

Practical Protection

CONSUMERS AND COMPANIES ALIKE SEEK Milder, BUT EFFECTIVE PRESERVATION SYSTEMS FOR PERSONAL CARE AND HOUSEHOLD PRODUCTS.

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What lies beneath the lid?
Proper preservation can protect
moisturizers from developing mold.

NOTHING SAYS pretty like an eyeshadow in a cappuccino brown...with a touch of *Bacillus cereus*. Or what about a rich moisturizer with a hint of mold? It happens, especially if a formulator—or its contract manufacturing partner—isn't prudent when it comes to production, and more specifically, preservation.

But product preservation has been complicated in recent years by small, but very vocal, groups publically railing against the use of traditional technologies like parabens and phthalates.

"It's been a continuing challenge with all the blogs, e-news-blasts and other stories stimulating the public's perception (some science-based and many not science based) about the efficacy of chemical ingredients, including preservatives," said Kevin D. Sathre, vice president of sales at Coast Southwest, which works with global preservatives manufacturer Sharon Laboratories.

As a result, marketers and suppliers in the personal care industry are seeking natural, milder yet still effective preservative systems and technologies.

Leading preservatives suppliers are up for the challenge, offering a wide range of solutions that provide adequate protection and answer consumer demands.

"The rules of the game for preservation have been changing," noted Sathre. "Customers want milder formulations than previous formaldehyde donor or isothiazolinone chemistries. Preservatives now can be multifunctional or using nontraditional materials to create 'preservative free' blends that offer broad spectrum efficacy that meets the standards of micro challenge testing and shelf-life requirements."

Sharon Laboratories, for instance, has blends with caprylyl glycol and 1,2-hexylenediol, which are emollients and humectants that are also potentiators or boosters that increase the efficacy of the preservative blend, according to Sathre. Some blends have the traditional phenoxyethanol and benzyl alcohol preservatives but others contain non-traditional phenethyl alcohol or phenylpropanol. Sharomix HP, CPA and CPP, he said, can be considered "preservative-free" blends that provide broad-spectrum efficacy even though they are milder than traditional preservatives.

Sharon Biomix blends, which are paraben-free, formaldehyde-free, and halogen-free, offer all-natural broad spectrum preservatives with Pure I and II, but the company also offers "nature identical" with Biomix Free I and II and ECO, which conform to Ecocert standards, according to Sathre.

According to Sathre, when one customer that had tried many natural preservatives in their all-natural body care line opted for Biomix Pure I in a lotion and body wash, each product in the line passed microbiological challenge testing.

"The customer had a successful launch of the product line with confidence that he will not have any contamination issues," Sathre said.

Preservation and Certification

Phil Hindley, global marketing manager-preservation, Lonza Consumer Care, also addressed the shifting tide around preservation, including pressure companies face in meeting global standards.



Contaminated eyeshadows pose a risk to end users.

“The cosmetics market continues to shift toward a need for more natural and less controversial offerings, and Lonza Consumer Care recognizes that providing natural or nature-identical preservative systems is integral to this shift and to the growing demands being placed on raw material manufacturers. In many markets we continue to see the need for more preservative blends that are natural or nature-identical, organic, Ecocert and/or Cosmo-approved.”

At In-Cosmetics in Barcelona, Lonza Consumer Care rolled out the “next-generation” of Geogard preservatives, specifically Geogard LSA, which is billed as a highly efficacious broad spectrum preservative blend that provides formulators with an easy-to-use and widely compatible preservation system, offering reliable protection in substrates ranging from baby wipes to hair gels, and from hand soaps to sun care systems.

The Geogard range, including Geogard LSA, offers a viable alternative to traditional chemistries, according to Hindley.

“Equally effective against bacteria, yeasts and molds, it allows the discerning formulator to continue to protect the integrity of its products whilst enacting the growing needs of some customers for greener and less controversial cosmetic ingredients,” he said.

On the household care side, Lonza is touting Proxel BC, a broad spectrum blend of three trusted antimicrobials in 1,2-benzisothiazolin-3-one (BIT), 5-chloro-2-methyl-4-isothiazolin-3-one (CMIT) and 2-methyl-4-isothiazolin-3-one (MIT) that provides effective preservation of a wide variety of homecare products including floor cleaners, floor waxes and polishes, hard surface cleaners, dish detergents and laundry additives.

Lonza ensures that its preservatives satisfy or exceed internal and external standards for safety-in-use, according to Hindley, who noted that three of Lonza’s core household preservation actives—1,2-benzisothiazolin-3-one (BIT), 5-chloro-2-methyl-4-isothiazolin-3-one (CMIT) and 2-methyl-4-isothiazolin-3-one (MIT)—are listed within the US EPA’s Safer Chemical Ingredients List (SCIL), formerly Design for Environment (DfE).

Due Diligence

Consumers are more engaged today regarding products they use at home and on themselves, and that concern has trickled down to the ingredient suppliers.

“We believe the consumer to be more diligent in her search for milder but still effective preservative systems,” added Pat Lutz of Lincoln Fine Ingredients and Lincoln Manufacturing (LMFG), Lincoln, RI. “Lincoln sees this as a welcome challenge and helps us develop more of the current consumers needs. Due to this consumer need, Lincoln has over 50 preservative and antimicrobial systems manufactured here in the USA.”

For example, the Lincoln, RI-based company has launched two new lines of multifunctional antimicrobial systems (MAS) for personal care products: Linatural natural/naturally derived systems and Lincoserve alternative systems (free of conventional preservatives).

“These MAS systems help our customers navigate around the regulatory as well as any of the perceived ideas out on the market and/or internet,” noted Lutz. These systems, he said, “give the formulator antimicrobial properties to protect their formulations and the ability to claim preservative free or no preservatives added while offering functional properties to the formulation such as moisturizer, humectant, skin and hair conditioning, pH adjuster, etc.”

In addition, Lincoln continues to provide milder preservatives and antimicrobial system with toxicity and safety testing around lower skin irritation and HET-CAM scores. For example, Lutz noted that Linatural MBS-1 in a tear-free baby shampoo gives a HET-Cam score of 0.25, where on-market baby shampoos have a score of 1.75 and higher.

Long-Term Success

For venerable preservatives supplier schülke—which has been combatting microbiological contamination since 1889—longevity has given the firm an edge in today’s evolving marketplace.

“Our expertise in blending chemistries to obtain broad-spectrum, easy-to-use preservative systems and preservative boosters gives us the flexibility to rapidly address changing market trends and regulations,” according to Linda B. Sedlewicz, country manager, schülke inc.

schülke’s most recent family of preservative blends is based on benzyl alcohol. The offerings include K 900 and K 903, which are broad spectrum, globally approved preservatives for personal care products. Both can be used in formulas designed for Whole Foods Premium Body Care products, and perform identically to phenoxyethanol blends in challenge testing, according to the company.

Finding Solutions

“In the past few years traditional preservatives have come under high scrutiny by consumers and regulating bodies leading to the recent trend of alternative preservation methods and

technologies. These technologies and methods include using the formulation approach to preservation, incorporating strategies to lower or eliminate the amounts of traditional preservatives or using hurdle technology," noted Fana Makonnen, area sales manager at Inolex.

Since 2008, Inolex has offered an innovative hurdle technology under the Spectrastat CHA range. This multi-mechanism system is a blend of a unique, patented chelating agent capryl-hydroxamic acid (CHA) with an assortment of alcohols and glycols. The range includes Optimized Systems, Budgeted System and Liquid Series, which is ideal for cold processes. According to Makonnen, the Spectrastat CHA range contains no biocides or typical preservatives. Instead, it uses multifunctional agents that have excellent efficacy as biostatic and fungistatic agents. It is ideal for formulations where a paraben-free or preservative-free claim is needed. It performs superbly at neutral pH, a state where many other fungistatic materials are ineffective.

Inolex recently expanded the CHA range with Spectrastat PHL and Spectrastat BHL, which were unveiled at In-Cosmetics in Barcelona. These ultra-mild, high-performing alternative preservative systems are ideal for sensitive facial applications, where low irritation is required, such as dermatological and

pharmaceutical type products. The low irritation characteristics can be attributed, according to Makonnen, to the 6 carbon chain length glycol used in these blends which has less membrane interaction and therefore causes less irritation compared to other 8 carbon chain length glycols. Eight carbon glycols are more lipophilic, with greater attraction to membrane lipid bilayer of skin cells.

According to Inolex, Spectrastat BHL and Spectrastat PHL, which are a complete system for preservative-free cosmetic and personal care products, are especially useful in high water, cold-process applications like toners, surfactant systems, and wet wipes, and are completely liquid, homogeneous, and pumpable even at low temperatures.

At the New York Society of Cosmetic Chemists Suppliers' Day in May, Vertellus showcased CPC, a cost-effective and safe ingredient to preserve cosmetic formulations. Manufactured under cGMP conditions, CPC (INCI: Cetylpyridinium chloride) is an active ingredient in leading oral care products.

With a long safety record, and multiple formulating benefits, including low-dosage, broad spectrum efficacy and a favorable environmental profile, CPC is an attractive alternative for formulators. The launch of CPC as a preservative is in response to the

CONTAMINATION RECALLS

- **Here's a look at past contamination-related recalls in the personal care,** as documented by the Food & Drug Administration.

Earlier this year, the US Food and Drug Administration (FDA) sent a warning letter to Gemdo Cosmetics of Valencia, CA following an inspection its cosmetic manufacturing facility. The inspection (Dec. 8, 2014-Dec. 23, 2014) was conducted in response to a Class II Recall of Juice Beauty Illuminating Eye Shadow products that were manufactured there and found to be contaminated with *Bacillus cereus*, an ocular pathogen that can cause rapidly progressive endophthalmitis and lead to possible loss of vision or the eye.

Subsequently, FDA also sent a letter to Juice Beauty about the issue at its contract manufacturer. In the letter, FDA noted that Juice Beauty's Illuminating Eye Shadow products are formulated with preservative systems other than the preservative systems listed under Appendix C of Compliance Program Guidance 7329.001. FDA wrote: "Because botanical and organic ingredients are particularly vulnerable to microbial contamination, these ingredients should be afforded increased scrutiny by cosmetic manufacturers prior to their use. Enforcement action against contaminated products, which may be caused by inadequate preservation, may be considered if FDA analytical data show the presence of microbial contamination at such levels that it may render the product injurious to users."

In October 2014, Nutek Disposables, Inc. initiated a nationwide voluntary product recall of all lots of baby wipes that it manufactured under the brand names Cuties, Diapers.com, Femtex, Fred's, Kidgits, Member's Mark, Simply Right, Sunny Smiles, Tender Touch, and Well Beginnings and sold at Walgreens, Sam's Club, Family Dollar, Fred's,

and Diapers.com. After receiving a small number of complaints of odor and discoloration, Nutek conducted microbial testing that showed the presence of a bacteria, called *Burkholderia cepacia* (*B. cepacia*), in some of the products. The company initiated a voluntary withdrawal of lots that had tested positive for the bacteria, as well as other baby wipes in the surrounding time frame.

Back in 2013, W.S. Badger Co. Inc. initiated a voluntarily recalling all lots of its 4oz SPF 30 Baby Sunscreen Lotion and one lot of its 4-oz SPF 30 Kids Sunscreen Lotion due to microbial contamination. The products were tested and found to be contaminated with *Pseudomonas aeruginosa*, *Candida parapsilosis* and *Acremonium* fungi.

"As a father and grandfather, the safety and well-being of children is my highest priority," said Badger founder and CEO Bill Whyte back when the recall was announced. "All of these lots passed the required microbiological and comprehensive challenge testing prior to sale. It was during routine re-testing that we discovered that the preservative system in several lots had been compromised."

According to Whyte, the voluntary recall is was the first in the company's 18-year history.

More recently, in enforcement reports released this Spring, Gilchrest & Soames and Sensible Organics initiated recalls due to similar issues. Gilchrest & Soames recalled several brands of shampoo, conditioner and bath and shower products because the products may be contaminated with *Pseudomonas aeruginosa* and *Enterobacter gergoviae*. Beaver Falls, PA-based Sensible Organics' recall centered around mold found in certain lot of Nourish Organic Face Lotion (Argan & Rosewater and Argan & Pomegranate varieties).



Milder preservation systems, especially for products like baby shampoos, are gaining popularity.

continuing trend to reduce, restrict or eliminate product ingredients considered hazardous to human health or the environment, according to Vertellus.

Available in several forms, CPC provides formulators with a new preservative option that can be used in a variety of rinse-off

and leave-on applications. Recent testing concluded that CPC is negative for skin sensitization potential and irritation at formulation levels up to 0.5% and testing using CPC in a leave-on emulsion showed broad efficacy against bacteria, mold and fungi.

“As pressure mounts on consumer goods companies to reformulate, CPC is a safe and effective ingredient that does not persist in the environment as evidenced by many environmental studies that we’ve commissioned,” according to Brad Buehler, business director, personal care at Vertellus.

The company has recent studies that point to the safety and efficacy of CPC as an alternative ingredient for triclosan, triclocarban, benzethonium chloride, formaldehyde-donors and parabens in cosmetic and personal care products.

Safety First

Ask any preservatives expert, and he’ll surely agree that consumer safety, via the use of an effective preservation system, will always be paramount—no matter what’s trending over in the marketing department.

“The criteria for determining adequate preservation is not something that should vary based on marketing claims,” concluded Sedlewicz. ●