COSMECEUTICAL SKIN CARE PRODUCTS
CLAIMS & SUBSTANTIATION

Wen Schroeder, RAC
SEKI Cosmeceuticals LLC.

ABSTRACT
The global demand for cosmeceuticals continues at an explosive rate. Discovery of new anti-aging medical interventions, coupled with new functional active ingredients, provide a fertile innovation ground for product developers. This presentation provides a practical guide for the development of product labels, claims and advertising that complies with the regulatory requirements.

SPEAKER BIO
Wen Schroeder, President of SEKI Cosmeceuticals, LLC., is a consultant in global regulatory affairs, chemical regulations & management, and cosmetic formulation & product development. She has over 20 years of personal care product development and pharmaceutical research experience with 30+ US patents and numerous foreign filings.

Wen has degrees in Pharmaceutical & Environmental Science specializing in Environmental Toxicology & Law. She is an RAC-certified Regulatory Affairs professional experienced in the regulations of cosmetics, food, OTC drugs, and chemical management. Wen served on the Personal Care Products Council's Air Quality Committee and is active in the Society of Cosmetic Chemists, the Drug Information Network, and the Regulatory Affairs Professional Society. She is a scientific advisor to the Taiwan Government External Trade Development Council and serves as key expert for the ASEAN-EU Programme for Regional Integration Support in the areas of cosmetic & pharmaceutical GMP and testing.

Wen is also an author of published articles & textbooks on cosmetic science & regulatory affairs. She teaches at the Center for Professional Advancement and frequently lectures on topics including “REACH”, “GHS”, “Global Chemical Control & Management”, “Cosmetic Regulations”, “Biocides, Plant Protectants, Preservatives & Pesticides”, “Food Additives, Supplements & Herbal Medicines”, and “Sunscreen Technology & Product Development”.

The Speed Networking Session is back and scheduled to take place prior to the speaker presentation this meeting, so bring your business cards and get ready to meet new people.

2009 Attendance Contest - Don't Forget!
All members who attend every meeting through November will be eligible for big prizes! Game cards were handed out at the January meeting. All you have to do is show up to all the regular meetings with your card - Jan, Feb, Mar, Apr, May, Sep, and Nov. If you complete your game card at the November meeting, you win a prize! Additionally, if you make all of the regular meetings there will be bonus prizes for the mid-year meeting in June, the golf outing in July, and the technical symposium in October.
As the saying goes, March comes in like a lion and leaves like a lamb. Since this is written before the end of March, I can only attest to the veracity of the lion-like entrance and hope for a lamb-like exit. After a few more fits and starts the real spring should be under way soon (I hope).

I hope everyone enjoyed another informative meeting with excellent food at our March meeting. Obviously it's what the committee members strive for each month and I think we delivered another great experience. The Parthenon is a member favorite and we were happy to return there this year. Dr. He gave an excellent talk about using material science to inform a number of formulation criteria, which was fascinating. It was great seeing numbers attached to factors like tackiness and how quickly aerosolized sprays reach equilibrium. These measurements are key to fast, efficient formula optimization.

I'm naturally looking forward to seeing you all at our April meeting. We'll be returning to Bohemian Crystal, which went over big last year due to their fine food and all-night open bar. Our speaker will be Wes Schroeder on the subject of cosmaceutical claims and substantiation. This is a very timely topic, with more and more heavy-hitting and confusing claims coming onto the market. Can you compete? Should you try? As usual, we'll have our ongoing attendance, raffle, and trivia contests.

Coming in April we also have our bi-annual Midwest Tutorial. This is a Midwest Chapter sponsored CEP-type course offered FREE to our members. This year's course is called "Expanding Your Use of the Internet to Obtain Valuable Technical and Marketing Information" and will be presented by Chicago's own Perry Romanowski (who also happens to be our SCC Area II Director, blogger, and juggler extraordinaire). With the way we take in information changing so quickly, this will be a great asset to any formulator. To illustrate, the Microsoft Word 2003 which I'm writing this on doesn't even recognize the word blogger, which is now ubiquitous. Attendance is limited, so be sure to register before all the available seats are gone! Due to high demand for these free courses, we do ask for a $50 deposit that will be refunded at the door.

SCC fun fact for the month: The Florida Chapter has the highest "per capita" of Emeritus & Honorary Members at 72%. Our chapter is in second with over 9%.

Don't forget to visit our website regularly, particularly the events page so that you can keep up to date on all the great events we'll be sponsoring throughout the summer. Finally, remember I'm available any time at chair@midwestsc.org
Next Chapter Meeting Venue

April 14th, 2009
MWSCC Chapter Meeting

Bohemian Crystal Restaurant
639 N. Blackhawk Drive
Westmont, IL 60559
(630) 789-1981

Schedule
5:15  Board Meeting
5:30  Social Hour
    (Open Bar)
6:30  Speaker
7:30  Dinner

Directions
From the West:
88 E to Warrenville Road E
Warrenville Rd becomes Ogden Ave E
Left on Blackhawk Drive

From the North/South/East:
294 to Ogden Ave West
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Emeritus Corner

Congratulations to the New Midwest Chapter Emeritus Members!
The Board of Directors have elected three Midwest Chapter members to Emeritus status:

August E. Fiebig
Gene Frank
Rosemary Gaudreault

2009 Midwest SCC Golf Outing
Tuesday July 14th at Carriage Greens Country Club in Darien, IL. Check-in 10:30-11:45am
Shotgun start – Four Person Scramble format
Golfers $125.00 per player, Dinner only $40.00.
This includes 5 ½ hour golfing with cart, Lunch
Cookout, 2 hour Open Bar and after golf
Family-style dinner with awards and prizes.
For more details, see www.MidwestSCC.org

SCC Emeritus Member Maso Passes

“He was an amazing and generous mentor to many in the industry,” noted Nancy Allured.

Maso was an integral member of the SCC for over 50 years. He first joined the SCC in 1957 and since served in a number of roles from the constitution and bylaws committee member in 1970 to honorary chair of the 23rd IFSCC Congress in 2004. Although he served on many advising committees such as chairman of the board in 1968, Maso also took an active role in education. He taught cosmetic chemistry courses for the SCC, having most recently taught a cosmetic raw material course in 2005. He also served as a Continuing Education Program advisor.

Maso was the recipient of the Robert A. Kramer Lifetime Service Award in 2006. The award is given at the discretion of the board of directors to an individual who has given extraordinary service over the course of his or her membership.

Although his professional mark certainly will go down in history, many personally will remember him for his sense of humor, his kindness and his love for music as Maso played the harmonica for the SCC band, the Chemtones.

“We all have lost a good friend and exceptionally kind and knowledgeable person. I personally cherish many fond memories experiencing Henry’s wisdom, humor and skills in mentoring new entries into the cosmetic industry. He will be missed, but he established the “gold standard” for integrity and caring,” reflected Paul Thau.

Condolences can be sent to his wife, Joyce at 700 Hollinshead Spring Road; Apt. A106; Skillman NJ 08588

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March Dinner Meeting Photos

The winners give this dinner get's a definite thumbs up.

Ashraf and Rita team up for the trivia contest.

Look out behind you, Peggy!

Our newest member Matt Hepfinger REALLY enjoys his first meeting.

There's fish what in this tasty sauce?

There's room for one more!

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Keep Eating Bacon, For the Rabbit’s Sake
By
Michelle Piehl
MB Research Laboratories

Manufacturers of commercial products are required to evaluate each product’s potential for adverse health effects due to inadvertent exposure or misuse. One aspect of this product safety testing is ocular irritancy, damage, and damage reversibility, traditionally addressed with animal-based testing—the Draize rabbit eye test. Several aspects of this test have been criticized including subjectivity, over-estimation, and primarily, the use of live animals. There has been a trend toward the refinement, reduction, and replacement (3R’s) of animal-based toxicological testing. The European Union is preparing to ban animal testing for cosmetics and cosmetic ingredients. This ban has rendered the development of reliable non-animal based ocular irritation tests more critical than ever before. In addition, manufacturers face criticism from activist groups. Consumer product companies often find their products boycotted because they perform animal-based safety evaluations. Societal pressure like this has spurred the creation of cruelty-free products with special industry applied standards like the “Leaping Bunny” logo.

This ongoing need for animal-free testing has yielded non-animal ocular irritation assays such as the Bovine Corneal Opacity and Permeability (BCOP) and EpiOcular irritation assays. The BCOP is used to evaluate the ocular irritancy potential of products exposed to excised (ex vivo) intact bovine corneal tissues that would be discarded by abattoirs. The EpiOcular assay is conducted on in vitro human epithelial cultured tissue equivalents. Over 4000 BCOP assays have been performed at MB Research to date, in addition to over 1000 EpiOcular assays. This experience has allowed scientists at MB to address two critical gaps in available non-animal ocular irritation assays: (1) ocular damage reversibility (permanent vs. temporary damage) and (2) low-level ocular irritation upon multiple daily exposures to test materials.

The key to addressing both these testing gaps is an appropriate model test system: an ex vivo cornea, maintained in a physiologically normal state. Porcine corneas are readily available from abattoirs as waste products from the meat industry. Scientists at MB research have determined that porcine corneas are of the proper size and shape for long-term culturing -- up to four weeks. Some basic corneal anatomy and physiology provides basis for the success of our ex vivo porcine corneal culture system, patent pending by MB Research. The superficial cells of the cornea, the corneal epithelium, subsist in a steady state of turnover or healing, renewing the entire epithelial layer of cells every 7-10 days. This process includes the centripetal migration of epithelial cells from a peripheral stem cell population, followed by cellular proliferation and multi-layer adhesion of the new tissue. This underscores the importance of the availability of multiple layers of epithelial cells in the cornea and the peripheral populations of epithelial cells to the natural health of the cornea. Our intact ex vivo porcine corneal corneas are maintained in a special “air-interface” culture system. They are exposed to culture medium nutrients through the agar gel on the internal corneal surface (see image above) and air on the external, superficial surface -- similar to eyes in a living organism. This natural culture system is the key to both our cultured porcine corneal assays at MB Research.

We have developed an alternative ocular damage reversibility assay: Porcine Corneal Ocular Reversibility Assay (PorCORA). PorCORA measures corneal damage and recovery for extended time periods using cultured porcine corneas. Test materials are dosed directly onto the corneal surface (see image above), and tissue damage and recovery is assessed by sodium fluorescein (NaFl) retention in the same corneas over time (21 days; see image below). We have confirmed that NaFl retention and corneal recovery in the PorCORA assay is indicative of actual tissue damage via several approaches. Both fluorescence and reflective confocal microscopy confirm damage indicated by fluorescein retention in the cultured corneas. In addition, we have shown histological evidence that also correlates well with NaFl staining in the PorCORA assay. Overall, PorCORA is predictive and representative of corneal tissue damage and recovery.

Continued on Page 7
Recently, we conducted a 32-reference chemical validation including chemicals from the following classes: acetates, acids, alcohols, alkaloids, esters, hydrocarbons, inorganics, ketones, surfactants, and several solid compounds. PorCORA generates a mean “days to clear” endpoint when corneas no longer retain NaF stain (1-21 days). When compared to mean days to clear (corneal effects) from the ECETOC Eye Irritation Data Bank (historical Draize rabbit eye test data), the correlation coefficient is r = 0.84. PorCORA predicted 30 of 32 compounds regarding reversibility results (reversible vs. irreversible ocular damage) and PorCORA data correlated very well with ECETOC data, yielding 94% accuracy, 93% sensitivity, 94% specificity, 93% positive predictivity, and 94% negative predictivity. This validation, funded by a grant from the Society of Toxicology –Colgate-Palmolive Grant for Alternative Research, provided sufficient data to allow us to submit this assay to ECVM for consideration as an alternative ocular irritation assay. In recent correspondence with ECVM, we were notified that PorCORA will be on the 2009 work schedule and will be considered for full prospective validation after a comprehensive technical review. In addition, we have recently performed PorCORA with a test set of household products such as antibacterial hand soap and dishwashing liquid with very promising results. Overall, PorCORA provides reliable long-term healing and recovery information for ocular product exposure without the use of animals.

Our second porcine corneal assay, the Porcine Cornea Confocal (PorFocal) assay, is simply a result of the development of our porcine corneal culture system and PorCORA. While conducting preliminary experiments using confocal microscopy to characterize PorCORA, we noted that staining and quantification of dead cells in the corneal tissue was possible. Conceivably, very mild corneal damage can be quantified as the number of dead cells per volume of corneal tissue. To test the feasibility of the PorFocal assay, we treated cultured porcine corneas with Phosphate Buffered Saline (PBS) or 0.01% Benzalkonium Chloride (BAC). These two test materials are extremely mild and separation of the irritation potential of these two compounds would clearly demonstrate the resolution and sensitivity of PorFocal. The mean number of dead cells per tissue volume for PBS was 70 ± 16 (see image) and for BAK was 150 ± 15 (see image; p<0.001). The number of dead cells for 3% SDS were not quantified, however, it is clear that the number of dead cells per volume is appreciably greater. Clearly, the measure of cytotoxicity and irritability within a tissue by quantifying individual cell death cannot be improved upon regarding sensitivity and resolution. Due to the extreme sensitivity of the PorFocal assay, this assay is highly applicable to the function of categorizing low-level ocular irritants. Finally, this cell death measurement can be conducted on the corneas immediately upon termination of the corneal treatment period with results within 48 hours, a significant improvement on the turn-around time compared to classical histopathology. PorFocal has shown encouraging preliminary results, and we at MB are looking forward to further development of this assay for use with products such as cosmetics used daily in the eye area, eye drops, contact lens solutions, or ocular medications.

For more information regarding PorCORA or PorFocal, please contact: mpiehl@mbresearch.com or bkweder@mbresearch.com, or see our website: www.mbresearch.com.

Michelle Piehl, PhD, is a Research Scientist and Study Director of the PorCORA, PorFocal, and EpiOcular (and other Epi-tissue) assays at MB Research Laboratories located in Spinnerstown, PA (north of Philadelphia). MB Research Laboratories, a GLP contract research organization, has been conducting acute and sub-chronic toxicology and pharmacology studies since 1972. With expertise in many areas of in vivo and in vitro/ex vivo alternative testing, research, and safety evaluations, MB Research serves the testing needs of both government and industry and has been a leader in the field of in vitro and ex-vivo alternative assays.
It's time to shake off the cold weather blues and get ready for golf!

The St. Louis Chapter of the Society of Cosmetic Chemists (SCC) is holding their Fourth Annual Golf Tournament at The Orchards Golf Club in Belleville, IL on Friday, April 24, 2009. The format is a FOUR-PERSON scramble. The shotgun start time is 1:00 PM.

The fee for golfers is $80 per player and includes: Greens fees and cart, refreshments served during the tournament, and the award dinner immediately following the tournament. There will be prizes for first place, longest drive and closest to the pin on selected holes, and various door prizes.

To register, please contact Christopher Heisig at (314) 290-4747 or Maria Heintz (314) 725-2600, ext. 201 no later than than Friday, April 10th. Please make checks payable to “SCC - St. Louis Chapter.” If you have the members of your “four-some,” please forward that information upon registration. If you would like to donate to prizes, or would like to sponsor a hole ($75/hole), please let us know.

Hope to see you there!

Fun with Science - Invisible Eggs

By S. Tschantz

For some, spring is a time of year when the family gets together and makes colorful eggs that a certain industrious bunny hides throughout the house or out in the garden. Whether you follow that tradition or not, here's a fun kitchen chemistry project you can enjoy anytime of the year.

You'll need:
- A raw egg
- A glass or a clear dish
- White vinegar
- Patience

Procedure

Set the raw egg in the container and fill with white vinegar or acetic acid, so that the egg is completely covered in the liquid. Bubbles should start to form on the surface of the egg's shell almost immediately.

Let the egg sit for a week and then carefully take the egg out.

What happened? The acid dissolved the calcium carbonate that the shell is made out of, but will not break down the membrane, leaving the yolk intact and visible inside. There may be some chalky white residue left on the egg that you can gently scrape off, but be careful as the membrane is very delicate. You will notice that the egg has also swelled, due to osmosis.

How does the shell-less egg feel? Carefully pick it up to avoid popping it. You may want to make multiple eggs, one for each of the kids, so they can each try picking one up without the risk of it popping before they have the chance to try it.
EXPANDING YOUR USE OF THE INTERNET TO OBTAIN VALUABLE TECHNICAL AND MARKETING INFORMATION

by Perry Romanowski

Saturday, April 25th
9:00am – 3:00 PM
Includes free continental breakfast and lunch
Hilton Garden Inn - O'Hare
2930 S. River Rd
Des Plaines, IL 60018; Tel: 847-296-8900

The world is changing rapidly, at Internet Speed and companies that don't adapt and incorporate new technologies will be left behind by the ones that do. This must-attend talk will get propel your approach to your job, whether it be in technology, marketing or the business end of our industry.

Perry Romanowski has spent the last 17 years researching and developing products to solve consumer problems in the personal care and cosmetic industry. His primary focus has been on hair & hair related products. He is currently Vice President of Brains Publishing which specializes in science education. He has also worked for Alberto Culver most recently as a Senior Project Leader for Hair Care Innovation.

Perry received his B.S. in Chemistry from DePaul University and an M.S. in Biochemistry. He has written and edited numerous articles and books, taught the Beginning Cosmetic Chemistry continuing education class, and developed successful websites. His latest book project is the third edition of Beginning Cosmetic Chemistry published by Allured. Perry can be reached thorough his website ChemistsCorner.com where he is available for consulting about cosmetic formulating, testing, and Internet solutions.

Space is limited therefore everyone must provide a $50 deposit check, returned un-cashed to you on the day of the event, in order to reserve a seat. This helps our Chapter, who is covering all expenses, to maintain an accurate count and recover losses if members reserve and do not show up. All registrations with check must be received by April 15, 2009. All registrations will be confirmed by e-mail. Your personal check will be returned to you at the tutorial making the event free. Checks from NO-SHOWS will be cashed.

Cancellations need to be made by April 20, 2009 to receive full refund. Contact Rita Massinople at rmassinople@charkit.com or

To reserve a seat, please mail a personal check made out to the SCC Midwest Chapter for $50 to:

Attn: Rita Massinople
1471 Glenside Dr.
Bolingbrook, IL 60490.

Paypal will not be available for this event. Emeritus and unemployed members must also provide the deposit check. For additional information on the event, please visit our chapter website at www.midwestScc.org.

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2009 Midwest SCC Chapter Tutorial Registration Form

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SCC Continuing Education Program

The following courses are accepting registrations. For course outlines and the registration form, please go to www.sccenline.org.

PRESERVATIVES
Instructed by David Steinberg
April 7, 2009
Sheraton Newark Airport Hotel

ANTIPERSPIRANT AND DEODORANT TECHNOLOGY
Instructed by Phillip Klepak
April 16, 2009
Sheraton Newark Airport Hotel

BOTANICALS AND NATURAL INGREDIENTS
Instructed by Arthur Georgalas
May 5, 2009
Sheraton Newark Airport Hotel

Peggy Dorrance Bennett
Technical sales and marketing professional with 20 years domestic and international experience in the chemical industry, looking for full-time technical sales position in the Midwest.

Please contact for more details at medbennett@comcast.net, or 630-571-0973.

Denise J. Winkelmann
Chemist with 10 years of hair and skin care product development experience and 2 years of sales experience seeks product development or technical and inside sales support position.

Please call 630-588-8619 or email at: denisewink@hotmail.com.

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For more information, see http://midwestscoc.org/s/careers or contact Jennifer Baures, MBA at Jennifer.baures@pricelesspsps.com or 800-625-6414 ext.107

Formulation Chemist

Vi-Jon is a privately held Health & Beauty Care Company, serving retailers globally.

We currently have an opening for a Formulation Chemist within Vi-Jon's Research and Development Department at our Swan Drive location in Smyrna, Tennessee. The formulation chemist will be responsible for developing new personal care product formulas and reformulating and/or improving current formulas including active participation in pilot plant-scale up activities. This position works primarily with Marketing, Regulatory Affairs, and Product Development Personnel. A BS Chemistry or related science degree; or four years related experience and/or training; or equivalent combination of education and experience is required.

For more information, see http://midwestscoc.org/s/careers or contact Stephanie Pimmel at spimmel@vijon.com or 314-592-1481.

Technical Director Wanted

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