FLORIDA CHAPTER SOCIETY OF COSMETIC CHEMISTS

2023

SUNSCREEN SYMPOSIUM 2023

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SCHEDULE OVERVIEW

WEDNESDAY, SEPTEMBER 13th 2023

- Registration: 7:00am – 8:30am, 4:00pm – 7:00pm; Desk outside Asbury Hall
- Continental Breakfast: 7:00am – 8:30am; Asbury Lobby
- CEP Course: 8:00am – 11:15am (part 1), 1:00pm – 4:15pm (part 2); Asbury Hall
- Golf: 8:00am – 2:00pm; Lake Buena Vista Golf Course
  - Meet in Yacht Club lobby at 6:45am for bus departure at 7am
  - Bus staging at golf course at 1:45pm for return at 2pm
- Cocktail Reception: 5:00pm – 7:00pm; Grand Ballroom
  - Ribbon Cutting: 4:55pm – 5:00pm
  - Informal Poster Session: 5:00pm – 5:30pm

THURSDAY, SEPTEMBER 14th 2023

- Breakfast: 7:30am – 9:00am; Grand Ballroom
- Registration: 7:30am – 4:00pm; Desk outside Asbury Hall
- Exhibit Hall: 7:30am – 4:00pm; Grand Ballroom
- Session A: 8:30am – 10:00am, Questions 10:00am – 10:30am; Asbury Hall
- Session B: 10:30am – 12:00pm, Questions 12:00pm – 12:30pm; Asbury Hall
- Lunch: 12:00pm – 1:30pm; Grand Ballroom
  - Student Networking Lunch Event: 12:30pm – 1:30pm; Cape Cod A/B
- Session C: 1:30pm – 3:00pm, Questions 3:00pm – 3:30pm; Asbury Hall
- Session D: 3:30pm – 4:30pm, Questions 4:30pm – 5:00pm; Asbury Hall
- Scavenger Hunt Forms due by 5:00pm!
- Gala: 7:00pm – 10:00pm; Epcot World Showplace
  - Meet at Shipwreck Beach at 6:30pm to walk over to the gala

FRIDAY, SEPTEMBER 15th 2023

- Breakfast: 7:30am – 9:00am; Grand Ballroom
- Registration: 7:30am – 12:30pm; Desk outside Asbury Hall
- Exhibit Hall: 7:30am – 2:00pm; Grand Ballroom
- Session E: 8:30am – 10:30am, Questions 10:30am – 11:00am; Asbury Hall
- Session F: 11:00am – 12:30pm, Questions 12:30pm – 1:00pm; Asbury Hall

CEP COURSE

Sunscreen Claims and Regulatory Overview
Presented by: Wen Schroeder (Seki Cosmeticals LLC)

- Section 1
  - Background: Sun Care Science, Market, & Legislation
    - A brief overview of sunscreen photobiology
    - Evolution of sun care market and legislative trends
      - Product types and classification
      - Drug vs. cosmetic?
- Section 2
  - Global Sunscreen Regulations
    - Product classification
    - Safety and effectiveness requirements
    - Claims and labeling
- Section 3
  - Current sunscreen OTC monograph status
  - Facility and ingredients control
  - Regulatory requirements/substantiation
    - Safety
    - Effectiveness
    - Claims, labeling, and promotion
- Section 4
  - Case studies: FDA sunscreen products GMP enforcement
  - Step-by-step guide: launch a sunscreen in the US Market

Wen Schroeder is the president of SEKI Cosmeticals, a consulting company she founded in 2007. In addition to serving the European Commission as a key expert, leading and supporting the ASEAN-EU Integration Programmes in the field of GMPs and testing of cosmetic & pharmaceutical products, she was Science/Technology Advisor to Taiwan External Trade Development Council in similar regulatory & scientific advisory roles. Ms. Schroeder has served on various scientific committees for the Personal Care Products Council and is active in the Society of Cosmetic Chemists and the Regulatory Affairs Professional Society. With 20+ years of industrial experience, 30 US patents and numerous publications, Ms. Schroeder is an internationally recognized lecturer on cosmetic science & regulatory affairs. Her lecture topics cover a wide range of areas from chemical management, biocide regulations to food, drug, medical device, and cosmetic law. Ms. Schroeder is the editor/author of Sustainable Cosmetic Product Development, published by Allured Books as the first comprehensive technical reference work in this field for the cosmetic and personal care industry.

Session A

Results of a nationwide survey on the application habits of sunscreen users in the United States
Presented by: Kimberly Norman (Personal Care Products Council)
Abstract: The objective of this study was to evaluate the habits and practices of US consumers who claim to use products with sun protection factor (SPF) on a regular basis. The approach was an online survey covering all geographies in the US. The survey assessed claimed usage of SPF-containing products, including the effects of season, weather, gender, age, and geographical location on the use of SPF-containing beach/recreational, facial skin care, cosmetic, and lip products. The results, based on 2283 surveys, showed that sunscreen was applied most frequently when subjects anticipated spending more than 3 hours in the sun. Reported sunscreen usage was highest during the summer, and sunny weather conditions prompted 99% usage of recreational/beach products, but usage dropped to approximately 50% and 30% on partly cloudy and cloudy days, respectively, regardless of product type. About 50% of subjects reported limiting time spent in the sun and wearing a hat as supplemental measures to reduce sun exposure. SPF products were not reapplied by approximately 20-60% of regular sunscreen users, and reapplication of all SPF product types was less than 33% on cloudy and partly cloudy days. Primary reasons for reapplication were water exposure, number of hours outside, and being active/sweating. This study represents the most comprehensive assessment of consumer habits and practices among SPF product users in the US in the past 20 years.

Kimberly (Kim) Norman is the Senior Director of Toxicology at the Personal Care Products Council. Kim obtained her Ph.D from Vanderbilt University in Cell and Developmental Biology and is a Diplomate of the American Board of Toxicology (DABT), a European Registered Toxicologist (ERT), and serves on the Board of Directors for the American Board of Toxicology. Previously, Kim worked as an Associate Research Fellow in Global Stewardship at the Clorox Company, supporting regulatory and safety compliance of consumer products. Kim has also served at the Institute for In Vitro Sciences (IIVS) as a Senior Toxicologist and Study Director, where she worked collaboratively on the development and regulatory acceptance of numerous assays replacing animal use in the personal care industry and served on the OECD Expert Panel for Skin Sensitization.

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Optimizing aesthetic elements of sunscreen formulations

Presented by: Julian Hewitt (JPH SunCare Technologies, Ltd.), Mark Chandler (ACT Solutions Corp)

Abstract: As regulatory hurdles create substantial barriers to development and adoption of new UV filters, recent sunscreen development has instead focussed on two main objectives: improving the aesthetic properties of formulations, and improving the efficacy of the existing active ingredients. These two objectives are in fact connected; if we can improve efficacy and thereby use lower levels of actives to achieve our SPF targets, this allows the formulator more flexibility to optimise skin feel. This paper will discuss how aesthetic properties of sunscreen formulations can be optimized, depending on the type of formulation and the active ingredients used. Sensory panel studies indicate that what is usually desired is a product that spreads easily with a moderately wet feeling during application, but feels smooth and dry afterwards with little or no perceivable residue. With organic UV filters, judicious choice of emollients helps to optimise both skin feel and efficacy. With inorganic UV filters, developments in manufacturing and coating technology have produced materials that are transparent on skin while still being effective and also deliver elegant skin feel. The effects of recent developments in emulsifier technology and "SPF boosters" will also be discussed. Novel O/W and W/O emulsifiers allow "lighter" skin feel to be achieved. SPF boosters can deliver substantial increases in UV filter efficacy, but this is sometimes at the cost of adverse effects on skin feel.

Julian Hewitt graduated from Oxford University in 1988 with a BA Honours Degree in Chemistry. After graduating, he joined Tioxide, working on new product development. In 1991, he joined Tioxide's physical sunscreens business, remaining with the business as it moved from Tioxide to ICI, Uniqema, and finally Croda. During this time, Julian represented Uniqema and Croda as a technical expert for sun care products, developed and delivered training programmes for both internal and external audiences, and guided the development and launch of innovative new sun care ingredients.

Julian left Croda in October 2011 and formed JPH SunCare Technologies, providing technical consultancy services, regulatory advice, and training to manufacturers of UV protection products and ingredient suppliers.

Mark Chandler is President of ACT Solutions Corp (Adaptive Cosmetic Technology Solutions), a formulation design consultancy and laboratory founded in 2012, serving the cosmetic and topical pharmaceutical industries.

Mark has been in the industry for over 35 years, most recently serving as skin care applications manager for Croda Inc. He has had roles in Sales, Marketing, Strategic Planning and Acquisitions, and R&D. Mark has taught courses for the SCC, CfPA, and SpecialChem on subjects including Cosmetic Formulation, Raw Materials, Emulsion Technology, Formulating for Efficacy, and Low Energy Emulsification for over 20 years.

Mark also is a lecturer in the Cosmetic Science and Formulation Design program at the University of Toledo. He was awarded Fellow status by the SCC in 2014, and is the current President of the SCC.

Threading All the Needles – Sunscreen Actives Safety Through the Lens of Retailer "No" Lists
Presented by: Iva Teixiera (The Good Face Project)
Abstract: Retail "no" lists have grown in breadth and complexity over the past 2 years and have become increasingly stringent in regulating sunscreen actives. The current analysis collects ingredient lists of the 23 Best Sunscreens of 2023, according to Allure Magazine, and screens them for compliance with the clean beauty policies of retailers in four categories: specialty beauty (Ulta, Sephora, Cos Bar, etc.), mass-merch (Target, Walmart, etc.), department stores, and clean beauty retailers (Credo Beauty, The Detox Market, etc.). Further, we draw out commonalities, differences and trends. Finally, the analysis extracts any noticeable trends which formulators should be aware of in order to successfully create sunscreen products which will not be blocked from distribution due to lack of "no" list compliance.

Iva Teixeira is the Co-founder and CEO of the Good Face Project, a chemistry informatics AI company powering up the fastest growing Cosmetics Formula Management, Regulatory Compliance and Innovation. A technologist with a background in strategy, engineering and consumer goods, Iva specializes in building and scaling data-driven venture-backed companies.

Iva holds a BS in Mathematics, an MS in Operations Research and Engineering from the University of Michigan, and an MBA from Harvard Business School.

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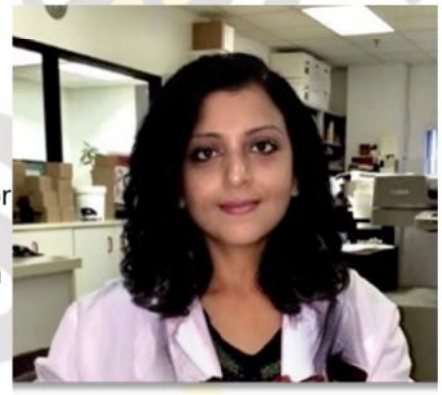
Session B

Evaluating Hybrid Sunscreens to Meet the Needs for Inclusivity and Safety
Presented by: Maitree Kanjilal (Kobo Products)
Abstract: In such a diverse world population, there is a need to protect people from the harmful effects of UV light including skin cancer and premature skin aging. Sunscreens are highly scrutinized by regulators, environmentalists, and consumers. Most sunscreen active ingredients have been challenged at some point due to safety concerns to humans or the environment. Some examples include the fear of skin penetration of organic UV absorbers, the disappearance of coral reefs and the safety concerns of titanium dioxide and zinc oxide nanoparticles. The ideal sunscreen active should be GRASE and have minimal environmental impact (i.e., negligible aquatic toxicity, low carbon emissions, etc.). Sunscreen formulations should be developed for all skin types. Much research has been investigated to optimize particle size for minimal skin whitening and overall pleasant product experience, but it is still challenging to create an inclusive formula using only mineral sunscreens. Currently there is a rising interest in hybrid formulations as they contain a blend of both inorganic and organic sunscreen actives which can help create aesthetically pleasing and highly effective formulas for a diverse community. This presentation will review some of the challenges of sunscreen actives, and evaluate hybrid sunscreen formulations that can combine the benefits of both organic and inorganic filters while being inclusive, efficacious and minimize environmental impact and human toxicity.



Maitree Kanjilal is currently a Staff Scientist at Kobo Products. Kobo is the leading Powder and Dispersion Specialist worldwide.

Maitree started her career at Dow Chemical Corporations as a technologist. She later worked at Schwan Cosmetics USA as a Chemist for many years before joining the KOBO R&D team. Maitree received a Master of Science degree in Physics from University of Calcutta (CU) with a specialization in Crystallography. She is a member of the Society of Cosmetic Chemists.

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Critical cleaning of sunscreens and formulations: life-cycle approach to cleaning validation
Presented by: Dijana Hadziselimovic (STERIS Corporation)
Abstract: Sunscreens are made of zinc oxide, titanium dioxide, oils, sun protection factor (SPF) boosters, avobenzone, octinoxate, oxybenzone, delivery systems, moisturizers, and chemicals to support skin elasticity. While these attributes are desired by consumers, marketing terms like "Waterproof", "SPF" and "Anti-aging" in the product labeling are subject to regulatory oversight, including the cleaning processes. These cleaning processes must be designed to result in robust and validatable cleaning. This presentation will discuss a comprehensive overview of the life-cycle approach to cleaning validation for product contact surfaces of equipment in the sunscreens and personal care facilities. The three phases of the life cycle approach: cleaning development, cleaning validation and cleaning monitoring will be discussed including how they contribute to a compliant, and evolving cleaning program. The cleaning development design phase takes the cleaning assessment and develops a protocol describing any needed cleaning development activities including defining critical quality attributes (CQA) and critical process parameters (CPP) for the proposed cleaning procedure. The cleaning validation phase will provide documented evidence through an executed protocol which provides a high degree of assurance that a cleaning procedure consistently removes residues to pre-determined acceptable levels and the cleaning procedure process capability parameters can be established to provide ongoing assurance that the cleaning procedure remains in a state of control. The cleaning monitoring phase will provide documented evidence that the validated cleaning program remains in a state of control. Annual document review including non-conformances, and change control evaluate whether the cleaning procedure under review continues to be effective and has not undergone changes that might impact the validated state.

Dijana Hadziselimovic is a technical services laboratory specialist for the Life Sciences Division of STERIS (Mentor, Ohio). She provides technical support in the area process and research cleaners, conducts laboratory experiments to recommend cleaning procedures and field support. Dijana has over 20 years of laboratory experience in the pharmaceutical and biotech industries. She holds a B. A. in Chemistry from the University of Missouri, St. Louis (UMSL). She has served as a St. Louis Society of Cosmetic Chemists Chair . Elect in 2016 and Chair in 2017. She is still continually active with the organization. She can be reached at dijana_hadziselimovic@steris.com

Empower UV Protection with a Natural Shield – looking at next generation sustainable film former solutions

Presented by: Anna Howe (Evonik Nutrition & Care)

Abstract: The global sun care market is expected to grow 5.6% annually from 2022 - 2027. In this market, we are seeing rising trend towards sustainability – ecofriendly, planet health, upcycled formula and eco claims. Consumers want their sunscreen to have protection, enjoyable sensory with long-lasting effectiveness with natural and safe ingredients with a focus on planet health. One key area for product design is the use of film formers to ensure water resistance. Conventional film formers use fossil-based feedstocks which are not biodegradable and affect nitrifying bacteria. In our paper, we will look at the proposed working mechanism of film formers for water resistance boosting. We will then compare the water resistance performance of non-biodegradable market standards to biodegradable sustainable options. Protect and care with responsibility.

Anna Howe is an Applied Technology Manager, North America, for the Personal Care business of Evonik Corporation at the Business & Innovation Center in Richmond, Virginia. Anna's responsibility focuses on new product developments, formulations, performance evaluations, test method development for claims, and technical services.

Anna earned a Bachelor of Science in Chemistry at Virginia Polytechnic Institute & State University in Blacksburg, VA. Anna joined the Personal Care Group of Evonik Corp. in 1997. Prior to joining Evonik, Anna held positions of increasing responsibility at Inolex Chemical Company, Rhône-Poulenc (Rhodia) and Alcolac Chemical Corporation. Further, Anna is a member of the Society of Cosmetic Chemists and holds several application patents as well as authored several scientific papers in the personal care arena.

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Session C

Global Disharmonization of SPF Test Methods: FDA, ISO 24444:2019, and ISO 24444:2010
Presented by: Jeff Field (Florida Skincare Testing, Inc.)
Abstract: Disharmonization between FDA and ISO methods and even ISO 24444:2019 vs ISO 24444:2010, coupled with regulatory and market pressures, makes it increasingly difficult to create globally compliant SPF formulations. Changes to testing methodologies coupled with regulatory and market pressures are making it increasingly difficult to create globally compliant SPF formulations. Formulators previously would get similar SPF results when they tested a product using FDA or ISO methods which allowed a formulation to be similarly labeled in various geographies. The harmony that once existed between FDA and ISO based SPF testing methods has significantly diverged since the ISO 24444 2019 revision. This presentation will highlight some of the changes in the ISO 24444 method compared to the previous version and how they compare to the current FDA test method and why differences in SPF results can be observed between these methods.

Jeffrey Field received his B.S. in Biochemistry from the University of Florida and has been in the personal care industry for over 15 years. He has held R&D roles for companies such as Hawaiian Tropic and Novamin Technology (a GSK company). He has also spent time on the sales and distribution side of the industry where he held the role of Technical Director and Consumer Care Sales Manager. He recently moved over to Florida Skincare Testing/IMS as the Chief Technical Officer.

He has extensive experience and knowledge in Sun Care, Skin Care and Oral Care Product Development and has successfully brought to market a number of global consumer products. He also holds a US patent in oral care technology. He is a longstanding member of the FLSCC and has previously been a speaker at two sunscreen symposium events.

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Overview of latest ISO Sun Protection test methods

Presented by: Sébastien Miska (Helioscreen Cosmetic Science)

Abstract: Nowadays, the harmful effects of sun light on human skin are well known leading to develop sunscreen products with UVB and UVA protection all over the world. For this purpose, a compliance to international official methods is mandatory for reliable sun protection results including SPF (Sun Protection Factor), UVAPF (UVA Protection Factor), CW (Critical Wavelength), Water Resistance, etc. In this way, the International Standardization Organization (ISO) developed and published several in vivo and in vitro methods with systematic review including the in vivo SPF (ISO 24444:2019), the in vivo UVAPF (ISO 24442:2022), the in vivo Water Resistance (ISO 16217:2020 & ISO 18861:2020), the in vitro UVAPF (ISO 24443:2021). Moreover, two projects are currently under development with the in vitro SPF (ISO/CD 23675) and the in vivo/in vitro HDRS SPF (ISO/CD 23698). Therefore, an overview of all norms with specifications of the latest versions including the futures alternatives SPF international method according to the projects draft ISO/CD 23675 and ISO/CD 23698 will be presented.

Mr. Sébastien MIKSA started his career at L'Oréal in the services of R&I Lipsticks, Foundation and Photo-protection and he is currently the General Manager at HelioScreen, an international company dedicated to in vitro sunscreen testing. Involved in sun protection evaluation for more than 10 years (SPF, UVAPF, Critical Wavelength, etc.), he acquired a large knowledge in this field and developed several innovations such as robotic spreading, reproducible sandblasted PMMA plates SB6, in vitro methods for Blue Light, Infrared, SPF multi-substrates approach, etc. In addition, he is the Project Leader of the ISO 24443 revision and an active member of AFNOR/S91KGT07, CEN/TC392/WG004 - Efficacy including sun protection products, ISO/TC217/WG7 - Sun Protection test methods, FEBEA/GT - Quality of efficacy measures of sun protection products, BIPEA/Technical Group - Sun protection products and in the Editorial Board of the International Journal of Cosmetic Science.

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Outdoor SPF testing – What can we learn?

Presented by: Uli Osterwalder (Consultant, Sun Protection Faciliator GmbH, ISO techcnial committee TC 217 Cosmetics Chair)

Abstract: "Outdoor SPF testing" had its origins in Schulze's first definition of SPF. It is now being revisited to measure sun protection performance under more realistic conditions. It has been known for some time that the minimal erythema dose (MED), i.e. the endpoint in the SPF determination is not the same when irradiated with a laboratory lamp as it is outdoors in the sun. It has been shown theoretically and practically that the SPF measured outdoors does not reach the high levels we know from the ISO and the FDA standard in the laboratory. Does this mean we should go back to outdoor SPF testing? I do not think so; as a routine method, it would simply be too complicated. But we should still learn from the outdoor testing results that has been published in the recent years. Neither the current SPF gold standards, ISO 24444:2019 or FDA 2011, nor any of the upcoming alternative methods, such as ISO/CD 23675 or ISO/CD 23698, can accurately reflect reality. No standard does. This means that we have to think about revisiting the interpretation of the results of these standards, e.g. UVA protection being at least 1/3 of the SPF may be more crucial than the absolute SPF value. Making it higher than 1/3 is possible, but is also a real challenge for the formulator, especially in the US.

Uli Osterwalder studied chemical engineering at ETH Zurich, Switzerland and at the University of Houston in Houston, Texas. He joined Ciba-Geigy in Basel. At Ciba Specialty Chemicals, he helped establish new business areas in Fabric Care and Personal Care. After the acquisition by BASF SE in 2009, he served in the Sun Care business, ending his corporate career at DSM back in Basel. In 2018, he founded Sun Protection Facilitator GmbH, committed to further improvements in sun protection. Uli Osterwalder has been working for ISO since 2006 and is chairing the Technical Committee for Cosmetics (ISO TC 217) since 2020. He is author of numerous scientific articles and book chapters and is also co-editor of a series of papers on Challenges in Sun Protection in Current Problems in Dermatology, published by KARGER, Basel in 2021.

Session D

Utilizing Active Ingredients to Elevate Sunscreens to the Next Generation

Presented by: Stephanie Hochstetler (Evonik Nutrition & Care)

Abstract: Sunscreen is a crucial part of a skincare routine to protect the skin from UV radiation. As consumers continue to strive for skin-minimalism, the promotion of hybrid cosmetics has begun blurring the lines between skin care and sun care. According to Mintel in 2021, in the United Kingdom, >33% of users of sunscreen (33%), after sun (39%), and self-tan (38%) reported that added skincare benefits were important when buying products. Paving the way for a 2022 report, global skincare and color cosmetic launches with the incorporation of SPF comprised of 34% foundations/fluid illuminators and 8% face/neck care. We continue to see the consumer desire for hybrid cosmetics, blending skincare and sunscreen into one. The efficacy of sunscreen can be improved by incorporating active ingredients such as ceramides, peptides, vitamins, and botanical extracts that will work together with traditional sunscreen components. In this paper, we will explore the enhanced skin benefits the addition of actives can provide for consumers. In addition to the intrinsic UV protection from sunscreen, specific hero ingredients can protect DNA on a molecular level from UV, increase the hydration of the skin through the strengthening of the stratum corneum, and mitigate damage induced from free radicals.

Stephanie Hochstetler is an Applied Technology Manager for Active Ingredients at Evonik Corporation in Richmond Virginia. She holds a Bachelor of Science degree in Chemistry from Western Carolina University and an M.S. in Chemistry from the University of North Carolina at Charlotte where her research centered around Organometallic synthesis. She has worked as a synthetic chemist for 15 years at multiple CRO's, advancing to Senior Scientist prior to joining Evonik. Stephanie joined Evonik as a synthetic chemist performing oleochemical synthesis. After several years, she transitioned to an applied innovation role involving new product development and technical services for Home Care and I&I applications. Most recently, she has transitioned to working with Evonik's Active Ingredients team for Person.

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Impact of UV filters on the formation of ROS and the balance of the skin microbiome
Presented by: Marek Busch (Symrise)
Abstract: The health and beauty benefits of applying sunscreens daily has been well established. Protecting your skin from UV rays has so many benefits; preventing premature aging of the skin, helping to maintain an even skin tone and most importantly lowering the risk of skin cancer just to name a few. In the past few years, as the FDA informed the industry that many of our sunscreen filters needed more testing to regain their GRASE status the question of the safety of UV filters has come under more scrutiny than ever before. As most typical products on the market contains a high percentage of UV filters, it is important to reassure consumers that the UV filters do not have a negative effect on the skin, particularly daily users of SPF products. In this presentation, we will look at the effect of UV filters on two key areas; ROS generation as well as the skin's microbiome. An in vivo study was designed that mimicked a typical 14 day vacation with three daily applications of different UV filter combinations. The results impressively show that the natural skin microbiome does not change in the presence of the UV filters. As a consequence we provide effective protection against UV radiation while maintaining the natural microbiome of the skin protecting us from biological threats. Second we could show with electron magnetic resonance (EMR), that the UV filters did not form any ROS under normal light conditions and generate only minor amounts of ROS after UV-irradiation. Altogether we were able to show the lack of noxal capacity of the depicted UV-filters. The UV-filters neither were disturbing the microbiome, nor generating relevant amounts of ROS.

Marek Busch is a global project manager in the sun protection business unit at Symrise AG. Marek started his career at Symrise by evaluating the impact of naturally based polymers in sun care during his bachelors thesis. After graduation, he subsequently began working as an application technologist in the field of cosmetic formulations he is now in his current role managing new development projects and bringing innovative raw materials for the sun care category to the personal care market with Symrise. Marek has an applied bachelor's degree (BASc) in cosmetics and detergents from the University of Applied Sciences and Arts in Nordrhein-Westfalen, Germany.

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Session E

Overview of the U.S. Cosmetics Regulatory Framework

Presented by: Linda M. Katz, M.D., M.P.H., F.A.C.P., F.A.C.R., Director, Office of Cosmetics and Colors, CFSAN, (FDA)

Abstract: Cosmetic products in the U.S. are regulated by the Food and Drug Administration (FDA). Although FDA does not have the authority to pre-approve cosmetic products or their ingredients, except color additives, FDA can take enforcement action on cosmetic products shown to be adulterated and/or misbranded. The Federal Food, Drug, and Cosmetic Act has provided for FDA's regulation of cosmetics since 1938. The Modernization of Cosmetics Regulation Act (MoCRA), enacted in December of 2022, significantly expanded and reformed regulations overseeing cosmetics in the U.S. MoCRA is the result of more than a decade of discussions with stakeholders. Included in the MoCRA provisions are facility registration and product listing, mandatory recall authority, reporting of serious adverse events, a requirement that FDA propose a rule for good manufacturing practices, etc. This presentation will provide an overview of cosmetics regulations including the major provisions of MoCRA and examples of ongoing work that supports the mission of the FDA to protect public health.

Dr. Linda M. Katz is the Director of the Office of Cosmetics and Colors (OCAC) at the Center for Food Safety and Applied Nutrition (CFSAN), which regulates cosmetics and certifies colors used in foods, cosmetics, drugs, and devices. Dr. Katz joined FDA in 1989 in the Center for Drug Evaluation and Research (CDER) first as a primary medical officer and later as Team Leader and Acting Director of the Pilot Drug Evaluation Staff which reviewed anti-rheumatic drugs, anesthetic agents, and drugs of abuse. Her subsequent appointments in CDER included: Deputy Director of the Division of Dermatologic and Dental Drug Products and Deputy Director of the Division of Over-the-Counter Drug Products. In 2002, Dr. Katz joined CFSAN in her present position and additionally served 10 years as the Acting Chief Medical Officer. In her current role as OCAC Office Director, Dr. Katz is responsible for establishing the strategic plans for OCAC and directing regulatory and research activities. She also is responsible for liaising with industry, nongovernmental organizations, consumers, stakeholder groups, and national and international regulators on policy and research related issues. She is recognized nationally and internationally for cosmetic initiatives involving harmonization, safety, and legislative activities. Dr. Katz received her MD from the University of Connecticut School of Medicine, her MPH in Epidemiology from the University of Michigan School of Public Health, and her BA in Biology from the University of Pennsylvania. She did her internship and residency in Internal Medicine and fellowship in Rheumatology at the George Washington Medical Center. Dr. Katz is an elected Fellow in the American College of Physicians as well as a Fellow in the American College of Rheumatology. In addition, Dr. Katz has taught at Walter Reed Army Medical Center and the Uniformed Services University of the Health Sciences, and has numerous publications in the scientific and medical literature.

Regulatory overview under an NDA process versus a monograph process, and clinical pharmacology assessments for topical sunscreens

Presented by: Chinmay Shukla (FDA, Office of Clinical Pharmacology)

Abstract: This presentation will provide a high level overview of regulations under an NDA process versus a monograph process which would be applicable to sunscreens. Further, the presentation will be designed to delve into details with regards to Clinical Pharmacology assessments for topical sunscreens. Core concepts and the design of a maximal usage study (MUsT) as well as how the pharmacokinetic (PK) data obtained in the MUsT are used to inform the systemic safety of the sunscreen product will be covered in detail. Several examples from NDA reviews of topical drug products will be shared to enhance understanding of the building blocks of MUsT. This presentation will also provide an overview on in-vitro drug permeation study (IVPT) and dermal modeling and simulation approaches. One of the aims of this presentation would be to provide background to help segway into other topics which will be presented by FDA speakers and will be more focused on the clinical sunscreen MUsT study, modeling and simulation approaches and IVPT.

Chinmay Shukla, Ph.D., is a Clinical Pharmacology Team Leader of the dermatology, dental, sunscreen and topical health care antiseptic review teams with Office of Clinical Pharmacology at U.S. Food and Drug Administration (FDA).

His work involves review of clinical pharmacology information submitted to support approval of New Drug Applications (NDAs), Biologics License Applications (BLAs) and OTC Monograph qualifications. He received his Bachelor of Pharmacy from Mumbai University, India and Master and Doctorate in Pharmaceutical Sciences from Long Island University, New York.

His research interests are design of clinical pharmacology studies under maximal use conditions for topical dermatological products, dermal microdialysis and transdermal drug delivery. He has published several research papers in peer reviewed journals and has also coauthored a book chapter addressing the regulatory aspects of microdialysis. He serves as a reviewer for several scientific journals and is also currently serving as a Scientific Advisor to the Editor of Journal of Pharmaceutical Sciences.

With American Association of Pharmaceutical Sciences (AAPS), he served as the Secretary and Treasurer of Pharmacokinetics Pharmacodynamics Drug Metabolism (PPDM) Section and also served as a Chair of the Microdialysis Focus Group for 2 years.

In 2012, he received FDA Division of Clinical Pharmacology III Award for Outstanding Performance as a Clinical Pharmacology Reviewer. In 2014, he received the prestigious FDA Outstanding Service Award for consistently delivering excellent clinical pharmacology reviews and demonstrating outstanding leadership and outreach. In the same year, he was also recognized for his contributions to the Pediatric Bone Health Working Group by the Commissioner of FDA. In 2015 he was awarded the AAPS PPDM section award for outstanding service and leadership. In 2015, 2019 and 2020, he was awarded the FDA Division of Dermatology and Dental Products (DDDP) “Out of the Box Peer Recognition Award” for his outstanding contribution in the review of NDAs and BLAs.

Unraveling the current and future changes in the nano-regulatory landscape in Europe
Presented by: Jeroen van den Bosch (Uviva Technologies)
Abstract: "Nano" is probably one of the most talked about regulatory topics in our industry of the past decade. It continues to get attention from consumers, boasted by platforms and apps that try to educate that "nano is unsafe", while at the same time "nano" enables the creation of mineral-based sunscreens that are more inclusive across skin types and tones. Industry professionals are faced with constantly changing regulatory landscape related to "nano". The 'nano' discussion seems to be predominantly driven by Europe where multiple definitions of a "nanomaterial" exist, each of them different from another and each serving a different purpose. These include the pan-European horizontal definition, Cosmetics regulation, the infamous 'French Decree' and recent actions of the DGCCRF (French authorities for consumer protection). Furthermore, the nanodefinition in the EU Cosmetics Regulations is being updated and is expected to come into force in 2024/2025. This presentation aims at provide clarity on the different nano definitions in Europe and what the future expected changes of the Cosmetics Regulations will be. Zinc oxide will be used as a case study to explain and explore the different interpretations and what the future implications of the new nanodefinitions in Europe will be.

Jeroen van den Bosch has been involved in the development of ultrafine zinc oxide products, applications and regulatory approvals for close to 25 years. He started his career in an R&D capacity at Umicore where he focused on the development of a range of zinc oxide products for sunscreens and industrial applications and the development of dispersion and particle sizing techniques for nano-sized materials. From R&D he moved into various business development roles with a focus on sunscreen applications and has been responsible for the growth and development of what later became EverCare and is now heading up Uviva technologies.

Jeroen was one of the driving forces in the Cosmetics Europe consortium responsible for the approval of nanoform zinc oxide as UV filter in Europe back in 2012 and has been involved in various nano-related discussions and working groups at European level.

Next New US Sunscreen Active? Status of US FDA GRASE Determination for Bemotrizinol
Presented by: Carl D'Ruiz (dsm-firmenich)
Abstract: No new UV filters have been added to FDA's OTC sunscreen drug monograph in over 20 years. This situation severely limits broadening the selection of sunscreen products that help protect Americans from skin cancer and the harmful effects of overexposure to the sun. A generally recognized as safe and effective (GRASE) determination is being sought by DSM for the inclusion of a new broad-spectrum, stable UVA-B filter sunscreen active ingredient called Bemotrizinol (BEMT) 6% on FDA's OTC Sunscreen Monograph. BEMT represents the first new sunscreen active ingredient to be evaluated under FDA's revised GRASE and new Maximum Usage Trial (MUsT) testing guidelines for OTC substances. All FDA required clinical pharmacokinetic (PK), human dermal safety, nonclinical and efficacy studies for BEMT have been completed. The results of these studies indicate that maximal topical applications of 6% BEMT are safe and do not contribute to meaningful systemic exposure. As such, it is expected that this data will inform and support an FDA GRASE determination for BEMT. This presentation will review the results of our findings to date and provide an update on when BEMT might be available for use for sunscreens in the US.

Carl D'Ruiz is the Senior Manager of Regulatory and Scientific Affairs at DSM. He has 25+ years' experience in providing strategic scientific, regulatory and pre-market approval advice and direction for the commercialization and marketing of OTC drug, cosmetic and personal care products, ingredients and brands.

He is currently Chair of PCPC's Sunscreen Consortium, championing industry's efforts to substantiate the safety and efficacy of existing sunscreens and paving the innovation path for the inclusion of new sunscreen ingredients under FDA's sunscreen monograph.

He has a master's from Yale and a bachelors from Fordham and has executive business certifications in negotiations and marketing from The Darden and Wharton Business Schools. He is a member of the Society of Toxicology, Photodermatology Society and Society for Cosmetic Chemists.

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2023

Session F

Sunscreen Consortium: Latest News
Presented by: Alexandra Kowcz (Personal Care Products Council)
Abstract: The Personal Care Products Council (PCPC) established a Sunscreen Consortium of member companies in late 2019 to address the U.S. Food and Drug Administration's (FDA) request for additional safety data on seven sunscreen active ingredients proposed as GRASE (Generally Recognized as Safe and Effective) Category III under the 2019 Tentative Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use. The Consortium is supporting seven sunscreen active ingredients: Avobenzone, Ensulizole, Homosalate, Octinoxate, Octisalate, Octocrylene, and Oxybenzone. Since the inception of the Consortium, several teams were organized to address the clinical, non-clinical, and formulation aspects of the identified work streams. The Consortium developed several unique, single active formulations in four different product forms as recommended by the FDA. These product formulations were developed solely for evaluation in clinical human pharmacokinetic studies (i.e., Maximal Usage Trials (MUsT)). The FDA requested that the formulations be "market image" products, representative of commonly marketed US sunscreen products with the highest potential for absorption of each sunscreen active ingredient. The Consortium presented the proposed study formulations to be used in the in vitro permeation tests (IVPTs) and MUsTs for review and comment by the FDA. The main focus of the presentation will be a review of the current regulatory landscape, the technical workstreams, proposed approaches and FDA communications.

Alexandra Kowcz is currently the Chief Scientist for the Personal Care Products Council. Most recently, she served as Vice President of US Research & Development at Beiersdorf, Inc. Her various responsibilities included the management of US product development, medical and scientific affairs, clinical testing, product safety testing, analytical testing, microbiology, regulatory, claims substantiation, chemical processing and new technology research.

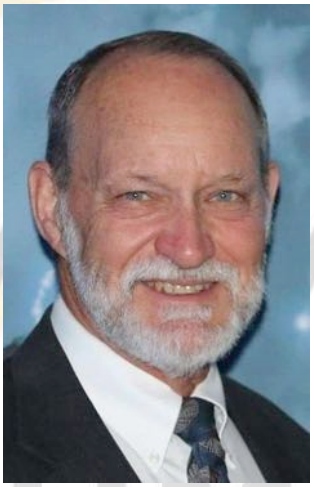
She has held a number of R&D positions of increasing responsibility at Procter & Gamble, Bristol Myers International, Richardson-Vicks, Clairol, Inc., Centerchem, Rhone-Poulenc Rorer and most recently Beiersdorf. Additionally, she is the author and co-author of numerous patents, publications, chapters, and scientific poster presentations.

She holds degrees in Biology and Chemistry from Fairfield University and completed her graduate studies at the University of Connecticut. She continues to be an active member of the American Academy of Dermatology, the Society of Cosmetic Chemists and the Photodermatology Society.

Blue Light Protection and Testing

Presented by: Dennis Lott (Lott Research Inc, & Florida Skincare Testing, Inc.)

Abstract: Today, much is said about the need for Blue Light Protection. Products can be found on the shelves promising Blue Light Protection. This talk will explain Blue Light, how it can be tested, claims as to Blue Light Protection, and some suggestions as to how to formulate products offering this protection. And whereas most of the discussion concerning Blue Light revolves around the use of cellular phones, computer screens, and other mobile devices it should not be forgotten that Natural Sunlight is a huge source of Blue Light. It will be discussed how protection in the entire Visible Light spectra, including blue Light, will make Suncare products more protective. Mid day summer Natural Sunlight sun contains a tremendous amount of visible light energy and if Suncare Products are to offer the protection promised by the SPF claimed they must offer some protection in this spectra as well as protection in the Ultraviolet spectra.



Dennis Lott has over 50 years in pharmaceutical and cosmetic industry. He has 30 plus years in major companies marketing Suncare, including the Hawaiian Tropic, Banana Boat and Coppertone brands. He has worked in more than one company in Private Label and Contract manufacturing of pharmaceutical and cosmetic products with a heavy emphasis in Suncare. His career includes being involved in all aspects of pharmaceutical and cosmetic companies including R&D, Quality, Manufacturing, and Management. He has developed literally hundreds of products and authored or co-authored several patents, with many in Suncare. For approximately 8 years he represented Ireland on the expert sunscreen COLIPA committee. His speaking experiences include multiple stints at the Sunscreen Symposium.

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Environmental Impact of Currently Marketed Sunscreens and Potential Human Impacts of Changes in Sunscreen Usage

Presented by: Dr. Carys Mitchelmore, Professor and Interim Director at the University of Maryland Center for Environmental Science, Chesapeake Biological Laboratory

Abstract: Concerns have been raised about the potential toxicity of sunscreens to a variety of marine and freshwater aquatic organisms, particularly corals. At the same time, there are concerns that people will use less sunscreen as a result of environmental concerns. An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine reviewed the state of the science on the use of the active ingredients in sunscreens (UV filters) currently marketed in the United States. This review was conducted to provide information useful for future application in ecological risk assessments, by reviewing information on UV filter fates, exposure, and effects. The report also includes review of the potential human impacts that could result from changes in availability of certain UV filters for use in sunscreens, in order to inform management of both human and ecosystem health. This presentation will describe the committee's findings, conclusions, and recommendations related to this issue, as well as the priority knowledge gaps to fill to inform higher tiered risk assessments. The presentation will include discussion of the intersection of aquatic chemistry, ecotoxicology, ecology, and epidemiology to understanding the potential for risks from UV filters and implications to human health for changes in sunscreen use. An EPA workshop to help identify research needs took place in early 2023 and some highlights from that workshop will be presented along with related activities.

Dr. Carys L. Mitchelmore is a Professor and Interim Director at the University of Maryland Center for Environmental Science, Chesapeake Biological Laboratory in Solomons, Maryland. Her expertise is in environmental health and toxicology spanning both fundamental and applied questions concerning the exposure, fate and effects of biological, physical and, chemical pollutants. Research is directed towards the detection of chemical contaminants in various environmental matrices and understanding their toxicity and implications to organism and ecosystem health. Her research includes toxicity testing and contaminant monitoring for application to risk assessment, regulation and management activities to provide solutions to environmental problems.

Dr. Mitchelmore is heavily invested in integrating scientific research for the management and regulatory communities serving on numerous International and National science advisory groups and as an environmental toxicologist including five National Academies of Science, Engineering, and Medicine committees, including the 2022 "Review of Fate, Exposure, and Effects of Sunscreens in Aquatic Environments and Implications for Sunscreen Usage and Human Health". She has also provided testimony at Federal, State and local hearings and served as an expert witness in numerous court with respect to aquatic toxicity, hazard assessment and environmental regulations and management.

Moderators

Thursday, September 14th 2023

Krupa Koestline Entrepreneur and Cosmetic Chemist Krupa Koestline merges her background in biology, biochemistry, and biotechnology with her lifelong practice of Ayurveda to create new concepts and innovations in the beauty space. Starting her 10+ year career at Estee Lauder and Neutrogena, Krupa pivoted her focus to creating safer products after seeing firsthand the impact of potentially harmful ingredients used in personal care products. As the founder of KKT Consultants, Krupa understands the importance of innovation in today's competitive and saturated beauty market. As an expert resource, Krupa strives to dispel myths and misinformation around clean beauty, to see through convenient marketing tactics and buzzwords, and forecast insights into the next trendy ingredient.

Friday, September 15th 2023

Scott Cardinali is currently the Business Development Director for Croda's Beauty Care SBU, based in Princeton, NJ. He is responsible for coordinating Croda's sales development effort in initiatives to identify emerging and unmet customer needs and to recommend and deliver appropriate technology solutions for the photoprotection/sun care, skin care, and hair care markets. Since joining Croda in 2008, Scott has also functioned as the Hair Care Applications Manager, Export Sales Manager, North American Technical Business Development Manager, and Hair Care Business Director at Croda. Scott has 39 years of broad industry experience, having also worked in R&D and commercial positions at National Starch and Chemical, Kline & Co., and Unilever Research.

He has a B.A. in Chemistry from Cornell University, and a M.B.A. in marketing from New York University.

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