OTC SUNSCREEN FILTERS ARE ON LIFE SUPPORT

THE STATUS of the 24 over-the-counter (OTC) ultraviolet absorbers approved for use since 1978 is on life-support. If my treatise here does not move the US Food and Drug Administration, the Personal Care Product Council (PCPC), cosmetic scientists, and even the Public Access to Sunscreens (PASS) Coalition to act, then we are all in deep denial.

Allow me to back track and review the relevant events in history. A panel was convened early in the 1970s to issue a monograph governing the use of sunscreens in the USA. On August 25, 1978, the first Advanced Notice for Proposed Rulemaking (ANPR) was published by the FDA and it listed 21 UV filters as Category I ingredients (see Table I at right). Note that three additional ingredients were added later on for a total of 24 approved UV filters including avobenzone (September 16, 1996), zinc oxide (October 22, 1998) and ecamsule through a New Drug Application (NDA) issued to L'Oréal (July 24, 2006).

On May 12, 1993, the Tentative Final Monograph (TFM) was issued and the Final Rule was released in 2011. Yet, there is no Final Monograph. The Final Rule of 2011 listed the 17 Category I Ultraviolet Filters. They are listed in Table II (above, right) with notations signifying if they are UVA/UVB filters, water soluble (WS) or banned in Hawaii.

With the recent developments in Hawaii and the banning of both oxybenzone and octinoxate beginning in 2021, and the potential of a nationwide ban, [Congressman Tulsi Gabbard (D-Hawaii) tweeted on 7/3/2018, "I am working on a legislation to take this ban national."]

Here are the seven currently usable ultraviolet filters in the US (Table III below).

In reviewing Table III, you will note that only seven ingredients will be used in

Table I: Category I UV Filters

UV Absorbers/Reflectors	%
Oxybenzone	2-6
Sulisobenzone	5-10
Dioxybenzone	3
Menthyl anthranilate	3.5-5
Red petrolatum	30-100
Titanium dioxide	2-25
UVB Absorbers	
Aminobenzoic acid	5-15
Amyl dimethyl PABA[a]	1-5
2-Ethoxyethyl p-methoxycinnamate	1-3
Diethanoloamine p-methoxycinnamate	8-10
Digalloyl trioleate	2-5
Ethyl 4-bis(hydroxypropyl) aminobenzoate[a]	1-5
2-Ethylhexyl-2-cyano-3, 3-diphenyl-acrylate	7-10
Ethylhexyl p-methoxycinnamate	2-7.5
2-Ethylhexyl salicylate	3-5
Glyceryl aminobenzoate[a]	2-3
Homomenthyl salicylate	4-15
Lawsone with Dihydroxyacetone[a]	0.25
Octyl dimethyl PABA	1.4-8
2-phenylbenzimidazole-5-sulfonic acid	1-4
Triethanaolamine salicylate	5-12

a-These items were deleted from the Final Monograph in 1999. Three additional items were added: avobenzone (1-3%), ecamsule (up to 10%) and zinc oxide (2-25%).

Table II: The 17 More Recently Approved Ultraviolet Filters (The Final Rule 2011)

UV Absorbers/Reflectors	%
Aminobenzoic acid	(X)
Avobenzone	(A)
Cinoxate	(X)
Dioxybenzone	(X)
Homosalate	(B)
Meradimate	(A) (X)
Mexoryl SX*	(A) (WS)
Octocrylene	(B)
Octinoxate	(H)
Octisalate	(B)
Oxybenzone	(A) (H)
Padimate O	(X)
Phyenylbenzimidazole sulfonic acid	(WS) (X)
Sulisobenzone	(X)
Titanium dioxide	(A)
Trolamine salicylate	(X)
Zinc oxide	(A)

Note: UVA Filter (A), UVB Filter (B), Water Soluble (WS), Hawaii Ban (H), Rarely used (X) Approved in specific L'Oréal formulations only.

Table III: The 6 (+1) Currently Usable Ultraviolet Filters

Avobenzone
Homosalate
Octisalate
Octocrylene
Titanium dioxide
Zinc oxide
Ecamsule (Mexoryl SX)°

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the US in the near future. The three large molecules, zinc oxide, titanium dioxide and ecamsule (only for L'Oréal products), are in compliance with the Dalton 500 Rule, which ensures that these UV filters do not significantly permeate the skin. The remaining four UV filters, avobenzone (MW 310), homosalate (MW262), octisalate (MW250) and octocrylene (MW 362) are all smaller molecules of less than 500 Daltons and, hence, possibly penetrate the skin. In addition, avobenzone is photo-unstable and is a UVA filter only if adequately formulated and quenched with other UV filters. These quenching UV filters include octocrylene, methyl benzylidene camphor, oxybenzone, polycrylene, Synoxyl HSS, Corapan TQ, Oxynex ST, etc.). In fact, the Diketo Avobenzone (butyl methoxydibenzoyl methane) has a λmax of around 260nm. This is neither a UVA nor a UVB filter! Only its Enol tautomer qualifies it to be a UVA filter with a λmax of 357nm.

Hawaii is banning sunscreen to protect coral reefs.

Table IV: The TEA-Pending Ingredients

Ingredient	TEA Date	Docket	(MW)(g/mol)
Octyl triazone	8/21/2002	FDA-2003-N-0196	823
Bemotrisinol	(4/11/2005	FDA-2005-N-0453	628
Bisoctrizole	4/11/2005	FDA-2005-N-0453	659
Isocontrizinol	9/16/2005	FDA-2006-O-0314	766
Ecamsule	9/18/2007	FDA-2008-N-0474	523
Drometrizole trisiloxane	1/21/2009	FDA-2003-N-0196	502

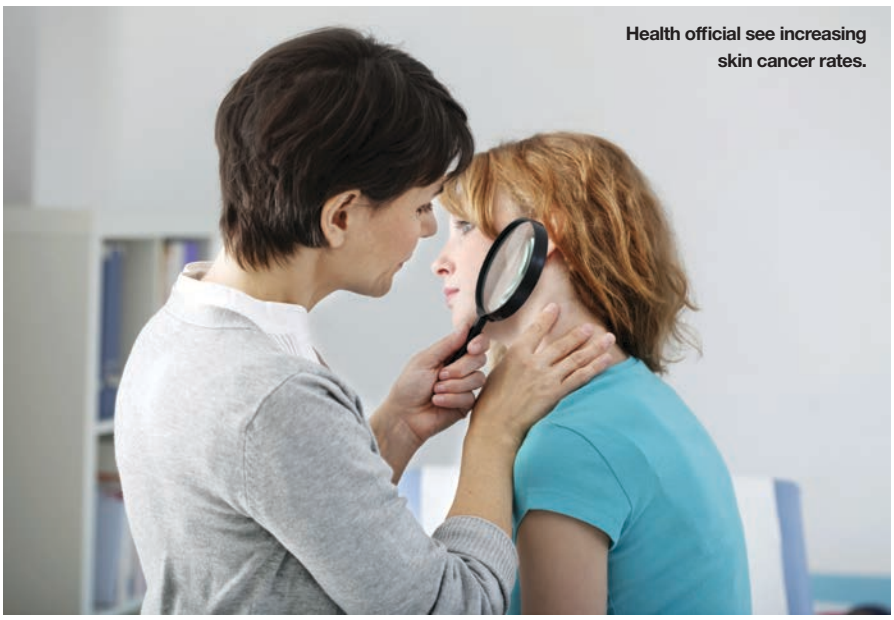
A Grim Future

If, in the future, these four small molecules were eliminated and replaced with the TEA (Time and Extent Application) European UV Filters (see Table IV), we can revolutionize the sunscreen industry and, more importantly, change how ultraviolet filters are classified in the US. All six TEA ingredients below have high molecular weights (MW) and are designed based on the 500 Dalton Rule.

Ensuring that none of the ultraviolet filters used in sunscreen cosmetics penetrate the skin, we will have an excellent case in re-classifying sunscreens as special "cosmetics" instead of "drugs." Most of the world classifies sunscreens as "cosmetics" with no unusual adverse effects or potential harm to the consumers.

Sunscreens as cosmetics will clear the way for new research, innovation and the introduction of far more superior ingredients (both synthetic and natural) that adequately protect from the ravages of harmful solar radiation. So long as we can ensure that the new filters are large non-skin penetrable ingredients and are both safe and effective, then a host of filters will be produced that will provide protection against UVB, UVA, high energy visible (HEV) and infrared (IR) radiation.

If sunscreens are classified as special cosmetics it will undoubtedly ensure the introduction of far more superior ultraviolet filters. Sunscreens will once again be thought of as safe and effective ingredients for protection. Consumers will use them freely without the current shadow of applying ineffective or unsafe sunscreens. Compliance will clearly boost prevention protocols and, hopefully, reduce the spiraling incidence of skin cancer. ●



Health official see increasing skin cancer rates.