

WP-Chitosan: Reformulation Opportunities in Personal Care Products

Demand in the personal care market is subject to the multitude of forces influencing consumer purchases. Complicating matters, consumer preferences and trends are dynamic, fed by a constant stream of influencing news, advertisements and information. Companies are challenged to forecast the nuances of this demand to remain relevant within the personal care products market place. In 2012, Johnson & Johnson (J&J) announced several product reformulations of staple goods in personal care on a scale unlike anything ever seen in the industry.¹ Their intent was to favorably differentiate their products to stay in front of consumer trends. J&J invoked the industry's time-proven method of maintaining and gaining market share while leveraging their existing branded products. Reformulation, and the associated addition of new, high performing ingredients, introduce multiple opportunities for significant product improvement and differentiation. These include **increased safety, improved product efficacy, access to new markets, and reduction of product production costs.**

In this day and age, instant access to safety information influences consumer actions, drives purchase decisions, and can inflame consumer product composition concerns. The 24/7 information flow amplifies the awareness of potential good and bad effects of chemical ingredients, often without the contextual framework to properly assess the risk. The Federal Food, Drug, and Cosmetic Act, written in 1938 governs cosmetics and other personal care products; and tends to protect grandfathered ingredients that have been used for long periods of time as a proxies for safety.² This law may inadvertently discourage innovation, as new technologies often do not fit the regulated categories. Today, websites and organizations such as safecosmetics.org or the Campaign for Safe Cosmetics list properties and rank ingredients as a method of determining whether an ingredient can be labeled as safe. Manufacturers require new technologies and ingredients to differentiate products or maintain the product performance their customers have come to expect from an ever-shrinking pool of ingredients to choose from that meet 'safe' and 'sustainable' standards. An example of this can be seen in cosmetics. Consumers are now expressing concern and demanding new preservatives following media reports regarding formulations containing aldehydes or parabens. Awareness may be at an all time high³, but consumer expectations of safety and performance may at the same time remain ill served. This paradox provides opportunities for new ingredients that meet sustainability, safety and performance criteria.

Consumer demand for improved product performance while meeting product safety and sustainability goals presents significant business opportunity. Imagine a reformulation that leads to a sunscreen that extends wear time by adhering better to the skin while simultaneously protecting and nourishing the skin. Or, consider a hair

¹ <http://www.nytimes.com/2012/08/16/business/johnson-johnson-to-remove-formaldehyde-from-products.html>

² <http://www.law.georgetown.edu/library/research/guides/fooddruglaw.cfm>

³ <http://www.prweb.com/releases/2012/9/prweb9905942.htm>

conditioner that requires fewer applications because it persists on the hair while providing body, retaining moisture and delivering fragrance. These product adjustments offer advantages that can be quantified and appreciated by users. Reformulation and resulting product differentiation based on measurable attributes is a reliable method to capture or extend market share.

Recognizing and accommodating a new market trend can re-invigorate a product after it has, over the years, settled into a mature, low growth market. One example would be the new market trend for all-natural/organic skin care products where the CAGR is 9.9% in the US⁴ (much higher than the rest of the market). If a product can replace select synthetic ingredients with all natural or naturally derived ingredients, the market has shown a propensity to respond quickly and favorably. Successful product managers will have their fingers on the pulse of the market to identify and recognize new trends they may be exploited in reformulated product offerings.

In some cases, product reformulation can provide the very fundamental benefit of increased profitability through reduction of product cost. Addition or substitution of a new ingredient that enhances the delivery and bioavailability of an active ingredient is a dependable method of reducing the quantity used in a formulation and its associated cost. Informed personal care product managers appreciate the importance of cost savings in this market of elastic demand and often very little product differentiation. The significance is sizable where the active ingredient is a costly material.

Few will deny that these types of reformulation processes as well as many others have great potential for impacting producers and consumers. But, how in precise terms does the product manager proceed? How does she identify the specific, new ingredient or material that can confer meaningful benefits to his product through reformulation? A particularly promising candidate is WP-Chitosan, WavePharma's new proprietary biomaterial.

WP-Chitosan is a modified form of chitosan, a venerable mainstay in skin care, hair care and other fields. Generic, unmodified chitosan possesses a number of interesting properties applicable to personal care products. It is adhesive, antibacterial/antifungal, hemostatic, humectant, and biodegradable. Industry frequently exploits these qualities in moisturizers, emollients, film formers, hair conditioners, and wound dressings. WP-Chitosan shares these properties and their utility, but offers much more.

"I refer to it, quite justifiably, as a new material. It's more than just a technical advance, a new feature, or even a new product. WP-Chitosan is chitosan-based, but it's chemically and physically different. And, importantly, it has a number of novel, useful properties especially in the fields of skin care, transdermal delivery of active agents, and hair care." So says Jack Foster, the head of WavePharma, describing the

⁴ <http://www.cosmeticsdesign.com/Market-Trends/Global-market-for-organic-personal-care-expected-to-continue-rapid-growth>

company's proprietary WP-Chitosan technology. He goes on to characterize WP-Chitosan as "the muscular, smart, very accommodating cousin of unmodified chitosan." To date, development of the WP-Chitosan has been primarily focused on ocular drug delivery and related applications, but its characteristics offer the potential for reformulation of products in the personal care industry along several different vectors.

First, all evidence points to WP-Chitosan being safe and biocompatible. This is not surprising given native chitosan's long history of internal and topical human use. Cell cultures and *in vivo* evaluations (performed in corneal studies of rabbits) revealed no adverse issues with cell death, significant inflammation, or immune response.

Consumer perceptions regarding the relative toxicity and compatibility of chemicals present in personal care products are changing, and the time is now to move toward safe, proven alternatives. Product lines in skin care, hair care, fragrance, deodorant/antiperspirant, and others are likely to realize benefits from reformulation with WP-Chitosan. For example, WavePharma's proprietary material can be used as a safe, strong substitute in personal care products for widely-employed commercial adhesives such as the cyanoacrylates and the glutaraldehyde fixed proteins which have toxicity issues. Further, WP-Chitosan introduces a promising safety feature when used in conjunction with popular commercial product preservatives such as parabens and chloroacetamides. This is achieved by bonding the preservatives of questionable safety profile to the skin's surface thereby preventing the preservatives' access to the underlying vascular bed.

The adhesive strength of WP-Chitosan is notably superior to native chitosan and to competing commercial adhesive technologies such as cyanoacrylates and fibrins. Bond shear strengths (g-f/cm²) tell the story. In cornea-to-cornea competition, WP-Chitosan bests native chitosan 1164 ± 546 vs. 238 ± 92 and, in a skin-to-skin matchup, WP-Chitosan comes out on top 516 ± 258 vs. 385 ± 119 (cyanoacrylate) and 261 ± 51 (fibrin). WP-Chitosan's strong bonding permits significantly extended retention of chemically-linked or occluded pharmaceutical, cosmeceutical, and other active agents at the skin's surface and on hair.

And what about a "smart" WP-Chitosan? The drugs, cosmeceuticals, and other actives that WP-Chitosan bonds to skin and hair for prolonged periods can be released in a controlled manner. This programmed release can be on a timed basis or in response to a change of physiological state, (e.g. hydrolytic, photolytic, and enzymatic). The bonding and release intervals may be selected for periods that range from a few minutes to several days.

Chitosan is naturally occurring and commonly obtained from crustacean shells. Thus, it qualifies as a sustainable resource and a responsible consumer choice. WP-Chitosan is well positioned as a "naturally derived" product ingredient, a rapidly growing segment in the personal care market.

Further, the WP-Chitosan can be optimized for specific applications and uses by selectively altering a number of its properties. For the most part, this is accomplished by covalently linking specific functional groups to the WP-Chitosan. These modifiers include hydrophobic, hydrophilic, and ionic functional groups as well as mixtures thereof. Through linking specific functional groups, WP-Chitosan's water retention, viscosity, pH, and bonding targets can be selected and controlled.

Much of the proof of concept work for WP-Chitosan has involved drug delivery applications in the eye. Long-term retention on the cornea of WP-Chitosan laden with selected pharmaceutical agents has been demonstrated, resulting in improved delivery and bioavailability of active agents. In tests designed to compare ocular delivery of currently marketed prescription drugs with that of a WP-Chitosan proprietary formulation, WP-Chitosan was shown to be superior in terms of the relative bioavailability of the drugs. In one test, one-half of the commercial concentration of the active ingredient combined with the WP-Chitosan resulted in 136% bioavailable active after one hour and 157% after four hours when compared to the control. In another case, the WP-Chitosan system used twenty times less active drug (0.05% vs. 1.00% concentrations) and delivered 138% of the active ingredient after one hour and 71% after four hours.

WP-Chitosan can be easily formulated in a wide range of forms and states. These include liquids, solids, hydrogels, nanoparticles, and nanospheres. It also acts as a durable film former. WP-Chitosan's synthesis employs stable chemistry throughout and uses relatively abundant, low cost materials. Shelf inventory of the synthesized product is customarily maintained in freeze-dried form. These material specifications provide opportunities for product managers to quickly incorporate WP-Chitosan into existing personal care products to achieve enhanced performance with this versatile ingredient.

When asked what he foresees as the technology's most important application or product, WavePharma's Jack Foster explains, "We've learned a lot about the technology, it's reasonable to anticipate that it will spawn a number of high utility, profitable products. I don't think I should select a single application." No doubt, the technology promises an interesting future. Many will want to further investigate WP-Chitosan.

WavePharma is currently undertaking further proof of concept testing for applications related to the skin and hair. Joint efforts with industry partners is a likely direction for the company. Innovation company Emergent Technologies, Inc. is interfacing on behalf of WavePharma with companies that have proven capacity to test, develop and market new science-based products in personal care fields. To contact Emergent Technologies regarding opportunities with WavePharma, please visit www.WP-Chitosan.com.