“Isothiazolinone Contact Allergies”
By Annalise Burke

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Madeline Rivera  
Program Officer, Johnson & Johnson Health Care Systems, Inc. Contributions Fund  
35 Knox Hill Road, Post Office Box 338  
Morristown, NJ 07963-0338

Dear Ms. Rivera,

Re: Isothiazolinone-Free Hypoallergenic Products

Foremost, I would like to thank you for attending my presentation on April 25 on the subject of isothiazolinone product alternatives at the New Brunswick campus of Rutgers, The State University of New Jersey. As one of the largest conglomerates within the United States skincare industry, I greatly appreciate the interest Johnson & Johnson’s Contribution Fund has shown towards this topic.

I presented on the highly irritating qualities of methylchloroisothiazolinone and methylisothiazolinone. Additionally, I outlined a plan to remove isothiazolinone compounds from Johnson & Johnson’s family of skincare consumer products with “sensitive skin” or “hypoallergenic” labels, including those within Johnson’s Baby, Aveeno, Clean & Clear, and Neutrogena product lines. This will be achieved by replacing the two parabens with airless packaging for compatible products and by utilizing cosmeceutical alternatives for sensitizing ingredients.

By implementing these changes, Johnson & Johnson would not only profit from an underserved customer-base but also garner positive publicity by acquiring more proof of the company’s commitment to public health initiatives. Thank you again for your time and commitment to this issue. Please feel free to contact me with inquiries by calling to (208) 697-1462 or through e-mail to amb617@scarletmail.rutgers.edu.

Sincerely,

Annalise Burke
Isothiazolinone Contact Allergies: A Proposal for Product Change
Abstract

As one of the latest allergens for contact dermatitis, isothiazolinones, in the form of methylisothiazolinone and methylchloroisothiazolinone, are heavily irritable to sensitive skin but remain in many hypoallergenic products. The author proposes a plan to Johnson & Johnson Health Care Systems, Inc. Contributions Fund based on the success model of South Korean skincare to discontinue the two parabens from future Johnson & Johnson products. Using a three-pronged strategy of airless packaging, cosmeceutical alternatives, and a social media public health campaign, the company is expected to decrease the number of allergic reactions caused by their products and see a rise in its revenue from hypoallergenic products. Following a proposed 2-year research trial and 3-year limited product trial, Johnson & Johnson is expected to be an industry leader in natural and innovative product design among its peers. After the conclusion of the 5-year trial period of this project, Johnson & Johnson will have financial and social media data to support or disprove the further implementation of the three-prong strategy of the author.

Keywords: contact dermatitis, skincare, methylisothiazolinone, hypoallergenic, cosmeceuticals, korean beauty
Abstract

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Executive Summary

This proposal to Johnson & Johnson is for a change in the ingredients and product design of products marketed as “hypoallergenic” or for “sensitive skin” to be redesigned with cosmeceutical antioxidating alternatives instead of isothiazolinones, packaged using airless dispensers, and to be marketed with a public health campaign for contact dermatitis.

Contact dermatitis from methylisothiazolinone and methylchloroisothiazolinone is concerningly common, with 10.7% of patch-tested patients reacting to methylisothiazolinone and 6.3% of patients reacting to methylchloroisothiazolinone (Zirwas, et al). Given that half of those allergic experience reactions at concentrations half the United States limit of 0.01% aqueous, (Zirwas et al), dermatologists recommend that people suffering from atopic dermatitis, seasonal allergies, or general skin sensitivity avoid any products containing either of these two parabens since prolonged use of products containing isothiazolinone increases skin sensitivity and susceptibility to other contact allergies (Ezamdam et al). This is especially the case for children because compromised epidermal barrier function leaves them more susceptible to developing allergies (Schlichte & Katta). Furthermore, the high rates of misdiagnosis for common to serious health issues instead of this allergy (Chang & Nekrani), the health and cost impacts of these misdiagnoses (Abraham & Roga), and general misguidance that skincare packaging provides to consumers (Schlichte & Katta) all play a critical role in determining why a common contact allergy has become dubbed, “Allergen of the Year”.

Not only can Johnson & Johnson improve their products’ health impacts, but if you do so, the company will see profit from several underserved, growing segments of the skincare market. This would be a crucial move for the company’s success, since Johnson & Johnson’s skincare market share has steadily decreased since 2013 and is expected to continue until at least 2021 (Trefis). One trend in skincare are products focused on ingredient lists that are short and perceived as natural, which has only grown in popularity with the rise of South Korean beauty in the United States (Baukneckt). South Korean cosmetics sales to the United States rose 30% from 2015 to 2016 as a result of popularity with both allergy sufferers and general consumers alike (Baukneckt). Part of this popularity boost has been the successful marketing of the use of cosmeceuticals in consumer products, which reflects the desire worldwide for natural cosmetics, as seen in the market more than doubling in value from $6.8 billion USD in 2007 to $14.8 billion USD in 2017 (Organic Monitor). The best cosmeceuticals to replace isothiazolinones in one of the most allergy-inducing products, sunscreen, are calendula and geranium oil (Lohani et al), propolis (Gregoris et al), silibinin (Singh & Agarwhal), algae bioactives (Jahan et al), and blackberry extract (Cremenescu et al). Another aspect popular with consumers that is derived from South Korean skincare is the implementation of “airless” packaging, or packaging that ensures product shelf-life and eliminates the need for bacteria-fighting preservatives by inhibiting air from coming into contact with the solution until it is dispensed for consumer use. The use of isothiazolinones is to prevent oxidization, so if the package design prohibits that from occurring, less of antioxidants are needed and gentler cosmeceuticals can be employed (Zirwas et al). Airless packaging solutions also “provide high evacuation rates with a restitution rate of 95-97%” (Pharmaceutical Technology Europe), acting as a hygienic, reliable form of packaging alternative.
Social media is predicted to become increasingly important for medical purposes (Fogel & Teng) but is currently underutilized in the field of dermatology on both the clinical and consumer products sectors. Campaigns that are considered more useful, informative, and direct user engagement have the greatest positive impact on a customer’s attitudes towards a brand or social issue (Arli), so with this and Fogel & Teng’s remarks in mind, the skincare market is seeing underutilization in the social media sector and would see great benefit in investing in social media marketing that involves direct user engagement.

In order to decrease methylisothiazolinone and methylchloroisothiazolinone concentrations in consumer skincare products, cosmeceutical alternatives, airless packaging, and directed online awareness and rebranding campaign together are the most suitable options for changes with Johnson & Johnson sensitive skincare products. For a trial period, the plan will begin with Neutrogena Sensitive Skin Sunscreen. To create an awareness and rebranding campaign, a new label of “Nature’s Hypoallergenics” is suggested that can stand for a certain standard of allergen avoidance, something that is not required by law and is therefore not honestly conveyed in advertising (Schlichte & Katta). This, in addition to an online presence for the label that features interactivity, including skincare forum participation and product ingredient transparency. To replace methylisothiazolinone, another antioxidant and UVP enhancing compound needs to be found. calendula and geranium oil (Lohani et al), propolis (Gregoris et al), silibinin (Singh & Agarwal), algae bioactives (Jahan et al), and blackberry extract (Cremenescu et al) are all viable candidates alone or in conjunction to be replacements. A chemical research trial will need to be performed to determine the best match for the Neutrogena and will be performed at Rutgers, The State University of New Jersey: New Brunswick with two research scientists. The final aspect of the product redesign, the implementation of airless dispensers, will prohibit air oxidation, drying out, and discoloring that will both remove the need for isothiazolinones and improve product quality (Faulk).

The typical steps for creation of a skincare product include: 1) initial research, 2) group of prototypes, and 3) independent testing, 4) sourcing, 5) packaging and 6) launch (Miller), and the redesign of the Neutrogena Sensitive Skin Sunscreen will follow the same steps. A hypothetical 2-year research and development period for the redesign will be implemented and includes: 1 year of initial research, prototyping, and testing, and 1 year of sourcing, packaging, and product launch. Including research costs, Johnson & Johnson is expected to see $265,650 profit from 100,000 units from 2020-2025. Continued manufacturing past the trial date is highly recommended to maximize costs to expenditures.
Introduction

Allergen of the Year: The Problem Paraben

In 2013, the American Contact Dermatitis Society named methylisothiazolinone and methylchloroisothiazolinone parabens as “Allergen of the Year” as a result of having an allergy frequency already on par with other allergens that have been utilized for much longer (Worchester). Within the last decade, the concentration of these isothiazolinone preservatives within cosmetic products has significantly increased. As a result, allergic reactions to this compound have also increased, with one study finding 10.7% of patch-tested patients reacting to methylisothiazolinone and 6.3% of patients reacting to methylchloroisothiazolinone (Zirwas, et al). The United States has a limit of 0.01% aqueous, though Zirwas et al’s study found that half of those allergic experience reactions from smaller concentrations than the US limit. Furthermore, another study found that prolonged use of products, particularly sunscreen, containing these isothiazolinones increase skin sensitivity and susceptibility to other contact allergies (Ezamdam et al). Notably, use of baby wipes or soaps containing one of the isothiazolinones during infancy or childhood increases the likelihood of developing an allergy to the paraben, as compromised epidermal barrier function leaves them more susceptible (Schlichte & Katta). Research finding such a strong sensitizing relationship and high allergenic rates below the United States’ federal limit solidifies isothiazolinone contact dermatitis as a public health concern whose full impact has yet to be fully realized.

Figure 1: Contact dermatitis on child, before and after discontinuation of Huggies Wipes containing methylisothiazolinone (Chang & Nekrani).
The rise of methylisothiazolinone and methylchloroisothiazolinone in skincare and cosmetics has long-term public health impacts that are a great concern to dermatologists worldwide. Many cases of contact dermatitis to isothiazlinone compounds are misdiagnosed as eczema, psoriasis, impetigo, and lupus, leading to costly treatments that do not resolve their skin condition and may bring their health at risk in the process (Chang & Nekrani). Additionally, common treatments for these conditions can include topical steroid creams that cause atrophy and sensitize the skin; these treatments on skin already suffering from contact dermatitis may further exacerbate the reactions from isothiazolinone (Abraham & Roga). As a result, it is in the best interest of skincare companies to solidify their hypoallergenic skincare products as trustworthy to those with such a common allergy. Unfortunately, marketing terms such as “hypoallergenic”, “gentle”, and “sensitive skin” are used to imply that a product is less likely to trigger a reaction but are not held to any standards to assess the validity of these claims (Schlichte & Katta). This ultimately leaves the responsibility for standards up to the brand to uphold and ignorance on this topic can result in consumers using products that are ultimately harmful to them.

Figure 2: Positive patch test reaction to methylisothiazolinone (Schlichte & Katta).
Despite this, American companies are continuing to utilize isothiazolinone preservatives in products for sensitive skin and are failing to grasp the trust of a growing segment of the United States population. An analysis from Trefis shows that Johnson and Johnson has steadily lost market share in the cosmetics share and is expected to continue declining through 2021 (Trefis). A market that Johnson & Johnson’s multiple skin care brands may be missing out on is the growing number of consumers world-wide that suffer from isothiazolinone allergies, as mentioned prior.

Figure 3: Johnson & Johnson’s share of the skin care products market worldwide from 2013 to 2021*.

Literature Review

Looking East: Preservative & Production Alternatives

The most recent research finds that an increased sensory irritation can occur by combining different preservatives, a practice common in the American beauty industry (Lee, et al), so paradigms that avoid the use of chemical preservatives entirely have been selected. In one of the fastest growing beauty markets, South Korea, there have been several innovations in skincare and cosmetics ingredients and packaging mechanisms. As many South Korean brands have developed successful, affordable products without methylisothiazolinone and methylchloroisothiazolinone, I will evaluate the alternatives employed by their business strategies. By analyzing cosmeceuticals and airless packaging, a model to appeal to consumers with isothiazolinone allergies can be created for implementation within the Johnson & Johnson family of beauty products.

Cosmeceuticals in South Korean Products

Many American products that claim to be for sensitive skin or hypoallergenic still contain methylisothiazolinone and methylchloroisothiazolinone preservatives, leaving those who suffer from this allergy to resort to foreign imports from countries with greater restrictions on concentrations. Notably, one of the fastest growing beauty industries in the world, South Korea, has a limit of 0.0015% aqueous (Australia Department of Health). South Korean products are increasingly popular not only among allergy sufferers, but the general public, with South Korean cosmetics sales to the United States rising 30% from 2015 to 2016 (Bauknecht). A major aspect that South Korean beauty products owe their popularity to is the use of cosmeceuticals, or natural ingredients such as green tea and snail secretion to replace sensitizing additives, which are often the most heavily advertised aspect of the product (Juhasz, et al). The use of cosmeceuticals in consumer products reflects the desire worldwide for natural cosmetics, as seen it the market more than doubling in value from $6.8 billion USD in 2007 to $14.8 billion USD in 2017 (Organic Monitor), with no slowing of this rate -in sight. As international products are becoming more readily available online, foreign companies are able to grasp a segment of the international beauty industry through the use of unique, cosmeceutical ingredients.

![Figure 4: Cosmeceutical alternatives with UVP and antioxidant properties](image)

Calendula (Natural Way Landscaping)
Honey & Propolis (Gregoris)
Blackberries (Cremenescu et al)
Silibinin (Max-Planck-Gesellschaft)
In order to reduce the use of methylisothiazolinone and methylchloroisothiazolinone, antioxidant-rich cosmeceuticals can be used to replace these parabens. As was aforementioned, the most reactionary products are sunscreens so therefore alternatives to isothiazolinones in these products should be our greatest concern. In a 2018 study, a combination of geranium and calendula oil together provides a synergistic effect of both sun protection factor (SPF) and prevent oxidative stress (Lohani et al). This is also the case for propolis, or “bee glue”, which has strong antioxidant activity and provides ultra-violet radiation (UVR) protection higher than that of its on-market contemporaries (Gregoris et al). The list of alternatives with similar antioxidant and SPF protection continues on and includes silibinin (Singh & Agarwal), algal bioactive components (Jahan et al), and blackberry extract (Cremenescu et al). These alternatives and more are utilized in South Korean products for their ultra-violet radiation protection and prevention of oxidative stress but are much less common in the United States skincare market.

**Airless Packaging**

Another aspect popular with consumers is the implementation of “airless” packaging, or packaging that ensures product shelf-life and eliminates the need for bacteria-fighting preservatives by inhibiting air from coming into contact with the solution until it is dispensed for consumer use. The use of isothiazolinones is as a preservative to keep the skincare solution from being oxidized, so if a product is unable to be oxidized as a result of the packaging design, less antioxidants would be necessary to keep the solution from spoiling.

![Airless Bottle Design](Figure 5)

This new development, which began in South Korea through packaging manufacturers Yonwoo, AcosPack, and UniPack, is projected to grow from $4.046 billion USD in 2016 to $5.938 billion in 2023 (Khandelwal). Airless packaging solutions also “provide high evacuation rates with a restitution rate of 95-97%” (Pharmaceutical Technology Europe), acting as a hygienic, reliable form of packaging alternative. Finally, airless product designs are found to be the best match for more natural ingredients because of the air exposure protection, according to
industry expert Jeff Falk. Therefore, if the aforementioned cosmeceuticals are implemented, airless packaging would be ideal for their implementation.

Social Media Campaign: Public Health Awareness Initiative

Social media is predicted to become increasingly important in participant recruitment for clinical trials, public engagement in health care, and scientific discourse (Fogel & Teng), but is currently underutilized in the field of dermatology on both the clinical and consumer products sectors. Furthermore, social media campaigns that are considered more useful, informative, and direct user engagement have the greatest positive impact on a customer’s attitudes towards a brand or social issue (Arli). With these two pieces of research in mind, a social media campaign for awareness on isothiazolinone allergies is unprecedented and would require directed marketing to impacted groups. The groups with the greatest interest in a product redesign by Johnson & Johnson brands would include allergy support groups, Korean beauty communities, and natural beauty advocacy forums. This option is particularly attractive, as there is no “pro-isothiazolinone” community that would counter this move.

Paradigms for Success

In order to decrease methylisothiazolinone and methylchloroisothiazolinone concentrations in consumer skincare products, cosmeceutical alternatives, airless packaging, and directed online awareness campaign together are the most suitable options for changes with Johnson & Johnson sensitive skincare products. All three of these avenues applied directly to a Johnson & Johnson product will be explored in the “Plan of Action” section below.

![Figure 6: Isothiazolinone-Free Product Design and Promotion Paradigms](image-url)
Plan of Action

An Airless, Parabenless, and Allergyless Plan

As a leader of your industry, I believe that if Johnson & Johnson were to aggressively and publicly remove methylisothiazolinone and methylchloroisothiazolinone from their products, they would not only benefit from increased trust from those who are allergic and have lost consumer faith in American cosmetics, but also see financial windfall from this increased trust. This is particularly notable given the aforementioned growing share of the skincare industry that South Korean and natural beauty products are cornering; this is a niche in the industry that Johnson & Johnson currently lacks a segment of.

In order to test the viability of the following proposal on all Johnson & Johnson hypoallergenic or sensitive skin products, a 5-year trial period will be implemented starting January 2020 using Neutrogena Sensitive Skin Sunscreen and is as follows:

Step 1: Public Health Initiative & Rebranding

Although Johnson & Johnson representatives have been quoted stating that they are reducing isothiazolinones from their products in news articles as early as 2014, there is no official stance or removal goals on their website regarding the preservatives. By publicizing dedication to fighting contact dermatitis and setting a goal for the allergens’ removal, the initiative will garner positive publicity from medical associations, such as American Contact Dermatitis Society. Furthermore, Johnson & Johnson’s brands will experience positive feedback from online communities that discuss this allergen and have since moved to South Korean products to avoid their allergies, such as those on reddit.com and talkeczema.com.

Another aspect of the public health initiative will be the rebranding of Johnson & Johnson’s products reconfigured without isothiazolinones under a banner of “Nature’s Hypoallergenic”, since phrasing with “sensitive skin”, “hypoallergenic” and similar branding has little practical meaning and is not held to any government-issued standards. However, Johnson & Johnson can reaffirm their dedication to allergen-free products by creating a standard of their own that is communicated in both the product design and through social media advertising. In the case of the Neutrogena sunscreen, it would be renamed “Neutrogena Nature’s Hypoallergenic Sunscreen”, with the exclusion of isothiazolinone parabens and highlighting the cosmeceutical alternative used, as was mentioned previously as a common marketing tactic used in South Korean skincare products.

Step 2: Hypoallergenic Products: Ingredient Reconfiguration

Removing methylisothiazolinone and methylchloroisothiazolinone from products labelled as hypoallergenic is the primary goal of this proposal but is best supported by the two other steps outlined. However, the best cosmeceutical options depend entirely on the chemical makeup of the ingredient list. In implementing this project, a new product will be created to replace Neutrogena Sensitive Skin Sunscreen, a product that claims to be free of irritating chemicals and contains methylisothiazolinone.

To replace methylisothiazolinone, another antioxidant and UVP enhancing compound needs to be found. As was found in the literature review, geranium and calendula oil, propolis, silibinin, algal components, and blackberry are all viable candidates alone or in conjunction to be
replacements for methylisothiazolinone or methylchloroisothiazolinone. However, since all chemicals within any given product may react differently to a compound, a research and development period should be implemented in order to test and determine the most suitable replacement(s). Since the Johnson & Johnson’s operations are headquartered next to the Rutgers, The State University of New Jersey: New Brunswick campus, the close relationship between Johnson & Johnson and the research university can be utilized while creating this product. A small team of two research scientists, in conjunction with Robert Wood Johnson Medical School’s Biochemistry Department, should be recruited to assess the best cosmeceutical option to be used in the Neutrogena sunscreen.

The typical steps for creation of a skincare product include: 1) initial research, 2) group of prototypes, and 3) independent testing, 4) sourcing, 5) packaging and 6) launch (Miller), and the redesign of the Neutrogena Sensitive Skin Sunscreen will follow the same steps. There were no credible sources for suggested time durations for each step to take place as each company has standards and contacts that can make the process longer or shorter. With this in mind, a hypothetical 2-year research and development period for the redesign will be implemented and can be altered to fit the standards of Johnson & Johnson. This includes: 1 year of initial research, prototyping, and testing, and 1 year of sourcing, packaging, and product launch.

**Step 3: Airless Dispensers for Preservative-Free Products**

Johnson & Johnson have cited their reason for not removing methylisothiazolinone and methylchloroisothiazolinone preservatives as ensuring product shelf-life and avoiding bacteria growth, but the affordability and success of South Korean cosmetic products aforementioned prove that it is possible to create affordable, hygienic products without compromising skin sensitivity. However, in order to implement the airless dispensers into Johnson & Johnson’s hypoallergenic product lines, it will come at a cost. Jeff Falk reported that, “... while we have seen airless packaging prices come down of late, the technology does cost more than traditional pump and bottle configuration, but the ability to use the entire product without contamination or drying out and discoloring is enough to make the packaging very desirable”. As the technology’s cost is dropping further yearly and will prove relatively affordable to implement, net loss from program integration is easily obtained from the product price, as sensitive-skin products have higher median price per ounce of $0.79 (Xu, et al). This is not including the projected increase in sales from the isothiazolinone allergic, natural beauty, and Korean beauty community that will more than account for the increased cost of packaging.
Proposed Budget

*Sensitive Matters: Approximate Budget*

The budget of this project will be calculated using approximated research and development costs for cosmeceutical ingredients for the aforementioned redesign to replace the Neutrogena Sensitive Skin Sunscreen. Costs are generously overcalculated at market values; Johnson & Johnson likely has existing connections and contracts that can greatly cut the cost per unit. The research scientists’ salary has been estimated using the average salary for chemical researchers in the region, according to Glassdoor; this is also the same for the product designer and industrial designer.

Precedent information online is nonexistent about how much the research and development period will cost beyond salaries. So, in order to calculate this, it is assumed that research and development costs are considered when calculating company profit margin. Johnson & Johnson has had an average quarterly profit margin of 17.71% within the last 5 years (YCharts), which will be used to approximate the research and development costs to manufacture a sunscreen sold for $15, as per its current price, at a standard demo launch of 100,000 units, divided by the five-year time frame proposed.

If the project hypothetically begins January 2020, with a 2-year research and development team, the first-year and second-year expenditures are as follows:

### 2020 / First Year: initial research, prototyping, and testing

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### 2021 / Second Year: sourcing, packaging, and preparation for product launch

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2022-2025 / Third Year – Fifth Year: Yearly Product Cost / Revenue

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Three-year revenues: $759,390

Five-Year Expenditure & Revenue Analysis: 2020-2025

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Discussion

If the redesign of Neutrogena Sensitive Skin Sunscreen continues to be manufactured past the project trial year of 2025, Johnson & Johnson will continue to see additional return from investment, as additional research and development costs and salaries are not needed past the initial two years. If the redesigned sunscreen is a success during 2022-2025, I highly recommend that production quantity is increased and that the “Nature’s Hypoallergenic” branding and development is expanded to other products under Johnson & Johnson brands.

I would also like to reiterate that while a highly advantageous business decision, the removal of methylisothiazolinone and methylchloroisothiazolinone from products marketed as hypoallergenic is also a move important for public health. Johnson & Johnson is also a health provider, through your medical devices and pharmaceuticals sectors of operations, and the increasing prevalence of allergens like isothiazolinones is undoubtably noticed in those two sectors as well.
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Burke


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