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Safety and regulatory issues on sunscreen products in India

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ABSTRACT

Sunscreens are products that are placed in contact with human skin with the intention of absorbing, scattering, or reflecting solar UV radiation. Their frequency of use has increased remarkably in India due to greater awareness of the damaging effects of skin exposure to sunlight. Sunscreen chemicals (UV filters) are used not only to protect the skin of the user but also to prevent the product from photo-degradation. Sunscreen chemicals and products are regulated as cosmetic or drug depending upon the regulation of the country in which it is manufactured. Adverse effects due to sunscreen chemicals are of concern all over the world. Variation in the regulation affects the safety assessment of UV filters and its products. Amendments are required in the existing regulation in this country.

Key words: Sunscreen chemicals (UV filters), regulation, drug, cosmetic, adverse effects.

INTRODUCTION

Ultra violet (UV) radiation in the Earth's surface is in the 290–400 nm wave length and is conventionally divided into UVA (320–400 nm) and UVB (290–320 nm) . UVA causes direct tanning, photo-oxidation of melanin and premature skin aging. Whereas UVB causes sunburn and are the major cause of skin photo carcinogenesis and immunosuppression [1-3]. Sunburns in childhood are associated with melanoma in later life [4]. World Health organization has also classified UV radiation as carcinogenic which produces mutagenic effects, immune depression of the skin and the organism, accelerated skin ageing and photo-dermatoses [5]. Chronic exposure to solar irradiation is the primary cause of extrinsic skin aging and is responsible for the main age-related alterations, such as roughness, fine wrinkles, spotty hyperpigmentation, vasodilatation, and loss of skin elasticity [6]. During the past decades, skin cancer has become the most frequent neoplastic disease of the Caucasian population of Europe, North America and Australia. Products containing sunscreen chemicals (UV filters) are used to filter certain UV rays in order to protect the skin from certain harmful effect of these rays. In addition to this sun-screen chemicals are also being incorporated in different cosmetic products like moisturizers, body lotions, shower gels, shampoos, hair dyes, conditioners, lip balm, lipstick, anti-aging creams etc. to stop photo degradation of the products.

UV filters are physical (inorganic) or chemical (organic). Inorganic ingredients consist of metal derivatives, especially zinc oxide (ZnO) and titanium dioxide (TiO_2), which reflect, absorb and disperse most UV rays and are generally stable. Organic sunscreens are synthetic chemicals that absorb UV energy by virtue of their molecular structure. These generally contain aromatic rings that absorb radiation of certain wavelengths. The sunscreen loose a degree of efficiency over time and this leads to breakdown of the absorbing molecule. Since these molecules are small, they may penetrate the skin and cause systemic effects. Certain chemical ingredients may also act as haptens and become complete antigens, causing sensitization reactions.

In a tropical country like India, where the ambient UV radiation levels in sunlight is greater than other areas [7] and most of the human activities are sunlight oriented sunscreen products are routinely used by the people particularly in urban areas. Many recent reports from Europe and other western countries have highlighted increasing cases of allergic and photo allergic reactions to sunscreen products [8, 9]. Most reports of patients of photo allergic dermatitis

or cosmetic allergy reveal close to 20% of them being attributed to sunscreen agents [10]. This article analyzes the regulatory and safety issues on sunscreen ingredients and its products in India with respect to other nations and suggests suitable amendments in Drugs and Cosmetics Act 1940 and Rules 1945.

REGULATORY OVERVIEW

The first "sunscreen creams" were marketed in the 1930s in Europe and USA when sunbathing became fashionable [11]. Later in Germany and France, para-aminobenzoic acid (PABA) was patented and widely used as ingredient in sunscreens in 1943 [12].

Sunscreens are regulated in all developed countries. The list of substances classified as UV filters and the maximum allowable concentration are established by each country, for example, European Union (EU), United States of America (USA), Australia, Canada, ASEAN and India. UV filters approved in India and other nations are summarised as Table I.

In the EU, sunscreen chemicals (UV filters) are classified as cosmetics (subject to positive list) [13, 14]. The lists are updated on the basis of scientific research and approved by The European Cosmetics Association, a body that liaises with the European Commission.

In the USA, sun products are classified as over-the-counter drugs, a class for which it is necessary to indicate active ingredients demonstrated to be effective and safe. Production and marketing of these products is regulated by US FDA monographs published in the Federal Register. These monographs have been constantly updated since 1978. Sunscreen chemicals like dioxybenzone, cinoxate, menthyl anthranilate,, trolamine salicylate, zinc oxide are approved in USA but not in India [15, 16].

In Canada, Sunscreen products are classified as prescription drugs and must meet the requirements set out in Canada's *Food and Drugs Act* before they may be imported, advertised, or sold in Canada. Sunscreens are classified as natural health products (NHPs) if they contain ingredients like titanium oxide, zinc oxide and para amino benzoic acid.. Sunscreens are classified as drugs if they contain at least one ingredient from Avobenzone, Ensulizole, Homosalate, Meradimate, Octinoxate, Octisalate, Octocrylene, Oxybenzone, Sulisobenzone, Drometrizole trisiloxane, Enzacamene, Padimate-O, Terephthalylidene dicamphor sulfonic acid, Cinoxate, Diethanolamine-methoxycinnamate, Dioxybenzone and Triethanolamine salicylate. Health Canada has recently announced the release of the draft of revised Sunburn Protectants Monograph. The document is now titled “Guidance Document Sunscreen Monograph”, to reflect the common Canadian term for this category of drugs. It is the result of a thorough survey of existing regulations, guidance documents, policies and current practices within Health Canada and other leading regulatory agencies. This draft Monograph is intended to replace the existing Sunburn Protectants Monograph of October 12, 2006 [17]. Canada approves additional sunscreen chemicals as dioxybenzone, cinoxate, menthyl anthranilate, diethanolamine methoxycinnamate. ethyl dihydroxy propyl PABA , glyceryl PABA, trolamine salicylate, zinc oxide are not included in the UV filters list in India.

Australia has one of the highest rates of skin cancer in the world, and sunscreens are an important component of a sun protection regime. Many Australians use sunscreen every day of their lives, sometimes over large areas of their body surface. For safe, effective and quality sunscreen products, the TGA regulates some sunscreens as therapeutic goods in Australia. Sun screening agents permitted as active ingredients in listed Products have been corrected in 2006 by TGA [18]. The Australian regulatory guidelines for sunscreens (ARGS) have been developed to provide guidance to sponsors and manufacturers, and to assist in the understanding of the regulatory requirements for sunscreens in Australia [19]. SPF rating of 30+ may claim to prevent or reduce the risk of some skin cancers. There are different classifications for sunscreens like “listable”, “registrable” and “exempt” sunscreens depending on the SPF rating. Where SPF is 4 or greater and claims are limited to sunscreening only are listable sunscreens. Sunscreens that make therapeutic claims are registrable sunscreens. Only approved ingredients can be included in sunscreens, and each of these ingredients has been assessed for safety. The TGA requires the efficacy of each sunscreen product to be tested to determine the sun protection factor (SPF), which is printed on the label. UV filters like benzophenone-1, benzophenone-2, benzophenone-4, dioxybenzone, cinoxate, menthyl anthranilate, alpha-(2-oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts, salicylic acid salts (potassium, sodium and triethanolamine), triethanolamine salicylate, zinc oxide, bemotrizinol (tinosorb S), 2,2'-Methylene-bis-6-(2-H-benzotriazol-2yl)-4-(tetramethylbutyl)-1,1,3,3-phenol (tinosorb M) are approved in Australia but not listed in India [20].

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". Menthyl anthranilate and zinc oxide are not included in the UV filters list in India [21].

In India, Bureau of Indian Standards (BIS) has listed permitted UV filters which cosmetic products may contain [22]. There is no maximum SPF rating. For the purpose of this Directive, UV filters are substances, which contained in cosmetic sunscreen products, are specifically intended to filter certain UV rays in order to protect skin from certain harmful effects of these rays. Other UV filters, used in cosmetic products solely for the purpose of protecting the product against UV rays are not included in the list.

ADVERSE EFFECTS

Benzophenone-3 (BZ3) or oxybenzone is very hazardous, according to the Centre for Disease Control and Prevention (CDC). It is on the list of Registry of Toxic Effects of Chemical Substances (RTECS) because the chemical is absorbable through the skin and causes endocrine disruption. It is found in sunscreen moisturizers, lip balm and children's sunscreen. Synthetic versions of BZ3 are a direct causation of leucocytosis, anemia, and can reduce organ weight and both chronic/sub-chronic oral toxicity [23]. CDC published results from a national survey of 2,500 Americans, age 6 and up, showing that BZ3 readily absorbs into the body and is present in 97% of Americans tested [24]. A study has revealed that mothers with high levels of BZ3 in their bodies were more likely to give birth to underweight baby girls [25]. In a study of 82 patients with photoallergic contact dermatitis, over one quarter showed photoallergic reactions to oxybenzone [26] Another study reported 1 in 5 allergic reactions to photopatch tests resulted from exposure to oxybenzone [27]. Sunlight also causes BZ3 to form free radical chemicals that may be linked to cell damage, according to 2 of 3 studies [28]. . Under study conditions, oxybenzone and its metabolites cause weak estrogenic [29,30,31] and anti-androgenic effects [32]. The surface area of a child's skin relative to body weight is greater than adults. As a result, the potential dose of a chemical following dermal exposure is likely to be about 1.4 times greater in children than in adults [33]. The Environmental Working Group and other toxicology experts believe that oxybenzone is linked to hormone disruption and potentially to cell damage that may lead to skin cancer [34].

Para-aminobenzoic acid (PABA) is used to be a popular sunscreen ingredient but its use has declined because of problems with allergic dermatitis and photosensitivity. It is a known carcinogenic. Sunscreen manufacturers claim to be using only PABA's derivatives. US FDA has approved PABA to be used in "limited use" [35]. PABA and its metabolites were detected in the urine of volunteers who applied PABA-based sunscreens to their skin [36]. It is banned in sunscreens in ASEAN nations and Canada. Indian regulation allows up to 5% in cosmetics.

Padimate O (Octyl dimethyl PABA) has shown the ability to release free radicals and in turn causes DNA damage, estrogenic activity and allergic reactions [37]. It is allowed up to 8% in cosmetics in India.

Menthyl anthranilate (meradimate) has the ability to produce damaging reactive oxygen species when it's exposed to sunlight. A study published in 2011 explored the effects of pre- and post-natal exposure to high doses of octyl methoxycinnamate in rats and showed, for example, that the testes weight and testosterone levels were significantly reduced in male rats [38]. It is prohibited for use in sunscreen products within Europe and Japan but is still in use within the United States.

Sunscreen chemicals esp. 2-Ethylhexyl-4-methoxycinnamate, Isopropyl myristate , 3-(4'-Methylbenzylidene) camphor, 4-Tert-butyl-4'-methoxy dibenzoylmethane, 2-Hydroxy-4-methoxybenzophenone has been responsile for causing ACD [39]. 3-(4'-Methylbenzylidene) camphor is not approved in Australia, Canada and USA but allowed in India in concentration up to 6%. 4-Tert-butyl-4'-methoxy dibenzoylmethane is approved in USA in concentration up to 5% but in India it is approved up to 3%.

Many modern cosmetic or sunscreen products contain nano sized components, including nano-sized formulations or insoluble solid particles in the nano-range, i.e. 1 to 100 nm in diameter. Concerns were raised about the safety of solid nanoparticles in PCP, mainly TiO2 and ZnO in sunscreens. However, current evidence suggests that these particles are non-toxic, do not penetrate into or through normal or compromised human skin and, therefore, pose no risk to human health [40, 41].

On the basis of pharmacological and toxicological reports, regulatory agencies have sought opinion of different agencies like Colipa in case of phenyl benzimidazole sulfonic acid and its salts which opined that that the use of phenyl benzimidazole sulfonic acid and its salts as a UV-filter at a maximum concentration of 8.0% in the cosmetic sun protection preparations does not pose a risk to the health of the consumer [42]. 4-methylbenzylidene camphor was perceived by the general public and the Danish Ministry to be an endocrine disruptor having estrogenic activity which could damage human health particularly in small children [43,44] while scientific evidence showed that

there was no need for any regulatory action to protect the consumer [45]. It is important to consider that risk perception by the consumer, although subjective and completely dissimilar from the scientific determination of hazard and risk, really does matter, since it can importantly affect the cosmetic market [46].

DISCUSSION

In India cosmetic is defined as any article intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to ,the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic [47]. EU defines cosmetic as any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition [48]. ASEAN defines as any substance or preparation intended to be placed in contact with various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition [49]. EU and ASEAN definitions are same. US FDA defines cosmetics as an articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body… for cleansing, beautifying, promoting attractiveness, or altering the appearance [50]. The Canadian Food & Drugs Act defines a cosmetic as any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes [51]. US FDA and Health Canada further stipulate that claims of physiological effect are not allowed for cosmetics.

In US, Canada or Australia, ultraviolet filters are categorized as drugs. EU, ASEAN and India list UV filters for cosmetic products. That is why there is no harmonization in the percentage requirement of these chemicals. US, Canada and Australia require evidence for their safety and efficacy as well as approval by their respective agencies [39].

The definition of cosmetic in India is similar to the definition in US, but it adopts EU model for the list of UV filters instead of US model. Cosmetics products in India is regulated under the Drugs and cosmetics Act 1940 and Rules 1945. Bureau of Indian Standards (BIS) sets the standards for cosmetics for the products listed under Schedule 'S' of the Drugs and Cosmetics Rules 1945. UV filters or its products are not listed under Schedule S i.e. the Drugs and Cosmetic Rules do not prescribe for standard quality of UV filter chemicals or its products in India.

Good manufacturing practices and requirements of premises, plant and equipment for creams, ointments, emulsions, lotions etc. in drug category (Schedule M) is more stringent than those for cosmetics (Schedule M II). This explains why a sunscreen product classified as drug requires more time for approval than those categorised as cosmetics

UV filters are the active ingredients in sunscreen products. The concentration and combination of UV filters determine the efficacy of sunscreens as measured by Sun Protection Factor (SPF). There are differences in labelling requirements and permitted claims and different methods for assessing SPF. In United Kingdom a sunscreen would require performance data such as information to support its SPF and any UVA or UVB claims [52]. Similarly in Japan, Canada, USA and Australia SPF rating is mandatory. In Australia products having SPF value more than 4 are considered as drugs.

In India, there is no fixation of maximum SPF value. Natural and ayurvedic or herbal products with higher SPFs have emerged. The existing regulation of cosmetic products does not require disclosure of composition of the ingredients and there is no guideline for the claims [53]. Claims like broad spectrum or water resistant should be suitably evaluated. Due to these lacunas cosmetic manufacturers come with any SPF rating and exaggerated claims. Sunscreen products claiming SPF value as high as 40 are marketed as cosmetic product in India and at the same time similar sunscreen products are manufactured and sold as a cosmetic or drug in India.. Approval has been given for a sunscreen lotion containing octinoxate, avobenzone, oxybenzone and titanium dioxide as a *new drug* also in India.

Table I

Sl. No.	Substances (with INCI names)	Maximum Authorised Concentration					
		USA	EU	AUSTRALIA	CANADA	ASEAN	INDIA
1	PABA	Aminobenzoic acid (PABA) 15%	4-Aminobenzoic acid 5%	Aminobenzoic acid 15%	–	Deleted	4-Aminobenzoic acid 5%
2	Camphor benzalkonium methosulfate	–	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene-methyl)anilinium methyl sulphate 6%	6%	–	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene-methyl)anilinium methyl sulphate 6%	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene-methyl)anilinium methyl sulphate 6%
3	Homomethyl salicylate	Homosalate 15%	Homosalate (INN) 10%	Homosalate 15%	Homosalate 15%	Homosalate (INN) 10%	Homosalate (INN) 10%
4	Benzophenone-3(INCI) Eusolex 4360, Escalol 567	Oxybenzone 6%	Oxybenzone(INN) 10%	Oxybenzone 10%	Oxybenzone 6%	Oxybenzone (INN) 10%	Oxybenzone(INN) 10%
5	Phenyl benzimidazole sulfonic acid (INCI)	Phenylbenzimidazole sulphonic acid 4%	2-Phenylbenz imidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts 8% (expressed as acid)	Phenylbenzimidazole sulphonic acid 4%	Ensulizole 8%	2-Phenylbenz imidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts 8% (expressed as acid)	2-Phenylbenzimidazole-5-sulfonic acid and its potassium,sodium and triethanolamine salts 8% (expressed as acid)
6	Terepthalylidine dicamphor sulphonic acid (INCI), Ecamsule, Mexoryl SX	–	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2-oxobicyclo-[2,2,1] hept-1-yl-methanesulphonic acid) and its salts 10% (expressed as acid)	Ecamsule 10%	Terephthalylidene dicamphor sulfonic acid 10%	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2-oxobicyclo-[2,2,1] hept-1-yl-methanesulphonic acid) and its salts 10% (expressed as acid)	3,3'-(1,4-Phenylenedimethylene) bis (7,7-dimethyl-2-oxobicyclo-[2,2,1] hept-1-yl-methanesulphonic acid) and its salts 10% (expressed as acid)
7.	Butyl methoxy dibenzoyl methane (INCI)	Avobenzone 3%	1-(4-tert-butylphenyl)-3-(4-methoxy-phenyl)propane-1,3,-dione 5%	Butyl methoxy dibenzoylmethane 5%	Avobenzone 5%	1-(4-tert-butylphenyl)-3-(4-methoxy-phenyl)propane-1,3,-dione 5%	1-(4-tert-butylphenyl)-3-(4-methoxy-phenyl)propane-1,3,-dione 5%
8.	Benzylidene camphor sulfonic acid (INCI)	–	Alpha-(2-Oxoborn-3-ylidene)-4-sulphonic acid and its salts 6% (expressed as acid)	alpha-(2-Oxoborn-3-ylidene) toluene-4-sulphonic acid and its salts 6% (expressed as acid)	–	Alpha-(2-Oxoborn-3-ylidene)-4-sulphonic acid and its salts 6% (expressed as acid)	Alpha-(2-Oxoborn-3-ylidene)-4-sulphonic acid and its salts 6% (expressed as acid)
9.	Octocrylene	Octocrylene 10%	2-cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester (Octocrylene) 10% (expressed as acid)	Octocrylene 10%	Octocrylene 12%	2-cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester (Octocrylene) 10% (expressed as acid)	2-cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester (Octocrylene) 10% (expressed as acid)
10.	Polyacrylamido methyl benzylidene camphor	–	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene)methyl]benzyl}	–	–	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene)methyl]benzyl} acrylamide 6%	Polymer of N-{(2 and 4)-[(2-oxoborn-3-ylidene)methyl]benzyl} acrylamide 6%

			acrylamide 6%				
11.	Octyl methoxycinnamate	Octyl methoxycinnamate 7.5%	Octyl methoxycinnamate 10%	Octyl methoxy cinnamate 10%	Octinoxate 8.5%	Octyl methoxycinnamate 10%	Octyl methoxycinnamate 10%
12.	PEG-25 PABA	–	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA 10%	Ethoxylated ethyl-4-amino-benzoate (PEG-25 PABA) 10%	–	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA 10%	Ethoxylated Ethyl-4-Aminobenzoate (PEG-25 PABA 10%
13.	Isoamyl p-methoxy cinnamate	–	Isopentyl-4-methoxycinnamate(Isoamyl p-methoxycinnamate) 10%	Isoamyl Methoxy cinnamate 10%	–	Isopentyl-4-methoxycinnamate(Isoamyl p-methoxycinnamate) 10%	Isopentyl-4-methoxycinnamate(Isoamyl p-methoxycinnamate) 10%
14.	Octyl Triazone	–	2,4,6-Trianilino-(p-Carbo-2-Ethylhexyl-1' Oxy)-1,3,5-Triazine(Octyl Triazone) 5%	Octyltriazone 5%	–	2,4,6-Trianilino-(p-Carbo-2-Ethylhexyl-1' Oxy)-1,3,5-Triazine(Octyl Triazone) 5%	2,4,6-Trianilino-(p-Carbo-2-Ethylhexyl-1' Oxy)-1,3,5-Triazine(Octyl Triazone) 5%
15.	Drometrizole Trisiloxane)	–	Phenol,2-(2H Benzotriazole-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetra-methyl-I-(Trimethylsilyl)Oxy)-Disilox-anyl)Propyl)(Drometrizole Trisiloxane) 15%	Drometrizole Trisiloxane 15%	–	Phenol,2-(2H Benzotriazole-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetra-methyl-I-(Trimethylsilyl)Oxy)-Disilox-anyl)Propyl)(Drometrizole Trisiloxane) 15%	Phenol,2-(2H Benzotriazole-2-yl)-4-Methyl-6-(2-Methyl-3-(1,3,3,3-Tetra-methyl-I-(Trimethylsilyl)Oxy)-Disilox-anyl)Propyl)(Drometrizole Trisiloxane) 15%
16.	Dioctyl butamide triazone (INCI)	–	Benzoic acid, 4,4-((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino) 1,3,5-trizine-2,4-diyl) diimono)bis-,bis-(2-ethylhexyl)ester) 10%	–	–	Benzoic acid, 4,4-((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino) 1,3,5-trizine-2,4-diyl) diimono) bis-, bis-(2- ethylhexyl)ester) 10%	Benzoic acid, 4,4-((6-(((1,1-dimethylethyl)amino)carbonyl)phenyl)amino) 1,3,5-trizine-2,4-diyl)diimono) bis-, bis-(2-ethylhexyl)ester) 10%
17.	4- Methyl benzylidene Camphor	–	3-(4'- Methylbenxylidene)-d-1 camphor (4-Methylbenzylidene Camphor) 4%	4-methyl benzylidene camphor 4%	Enzacamene 6%	3-(4'- Methylbenxylidene)-d-1 camphor (4- Methylbenzylidene Camphor) 4%	3-(4'- Methylbenxylidene)-d-1 camphor (4- Methylbenzylidene Camphor) 4%
18.		–	3- Benzylidene camphor (3- Benzylidene camphor) 2%	–	–	3- Benzylidene camphor (3-Benzylidene camphor) 2%	3- Benzylidene camphor (3-Benzylidene camphor) 2%
19.	Octyl-salicyclate	Octyl Salicylate 5%	2- Ethylhexyl salicyclate (Octyl-salicyclate) 5%	Octyl Salicylate 5%	Octisalate 6%	2- Ethylhexyl salicyclate (Octyl-salicyclate) 5%	2- Ethylhexyl salicyclate (Octyl-salicyclate) 5%
20.	octyl dimethyl PABA	Padimate O 8%	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA) 8%	Padimate O 8%	Padimate O 8%	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA) 8%	4-Dimethyl-amino-benzoate of ethyl-2-hexyl (octyl dimethyl PABA) 8%

21.	Benzophenone-5	Sulisobenzone 10%	2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid(Benzophenone-5)and its sodium salt 5% (of acid)	Benzophenone 5 (Sulisobenzone sodium) 10% Benzophenone -4 (Sulisobenzone) 10%	Sulisobenzone 10%	2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid(Benzophenone-5)and its sodium salt 5% (of acid)	2-Hydroxy-4-methoxybenzophenone-5-sulphonic acid(Benzophenone-5)and its sodium salt 5% (of acid)
22.	Methylene bis-benzoyl triazolyl tetra methy lbutyl phenol(INCI)	–	2,2'-Methylene-bis-6-(2H-Benzotriazole-2yl)-4-(teramathyl-butyl)-1,1,3,3-phenol 10%	Methylene bisbenzotriazol yl tetramethyl butylphenol 10%	–	2,2'-Methylene-bis-6-(2H-Benzotriazole-2yl)-4--(teramathyl-butyl)-1,1,3,3-phenol 10%	2,2'-Methylene-bis-6-(2H-Benzotriazole-2yl)-4-(teramathyl-butyl)-1,1,3,3-phenol 10%
23.	Bisymidazylate (INCI)	–	Monosodium salt of2-2'bis-(1,4-pheny-lene) 1H-benzemidazole-4,6-disulphonic acid 10% (of acid)	–	–	Monosodium salt of2-2'bis-(1,4-pheny-lene) 1H-benzemidazole-4,6-disulphonic acid 10% (of acid)	Monosodium salt of2-2'bis-(1,4-pheny-lene) 1H-benzemidazole-4,6-disulphonic acid 10% (of acid)
24.	Anisotriazine (INCI)	–	(!,3,5)-Triazine-2,4-bis((4-(2-ethyl-hexy-loxy)-2-hydroxy)-phenyl)-6-($-methoxy-phenyl) 10%	–	–	(!,3,5)-Triazine-2,4-bis((4-(2-ethyl-hexy-loxy)-2-hydroxy)-phenyl)-6-($-methoxy- phenyl) 10%	(!,3,5)-Triazine-2,4-bis((4-(2-ethyl-hexy-loxy)-2-hydroxy)-phenyl)-6-($-methoxy-phenyl) 10%
25.	Polysilicone-15(INCI)	–	Dimethicodiethylbenzalmalonate (CAS No. 207574-74-1) 10%	–	–	Dimethicodiethylbenzalmalonate (CAS No. 207574-74-1) 10%	Dimethicodiethylbenzalmalonate (CAS No. 207574-74-1) 10%
26.	Titanium dioxide	Titanium dioxide 25%	Titanium dioxide 25%	Titanium dioxide 25%	Titanium dioxide 25%	Titanium dioxide 25%	Titanium dioxide 25%
27.	Diethylamino Hydroxyben-zoyl Hexyl Benzoate	–	–	–	–	Benzoic acid, 2-[-4-(diethylamino)-2-hydroxybenzoyl],hexylester(INCI name: Diethylamino Hydroxyben-zoyl Hexyl Benzoate; (CAS No. 302776-68-7) 10% in sunscreen products	Benzoic acid, 2-[-4-(diethylamino)-2-hydroxybenzoyl],hexylester(INCI name: Diethylamino Hydroxyben-zoyl Hexyl Benzoate; (CAS No. 302776-68-7) 10%

CONCLUSION

Considering the increasing attention to sun screen products and globalization of their market, international harmonization of product regulation would be useful. Two major international organizations have been working in this sense, the International Organization for Standardization and the International Cooperation on Cosmetics Regulation (ICCR). The ICCR is composed of experts from the USA (FDA), Canada (Health Canada), Europe (European Commission, DG Enterprise) and Japan (Ministry of Health, Labour and Welfare). It is important to have stringent safety assessment of their potential to produce local toxicity, such as irritation, sensitization, photo-toxicity, acute toxicity, dermal absorption/penetration, sub-chronic toxicity, genetic toxicity, carcinogenicity and photo-carcinogenicity etc. for the sunscreen chemicals in this country. SPF rating for cosmetic products and drugs needs to be fixed and guidelines for label claims on these products should be developed. SPF labelling should be made mandatory. Standard for sunscreen products should be fixed and made statutory. There is need to redefine "cosmetic" in global perspective.

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