



Hemina Skin Rebuilding and Reconditioning Therapy: Treating Ichthyosis & Xerosis



Heyde Lopez
Monica Sanders
Erin Sposato

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Executive Summary

The proposal of a package of moisturizers for treatment of ichthyosis vulgaris has been shown to be unprofitable because of high ingredient cost. The package consists of three separate products which function differently but collectively to treat a common skin disorder. The equipment cost and FCI are \$0.0765 million and \$0.42 million, respectively. The TCI for the project is \$0.499 million. Utilities and operating labor costs are \$0.004 million and \$0.240 million. Total annual product cost (TPC) is entirely dependent on raw material cost due to the extremely high cost of one particular ingredient, ceramide. The optimum formulation gives a TPC of \$58 million/yr while a formulation of decreased raw material cost formulation gives \$14 million/yr. These costs give a NPW of -\$219 million and -\$26 million for the optimum formulation and decreased raw material cost formulation, respectively, if sold at \$50/package. When the package is sold at \$90/package, the decreased raw material cost formulation has a positive NPW of \$1.5 million. Even sold at the higher price, profit decreases per year.

The package exists as a process in that there are steps to follow to reach the desired objective. A Pre-Shower Lotion is introduced to shed the dead skin layers that characterized the disorder. A Shower Gel is then offered to replace naturally-occurring components of the skin that are known to absorb water, both from the inside of the body and from the outside environment. The last product, an After-Shower Lotion, restores the lipid barrier present in the skin that works to hold moisture in the skin. Using these products in succession creates a system of restoration that will provide the consumer relief from the symptoms of the disorder.

Hemina, Inc. is a small development company that has pledged to improve the physical state of ichthyosis patients nationwide. Experienced members of management have worked to create the ideal formulation of the package that will give hope to patients suffering with dry, scaly skin. The company intends on using consumer feedback and research to further develop the package. The package will be sold locally at \$90/package, although lower prices were considered. Once the product is perfected, Hemina, Inc. expects to sell the formulation to a large company for nationwide sales.

The formulation was created based on extensive understanding of the structure and function of the skin and its components. A diffusion model of chemicals into the skin was used to determine the relationship between the concentrations of a chemical that reaches the inner layers of the skin with the concentration that is applied. Active ingredients were chosen based on the desired function of the product. Complementary ingredients were added to give physical properties that are important when creating a consumer product. The manufacturing process was designed based on the phase properties of the ingredients. Cost analysis was then performed to assess the product.

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1. Introduction

Hemina, Inc. is a small development company working to improve products in the skin care industry. Currently, there are three members of management working to develop the products and processes. All three members are chemical engineering graduates from the University of Oklahoma. These members have used their experience and knowledge to improve products in the skin care industry. Expansion is expected to fulfill needs in areas of marketing, research, and production.

1.1 Objectives

Hemina, Inc. is committed to improving symptomatic conditions for patients with ichthyosis vulgaris by offering a package of moisturizing treatments. These patients incur significant amounts of discomfort from the incurable disorder. Current treatments are limited in their functions and we intend to set our product apart from others by offering a system of treatments, that when employed, will restore the patient's skin to a more natural and balanced state.

1.2 Future

Future plans include further development of the package. The package is still in preliminary stages and more research and testing must be undertaken in order to best accommodate the consumer. Hemina, Inc. intends to use local sales of the protocol as funding and as a source of consumer preference information. Once the product is perfected, after approximately 5 years, Hemina, Inc. intends to sell the final product to a larger company, which will then introduce it into the national market.

2. The Product

The product is a package designed as a process of treatment for patients suffering from the hereditary skin disorder, ichthyosis vulgaris. Patients suffering from this disorder experience mild to severe scaling of the skin due to buildup of dead skin layers on the surface of the skin. Current treatment of this disorder involves symptomatic management as there is currently no cure for the disorder. Our package consists of three individual products: a pre-shower lotion, a shower gel, and an after shower lotion. Each individual

product performs separate tasks that will collectively restore the damaged skin to a more balanced state. The design is focused on active ingredient function and consumer aesthetics. The combination of the three products is intended to improve skin conditions above and beyond other current products on the ichthyosis market.

2.1 Skin Background

The skin is the largest organ of the body. It exists as a barrier to prevent water loss, along with many other roles such as protection, regulation of body temperature, wound repair, and perception of sensations. Hydration of the skin is very important and is governed by three factors:

- Desquamation – the shedding of the top layer of dead skin cells. This is a natural process that occurs constantly in normal skin and usually goes unnoticed because such small amounts are sloughing at a given time
- Natural Moisturizing Factors (NMF) – components normally present in the cells of the top layer of the skin. These components retain water inside the cells and intercellular space.
- Lipid barrier – the lipid barrier is a complex matrix that exists in the intercellular space in the top layer of the skin. The hydrophobic barrier prevents water from diffusing out into the environment.

2.2 Ichthyosis Vulgaris

Ichthyosis vulgaris is one of many forms of the family of ichthyotic disorders. These disorders are characterized by dry, scaly skin. They are primarily hereditary disorders that currently have no cure. Ichthyosis vulgaris is caused by a genetic defect in the expression of a protein that is the precursor to NMF components of the skin that absorb moisture in the skin. Without these NMF components, the skin is not as capable of retaining moisture which leads to poor hydration. Poor hydration leads to the buildup of dead skin layers on the surface of the skin which crack and form clumps that come off as scales.

2.3 Current Treatment of Ichthyosis Vulgaris

Treatments for ichthyoses are symptomatic treatments that work to rehydrate the skin. Many of these treatments exist as topically applied moisturizers. It is recommended to use occlusive moisturizers directly after bathing to “seal in” the moisture obtained from the bath. Many occlusive agents such as petroleum jelly are recommended to coat the skin and prevent water loss. The best occlusive agents are in the form of ointments. The drawback of this treatment is that occlusive moisturizers tend to be thick and greasy. Greasy lotions are inconvenient to the patient because they cannot be applied and left on the skin without causing problems like staining clothing. Other ingredients of moisturizers hold water to themselves and diffuse into the skin, consequently rehydrating the skin. Ingredients such as urea, ammonium lactate, sodium lactate, sorbitol, pyrrolidone carboxylic acid, and propylene glycol function in this manner. There are many lotions on the market that use one of these as an active ingredient in high concentration. Keratolytic agents, such as lactic acid, salicylic acid, and propylene glycol, are also currently being used in moisturizers to help the shedding of dead skin cells. It is important when using keratolytic agents, to pay close attention to the concentration, as high concentrations cause irritation.

2.4 Package Proposal

In order to effectively restore the skin, we have proposed a system of moisturizers incorporating knowledge of the components of the skin and their function with understanding of how water diffuses through the skin. There are three individual products included in the package. Since the products are designed to be cosmetics, the FDA does not regulate the development of the package. Certain ingredients such as alpha hydroxy acids are limited by their concentration amounts.

1. Pre-Shower Lotion – a lotion that promotes shedding of the scaly, dead skin
2. Shower Gel – a gel that cleanses as well as adds water absorbing components called natural moisturizing factors (NMF) that exist abundantly in normal skin. Ichthyotic skin lacks NMF which causes a reduced level of hydration.
3. After-Shower Lotion – a lotion that is meant to replace the barrier lipids, thereby restoring the matrix so that the skin can retain the water that it absorbs into the skin. There are also actives that are intended to hydrate and smooth the skin.

With this package, a process is developed that will better restore the skin to a balanced state. The dead skin that has built up will first be loosened and removed with the pre-shower lotion. Some form of scrubbing tool (i.e. loofah, pumice stone) will be recommended to facilitate removal of these cells. Then actives in the shower gel replace the NMF enhancing the ability of the skin to absorb water. The after-shower lotion contains actives that replace barrier lipids, restoring the matrix that prevents water loss. Also the after-shower leaves the skin smooth and soft, which is aesthetically pleasing to the consumer.

2.4.1 Package Ingredients

The package consists of one 16 oz Pre-Shower Lotion, one 20 oz Shower Gel, and one 16 oz After-Shower Lotion. The following tables represent the formulations that were designed to achieve the best results. Table 1, 2, and 3 represent the percentage of each ingredient in the Pre-Shower Lotion, Shower Gel and After-Shower Lotion, respectively.

Table 1: Pre-Shower Lotion Ingredients and Compositions

Material	Weight % in Pre-Shower Lotion
Deionized Water	60
Ammonium Lactate	10
Retinyl Palmitate (Vitamin A Palmitate)	5
Jojoba Oil	8
Cetyl Alcohol	2.9
Phenoxyethanol	0.196
Octyldodecanol	5.9
Maleic Acid	0.004
PEG	8

Table 2: Shower Gel Ingredients and Compositions

Material	Weight % in Shower Gel
Deionized Water	52
Sodium PCA	3
Lactic Acid	4
Urocanic Acid	3
Citric Acid	3
Urea	4
Polysorbate-20	20
Cocoamidopropyl Betaine	5
Phenoxyethanol	0.2
Oleic Acid (Glycerol Oleate)	3
Maleic Acid	0.004
Cetyl Alcohol	2.796

Table 3: After-Shower Lotion Ingredients and Compositions

Material	Weight %
Deionized Water	60
Lanolin	8
Dimethicone	10
Ceramide	0.03
γ -linoleic acid	0.01
Cholesterol	0.01
Palm Oil	0.01
Cetyl Alcohol	5
Phenoxyethanol	4.936
Isostearic Acid	5
Maleic Acid	0.004
PEG	7

2.4.2 FDA Regulations

Skin moisturizers are considered cosmetic products by the Federal Food and Drug Administration. Cosmetic product and ingredients are not subject to FDA pre-market approval authority, with the exception of color additives. FDA cannot require companies to do safety testing of their cosmetic products before marketing. Therefore, FDA is only able to regulate cosmetics after products are released to the marketplace and is able to pursue enforcement action against violative products, firms or individuals that violate the law.²⁶ In the alpha hydroxy acid preparations proposed in this package, a value less than 10% by weight regulated by the FDA was implemented in order to keep the product as a cosmetic product. The only requirement for the alpha hydroxy acid preparations is a proper package

labeling.³⁹ Proper labeling implies that the product ingredients must be listed sequentially in the order of highest concentration without reporting the actual concentrations. FDA does not have the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries after the product has been marketed. However, companies are encouraged to register their establishments and file Cosmetic Product Ingredient Statements with FDA's Voluntary Cosmetic Registration Program (VCRP).²⁶

3. Marketing

Marketing a product such as this one is a difficult task as there are hundreds of treatments out there that are already being used. Also, we are immediately concerned with marketing a trial product with intentions of changing the formulation based on consumer preferences and cost analysis. Special tactics must be employed to market the product as a work-in-progress.

3.1 Target Audience

Hemina, Inc. has an overall target objective to obtain 15% of the national market for patients affected with ichthyosis vulgaris which currently equals approximately 150,000 people. To reach this goal, Hemina, Inc.'s initial target audience is to provide products and services to the Central Midwest which includes Oklahoma, Texas, Arkansas, Missouri and Kansas. This is the audience that we will target while developing the final product. We will use consumer feedback and research to aid in this development. With the assumption that the Central Midwest represents 10% of the total market of ichthyosis vulgaris affected individuals, the initial target audience is about 15,000 people.

3.2 Distribution and Advertising

To introduce our product to our audience, free samples of each product will be distributed to patients on registration lists for ichthyosis organizations such as The National Registry for Ichthyosis and Related Disorders and The Foundation for Ichthyosis and Related Skin Types. The products will also be advertised on the websites for ichthyosis and skin disease related websites. It is impractical to use conventional forms of advertising such

as magazines and commercials since our production is low and we are still developing the product.

4. Manufacturing

The manufacturing of cosmetic lotions is a simple process. The process involves simple equipment and batch mixing procedures. There are two phases involved in the production of lotions and gels: aqueous and oil phase. The process involves heating and mixing the two phases separately and then combining the two phases into one batch.

4.1 Equipment and PFD

The equipment shown in the process flow diagram below describes the production of the package which contains the three products, the Pre-Shower Lotion, the Shower Gel, and the After-Shower Lotion. The material chosen for all of the equipment which includes tanks, pipelines and pumps was chosen to be stainless steel due to its capacity to resist side reactions and high and low temperatures (PT&W). In order to manufacture the package, three jacketed mixing tanks will be used along with a bottom opening for the product discharge. The tanks numbered 1, 2, and 3 along with the production flowsheet are presented in Figure 1. All tanks are assumed to include a sweeper and a mixer for the mixing equipment and Tank 2 will contain a homogenizer in order to help the emulsion of the oil and water phases.

Tank 1 was designed to contain the Shower Gel with a holding capacity of 2.25 m³. This capacity was computed based on the mass produced annually which was calculated to be 108,000 kg/yr and the operating time of making a batch for each product every week corresponding to 4 batches per month.

Tanks 2 and 3 would be used for the production of the Pre-Shower and After-Shower Lotion. The holding capacity for each of the tanks was computed to be 1.8 m³. This capacity was computed based on the 86,400 kg/yr produced annually for each tank and the production rate of 4 batches per month. Tank 2 would hold the oil phase while Tank 3 would hold the water phase. These tanks are connected by a pipeline that would pump the water phase into the oil phase by a pump.

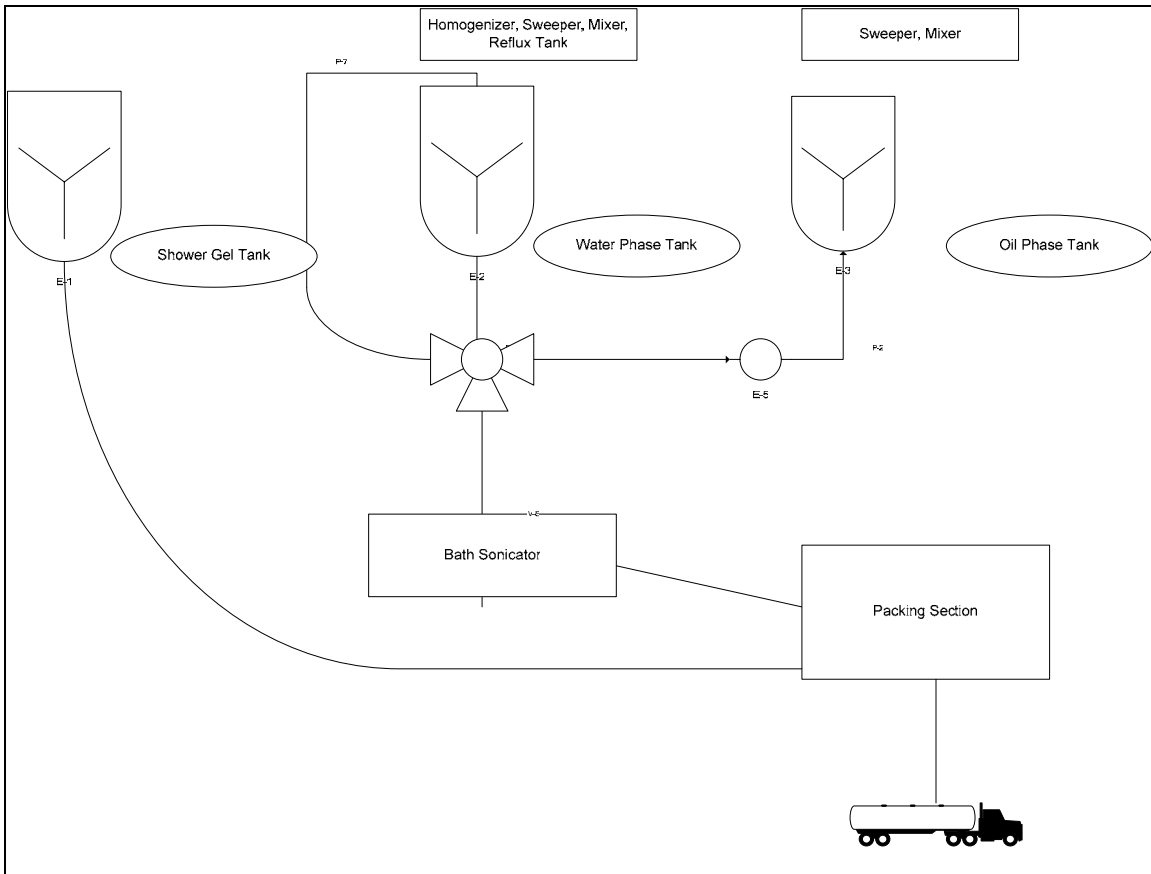


Figure 1: Process PFD

Additional equipment includes a colloid mill to decrease the particle size, a bath sonicator to produce the liposomes, a homogenizer to assist in the emulsion and a pump to push the product through the colloid mill. Table 19 summarizes the equipment costs.

Table 4. Equipment Cost

Equipment	Cost (\$)
Tank 1: Shower Gel	15,800
Tank 2: Lotion	14,000
Tank 3: Lotion	14,000
Colloid Mill	15,000
Bath Sonicator	800
Homogenizer	11,500
2 Pumps	5,500
Total Equipment Cost	\$76,500

4.2 Delivery Systems

To enhance the diffusion of the active ingredients through the skin, delivery systems are used. Many delivery system technologies are currently available. Two of these systems were chosen after extensive analysis of these available systems, liposomes and microemulsions.

4.2.1 Liposomes

The liposome delivery system was chosen since it is simpler and cheaper to manufacture in the industry. The key elements in the production of liposomes according to the innovative process by the department of physics and DEAS at the University of Harvard, include the organic continuous phase coating, the sonicator and the colloid mill.⁵⁷ On the other hand, technologies as the spheres and capsules require extra filtering material as well as more specialized ingredients when making the vehicle that would increase the total product cost. In the package proposed, the colloid mill setting would be adjusted to obtain a particle size of 0.5nm which would use the microemulsion technology. A multiple emulsion was not chosen since the number of ingredients in the formulation is insufficient to divide the oil and water phases in more phases. The nanoemulsion technology was not chosen since the equipment to reach the desired particle size would be very expensive to buy.

Today several techniques are being used in how to manufacture liposomes. Some of these include reverse evaporation, sonication, swelling and electro-swelling. For the project, the innovative procedure proposed by Sophiet Pautot and David A. Weitz from the department of physics and DEAS at the University of Harvard was chosen. This new process called the engineering large unilamellar vesicles with high encapsulation yield proposes an inverted emulsion along with general emulsification techniques as implementing a colloid mill and sonicator into the process.

4.2.2 Microemulsion

The inverted emulsion technique disperses small droplets of the aqueous solution in an organic phase which occurs when the mixing of the oil and water phases is taking place (water-in oil emulsion). Following, the solution is emulsified by an organic continuous phase (in this case Polyethylene Glycol) to stabilize the emulsion. Subsequent, sonicator and colloid

mill apparatus are used to control the size of the emulsion and the encapsulation yield of the active ingredient. Finally, to complete the bilayer of the liposome, the inverted emulsion droplets are allowed to settle across the surfactant layer between the oil and water phases following to the completion of the second lipid bilayer.⁵⁷

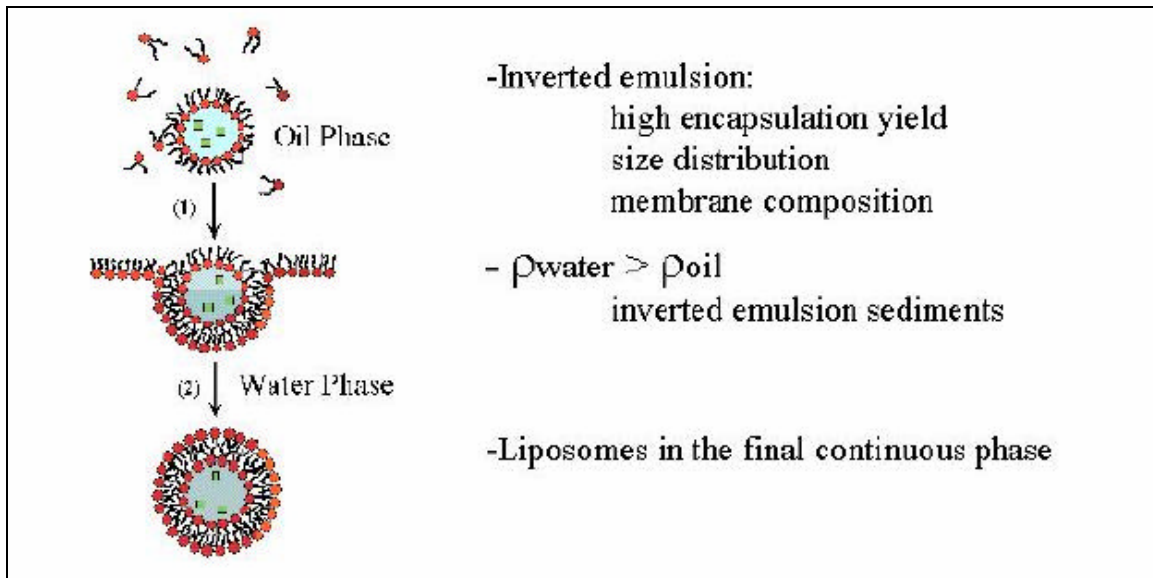


Figure 2: Formation of Lipid Delivery Vehicle⁵⁷

4.3 Production Timeline

The ingredients that have a higher melting point and those that have a higher weight percentage in the formulation are added first in their respective tanks. The phases are then mixed and additional ingredients are added. The following table shows the process for the Pre-Shower Lotion.

Table 5: Pre-Shower Production Timeline with Ingredients in Weight Percentage

Phase A- Oil phase		
Add	Jojoba Oil	8
Mix	Turn sweeper and mixer on	
Heat	Up to 54-56	
Add	Cetyl Alcohol	2.9
Cool	Stop heating cool to less than 40 C	
Add	Retinyl palmitate	8
Phase B- Water phase		
Add	Deonized water	60
Add	Ammonium Lactate	10
Mixing Phases		
Add Phase A- Oil phase to Phase B-water phase		
Constant and steady rate		
Homogenize for 15-20 min		
Add	Octyldodecanol	2.9
Add	PEG-4	8
Transfer	Move to sonicator for 15-20 min	
Add	Phenoxyethanol	0.196
Add	Maleic acid to adjust pH	0.004

5. Economic Analysis

A significant consideration to the development of the final product is the economic feasibility of the project as a whole. Factors such as anticipated demand and market trends comprise the assessment of economic worth. The largest contributor to this economic evaluation is the price of raw materials. Certain ingredients in the formulation are expensive and must be minimized without affecting the efficacy of the product. Based on the product costs, package pricing must be considered and made comparable to current treatments on the market. Net present worth estimation will be used to evaluate the profitability of the project and development of the final product. Several factors are necessary to obtain net present worth including capital investment, utilities and operating labor costs and annual product costs. To obtain a more accurate net present worth, risk assessment must be performed.

5.1 Determination of Demand

The amount of products to be produced was determined based upon an estimated demand for the product. Assuming that 15% of the approximately 10% of people affected with Ichthyosis Vulgaris in the Central Midwest will purchase the package, the demand would be about 15,000 people. The product was formulated to last one month. Thus, the demand for the product was estimated to be 180,000 packages sold per year. This is equivalent to 2.88 million oz of each of the lotions and 3.6 million oz of the shower gel.

5.2 Market Trends

Ichthyosis patients of all forms make up over one million people in the United States per year. It has also been found that 16,000 babies are born per year with one of the forms of this family of disorders. Since there is no cure for ichthyosis, it is unlikely that patients will no longer need a product to treat the disorder. Assuming that the number of people affected by ichthyosis remains constant, the demand should never decrease. The only case in which demand would decrease results from unfavorable response from the patients using our product. Since we are planning to consider consumer feedback to improve the product, we will assume that demand will not decrease. With favorable response, the demand could increase to more than the anticipated value.

5.3 Raw Material Costs

The raw material costs were determined from Peters, Timmerhaus & West⁷⁶ and the catalogs of Aldrich, FisherSci and Sigma-Aldrich. The mass produced per bottle for each ingredient was calculated by multiplying the percent of the ingredient by the amount in weight of the 16oz and 20oz bottles. The amount in weight was calculated by assuming that the ingredients had an approximate density similar to water. The annual mass produced was calculated by multiplying the mass produced per bottle and the annual demand. The volume produced per bottle for each ingredient was estimated by multiplying the percent of the ingredient by the volume of the corresponding bottle. The annual volume produced was calculated by multiplying the volume produced per bottle and the annual demand. The use of volume or mass was determined by whether volume or mass was given for the ingredient

cost in the product catalog. The raw materials costs were then added for each product for a total package cost.

5.3.1 Optimal Formulation

The formulations specified in Tables 1, 2 and 3 in 3.4.1 yielded a raw material cost that was greater than the product value. The raw material cost for the package was \$51.62 million dollars. Table 6 breaks down these costs into the individual products.

Table 6: Raw Material Cost per Product for Optimal Formulation

	Cost (million \$/yr)
Pre-Shower Lotion	6.99
Shower Gel	8.90
After-Shower Lotion	35.62
Total Package	51.62

5.3.2 Decreased Raw Material Cost Formulation

In order to obtain a more positive or less negative net present worth, the raw material cost must be reduced. Reducing this cost meant using less of the more expensive and, unfortunately, more effective ingredients, which reduced the quality of the product. Tables 7, 8, and 9 show these adjustments and the new composition for each product.

Table 7: Pre-Shower Lotion Ingredients and Compositions with Decreased Raw Material Cost Formulation

Material	Weight % in Pre-Shower Lotion	% Change
Deionized Water	70	+10
Ammonium Lactate	10	0
Retinyl Palmitate (Vitamin A Palmitate)	4	-1
Jobba Oil	4	-4
Cetyl Alcohol	3	+0.1
Phenoxyethanol	0.196	-0.8
Octyldodecanol	5.9	+3.9
Maleic Acid	0.004	0
PEG	8	2

Table 8: Shower Gel Ingredients and Compositions with Decreased Raw Material Cost Formulation

Material	Weight % in Shower Gel	% Change
Deionized Water	60	+8
Sodium PCA	2	-1
Lactic Acid	4	0
Urocanic Acid	0.8	-2.2
Citric Acid	2	-1
Urea	4	0
Polysorbate-20	20	0
Cocoamidopropyl Betaine	4.05	-0.95
Phenoxyethanol	0.5	+0.3
Oleic Acid (Glycerol Oleate)	1.25	-1.75
Maleic Acid	0.004	0
Cetyl Alcohol	1.396	-1.4

Table 9: After-Shower Lotion Ingredients and Compositions with Decreased Raw Material Cost Formulation

Material	Weight %	% Change
Deionized Water	70	+10
Lanolin	13.993	+5.993
Dimethicone	4	-6
Ceramide	0.0015	-0.0285
γ -linoleic acid	0.0005	-0.0095
Cholesterol	0.0005	-0.0095
Palm Oil	0.0005	-0.0095
Cetyl Alcohol	2	-3
Phenoxyethanol	1	-3.936
Isostearic Acid	4	-1
Maleic Acid	0.004	0
PEG	5	-2

Using these formulations instead of the original formulations, the raw material cost for the package decreased by almost \$40 million, yielding a new package raw material cost of \$11.86 million. These costs are summarized in Table 10.

Table 10: Raw Material Cost per Product with Decreased Raw Material Cost Formulation

	Cost (million \$/yr)	Change in Cost (million \$/yr)
Pre-Shower Lotion	4.33	-2.66
Shower Gel	4.67	-4.23
After-Shower Lotion	2.86	-32.86
Total Package	11.86	-39.76

5.4 Product Pricing

It's important to price the product as with competitor prices in mind. Our package is naturally going to be priced higher than competing moisturizing lotions, since we have a much larger product, in volume. Also, competing treatments tend to have one active that is costly mixed with other ingredients that are typically used in lotions such as emollients and thickeners. These ingredients are used because of their low raw material cost and good efficacy, but the active is used for its function. Our initial product price is \$50/package. This seems competitive to other products on the market, as other products are comparable when considering price per volume. The following table gives prices of competing lotions recommended for ichthyosis patients found on a range of online pharmacies and compares it to our package.

Table 11: Competition Prices Compared to Hemina

Lotion	Size (oz)	Price (\$)	Price (\$/oz)
LactiCare	7.5	9	1.2
	11.5	11.69-13.75	~1.04
Carmol 10	6	8.99	1.5
Nutraderm	8	7.99	1.0
	16	9.19-10	0.60
Lac Hydrin 5 w/ AHA	4	6.29-7.29	1.5
	8	10.99-12.99	1.5
Hemina	52	50	1.5

5.4.1 Optimal Formulation

Selling the package at \$50 each and distributing once per month yielded a product value of \$9.0 million dollars, which is over \$42 million less than the package raw material cost. Increasing the selling price to \$90 only yields a product value of \$16.2 million, which is still over \$35 million less than the package raw material cost. The actual profit will be lower due to the higher product costs. These costs are summarized in Table 12.

Table 12: Product Value with Optimal Formulation

Selling Price per Package (\$)	Product Value (million \$/yr)	Profit based on Raw Material Cost only (million \$/yr)
50	9	-42.62
70	16.2	-35.42

5.4.2 Decreased Raw Material Cost Formulation

Selling the package at \$50 still yields a product value less than the raw material cost by \$2.86 million dollars. However, increasing the selling price to \$90 per package yields a product value of \$16.2 million, which is \$4.34 million above the raw material cost. Although the actual profit will be lower due to higher product costs, this positive profit based on the raw material cost only is nevertheless encouraging. These costs are summarized in Table 13.

Table 13: Product Value with Decreased Raw Material Cost Formulation

Selling Price per Package (\$)	Product Value (million \$/yr)	Profit based on Raw Material Cost only (million \$/yr)
50	9	-2.86
70	16.2	+4.34

5.5 Capital Investment

The capital investment was estimated using a fluid processing plant by percentage of delivered equipment method. No construction or total product cost inflations were assumed in these estimations although they were included in the cost evaluation. To calculate this value the direct and indirect costs were estimated. The equipment cost was estimated to be \$0.0765 million. The fixed capital Investment (FCI) was estimated to be \$424,000, the working capital was estimated to be \$75,000 and the total capital investment was estimated to be \$499,000.

5.6 Utilities Cost

The required utilities for this process are electricity and cooling water. The electricity requirement was assumed to be 10,000 kWh based on expected plant area and local electricity prices. This corresponded to an annual cost of \$39,000. The cooling water requirement was determined from the surface area of the tanks used for the lotions. The height of both tanks was assumed to be 3m which yielded a surface area of 9.5m² for each

tank. It was assumed that the water was flowing continuously throughout the jacket. For both tanks the cooling water requirement was assumed to be 52,000 m³/yr, which corresponded to a cost of \$4000 per year. Table 14 shows the breakdown of these costs.

Table 14. Utilities Cost

Utility	Cost/unit	Annual requirement (unit/yr)	Annual Cost (million \$/y)
Electricity	\$0.013/kWh	3,000,000	0.039
Jacket Water	\$0.08/m ³	104,000	0.008
Total Utility Cost			\$0.047

5.7 Operating Labor Costs

Using Table 6-15 in PT&W⁷⁶, the labor index was found and extrapolated linearly to find the cost for 2005 which was \$37.94/hr. There will be 2 operators per shift and 1 shift per day. Operating time consists of 3 days per week, working 16 hours per day and 2 days per week, working 8 hours per day. This corresponds to an annual operating labor cost of \$240,000.

5.8 Annual Total Product Cost

Total product cost is dependent on raw material cost along with additional potentially variable expenses such as operating labor, utilities, and maintenance and repairs. Also, fixed charges such as rent and taxes affect the total product cost. Lower product costs give better profit and so it is important to keep it as low as possible. The formulation that was originally designed based on optimal formulation. Then, the formulation was altered in order to obtain lower product cost for later comparison.

5.8.1 Optimal Formulation

The total product cost without depreciation was estimated to be \$58.0 million dollars for the optimal formulation. This cost was based on the raw materials cost of \$51.6 million, operating labor, operating supervision, utilities, maintenance and repairs, operating supplies, laboratory charges and royalties. These costs represent a variable cost of \$52.6 million. The fixed charges include property taxes, a finance interest rate of 5% of the FCI and insurance and were estimated to be \$0.034 million. The general plant overhead was estimated to be

\$0.168 million. The variable costs, fixed charges and the overhead cost represent the manufacturing costs of \$52.8 million. The general expenses included administrative costs, distribution and selling and research and development and were estimated to be \$5.3 million. Table 15 summarizes these results.

Table 15. Total Product Cost without Depreciation of Optimal Formulation

Item	Cost (million \$/y)
Raw Materials	51.616
Variable Costs	52.561
Fixed Charges	0.034
Plant Overhead	0.168
Manufacturing	52.763
General Expense	5.280
Total Product Cost without Depreciation	58.0

5.8.2 Decreased Raw Material Cost Formulation

The total product cost without depreciation for the decreased raw material cost formulation was estimated to be \$14.0 million. The raw material costs were reduced to \$11.9 million which reduced the variable costs to \$12.5 million. This yielded a manufacturing cost of \$12.7 million and reduced the general expenses to \$1.3 million. Table 16 summarizes these costs.

Table 16. Total Product Cost without Depreciation of Decreased Raw Material Cost Formulation

Item	Cost (million \$/y)
Raw Materials	11.9
Variable Costs	12.5
Manufacturing	12.7
General Expense	1.3
Total Product Cost without Depreciation	14.0

5.9 Cost Evaluation

According to estimates, the first three years will be used to build the process and will start in the 4th year. Assuming a construction inflation rate of 2% per year, the fixed capital investment will be \$0.06 million for the start up year 1st year, \$0.15 million in the 2nd year, and \$0.22 million in the 3rd year. Including this interest rate increases the fixed capital investment to \$0.44 million. Additionally, the working capital increases in the 2nd year but is forecasted to be recovered in the 5th year of operation, the 8th year.

Assuming a total product cost inflation rate of 2% per year to take into account the rising raw materials cost, the total capital investment is equal to the fixed capital investment for the 1st and 2nd years. In the 3rd year the TCI is \$0.30 million. The start-up cost in the 4th year is \$0.04 million which represents 10% of the FCI.

Assuming a 3 year MACRS depreciation rate, the depreciation for the 4th year is \$0.15 million, \$0.19 million in the 5th year, \$0.06 million in the 6th year and \$0.03 million in the 7th year. The total depreciation received is estimated to be \$0.44 million over the 5-year project life.

Since production will begin at full capacity in the 4th year of the project, annual sales are estimated to stay constant at \$9 million from the 4th year to the 8th year which equals \$45 million for the length of the project.

Table 17 shows the capital investment costs for the first three years of the project.

Table 17. Capital Investment Cost (million \$)

	Year 1	Year 2	Year 3	Total
Fixed Capital Investment	0.06	0.15	0.22	0.44
Working Capital			0.08	0.08
Total Capital Investment	0.06	0.15	0.30	0.51

Table 18 shows the depreciation amounts for the project.

Table 18. 3-Year MACRS Depreciation in million \$

	Year 4	Year 5	Year 6	Year 7	Total
Depreciation Amount	0.15	0.19	0.06	0.03	0.44

5.9.1 Optimal Formulation

The extremely high raw material costs make this a very unprofitable process which is shown by the negative net present worth (NPW). NPW for this process is -\$219.8 million at a discount rate of 8% per year.

The annual total product cost without including depreciation is \$61.6 million in the 4th year and \$66.7 million in the 8th year for a total product cost of \$320.6 million for the life of the project.

The annual gross profit is -\$52.8 million for the 4th year and decreases to -\$57.7 million in the 8th year. The total gross loss would be \$276.05 million. While the annual gross profit is negative, the annual net profit equals the annual gross profit since no income tax credit is taken for losses.

The annual operating cash flow is -\$52.6 million in the 4th year and decreases to -\$57.7 million in the 8th year for a total operating cash flow of -\$275.6 million. The total annual cash flow is -\$0.06 million in the 1st year and decreases to -\$57.7 million in the 8th year for a total cash flow loss of \$276.1 million.

The return on investment on average would be -\$10,766 million with a net return of -\$55.25 million with a minimum acceptable rate of return of 8% per year. These costs are summarized in Table 19.

Table 19. Annual Costs & Profits of Optimal Formulation at \$50/Package (\$ million)

	Year 4	Year 8	Total
Total Product Cost (w/o Depreciation)	61.6	66.67	320.55
Gross Profit	-52.78	-57.67	-276.03
Net Profit	-52.78	-57.67	-276.03
Operating Cash Flow	-52.64	-57.67	-275.59
Total Cash Flow	-0.06 (2005)	-57.67	-276.1
Return on Investment			-10,766
Net Return			-55.25
Net Present Worth (NPW)			-219.83

5.9.2 Decreased Raw Material Cost Formulation

Optimizing the raw material cost decreased the amount of money lost and increased the revenue, although decreasing the raw material cost is not enough for this process to earn a profit. The net present worth (NPW) for this process is -\$26.1 at a discount rate of 8% per year and was calculated using the annual end-of-year cash flows and discounting method.

The annual total product cost without including depreciation is \$14.83 million in the 4th year and \$16.05 million in the 8th year for a total product cost of \$77.2 million for the life of the project.

The annual gross profit is -\$6.02 million for the 4th year and decreases to -\$7.05 million in the 8th year. The total gross loss was \$32.66 million. While the annual gross profit

is negative, the annual net profit equals the annual gross profit since no income tax credit is taken for losses.

The annual operating cash flow is -\$6.02 million in the 4th year and decreases to -\$7.05 million in the 8th year for a total operating cash flow of -\$32.22 million. The total annual cash flow is -\$0.06 million in the 1st year and decreases to -\$7.05 million in the 8th year for a total cash flow loss of \$32.74 million.

The return on investment on average would be -\$1,274 million with a net return of -\$6.6 million with a minimum acceptable rate of return of 8% per year.

These values are summarized in the following table, Table 20.

Table 20. Annual Costs & Profits of Decreased Raw Material Costs Formulation at \$50/Package (\$ million)

	2008	2012	Total
Total Product Cost (w/o Depreciation)	14.83	16.05	77.18
Gross Profit	-6.02	-7.05	-32.66
Net Profit	-6.02	-7.05	-32.66
Operating Cash Flow	-5.87	-7.05	-32.22
Total Cash Flow	-0.06 (2005)	-7.05	32.74
Return on Investment			-1,274
Net Return			-6.6
Net Present Worth (NPW)			-26.08

Since the annual gross profit is positive, an income tax rate of 35% was applied reducing the annual net profit. As Table 21 shows, the NPW is \$1.5 million/yr.

Table 21: Annual Costs & Profits of Decreased Raw Material Costs Formulation at \$90/Package (\$ million)

	Year 4	Year 8	Total
Total Product Cost (w/o Depreciation)	14.9	16.1	77.5
Gross Profit	1.1	0.09	3.05
Net Profit	0.73	0.06	1.98
Operating Cash Flow	0.88	0.06	2.42
Total Cash Flow	-0.06 (2005)	0.06	1.91
Return on Investment			77.4
Net Return			0.36
Net Present Worth (NPW)			1.52

The following figure compares the two formulations. As Figure 1 portrays, both formulations have negative profits but the optimal formulation is significantly less profitable. The chart also shows that the profit decreases with increasing years.

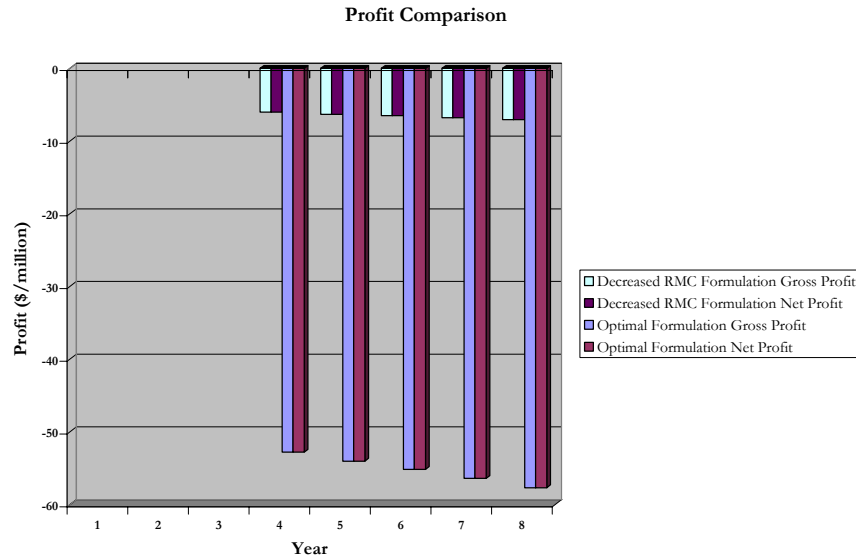


Figure 3: Profit Comparison of the Formulations with a Selling Price of \$50/Package

The following chart compares the cash flow of the two formulations. As Chart 2 shows, both formulations have negative cash flows but the optimal formulation yields significantly less cash flow. The chart also shows that the cash flow decreases with increasing years.

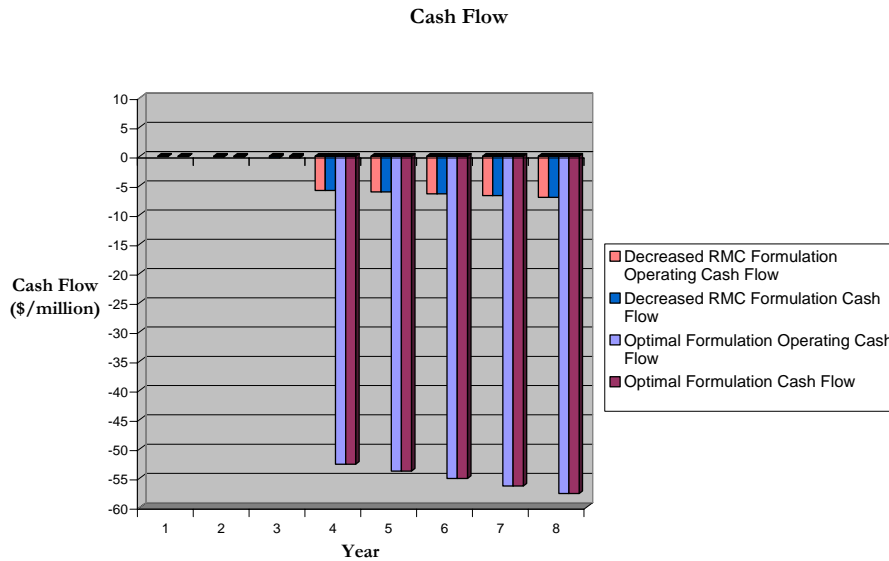


Figure 4: Cash Flow Comparison of the Formulations with a Selling Price of \$50/Package

The following chart shows the profit comparison of the two formulations if the package was sold at \$90. The profit for the decreased raw material cost formulation is positive but decreases with increasing years. The chart shows the optimal formulation but even selling the package at this price still produces very negative positive results.

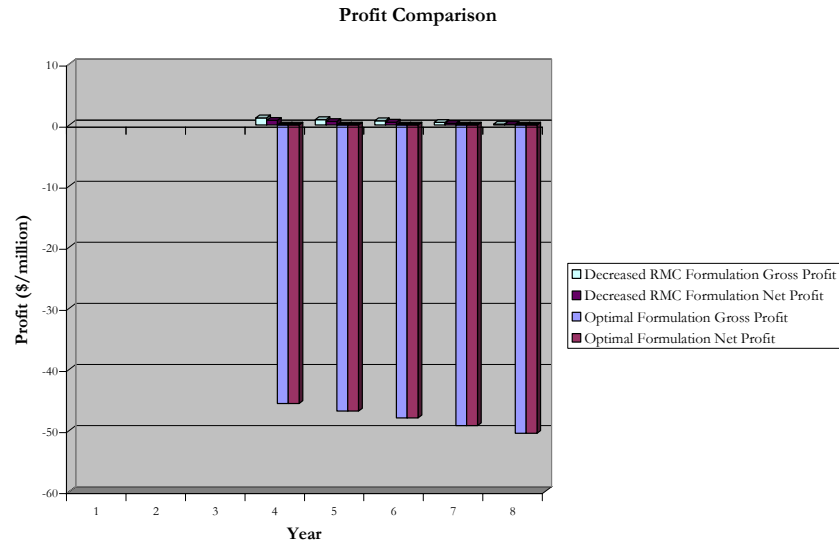


Figure 5: Profit Comparison of the Formulations with a Selling Price of \$90/Package

The following chart shows the cash flow if the formulations were sold at \$90 per package. The optimal formulation still yields very negative results but the decreased raw material cost formulation shows a slightly positive cash flow.

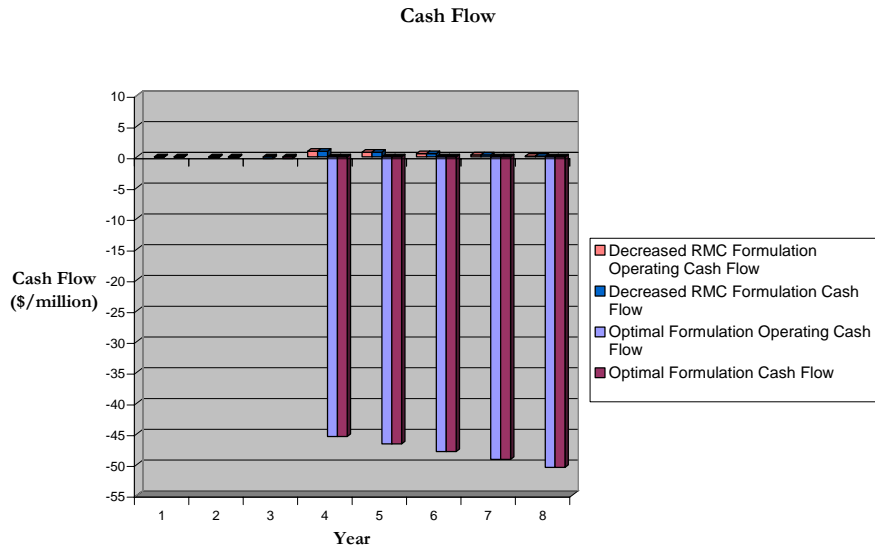


Figure 6: Cash Flow Comparison of the Formulations with a Selling Price of \$90/Package

5.10 Risk

When accounting risk for projects there are several factors that can be taken into account. For the risk analysis for this project, the change of the raw materials cost over the course of the 5 year life of the project was analyzed. In order to make the risk analysis, different but constant inflation rates were chosen randomly to affect the price of the raw materials used in each package. The risk analysis was only developed for the first four raw material that have the highest percent total cost of a yearly production of a product. Tables 1, 2, and 3 show the results when calculating the % total cost needed for each ingredient and the rows highlighted show the four ingredients that were used to make the risk analysis.

Table22: Percent Total Cost of Components in Pre-Shower Lotion

Material	%	Mass Needed/yr (kg/yr)	Cost (\$/year)	% Total Cost
Deionized Water	60	51840	\$4	0.00
Ammonium Lactate (Aldrich)	10	8640	\$1,479,905	20.46
Retinyl palmitate	5	4320	\$1,362,960	18.84
Jojoba oil	8	6912	\$1,695,851	23.44
Cetyl alcohol#	2.9	2505.6	\$245,298	3.39
Phenoxyethanol	0.196	169.344	\$5,793	0.08
Octyldodecanol	5.9	5097.6	\$2,306,538	31.89
Maleic acid (Aldrich)	0.004	3.456	\$92	0.00
PEG	8	6912	\$137,030	1.89
Total	100	86400	\$7,233,473	100.00

Table23: Percent Total Cost of Components in Shower Gel

Material	%	Mass Needed/ year (kg/yr)	Cost (\$)/ yr	% Total Cost
Deionized Water	52	56160	\$5	0.00
Sodium PCA	2	2160	\$975,217	10.95
Lactic Acid	5	5400	\$167,040	1.88
Urocanic Acid	2	2160	\$6,687,360	75.11
Citric Acid	2	2160	\$55,253	0.62
Urea	4	4320	\$31,752	0.36
Polysorbate-20	20	21600	\$584,137	6.56
Cocoamidopropyl Betaine	6.9	7452	\$37,357	0.42
Phenoxyethanol	0.3	324	\$11,243	0.13
Glyceryl oleate (oleic acid)	3	3240	\$58,369	0.66
Maleic acid	0.004	4.32	\$115	0.00
Cetyl alcohol	2.796	3019.68	\$295,627	3.32
Total	100	108000	\$8,903,475	100.00

Table24: Percent Total Cost of Components in After-Shower Lotion

Material	%	Mass Needed/year (kg/yr)	Cost (\$)/Year	% Total Cost
Deionized Water	60	51840	\$4.41	0.00
Lanolin	8	6912	\$233,625.60	0.65
Dimethicone	10	8640	\$946,944.00	2.65
Ceramide	0.03	25.92	\$33,675,264.00	94.26
γ -linoleic acid	0.01	8.64	\$49,766.40	0.14
Cholesterol	0.01	8.64	\$2,522.88	0.01
Palm Oil	0.01	8.64	\$317.00	0.00
Cetyl alcohol	5	4320	\$422,928.00	1.18
Phenoxyethanol	4.936	4264.704	\$147,985.23	0.41
Isostearic Acid	5	4320	\$125,202.58	0.35
Maleic acid	0.004	3.456	\$92.25	0.00
PEG	7	6048	\$119,901.60	0.34
Total	100	86400	\$35,724,553.95	100.00

Ten scenarios were developed for the ingredients chosen from Year 4-Year 8 since these are the years when the product is starting to be manufactured. The scenarios were developed by using different inflation rates chosen randomly. Table 25 shows as an example the active ingredient in the pre-shower lotion ammonium lactate.

Table 25: Development of Scenarios in Ammonium Lactate

Ammonium Lactate	Inflation	Year 4	Year 5	Year 6	Year 7	Year 8
Scenario #1	0.96	\$1,479,905	\$1,420,709	\$1,363,881	\$1,309,325	\$1,256,952
Scenario #2	1.02	\$1,479,905	\$1,509,503	\$1,539,693	\$1,570,487	\$1,601,897
Scenario #3	0.98	\$1,479,905	\$1,450,307	\$1,421,301	\$1,392,875	\$1,365,018
Scenario #4	1.01	\$1,479,905	\$1,494,704	\$1,509,651	\$1,524,748	\$1,539,995
Scenario #5	0.97	\$1,479,905	\$1,435,508	\$1,392,443	\$1,350,670	\$1,310,150
Scenario #6	1.05	\$1,479,905	\$1,553,901	\$1,631,596	\$1,713,175	\$1,798,834
Scenario #7	0.95	\$1,479,905	\$1,405,910	\$1,335,615	\$1,268,834	\$1,205,392
Scenario #8	1.06	\$1,479,905	\$1,568,700	\$1,662,822	\$1,762,591	\$1,868,346
Scenario #9	1.03	\$1,479,905	\$1,524,302	\$1,570,032	\$1,617,132	\$1,665,646
Scenario #10	1.04	\$1,479,905	\$1,539,101	\$1,600,666	\$1,664,692	\$1,731,280

Graphing these results in terms of price of the product versus time in years allow for better judgement when doing the risk analysis. Figure 7 provides an example of the multiple graphs developed for the ingredients in each product that affect greatly the cost of the raw materials.

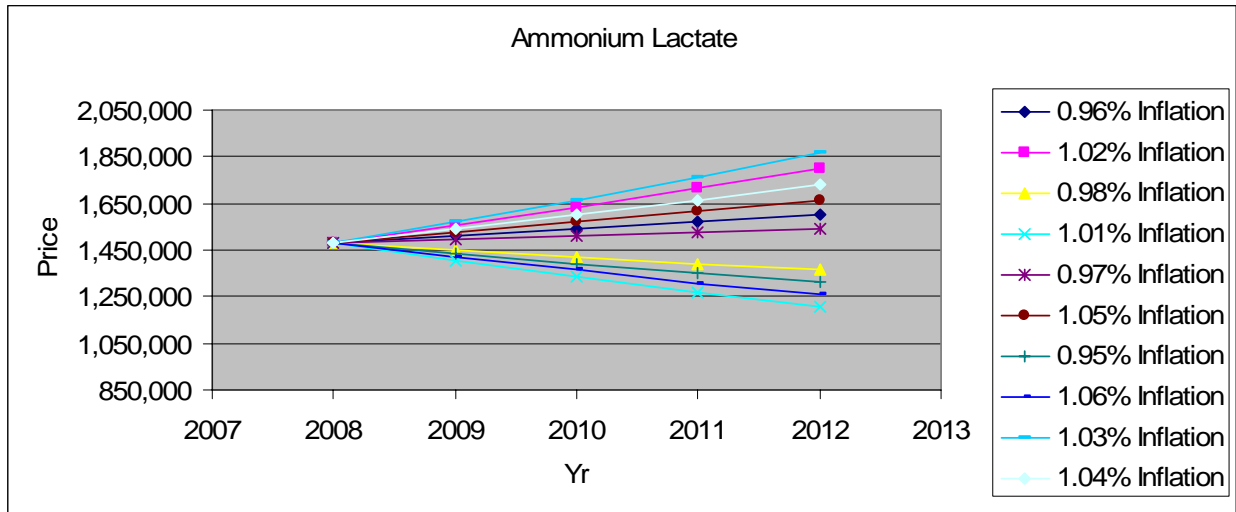


Figure 7: Risk Analysis of Pre-shower Active ingredient Ammonium lactate Scenarios

In the graph, it can be observed that the scenario #4 which has an inflation rate of 0.95% gave the lowest raw material cost after the life of the project with a value of \$1,205,392. After the same number of scenarios have been developed for the four ingredients in each product, the raw material cost at the 8th year are added and a final scenario is chosen upon the lowest raw material cost. Table 26 provides the results observed for the pre-shower lotion where scenario #2 which gave the lowest raw material cost per year for the four ingredients with a value of \$4,855,326. Table 27 shows the optimum values and inflation rates for the four ingredients in the lotion.

Table 26: Best Scenario for Ammonium Lactate

Best Scenario for Pre-Shower Gel				
Scenario #1	Scenario #2	Scenario #3	Scenario #4	Scenario #5
5,566,039	4,855,326	6,183,738	5,395,414	5,511,334
Scenario #6	Scenario #7	Scenario #8	Scenario #9	Scenario #10
5,905,220	5,200,631	5,518,325	6,444,204	5,047,176

Table 27: Best scenario for Pre-shower lotion

Scenario #2			
Ingredient	Inflation %	Cost in Year 4	Cost in Year 8
Ammonium Lactate	1.02	\$1,479,905	\$1,798,834
Retinyl Palmitate	1.02	\$1,362,960	\$1,475,312
Jojoba Oil	0.97	\$1,695,851	\$1,501,325
Octyldodecanol	0.95	\$2,306,538	\$1,878,690

The example shown above describes the best scenario in industry conditions. Further analysis could be done with the worse case scenario always keeping the fixed selling price according to the market.