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Preservative Update

The paraben controversy is no longer making headlines, but more suppliers are offering paraben-free alternatives for their customers.

Tom Branna
Editorial Director

The media frenzy regarding a paraben-cancer link has subsided, but behind the scenes have rolled out alternatives to placate customers searching for less-controversial systems. At the same time, formulators are engineering systems that require lower levels of chemical for example reduced water activity, addition of potentiators, pH manipulation and packaging as the regulatory situation remains as fragmented as ever.

A year ago, preservative suppliers and their customers got a wakeup call when headlines proclaimed a link between parabens and breast cancer. The impetus for the questionable research paper by Philippa Darbre. Most suppliers contacted by Happi, Darbre research was flawed.

"The controversy has subsided somewhat as the technical accuracy of the initial report is under challenge," noted Sandra Porter, Clariant. "Recent reports published and available in the public domain indicate that there is no conclusive evidence of harmful effects from parabens in cosmetics at typical usage levels."

In the Darbre study, chemists examined tumor tissues from 20 women with breast cancer. Parabens were found in 18 of the samples at levels exceeding their blank measurements. No cause and effect relationship was established.

"Paraben preservatives have been effectively used to protect both food and cosmetics from spoilage for many years (but) the parabens, 4-hydroxybenzoic acid esters, have come under suspicion recently," observed Rich Otterson, technical director, McIntyre Group. "Parabens, through their phenyl ring, are detectable at extremely low concentrations and, because they are lipophilic, some accumulation in fatty tissues would be expected."

Mr. Otterson added, however, that parabens are ester functional and are readily hydrolyzed by enzymes present in living tissues. Paraben preservatives, especially butylparaben, have been shown to exhibit some ability to mimic the action of the female hormone estrogen in cell-based systems. Estrogenic activity increases with alkyl chain length from methylparaben to n-butylparaben and isobutylparaben.

"Various studies have failed to establish any estrogenic effect from methyl or ethylparaben. The European Commission's SCCP opinion of Jan. 28, 2005 does not anticipate any change in allowable concentrations in cosmetics," Mr. Otterson added. "The SCCP did call for the provision of toxicological information for propyl, butyl and isobutylparabens. A causal link to breast cancer has not been established but efforts to minimize the potential for dermal absorption of parabens have been made by some cosmetic manufacturers."

Suppliers Respond

Dene Godfrey of MGS MicroPure insisted that his company does not, and will not, promote products as "paraben-free," as the term "lends credence to the false premise that there is a link between parabens and breast cancer, and we feel that it is highly irresponsible of preservative suppliers to do this," he told Happi.



Preservatives play a key role in the formulation of skin and hair care products.

"There are 55 entries on Annex VI of the EU Cosmetics Directive and 54 of them are paraben-free, so this is hardly a novelty," Mr. Godfrey added.

He insisted that the paraben issue may not only eliminate the paraben market, but also cause a massive increase in the use of the remaining preservatives, resulting in a greatly increased exposure to these compounds.

"Clearly the risk of adverse effects from these other preservatives would increase, the overall risk of these effects from the use of personal care products, which is the direction the industry should be taking," he charged.

Paraben Alternatives

Still, some major players have made the decision to move away from parabens and to answer customer requests for paraben-free systems.

"Parabens are one of several personal care ingredients that are getting their share of attention these days, and this can be difficult for suppliers and the cosmetic industry—because the problem does not really exist," said Dianne Carmody, business manager, personal care preservatives for home and fabric care, Rohm and Haas. "Regardless, it is important to have a choice. Our new Neolone family of preservatives for personal care includes both parabens and formaldehyde releasers, as well as a paraben-containing product so that customers have a choice in their preservative options."

International Specialty Products (ISP) has expanded the Optiphen line with the launch of Optiphen Plus. Both products are globally approved formaldehyde-free and paraben-free preservatives. Optiphens are based on optimized phenoxyethanol in an emollient base for broad spectrum coverage with good aesthetics.

"This new class of preservatives was developed as a result of numerous requests from customers and we responded quickly to answer the market need," said Steven Orofino of ISP.

Mason Chemical has been aggressive to meet customer demand for alternatives to parabens. "We offer parabens, such as paraben and paraben blends," said Pat Lutz. In May, Mason introduced Maguard Plus I and Maguard Plus H, a new line of paraben-free, formaldehyde-free, isothiazolinone-free, patent-pending blends.

"The paraben/cancer link remains questionable and continues to be investigated. More studies will no doubt be performed, but in the world of preservatives, perception rules and many companies are already exploring paraben alternatives," said Carl Cappabianca of Lonza.

To meet their demands, Lonza offers a wide range of preservative systems to formulate products for microbiologists who have an interest in paraben-free alternatives. The range includes

traditional Lonza products such as the Glydant series (hydantoins), Glycacil series (IF Glydant Plus series (hydantoin/IPBC blends). Additionally, Lonza's Geogard global platform (blends of acids, alcohols and quaternaries), Natrulon series (naturally-derived Lonzagard (benzethonium chloride) provide one of the broadest paraben-free preservative portfolios available worldwide, according to Mr. Cappa-bianca.

Linda Sedlewicz of Schülke & Mayr noted that changes in global regulation and consumer opinion have recently put a great deal of pressure on suppliers of cosmetic preservatives.

"This has forced us to take a step back and reevaluate how we can help our customers with formulations that are resistant to microbiological attack," she told Happi.

The Schülke & Mayr executive said her company broke new ground in this area with the introduction of Euxyl PE 9010, which combines a widely used, globally-accepted preservative, phenoxyethanol, with a proven preservative-enhancer, ethylhexylglycerin (Sensiva SC). Ethylhexylglycerin reduces interfacial tension on the cell wall of microorganisms, providing broader spectrum activity. According to Ms. Sedlewicz, the system provides a skin-friendly, Japan-approved, pH-stable preservative system without the use of any of the chemicals currently under discussion.

Euxyl PE 9010 joins Euxyl K 500, a diazolidinyl urea and sodium benzoate and potassium sorbate system that debuted last year.

Jeen International has dedicated marketing resources over the past 18 months in an effort to better understand the overall position its customers will take toward alternatives.

"This research has led us to the development of new broad spectrum, paraben alternatives, specially formulated to offer effective, safe preservation of personal care and cosmetic formulations that are globally approved," explained Chris Tarletsky of Jeen.

Jeen has introduced several new preservative blends that are designed to be broad-spectrum, paraben-free, formaldehyde-free, globally-approved and which will offer effective preservation against bacteria, yeast and mold.

"It's very difficult to comprehend the impact surrounding the recent request from consumers for 'paraben alternatives' based on the concern of a potential carcinogenic impact of these preservatives," said Mr. Tarletsky. "We have noticed a large portion of our preservative customers requesting assistance with developing paraben alternatives, as well as replacing the paraben in their formulations. But reformulation efforts toward paraben alternatives which are underway are slowing down and the situation is indeed global."

Other New Preservative Systems

That doesn't mean that suppliers are exiting the paraben market.

Schülke & Mayr's line of preservative blends contains both paraben and non-paraben preservatives. For instance, Euxyl K 300 [phenoxyethanol (and) methylparaben (and) butylparaben (and) (and) propylparaben (and) isobutylparaben] is widely accepted for global formulation.

Clariant recently introduced Phenonip XB, a phenoxyethanol/ paraben blend which is original Phenonip but without butylparaben or isobutylparaben. According to Ms. Portier, methylparaben has just cleared methylparaben and ethylparaben for safe use in cosmetics at typical levels. Propylparaben is expected to follow. Phenonip XB is a blend of phenoxyethanol, methylparaben and propylparaben.

In another move, Clariant globally and regionally integrated the former independent personal care business into its traditional personal care ingredients business.

"We see the need for these businesses to be managed as one as there are numerous synergies and benefits for the combined businesses as well as for our customers who previously dealt with multiple suppliers."

independent businesses,” said Ms. Porter.

ISP has introduced two new ingredients to the LiquaPar line, LiquaPar PN and LiquaPar MEP. LiquaPar PN is an easy-to-use, 100% active, clear liquid preservative combination of phenoxyethanol, methylparaben, ethylparaben, propylparaben and butylparaben. This combination of parabens and phenoxyethanol is designed to shield formulations against contamination from both Gram-negative and Gram-positive bacteria, yeast and mold. LiquaPar MEP is composed of methylparaben and propylparaben in phenoxyethanol and is effective against bacteria, yeast and mold. MEP was developed to meet butylparaben-free formulations.

Lonza added several product extensions to its Geogard line of global preservatives. “Our new blends allow us to meet additional needs of our customers, particularly for products that are used worldwide,” explained Rosita Nunez.

In addition, Lonza extended its Natrulon line of naturally-derived preservatives with a new version, Natrulon PCG. According to Ms. Nunez, the Natrulon PC series continues to offer unique and effective preservative solutions, particularly for natural formulations.

Even More Options

Lipo Chemicals recently introduced a preservative-free version of Liposilt Black, a free silt that is known for its moisturization and sebum reduction properties. The material is irradiated in small packages.

“Since raw materials that include water need to be preserved, our company is looking for an option of elimination of a preservation system in those systems, and have them gamma irradiated and tightly packed to be totally consumed in one production lot,” said Nava Dayan of Ispat. “This allows the customer to choose his own preservation system and is opening new markets for a product which may limit use of certain preservatives.”

Tri-K Industries offers a range of options for customers seeking preservative-free ingredients.

“We can offer some botanical blends that are paraben or preservative-free,” explained Antonopoulos. “But our position is that there is no paraben controversy, so we use the blends that fits our products.”

Body Blue has continued to further develop its Naturebak preservative replacement systems, significantly broadening the application spectrum for this technology.

“Clients outside of the natural market have shown an increasing level of interest in Naturebak,” explained Mike Hooper of Body Blue. “Obviously there is a desire for preservative-free formulations.”

“Customers are looking for alternatives to preservatives and new approaches to long-term stability formulations due to new natural raw materials, regulations and safety concerns,” said

To meet this demand, this month Mason is introducing Enhansys, a new line of nature enhancement systems that fortify personal care formulations.

The increasing use of natural raw materials has boosted interest in natural preservatives, said Mr. Cappabianca.

“On one hand, natural raw materials often bring with them additional bioburden and potential for formulation contamination, so preservative system effectiveness becomes key. On the other hand, formulators typically prefer naturally-derived preservatives for products containing many natural raw materials,” he explained. “However, such preservatives tend to lack the robustness to adequately control bacterial and fungal growth. This creates a preservative dilemma, working on providing additional solutions to address such applications.”

But whether natural or not, many formulators are searching for globally-acceptable preservation systems to match their global formulations. “Though regulatory, formulating and other

road are frequent when trying to attain this goal, investigating as wide a range as possible preservative choices—such as Lonza's Geogard series—can provide helpful solutions. Nunez.

Tri-K has not introduced any new preservative systems in the past year, but Ben Blinn says that the company is developing different blends with hinokitiol, which imparts synergistic preservative systems.

Other Moves

ISP's recent acquisition of Biochema Schwaben has allowed the company to introduce a product range of preservative systems to the global market.

"This enables us to provide more preservative solutions to meet our customer's formulation challenges," said Mr. Orofino.

Rohm and Haas has devoted more resources in three areas:

- develop and support its expanding product portfolio, which includes new active ingredients
- address customers' preservative needs as they innovate their own product portfolio
- continue to advance its preservative technology.

Ms. Carmody told Happi that Rohm and Haas recently secured approval for Neolone of methylisothiazolone-based preservatives for use in the personal care market.

"The market is looking for global solutions and greater choice for their leave-on and rinse-off products," she observed. "With the recent approval of Neolone in Japan and the upcoming publication in Europe, we are able to give our customers the additional preservative choice they are looking for."

In the home and fabric care market, Neolone M-10 is doing very well. The stability of Neolone and its efficacy in products with a pH greater than eight was needed because it offers compatibility with a wide range of end-use applications than many other preservatives.

"Neolone M-10 is also appealing because it is formaldehyde-free and has an excellent environmental profile," she added.

MGS MicroPure recently appointed Chris Nichols as sales & marketing director. Mr. Nichols previously was with Rohm & Haas, has more than 25 years of experience in both technical and commercial involvement in the preservation of personal care products.

Several years ago, Schülke & Mayr instituted an internal Cosmetic Market Development group comprised of global sales representatives, research & development, technical service and marketing departments. The purpose of this group is to guide the efforts of Schülke & Mayr of the varying needs around the world. Among the results of this collaboration have been the development of Euxyl K 700 and Euxyl PE 9010 preservative blends.

Dow Chemical has made a serious investment in its biocides business via increased technical expertise, according to Mr. Stritmatter.

"We have also made important advancements in our laboratory capabilities, including the development and implementation of Taunovate high-throughput microbiological screening techniques.

"These techniques are available globally and are a key component to providing optimal solutions to our customers," he said. "We are continuing to make these investments in various regions, like our new research and development facility being built in Shanghai, China, and our R&D capabilities specifically in Asia."

According to Mr. Cappabianca, Lonza will continue to expand current preservative products such as Geogard and Natrulon. In addition, the company is exploring novel technology platforms.

plans to launch some new products later this year.

"Internally, Lonza is fueling new product development and technical support in several areas, including an initiative called 'LonzaSquare,'" added Mr. Cappabianca. "One area of 'LonzaSquare' is personal care, where we will continue to develop products and services in flagship areas such as preservation and specialty additives, all with the goal of providing additional technical support."

Rick Stritmatter explained that Dow Biocides has made a long-term commitment to develop a new class of molecules that will have excellent health and safety profiles.

"We have experts on both technical and regulatory issues to deliver solutions that customers are looking for," he said. "And as part of The Dow Chemical company, we have toxicology, environmental health and safety (EHS) and product stewardship unequalled by any other company. As the global biocide leader, we believe that we are the only company with the resources to pursue this path."

For a detailed list of preservative suppliers, read the May edition of Happi.

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