sunburn, damages skin, and can contribute to skin cancer. The rough estimate that depends on skin type, intensity of sunlight and amount of sunscreen used. SPF is actually a measure of protection from amount of UVB exposure and it is not meant to help you determine duration of exposure. For best protection, experts recommend using a minimum SPF sunscreen of 15, applying the proper amount (2mg/cm² of skin, or about one ounce for full body coverage), and reapplying every 2 hours. Numeric SPF value need to mention on the label as given below in Table-1:

Table 1: SPF value must available on product Label

US (Label of Principal Display Panel)		
Information on the label	76 FR 35620 - Final Rule	
SPF value	SPF < 15	SPF > 15
Rating of effectiveness	SPF 2 -14	Broad Spectrum SPF 15 or higher
Water Resistance	No statement	Water Resistant (40 minutes or 80 minutes)
EU Labelling of sunscreen products		
Level of protection	Sun Protection Factor (Label)	UVA protection factor
Very high	SPF 50+	1/3 of labeled SPF
High	SPF 30, 50	
Moderate/Medium	SPF 15, 20, 25	
Low	SPF 6, 10	
Australia (SPF values in the old and new Sunscreen Standard)		
Level of protection	Sunscreen Standard-1998	Sunscreen Standard-2012
Very high	SPF 30+	SPF 50+
High	SPF 15 - 29	SPF 30, 40, 50
Moderate/Medium	SPF 8 - 14	SPF 15, 20, 25
Low	SPF 4 - 7	SPF 4, 6, 8, 10

The SPF value/limit of 50+ is harmonized with other countries, e.g. European Union, Australia and Japan. Consequently, sunscreen products are only allowed to use the maximum SPF label of 50+. The use of SPF values of 60 or 80 is prohibited, because US-FDA has not received sufficient data about an extra clinical benefit for SPF value above 50.

b) Types of sunscreen ingredients - Physical and Chemical:

Physical sunscreens are particles that reflect sun's rays away from skin. Two are approved by the FDA: Titanium Dioxide and Zinc Oxide. Both ingredients offer protection against UVA and UVB rays. On the other hand Chemical sunscreens form a thin layer on top of skin and absorb UV rays before they reach the skin. The downside of chemical sunscreens is that some of them form free radicals and can contribute to skin aging, cause irritation, allergic reactions, and possible long term health effects. The FDA approves 17 active ingredients for sunscreens, 15 of which are chemical sunscreens. Some are powerful free radical generators, estrogenic, mutagenic, and may even cause skin disease⁽³⁾.

Table 2: Summary of Physical and Chemical properties

Parameters	Physical properties	Chemical properties
Differences	Physical sunscreens protect the skin from the sun by deflecting or blocking the sun's rays.	Chemical sunscreens work by absorbing the sun's rays. Some chemical filters can scatter sun rays, but still mostly just absorb them.
Other Names	Sunblock; Inorganic sunscreen	Organic sunscreen
UV Filters: (UV filters are the active ingredient in sunscreens that protects skin from the sun.)	Titanium dioxide (TiO ₂), Zinc oxide (ZnO)	Octylcrylene, Avobenzone, Octinoxate, Octisalate, Oxybenzone, Homosalate, Helioplex, 4-MBC, Mexoryl SX and XL, Tinosorb S and M, Uvinul T 150, Uvinul A Plus
Stability	Generally stable	Most are photostable, but some are not. Avobenzone is notoriously unstable. However, it can be stabilized when formulated in conjunction with other UV filters.
Comedogenicity	Titanium dioxide can be problematic for some people. (If you break out from mineral make up and physical sunscreen, titanium dioxide could be the culprit.). Zinc oxide is generally safe. It can be used on delicate skin and is a main ingredient in diaper rash cream.	Chemical filters tend to be more irritating to skin. If it gets in your eyes, it can make your eyes sting and water. Some can cause allergic reactions.

Protection (How much protection is offered on the amount of the active ingredient in the sunscreen, particle size of the UV filters, photostability, and overall product formulation)	Titanium dioxide protects against UVB rays, but not the full spectrum of UVA rays. Zinc oxide protects against the entire spectrum of UVB and UVA rays.; Starts protecting immediately upon application.	Chemical filters offer more coverage against UVA and UVB rays than physical sunscreens, but the range of protection will depend on the particular active and its stability. Avobenzone, for example, protects against the full spectrum UVA rays. Must wait 20 minutes after application for effective sun protection.
Texture	Thick and opaque, may be hard to apply. Tends to leave a white cast or tint. Rubs off more easily and must be frequently reapplied.	Colorless, odorless, usually runny. Can sometimes double as a makeup primer, depending on the active and the formulation.
Safety	Pretty safe, FDA approved. Don't cause free radicals.	Generally safe, however some chemical filters generate free radicals which can cause skin damage, irritation, and aging. Many chemical UV filters have not been FDA approved in the States, but are in sunscreens sold in Europe and Asia.

c) ISO testing for sunscreen – SPF standards by country:

Most of the countries are following ISO testing of sun care products as per certified standards which is for implementation of quality safety and efficacy of product. As testing are classified by below mentioned standards for sunscreen:

- **ISO 24442:2011:** specifies an in vivo method, It is applicable to cosmetics, drugs and other products intended to be topically applied to human skin&provides a basis for the evaluation of sunscreen products for the protection of human skin against UVA radiation from solar or other light sources.
- **ISO 24443:2012:** specifies an in vitro procedure to characterize the UVA protection of sunscreen products. Specifications are given to enable determination of the spectral absorbance characteristics of UVA protection in a reproducible manner. This method relies on the use of in vivo SPF results for scaling the UV absorbance curve.

- **ISO 24444:2010:** specifies a method for the in vivo determination of SPF. This is applicable to products that contain any component able to absorb, reflect or scatter ultraviolet (UV) rays. It evaluate the sunscreen products for the protection of human skin against erythema induced by solar ultraviolet rays.

Table 3: ISO-SPF standards accepted by countries

Region	In vivo ISO 24444	In vitro ISO 24443	In vivo ISO 24442
Australia	YES	YES	NO
EU	YES	YES	YES
USA	NO	NO	NO
ASEAN 10	YES	YES	YES
India	YES	YES	YES
Japan	YES	N/A (in vivo required)	YES
Taiwan	NO	NO	NO
Korea	Under Review	N/A (in vivo required)	Under Review
Canada	Under Review	Under Review	Under Review
South Africa	YES	Planning	YES
Mexico	YES	YES	YES

- d) **Sunscreen category:** Each region/country has own category of the sunscreen product which are regulated by the national or competent authority and need to follow all regulation as per specific parameters:

Table 4: Category of Sunscreens as per region

Region	Category of Sunscreens
USA	Therapeutic/OTC drug
Australia	Therapeutic
ASEAN 10 countries	Cosmetic
European Union 28	Cosmetic
India	Cosmetic
China	Therapeutic
Japan	Cosmetic or Quasi drugs
Taiwan	MedicatedCosmetics
Thailand	Controlled cosmetics
Korea	FunctionalCosmetic
Mexico	Cosmetic
Canada	Therapeutic

1. Regulatory scenario for Sunscreen products in certain countries:

1) US Regulatory scenario for Sunscreen products:

Food and Drug Administration continuously functioning on the safety and effectiveness data needed to determine whether a nonprescription (also referred to as over-the-counter (OTC) sunscreen active ingredient or combination of active ingredients evaluated under the Sunscreen Innovation Act (SIA) is generally recognized as safe and effective (GRASE) and not misbranded when used under specified conditions⁽⁴⁾.

USFDA says: As spending time in the sun increases the risk of skin cancer and early skin aging. To reduce this risk, consumers should regularly use sun protection measures including. Prior rules on sunscreens dealt almost exclusively with protection against sunburn, which is primarily caused by ultraviolet B (UVB) radiation from the sun, and did not address ultraviolet A (UVA) radiation, which contributes to skin cancer and early skin aging. After reviewing the latest science, FDA determined that sufficient data are available to establish a "broad spectrum" test for determining a sunscreen product's UVA protection. Passing the broad spectrum test shows that the product provides UVA protection that is proportional to its UVB protection⁽⁵⁾.

FDA has discussed and keep updating websites regarding all information for companies and consumers, which comes in "OTC section" such as Sunscreen and Sun Protection: Sun Safety, FDA Sheds Light on Sunscreens, Stay Safe in the Summer Sun, New rules governing sunscreen labeling are now in effect, Skin Cancer Screening, Tanning, More about SPF and FDA Basics Webinar on Sun Protection

They have described in details about complete contents like Tanning is a sign of the skin reacting to potentially damaging UV radiation by producing additional pigmentation. A "sun protection factor" (SPF) of 15 or more. SPF represents the degree to which a sunscreen can protect the skin from sunburn. "Broad spectrum" protection: sunscreen that protects against all types of skin damage caused by sunlight, Water resistance: sunscreen that stays on

skin longer, even if it gets wet. Reapply water-resistant sunscreens as instructed on the label and Labels claiming sunscreens are "waterproof," "sweat proof," or "sun blocks" are not legally permitted as these claims overemphasize the product's efficacy. If a product claims to be water resistant, the label should clearly indicate

As we look into USFDA web site which contains information about the safety, testing, and regulation of cosmetics and personal care products and their ingredients. The site is divided into two primary sections; safety information pages and an ingredient database. Safety information pages give an overview of how cosmetics are regulated in the U.S. and abroad, components of cosmetic ingredient labeling, the authority of the U.S. Food and Drug Administration (FDA) to regulate cosmetics, and how companies evaluate the safety and efficacy of their products.

2) EU Regulatory scenario for Sunscreen products:

COLIPA (The European Cosmetic, Toiletry and Perfumery Association) is an association within the cosmetic industry that voluntarily initiates the harmonization of labelling and product testing activities for sunscreen products. It is mostly responsible for the dialog between the industry and the authorities and has influenced the legal framework to use tested efficacy claims and harmonized consumer information. It is worth mentioning that labelling and product testing have always been outside of the scope of the Directive 76/768/EEC. Milestones of COLIPA include the development of a standardized SPF testing, the introduction of a standardized test protocol for the SPF, water resistant and photostability testing and the development of a method for UVA protection measurement^[10].

The EU Cosmetics Regulation protects consumers and makes sure that all cosmetic products on the European market are safe. It requires cosmetics to cause no damage to human health when applied under normal or reasonably foreseeable conditions of use. For sunscreen manufacturers, safety is the guiding principle in everything they do across their operations,

their research and development and their innovation. They check each product's formulation, to be used in all reasonably anticipatable conditions, its packaging and labelling (including any warning or instructions for use) and its disposal.

The Cosmetics Regulation's principles of in-market controls confer on manufacturers and importers - or the persons responsible for placing the cosmetics products on the market - the main obligation to ensure that their products meet safety requirements. Compliance with the regulations is controlled by the national or regional competent authorities in the EU member states. The cosmetics industry welcomes this responsibility and supports fully the Regulation's safety objectives.

Sunscreen products protect against UV radiation. They are cosmetics according to Regulation (EC) No 1223/2009. The efficacy of sunscreen products, and the basis on which this efficacy is claimed are important public health-issues specially:

- Products should contain protection against all dangerous UV radiation
- An indication of the efficacy of sunscreen products should be simple, unambiguous, and meaningful; and it should be based on standardized, reproducible criteria
- Labels and claims should provide sufficient information to help consumers choose the appropriate product and apply it correctly.

European standard for testing methods for the efficacy of "sunscreen product" shall mean "any preparation (as, for example, cream, oil, gel, spray) intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation through absorbing, scattering or reflecting radiation". The European standard for testing methods for the efficacy of sunscreen products shall address:

- ✓ Protection from sunburn (i.e. mainly UVB radiation);
- ✓ Protection from UVA radiation;
- ✓ Determination of the critical wavelength, i.e. the wavelength for which the section under the integrated optical density curve starting at

290 nm is equal to 90% of the integrated section between 290 to 400 nm.

The sunscreen must meet the EU industry guidelines for Evaluation of Water Resistance. ISO tests must be conducted to evaluate the SPF rating and UV protection through in-vivo and in-vitro testing.

As discussed, above mentioned EU regulations describe the need for intended implementation approach with respect to sunscreen products marketed as cosmetics and the regulations in terms of Sun care products activities for pre-approval and post approval changes, they have standardized recommendations and indications of the efficacy and testing parameters guidelines because all variations have significant effects for both companies and consumers, everyone can get adequate details on the European commission and Cosmetics Europe websites.

EU regulations are clear about sharing the information time to time, they have been continuously occupied on that in favor of safety issues.

3) Australia Regulatory scenario for Sunscreen products:

In Australia, sunscreens are classified as therapeutic goods or cosmetic products. Therapeutic goods are equivalent to medicinal products. Most of the therapeutic sunscreen products that are marketed in Australia have to be listed in the Australian Register of Therapeutic Goods (ARTG). Authority has published the detailed information according to Sunscreen standard 2012: information for industry, information for retailers: Questions and answers for people selling sunscreens about changes to how new sunscreen products are authorized for supply in Australia and Information about SPF ratings, sunscreen regulation, and nanoparticles in sunscreens etc.

Categories of sunscreens (Online/On website): Most therapeutic sunscreens marketed in Australia are currently defined as 'listable' therapeutic goods which means that they must be 'listed' in the ARTG. Other sunscreen products must be 'registered' in the ARTG, while others are exempt from registration or listing (see below). General information on listing and registration of therapeutic goods is available on the

TGA Internet site. Therapeutic sunscreen products are divided into three categories, namely primary, secondary and exempt sunscreen products. As per current regulation of the 3 categories of sunscreens is summarized in Table 3:

Table 5: Summary of the current regulation for the various categories of sunscreens:

Summary of the current regulation for the various categories of sunscreens.		
Product category	Sub-category	Currently regulated by:
Listable sunscreens	<ul style="list-style-type: none"> Primary sunscreens carrying SPF claims of at least SPF 4 and not greater than SPF 50+ Secondary suncreening products that meet the definition of a therapeutic sunscreen 	Listing in the ARTG under s.26A of the Act
Registrable sunscreens	Sunscreens that make therapeutic claims other than suncreening and/or reduction of risk of skin cancer, solar keratosis, sunspots or premature ageing.	Registration in the ARTG under s.25 of the Act
Exempt sunscreens	Primary sunscreens with an SPF less than 4 and not containing ingredients of human or animal origin.	Exempt from the requirement of listing or registration in the ARTG
Cosmetic sunscreens (Excluded sunscreens)	Some secondary sunscreens that are excluded from regulation by the TGA but meet the definition of a cosmetic.	Regulated by NICNAS and the ACCC as cosmetics and not regulated under the Act

Finally, TGA has categorized sunscreen products as therapeutic goods under section “industry” & sub-section “sunscreen” within their website and such products are required to be included in the Australian Register of Therapeutic Goods (ARTG), before being legally marketed in the territory of Australia.

The manufacturers and the Therapeutic Goods Association, which regulates the products, should be held accountable for ensuring SPF claims were met. TGA has certain standards for regulation of sunscreen products & shares information for industry time-to-time accordingly.

4) ASEAN Regulatory scenario for Sunscreen products:

The necessary documents are to be completed in accordance with the ACD guidelines. Labeling of cosmetics according to the Act is required. No person

or entity shall sell or supply any cosmetic product unless the product’s label establishes the name of the cosmetic product, its function and usage instruction (unless such features are clearly evident from the product’s presentation), the ingredient listing and materials used to manufacture the formulation such as solvents, perfume carriers or aromatic compositions. The ingredient listing does not have to include impurities in the raw materials used or ancillary technical materials used in the preparation but not present in the final product.

Other details required include: the ingredients’ weight/volume in the primary packaging and/or outer packaging (expressed in the metric system); batch number; name and Singapore address of the responsible entity placing the product on the market; country of origin; precautions during usage; expiration date where the durability of the product is less than 30 months; and date of manufacture—except when the expiration date of the cosmetic product has been specified on the label⁽⁶⁾.

ASEAN has listed UV filters which cosmetic products may contain in Annex VII of ASEAN cosmetic Document, published in 2009. Document requires that the conditions of use and warnings must be printed on the label as “do not stay too long in the sun, even while using a sunscreen product”.

Registration requirements for sunscreen product:

There is “notification” rather than a registration process to bring a sunscreen to market. This notification process entails a 2 week lead time where companies must provide specific information on product formulation, including ingredients, name, level and function, along with their stability testing and a special certificate if any animal derived material* is used in the formula. Japan allows a maximum SPF of 50+. ASEAN is similar to Japan, but there is not a special certificate required for animal derived materials, and they do not have a maximum allowed SPF rating. Finally, Singapore (Member of ASEAN countries) has same regulations about cosmetics as collaborated with ASEAN countries and they have certain procedures and specifications for cosmetics related to manufacturing, commercializing, advertisements, claims and others but not given any

special provision for sunscreen products on health ministry websites.

5) India Regulatory scenario for Sunscreen products:

Provision is required to be made in the Drugs and Cosmetics Act and Rules for the ingredients to be listed along with their percentage on the label of the cosmetic products so that the manufacturer's claims are not false and at the same time consumers can aware themselves of the allergens/toxicants present in the product and avoid them. Provision should be made in the act for compulsory disclosure of the heavy metal content on the cosmetics labels. Necessary amendments in the act are required. Furthermore, manufacturers and importers must ensure that products are safe and do not pose a risk to the users. In India, there are no specific guidelines and regulations for standardizing sunscreen agents and there is no detailed list of approved products on the Indian regulatory agency's official websites.

Many products are classified as cosmetics and are not listed in this section. Apart from routinely used agents, such as BZ-3, ZNO, and TiO₂, other agents, such as camphor benzalkonium methosulfate (6%), octyl salicylate (5%), camphor derivatives, and broad-spectrum UV filters (i.e., bis-ethylhexyloxyphenol methoxyphenyl triazine [10%] and methylene bis-benzotriazolyltetramethylbutylphenol [10%]) are widely used⁽⁷⁾. There are differences in labelling requirements with permitted claims and different methods for assessing SPF when we compare the requirements/regulations between cosmetics (especially for sun care products) and other regulated countries. Many manufacturers of cosmetic products containing herbal ingredients label the product as "Ayurvedic medicine" and try to bypass the specifications and evaluation Standards laid down by various regulatory agencies.

Indian skin is classified as darker in color, rarely burns, and is more prone to rapid tanning. This skin is comparatively smoother, with a slight yellowish tinge and is more prone to pigmentation. Indian population shows the effects of photodamage in terms of pigmentation, wrinkling, and sunburn. For sunscreens,

the requirements generally follow the broad principles of E.U., and BIS is a Participating Member of the ISO Working Group 217. Sunscreens are considered as cosmetics. Stability summary/report is required which similar to Australian storage & testing conditions. There is no maximum SPF rating⁽⁸⁾. To conclude, "The product is regulated either as a cosmetic or a drug depending on the claims it makes and/or the composition of the product. In the absence of clear cut guidelines in India, companies deviate from the norms. This term is widely used by the industry to sell cosmetics by mixing drugs to make exaggerated claims though it has no legal sanctity".

3. RESULTS AND DISCUSSION

I. Health Risks of Sunscreening Agents:

Some products assessed in the US in 2011 revealed in one case that is retinyl palmitate, a form of vitamin A, which is a widely used compound in cosmetics and sunscreens (as an antioxidant against the aging effects of UV radiation), is thought to increase the rate of the development of skin tumors and lesions. However, another study said that its role in human carcinogenesis is doubtful as there is a lack of evidence (9). And on the other case is Benzophenone-3, which is commonly used to absorb ultraviolet (UV) radiations. BZ-3 penetrates the skin & can be found in the urine but disturb the hormones in the body. The Centers for Disease Control and Prevention has detected BZ-3 in the 97% of Americans tested during biomonitoring surveys. Although there have been reports of adverse events with this agent, studies have shown that products formulated with 1 to 6% of BZ-3 do not possess a significant sensitization or irritation potential for the general public⁽¹¹⁾.

II. Selection of the sunscreen products:

Environmental Working Group (EWG) scientists and other health experts offer the following tips for choosing a sunscreen and reducing sun exposure:

- **SPF considerations:** Buy sunscreens with a broad spectrum SPF (sun protection factor) level of between 15 and 50. Be sure to follow instructions on how to apply and re-apply.
- **Skin realization:** If sunscreen stings your skin or turns it red, you may want to switch to an all

physical sunscreen. Chemical UV filters tend to be more irritating than physical UV filters.

- **Read labels:** Choose products with natural ingredients that block UVA and UVB rays, such as titanium dioxide and zinc oxide. Avoid those with oxybenzone, methylisothiazolinone, and retinyl palmitate (a form of vitamin A).
- **Be wary of spray sunscreens:** Spray-on sunscreens are easier to apply than lotions and creams, but the fumes can be dangerous when inhaled, can ignite if they are near an open flame (such as a grill), and don't cover skin completely.
- **Limit sun exposure:** Spending long hours in the sun can put you at risk for sunburn, skin, cancer, and wrinkles. Go outdoors in early morning or late afternoon. Bring an umbrella to the beach. Find a tree to picnic under. Seek shade from outdoor shelters, cabanas, and other structures, wherever possible.
- **Cover up:** Wear clothing and a hat to cover exposed skin when at the beach or spending time in the sun. Also, a cool pair of shades isn't just a fashion accessory; sunglasses protect the eyes from UV radiation⁽¹²⁾.

III. Required labelling statements:

Each country has own labeling statements on the product, like in US sunscreens commercialize by "Broad spectrum"(protects against both UVA and UVB rays) even India and Australia are also using same title whereas in India, many products are available with PA with plus signs (ex. PA++ or PA+++) that signal UVA protection strength is also known as PPD (persistent pigment darkening)The higher the PPD number or the greater the number of plus signs, the better a sunscreen protects against UVA rays. In Australia, the new sunscreen standard allows labelling of "water resistant up to 2 hours" for sunscreen products with an SPF 15 and less than 30 and "water resistant up to 4 hours" for sunscreen products with an SPF 30 and more. The use of claims on the label, e.g. "sun block", "waterproof" or "sweatproof", are prohibited

Table 6: Summary of required statements on label:

S. No.	Required statement	Countries
1	SPF	All
2	Broad Spectrum	US/Australia/India
3	Water Resistant	All
4	UVA Circle	Europe
5	PA+ to PA+++	India/Japan
6	Sunblock	India
7	Mandatory drug panel	US

IV. Stability requirements in regulated market:

Regulated countries (in US, EU Australia) are properly ensuing and conducting the stability testing in accelerated or long term conditions to find the degradation of sunscreen products with various factors like: Physical, Chemical, Photostability & Microbiological changes. Stability Protocols or reports are designed to regulatory agency. In Europe, Accelerate testing is very common by storing testing samples under temperatures between 30 °C to 45 °C for 1 - 3 months, in order to obtain tentative data about the shelf life. Real time testing is essential and has to be monitored to ascertain the precise shelf life where as In Australia, Accelerated testing is conducted at lower temperatures between 10 °C to 15 °C for a period of 6 - 9 months. If a sunscreen product contains water, microbiological stability has to be analyzed, while if preservatives are used, then the efficacy also has to be checked and India is recommending the Australian stability testing mainly⁽¹³⁾.

Table 7: Summary of Australian stability requirements:

Temperature above labelled storage conditions	Time period	Test time points	Shelf life prediction (Possible)
+10°C	6 months	0,(1 or 2), (3 or 4), 6 months	2 years
+10°C	6 months	0, (1 or 2), (3 or 4),(5 or 6), 9 months	3 years
+15°C	6 months	0, (1 or 2), (3 or 4), 6 months	3 years

V. Harmonization requirements for Sunscreen products in certain countries:

Generally, sunscreens are available in the form of creams, lotion, gels, ointments, pastes, oils, butters, sticks, and sprays, which are considered over-the-counter (OTC) products, many substances prohibited

in other countries are not yet prohibited in India. For example, formaldehyde is banned in cosmetics in both Japan and Sweden. Methyl anthranilate is prohibited for use in sunscreen products within Europe and Japan. PABA is banned in sunscreens in ASEAN nations.

Skin care companies usually having the words “broad-spectrum” labeled on their products. However, just because a sunscreen has this label doesn’t mean it protects against 100% of all UVA and UVB rays. Instead of looking for the words “broad-spectrum”, it is better to look at a sunscreen’s **SPF** and **PPD**⁽²⁾.

According to the USFDA-federal department, SPF levels max out at about 50. Europe, Australia and Japan have already banned brands from advertising SPF levels over 50. BIS need to have certain maximum limit of SPF in India. Sunscreen products information, guidelines and regulations are provided on ministry of health–website for companies and consumers:

Table 8: Sunscreen products information & regulations on health authority website

Countries	Sunscreen categorized information and website for articles	Online Queries portal, Published information	Detailed quality & safety information	Labelling & claim regulations	Market Surveillance for sunscreen
USA	Available	Available	Available	Available	Available
Australia	Available	Available	Available	Available	Available
ASEAN	Not available	Not available	Not in detail	Not in detail	Not available
EU	Available	Available	Available	Available	Available
India	Not available	Not available	Not in detail	Not in detail	Not available

On the other hand, probably the widely recognized lack of harmonization is to formulations continuing nightmare of variability in both qualitative and quantitative (ingredients percentage) and safety with efficacy allowable in different markets such as Variation in limits of Zinc & Titanium and variation in water resistance requirements:

Table 9: Permitted actives counts & variation in water resistance requirements

Region	Organic actives	Zinc	Titanium	Water Resistance	Wash Off Allowed
Australia	27	No specified limit	25%	4 hour	No
ASEAN 10	26	25%	25%	80 min	50%
European union	29	Under Review	25%	80 min	50%
India	25	No specified limit	25%	Not specified	Not specified
China	27	25%	25%	80 min	50%
Japan	30	No specified limit	25%	80 min	50%
USA	15	25%	25%	80 min	NO
Canada	18	25 % Exempted Test	25%	ISO or FDA	Either
New Zealand	27	No specified limit	25%	4 hour	NO

4. CONCLUSION

It is readily seen from an evaluation of this study that the conclusions arrived at, relative to the harmful effects from the lack of regulatory regulations and guidelines which is directly related to safety of cosmetics. Regulation of sunscreen, their safety and efficacy support still remain complex and insufficient which must be evaluate and adopt in favour of public health safety. The purpose of the Regulatory requirements were to enable goods produced or marketed in one country to enter additional/new participating countries by removing the barriers linked to standards, technical regulations and conformity assessment.

India has many seasons/weather conditions which are based on the different locations (north, south, east & west India) and each location has specified weather conditions: that becomes more risk for Indian population so Indian ministry of health must work on the quality, safety, efficacy with certain stability conditions (temperature & humidity) of skincare products in the way of protection.

In India, there are numerous websites which correlate with general requirements of products (pharma.-

drugs, food and cosmetics) before and after commercializing into the market but for sunscreens need to launch websites and all mandatory information, instructions, guidelines, regulations and other safety related sections must be provide on the single portal for companies and consumers. At present there is no Cosmeto-vigilance programme running in India and hence there is no reporting of adverse events in cosmetics. Most of the adverse events go unnoticed. Countries like Italy and France have started separate Cosmeto-vigilance programme so India must have this surveillance programme. Claims and labelling are perhaps still the greatest area of difference. The regulatory requirements of sunscreens must harmonized and especially India should take mandatory steps on legal regulations. The variations in requirements which appear due to all of the above concerns must be controlled, harmonized and more stringent in India like other regulated countries.

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