

### May 2004

#### Subscribe

##### Current Issue

Breaking News  
Formulary  
Grayson Report  
New Products  
New Package  
Personnel Round Up  
Meetings  
Print Version  
Ad Index

##### Suppliers

Company Profiles  
Literature Showcase  
Corporate Profiles

##### Editor's Page

About Happi  
2004 Media kit

##### Welcome to

Cosmeticpackaging&  
Design.com!

##### Welcome to

Happi Latin America!  
Happi China

##### Article Library

Index To Stories  
Formulary Archive

##### Web Guide

Company Websites  
Professional  
Resources

##### Personal Care Cybrary®

Join our **email**  
mailing list



subscribe



unsubscribe

## A Preservative Update

Regulatory issues still cause headaches for suppliers.  
Now, a dubious paper linking parabens to cancer  
makes the job even tougher.

Tom Branna  
Editorial Director

**Y**ear after year, many of the issues surrounding preservatives remain the same: The search for natural systems continues, regulation harmonization remains a long way off and bringing a new product to market is as tough as ever. In the past year, however, a new fly has been added to the ointment—a group of researchers has linked parabens to incidence of breast cancer. That paper, “Concentrations of Parabens in Human Breast Tumours,” by Darbre et. al., has created an uproar in the preservative industry in recent months, although many industry experts insist the paper is without merit.

“I have studied the Darbre paper very closely and my conclusion is that the rationale was illogical, the results highly questionable and the interpretation deeply flawed,” said Dene Godfrey, sales & technical director, MGS MicroPure Ltd. “I do not believe that parabens were actually present in the breast cancer tissue as was claimed.”

Most industry experts agree that the paraben-cancer link is dubious, yet they are carefully monitoring the controversy and working closely with the CTFA to make sure the correct information about parabens reaches formulators and the public.

“The use of parabens is time-tested and proven to be safe and effective,” said Vispi Kanga, president of Cosmet-Pharm Consultants, LLC. “I am glad that CTFA has commented on this publication by Darbre. Still, this will not prevent the public advocates from lashing out at the industry for putting out products which are not safe.”

Nevertheless, Mr. Kanga urged the cosmetic industry to develop tools for risk assessment, monitoring and consumer education concerning the appropriate use of preservatives in cosmetics and toiletries. He noted that an article in the Journal of Cosmetic Science (54, 239-250, May/June 2003), describes a method of controlling the extent of diffusion of parabens from topical formulations in order to minimize percutaneous absorption.

According to Mike Hooper, director of R&D, Body Blue, it is difficult to separate any actual preservative trends from the effects of the recent publication of results concerning parabens and estrogen-dependent tumors.

“As is often the case, the vast majority of consumers do not understand that results



Suppliers are searching for natural preservative systems for personal care formulations.

Submit

such as these require further scientific testing and validation before action is taken to remove any offending materials in personal care products.”

Mr. Hooper said that Body Blue has recently received a number of requests from clients to remove parabens from all of their products, not just deodorant sprays (as implicated in the study). He said consumers are becoming increasingly aware of ingredients and some are linking this unproven relationship between parabens and tumors to any formaldehyde-producing preservatives.



Damp, humid conditions in showers can create challenges for preservative systems.

“This is already creating panic in the natural products market and there is a risk that this movement will eventually make it to the wider audience, whether there is any basis for concern or not,” he added.

### Reality vs. Perception

While researchers debate the merits of the Darbre study, the fact is that the damage may have already been done to the preservative industry, observed Shyam Gupta, president, Bioderm, who noted that scientific facts and consumer perception are frequently contradictory thought processes.

“Scientific testing data, based also on long-term safe use of parabens, is indicative of their consumer safety and preservative efficacy,” observed Dr. Gupta. “However, consumer perception relative to the safety of parabens has been tainted due to misinformation or inconclusive test data. Consumers buy the products. Marketers develop products for consumers. Marketers frequently have to ignore

scientific facts and follow consumer trend or perception. Since there are substitutes for parabens, marketers are abandoning the use of parabens in favor of better substitutes.

Not all industry experts, however, agree with Dr. Gupta. Despite the uproar, some suppliers insist the paraben issue has had a negligible impact on their preservative business.

“The paraben issue, to my knowledge, revolves more around unwanted estrogenic activity, especially for the higher alkyl analogs and low incidence sensitization issues,” observed Art Georgalas, R&D technical director, TRI-K Industries. “To date this has been more of a concern in Europe and I do not think it has yet affected us.”

Added Tom Goode, vice president of sales, RITA, “there seems to be a grassroots movement concerning parabens but they may just be the new ‘in vogue’ raw material to persecute.”

Tom Schoenberg of McIntyre Group agreed.

“As far as the paraben-cancer controversy, it seems like it is one of these issues that never die,” said Mr. Schoenberg. “Actually, our paraben blend business showed strong growth during 2003 and we expect it to continue through 2004. We do not see it affecting our business.”

Meanwhile some companies manage to benefit from the controversy. The Schülke & Mayr product line encompasses a wide variety of preservative actives, according to Linda Sedlewicz, marketing manager.

"The majority of our products have always been non-paraben systems. If anything, the paraben controversy has given us the opportunity to discuss some of our more unique preservative blends," she said.

Blends include Euxyl K 700 (phenoxyethanol/potassium sorbate blend), for products pH 5 and below, Euxyl K 600 (liquid iodopropynyl butylcarbamate blend), for wet wipes and leave-on products, and new Euxyl K 500 diazolidinyl urea/organic acid blend), for rinse-off and leave-on products.

The controversy has created unprecedented interest in Lonza's paraben alternatives, according to Carl Cappabianca, global marketing director, Lonza.

"In the world of preservatives, even if the science of the toxicological testing is potentially questionable, perception rules. The paraben controversy has certainly created a perception issue and alternative chemistries—such as those found in Lonza's Glydant Plus, Glycakil, Geogard and Natrulon preservative platforms—are being tested at an accelerated rate."

### **What's New from Suppliers**

International Specialty Products recently introduced Optiphen, which it bills as a unique liquid preservative blend featuring phenoxyethanol as the primary active ingredient in an emollient base of caprylyl glycol.

"Optiphen is a highly effective antimicrobial which is paraben-free and formaldehyde-free with global approval," noted Mr. Orofino. At the same time, ISP is dedicating a major portion of its resources toward development of global and paraben- and formaldehyde-free preservatives, according to Mr. Orofino.

In addition, ISP recently acquired Biochema Schwaben, a formulator of preservatives and biocides for industrial and personal care applications which also has a reputation for customer service and new product development, said Mr. Orofino.

Dow Biocides recently introduced Amical PC for the cosmetics and personal care market. According to Jerry Konst, marketing manager, Dow Biocides, the EPA-registered version of this product has a very good toxicological profile and there is a need for a very efficacious fungicide that has good toxicological characteristics.

"Additionally, we have been pushing our Bioban BP Pharma and BP-30 Pharma products to promote the improved efficacy and price performance offered by a combination of C/MIT and bronopol chemistries," said Mr. Konst.

In other moves, during the past year, Dow has positioned the Biocides Business within its Specialty Polymers Global Business Unit which also houses the Amerchol business.

"This should improve our ability to serve the high service oriented biocide/preservative marketplace," said Mr. Konst.

R. Lynn Oakes, marketing manager, Rohm and Haas, reported that the company's Neolone preservative line continues to move through the MHLW and SCCNFP review processes.

"We believe that Neolone will be judged to be safe for leave-on applications at 100 ppm," said Mr. Oakes. "The global approval of Neolone will provide Rohm and Haas with a new preservative platform to serve the cosmetic and toiletry industry."

Over at TRI-K Industries, the company recently introduced three unique blends—Trisept Complex K, Trisept Complex U and Trisept Complex H-2, according to Ben Blinder, director of marketing, the introduction is part of the company's search for a

globally-acceptable blend of preservatives with broad spectrum activity.

"We have an ongoing project to continue compounding and evaluating new iterations of globally acceptable broad spectrum preservative cocktails," added Mr. Georgalas.

Mr. Blinder told Happi that there will always be two markets for preservatives—one for the tried-and-true preservatives that are considered standards in the industry, and the other for new and innovative preservatives with different functional attributes.

"TRI-K will be active in both market arenas," he insisted.

Schülke & Mayr recently launched Euxyl K 500, a diazolidinyl urea/organic acid blend that was developed as a substitute for the typical "formaldehyde-donor"/paraben blends that are widely used throughout most of the world, according to Linda Sedlewicz, marketing director.

"This product has much better solubility in water than traditional paraben-blends do and functions well up to pH 7, which is much higher than would normally be expected for an organic acid-blend."

A year ago, Lonza expanded production in Europe. Since then, demand has actually has exceeded expectations, according to Muriel Girault, marketing manager, Europe.

"This is due to a variety of factors--from reduced lead times, to technical service support to strong regulatory consultation," said Ms. Girault. "We expect this to continue, particularly as we expand our product offerings through our production capabilities in Europe as well as other regions."

### **Preservative-Free?**

Some companies are trying to circumvent the preservative issue entirely via new technology. For example, Melissa Frischling told Happi, that Lipo Chemical is taking a closer look at irradiation.

"We are looking into the possibility of removing the preservative systems from some of our natural products and offering an irradiated product for those that want a preservative-free option," said Ms. Fischling. "This is still in the research stage."

Other suppliers too, are taking a hard look at preservative-free systems. Mr. Hooper of Body Blue told have that there is growing use of naturally-derived preservatives; i.e., benzoic acid extracted from cranberries as opposed to petrochemical derived preservatives. "The cost-effectiveness of such an approach is still to be seen and will be dependent on the demand from the natural product brands," he observed.

Mr. Hooper also noted that new material blends allow for the formulation of preservative-free products. "Such systems are not limited to natural products either; some mass market brands are using this approach," he said. "Yet, blends such as these often have negative side effects such as a pungent odor, strong color and in some cases increased irritation potential."

Body Blue has developed a preservative replacement system called Naturebak (patent-pending) which has been shown to be effective even in troublesome formulations, without the negative side effects mentioned by Mr. Hooper. According to the Body Blue executive, Naturebak was developed over two years through the extensive testing of materials and has been successfully used in all types of personal care applications from surfactant-based formulas to skin creams with high protein loads.

"Naturebak is made up of a number of natural materials and is modular, ensuring that only the minimum amount is used to preserve the product," said Mr. Hooper. "This effectively minimizes the cost, any impact on the base formula and the irritation

potential. In fact, Naturebak has been successfully incorporated into a product that was previously preserved using a paraben system and was found to be irritating, but has now achieved a hypoallergenic claim."

Although Body Blue and other suppliers have benefited from the high demand for preservative-free products, Mr. Hooper offered a caveat.

"There are some brands on the market that have exploited a loophole in the regulations in order to claim preservative-free," he insisted. "If a raw material used in the product is preserved unnecessarily, or is over preserved using any preservative—whether synthetic or natural—then the preservative does not have to be listed on the ingredient deck. This is misleading to the consumer and is potentially damaging to the whole industry."

For its part, TRI-K offers natural hinokitiol for customers who prefer natural preservation systems.

"Companies have always kept an open mind about natural preservatives, but it seems lately that they are seeking out such ingredients on a more active basis," noted Elzbieta Kasprzyk, R&D group leader. "Other than that, companies are looking for globally-approved ingredients whenever possible."

Yet, Dr. Gupta says the industry continues to come up empty when it comes to natural preservation systems. "A single natural preservative that is effective at low use levels; tasteless, odorless, and colorless; effective against both bacteria (Gram-positive and Gram-negative) and fungi (yeast and mold); useable in both hot and cold phases; effective and stable in the pH range of 2.5 to 10.5; acceptable by the regulatory agencies worldwide; and cost-effective is still elusive," said Dr. Gupta.

He urged preservative suppliers and marketers to form a team to develop a new natural preservative that meets a variety of criteria including:

- efficacy at low use levels;
- tasteless, odorless and colorless;
- effective against both bacteria (Gram-positive and Gram-negative) and fungi (yeast and mold);
- useable in both hot and cold phases;
- effective and stable in the pH range of 2.5 to 10.5;
- acceptable by the regulatory agencies worldwide and
- cost effective.

"We must combine science and practicality with consumer perception in the design of new preservatives," he said.

#### **Other Formulation Trends**

Of course, not every formulation trend revolves around the growing use and demand for natural materials. For example, Mr. Georgalas of TRI-K pointed out that the move toward more inverse emulsions using silicone materials may become an issue since they may require a different strategy for preservation and good preservation testing and validation.

Meanwhile, the popularity of wipe-type products is also having an impact on product formulation. Steve Orofino, section manager II, skin care technical service, International Speciality Products, noted that the wipes market has been expanding quickly, creating the need for highly water-soluble preservative systems.

"Our Suttocide A product has the efficacy and water solubility that makes it ideal for use in wipes," he added.

According to Tammy Gaffney of Nalco, both the nonwoven cloth and the surrounding liquid must be protected against microbial growth.

"Finding an appropriate test method to determine whether these formulations are adequately preserved is another challenge for the microbiology laboratory," she noted.

Chris Tarletsky, director of marketing, Jeen International, told Happi that technology-transfer is playing a more significant role in formulation trends.

"We sense that our customers are increasing their dependency on technology transfer, and we are searching auxiliary markets for ways to enhance the overall preservation of their products."

### No Harmonization in Sight

Of course, no article on preservatives would be complete without a mention of the regulatory situation. Nearly every industry expert agrees that harmonization remains a long way off.

According to Pat Lutz, Lonza's global preservatives technical manager, the regulatory climate rarely improves; rather, the situation is merely different year to year.

"While some regions of the world remain, thankfully, unchanged from a regulatory standpoint regarding preservatives (such as the U.S.), others such as Europe and Japan continue to experience some changes in both regulations and market perception," said Mr. Lutz.

"Regulations continue to become even more fragmented," agreed Ms. Gaffney of Nalco. She pointed out that methyldibromo glutaronitrile has been approved by the CIR for use in leave-on formulations up to a concentration of 0.025%, and was approved in Europe for both leave-on and rinse-off formulations up to a concentration of 0.1%.

"(But) Last year, the molecule was banned for use in leave-on formulations in Europe until a 'safe level' can be established," she said. "This, and most of the other recent preservative regulatory issues, appears to be based more on negative perceptions through the media than sound scientific justification."

"Regulations still seem to be very fragmented especially those for cosmetics and personal care products in Japan," agreed Mr. Konst. "The Biocidal Products Directive (BPD) seems to be underway in with the EU countries, but it looks to be many years before it's all completed."

Looking for a preservative system? A list of suppliers can be found in the print version of Happi.

| [home](#) | [about us](#) | [what's new](#) | [current issue](#) | [web guide](#) | [meetings](#) | [article library](#) |