

FDA SUNSCREEN REGULATION REMAINS A GAME OF SHADOWS

THIS SUMMER was supposed to herald the first ever Final FDA Sunscreen regulations in the United States. Instead, the regulations were postponed yet again to December, and the summer season passed without too much fanfare. Developments in the last few months have been relatively few except for two significant incidents:

1. A false advertising suit was filed against Merck & Co. (Aug. 24, 2012).
2. A Friends of the Earth (FOE) complaint about Antaria Ltd. was sent to the Australian Securities Exchange (Aug. 28, 2012).

This column will elaborate on both events since they have serious implications for our industry.

Three plaintiffs (Steven Brody, Chaim Hirschfeld and Suzanne Grunstein) filed a false advertising lawsuit against Merck & Co., the maker of Coppertone sunscreens, which claimed the products deceptively promised “full defense” against the sun.¹ They alleged that Merck & Co., Inc. “engaged in, and continue to engage in, unconscionable business practices and deceptive acts in connection with the

labeling, advertising, marketing and sale of their sunscreen products which have harmed Plaintiffs and the Class and which will continue to harm consumers unless the practices are stopped.”²

They argued that Coppertone’s sunscreen products fail to protect against all the UVA rays despite its “full defense” claim. The plaintiffs alleged that calling products “sunblock,” “waterproof,” “sweatproof” and providing “all-day protection” was also misleading. The plaintiffs referenced the new FDA rules—that have not yet been finalized—as support for their argument that Merck knew or should have known that its labeling and advertising of those claims was deceptive. Additionally, the plaintiffs claimed that “Coppertone sunscreen products contain avobenzone for protecting the skin against UVA rays, which was found to quickly degrade after being exposed to sunlight.”

The National Advertising Council (NAD) had suggested last December that Merck stop claiming that its product, with a sun protection factor of 15 or higher, “protects across 100% of the UVA/UVB spectrum.”³ Earlier, the FDA had announced major changes in the labeling and marketing requirements of OTC sunscreen products requiring that claims of “waterproof,” “sweatproof,” and “sunblock” be abandoned. In all fairness, these rules have not been finalized and to hold consumer companies accountable is debatable. Most of these terms have been allowed, or at least not objected to, by the FDA for years. The fact that avobenzone degrades after being exposed to sunlight is well known; however, most manufacturers have addressed this issue by incorporating quenchers that photostabilize avobenzone. The FDA has never raised any concerns on the issue of photostabilization of avobenzone with quenchers and, more importantly, has not allowed any of the presumably photostable European TEA ingredients on the US market. This lawsuit, and perhaps others to follow, is a direct

consequence of the lack of definitive and timely regulations in the US.

In addition to the confusion that arises from the lack of regulations governing the use and manufacturing of sunscreen products in the US is the alarming fact that skin cancers are on the rise in the country—especially among younger females—and warrants serious investigation.

Zinc Oxide Filters

The second issue that I wish to address relates to zinc oxide filters. Inorganic particulates are growing rapidly in popularity, especially in the US yet they face varied opposition. Environmental groups such as the FOE object to the use of nanoparticles in sunscreen formulations, the Environmental Working Group (EWG) and others slam (unfairly most of the time) the so-called “chemical” filters in sunscreens. This leaves the practitioner, manufacturer and, most importantly, the end user in a quandary as to which ingredients to select and use in sunscreen products. A case in point has been the unfair targeting of the Australian manufacturer, Antaria, makers of Zinclear IM dispersions that are promoted by Dow Chemical in the USA and other regions. The FOE claims that Antaria’s line of inorganic particulate sunscreen ingredients contains nanoparticles and after repeated warnings, they filed a formal complaint with the Australian Securities Exchange (ASE).⁴

According to the FOE, Antaria’s Zinclear IM is a nanomaterial based on past statements by Antaria senior employees and also its US patent⁵ which states that the product is “meso-porous” and is based on aggregates of primary nanoparticles. This claim by the FOE was supported by Australia’s National Measurement Institute (NMI) that stated that the “meso-porous zinc oxide powder” is a “nanomaterial” based on the International Organization for Standardization (ISO) technical specifications.



Nadim Shaath
*Alpha Research
& Development Ltd*
Email: alhamd@aol.com

Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he formed a consulting company serving the cosmetic industry called ShaathMeadows Corporation (SMC) with laboratories in New York, New Jersey, Texas, Florida and Egypt.

I contacted Antaria and Dow Chemical and received the following comments:

- Since 2007 Antaria has represented ZinClear-IM as a porous micron-sized zinc oxide particle. However, the definitions and working definitions of “nanoparticle” and “nanomaterial” have evolved since ZinClear-IM was commercialized. ZinClear-IM is not a nanoparticle—the particles are micron-sized. Under the recently emerging definitions of “nanomaterial,” ZinClear-IM would be a nanomaterial because of its porous structure, which is on a nano scale. The current EU definition of a nanoparticle is “non-soluble or bio-persistent substances, produced intentionally, characterized by one or more external dimensions or by an internal structure, on a scale of 1 to 100 nm” (Definition from Regulation (EC) N° 1223/2009 of the European Parliament and of the Council of 30 November 2009 relative to cosmetics, published in the Official Journal of the European Union of 22/12/2009). This type of ingredient is prohibited by this standard.

Antaria makes only one substantial commercial claim in respect to ZinClear IM—its exceptional transparency in cosmetic use. The fact that this transparency is delivered in a micron-sized particle is the central triumph in its innovation. Antaria has been careful to never make any commercial claim that this micron size improves product safety.

For those customers that, for one

reason or another, are worried about nanoparticles: Antaria confirms the ZinClear-IM particle is a micron-sized particle as measured by laser light scattering, well above the size that is considered a “nanoparticle.” These measurements indicate there are very few free nanoparticles in ZinClear-IM dispersions.

Irrespective of the above concerns, Antaria is having difficulty in fathoming why the structure of ZinClear-IM is such a issue. Whether nanoparticulate or not, zinc oxide is considered completely safe for personal care use by the FDA and other international regulators. No new evidence has been shown that there is any hazard whatsoever relating to zinc oxide in any form.

I have received several emails from Dow Chemical and data that clearly demonstrate that ZinClear IM is not a nanoparticle under the most current and widely accepted definition of the term. In 2008, the ISO defined nanoparticles as the size range of approximately 1nm to 100 nm (0.001-0.1 micron).⁶ This definition is internationally recognized and used as the foundation for establishing agency or regional specific definitions. Below is a graph of a laser light scattering conducted by three different laboratories that shows the average particle size of ZinClear IM is 1.5 microns. No particles were observed below 200nm (0.2 microns).

As I have mentioned in earlier columns, inorganic particulates are gaining acceptance in our industry. Considerable knowledge has

been attained by chemists, formulators, manufacturers and most notably by consumers and end users as to their attributes and value in suncare products. The two cases presented in this column demonstrate the depth of knowledge that consumers have attained but also the serious consequences that can be caused by the rapid

dissemination of information in our industry. Addressing consumer concerns head-on is prudent but also fraught with pitfalls if not handled wisely.

I rarely comment on internet columns, but a series of articles written by a young blogger named John Su are worth noting. This aspiring dermatologist wrote four parts of a presumably five-part series on inorganic sunscreens that were excellent despite a few errors and the scientific incompleteness of his treatises. He addressed the irritation potential, aesthetics, photostability, photoreactivity, permeability, toxicity, level of protection and practicality of inorganic sunscreens as compared to the so-called organic sunscreens.⁷ It is well worth reading.

Another publication that is well written is the Melanoma letter which is issued by the Skin Cancer Foundation.⁸ In its Summer 2012 issue, three articles were published. The first is entitled “Regular Use of Sunscreen Can Reduce Melanoma Risk” by Adele Green and Gail Williams, the second “Challenges in Making an Effective Sunscreen” by Steve Wang and Judy Hu and the third “Everyday and High-UPF Sun-Protective Clothing” by Peter Gies and Alan McLennan.

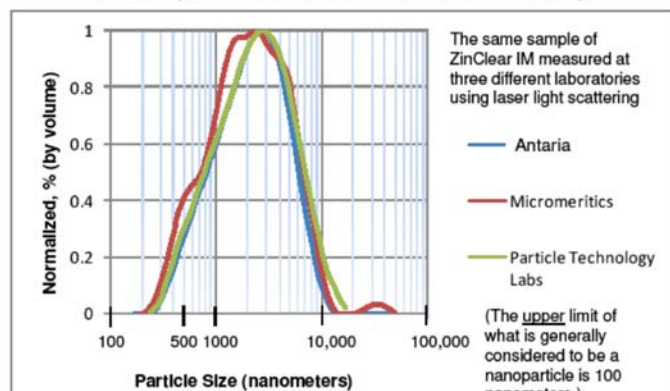
In conclusion, regulations systematize the expectations for our industry. They hold manufacturers to agreed upon standards so that the consumer base can rest assured. Without such standardization, constant use of the legal system seems the only retreat and the gossip mill guides consumer confidence. To save us needless misspent energy and other dangers, we prevail upon the FDA to standardize and regulate. •

References:

1. <http://www.manatt.com>
2. http://www.manatt.com/uploadedFiles/Content/4_News_and_Events/Newsletters/AdvertisingLaw@manatt/Brody
3. www.cosmeticsDesign.com/USA December 21, 2011
4. www.FOE.org.au/articles
5. US Patent 2010/0310871 (Antaria)
6. ISO/TS 27687:2008
7. www.futurederm.com/2012/09/06/AreInorganicSunscreensBetterThanOrganicOnes
8. www.skincancer.org, The Melanoma Letter, Summer 2012.

Particle size of ZinClear IM Zinc Oxide

The average ZinClear-IM particle size is in the micron range



Average particle size = ~1,500 nm = ~1.5 micron

Very few free nanoparticles are detectable in ZinClear-IM dispersions