ANTICAVITY TOOTHPASTE DESIGN

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

Dental caries present a unique health problem, and yet they are considered a widespread infectious disease. If the prevalence of caries could be decreased, Americans could save the money, time, and personal pain involved with dental services for caries. A novel active ingredient has been explored as an additive for a dentifrice, extracted from the byproduct of wine-making, grape pomace. This polyphenolic extract shows strong inhibitory power toward the virulence factors of oral bacteria, such as the production of polysaccharides and acid. The consumer preference model is used to connect consumer survey data to a product composition for toothpaste, including the polyphenolic extract. This exercise results in a product composition that boasts 98% consumer satisfaction.

INTRODUCTION

Dental carries is a widespread and costly infectious disease. It is the next most common ailment after the common cold (U.S. National Library of Medicine). According to the CDC (2005), tooth decay affects more than one-fifth of U.S. children aged 2-4, half of those aged 6-8, and nearly 60% of those aged 15. Additionally the CDC report states that in 2004, approximately $78 billion was spent on dental services and a collective 500 million visits were made to the dentist by the American population. It is estimated that the average American will have over 17 cavities in a lifetime (Beltrán-Aguilar, 2005). The solution that this study suggests is the development and mass usage of anti-cavity toothpaste which would reduce the risk of acquiring a cavity.

DENTAL CARIES

Dental caries, also known as tooth cavities and tooth decay is the condition that describes holes or other structural damage in the tooth. The oral bacterium, Streptococcus mutans, is the most responsible bacteria that cause the conversion of food carbohydrates to acids (Satcher 2000). The combination of bacteria, acid, food debris, and saliva combine to form a bio-film (plaque) on the surface of the tooth (U.S. National Library of Medicine). The bio-film formation leads to anaerobic fermentation and an eventual acid build up (Satcher 2000). Figure 1 illustrates the multifactor concept of tooth caries.

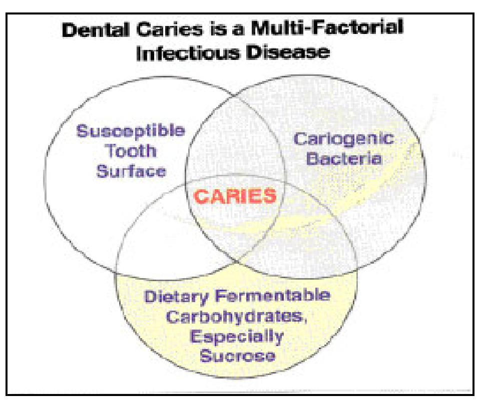
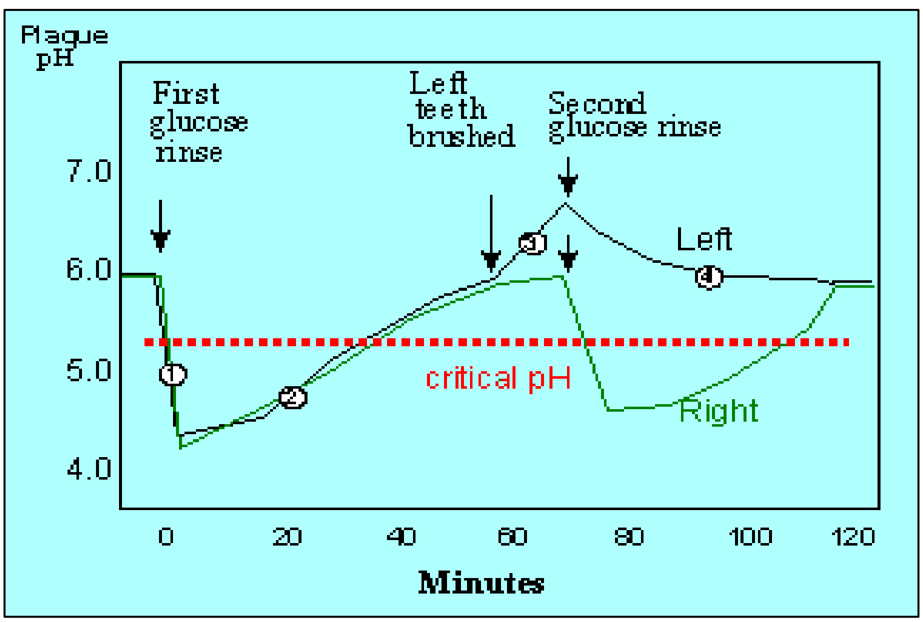


Figure 1: Factors Contributing to Dental Caries

This activity shifts the mouth's pH to below 5.5 which causes the teeth to cycle towards demineralization. Over a period of time, a cavity will form at the site of continuous demineralization. However, the process of demineralization can be reversed by calcium, phosphate, and fluoride (salvia components) diffusion into the tooth at the site of the cavitations (Featherstone 2004). This process of demineralization and remineralization occurs frequently each day and dependant on the more dominant process may result in cavities, repaired surfaces, or maintenance of the status quo (Featherstone 2004).

The affect of pH cycling of the mouth can be described by the Stephan Curve, which gives an estimate of the cariogenic risk that a tooth would face. The Stephan Curve in Figure 2 (Wilding 1999), illustrates how the intake of food and action of brushing the teeth affects the plaque's pH level. The beginning of the graph begins in the consumption of food (in this case glucose) which causes the plaque's pH to fall below 5.5 and promote demineralization. Then the teeth on the left side of the mouth were brushed and another glucose rinse was performed. The Stephan curve shows that brushing the left-side teeth elevates the plaque's pH and promotes remineralization. It also shows that the right-side teeth pH slowly increases due to the action of the mouth's salvia.

Figure 2: Stephan Curve (Wilding 1999)



NOVEL ACTIVE INGREDIENT: GRAPE POMACE

Polyphenols have long been considered a beneficial bioactive molecule in foods. Recently, it has been found that an extract made from the waste of winemaking, known as grape pomace, is especially high in polyphenols (especially catechin, Figure 3), and can greatly reduce the virulence factors of *Streptococcus mutans*. This extract has been shown to reduce the synthesis of polysaccharides and acid without showing any death effects to the bacteria (Thimothe 2007). The method of reducing the virulence factors of *S. mutans* without killing all the oral bacteria, would be a precise and selective method for reducing dental caries. With an antibiotic toothpaste formula, there is the risk of disrupting the other oral flora and, the even greater risk, is of consumer allergic reactions and bacterial resistance. A toothpaste with this extract would not have those disadvantages (Thimothe 2007).

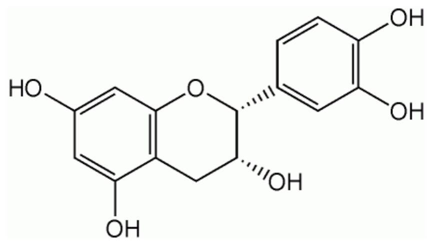


Figure 3: Catechin

CHEMISTRY

S. mutans synthesizes extracellular polysaccharides, which can be up to 40% glucan (Koo, 2003). These are polysaccharides, which are nearly insoluble in water, make up the bulk of plaque. Plaque is one of the primary contributors to causes of dental caries. The bacteria produce these polysaccharides from sucrose through the use of glucosyltransferases, which are a specific class of enzymes. Three glucosyltransferases produced by *S. mutans* are glucosyltransferase B (GTF B), GTF C, and GTF D, which each synthesize their own glucans (Koo, 2003). The activity of these enzymes represent the production of the GTFs, which would also represent the production of the polysaccharide building blocks of plaque. The effect of the wine pomace extract (specifically, pomace from Pinot Noir grapes) upon the *in vitro* GTF B activity can be seen in Figure 4.

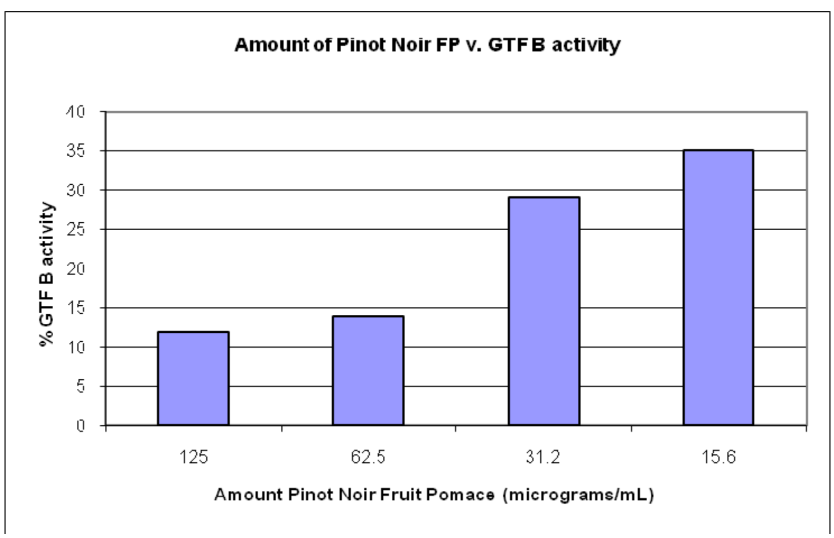


Figure 4: Glucosyltransferase B activity with Pomace Extract

Another virulence factor of *S. mutans* is its nearly unique ability to produce and tolerate acids. These acids result in low pH values in the plaque, pushing the mineralization cycle toward demineralization of the teeth, contributing to dental caries. Because they are creating such acids in a microenvironment, *S. mutans* have developed methods to alleviate the acidic stress by transporting protons out of the cells. This is done through F-ATPase activity in the presence of low pH. During ATP hydrolysis, the enzyme transports protons out of the cell to maintain an appropriate intercellular pH, more alkaline than the environment (Thimothe, 2007). The activity of F-ATPase can also be considered a method for quantifying the virulence factors of *S. mutans*.

In Thimothe, 2007, the pH of a solution of S. mutans in excess glucose varied from the control and the solution with the pomace extract, seen in Table 1. A marked increase in pH was seen, which was connected to the percent F-ATPase activity. In Figure 5, a correlation is made between the percent F-ATPase activity and the estimated percent change in mouth pH.

Table 1: Change in pH for S. mutans solution in the presence of fruit pomace extract. From Thimothe, 2007.

Extract	pH	Percent F-ATPase activity (125 µg/mL)
Control	3.97	100
Cabernet Franc FP	4.31	35
Pinot Noir FP	4.47	30

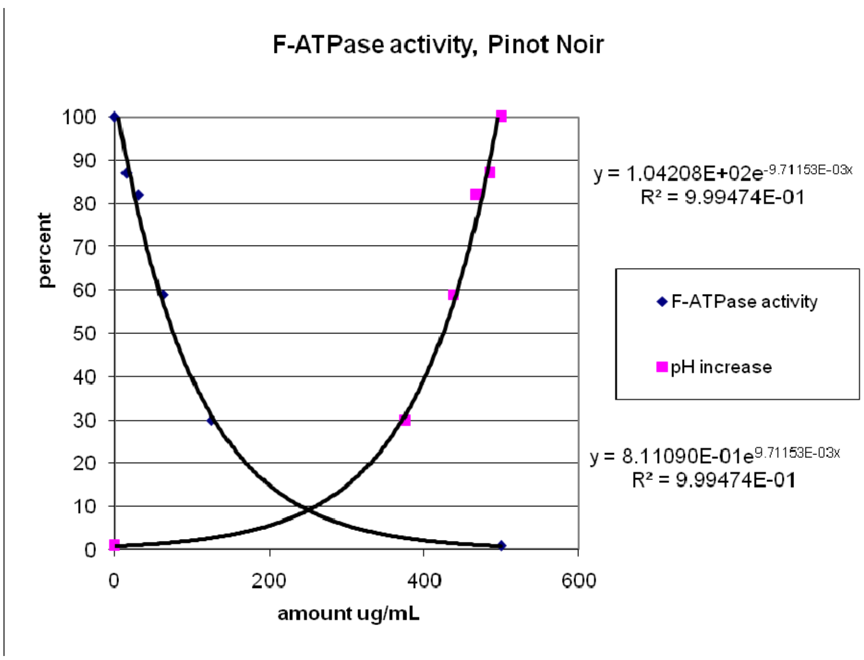


Figure 5: F-ATPase Activity and pH Increase for Pomace Extract

To illustrate the beneficial properties of using a dentifrice containing this pomace extract, a predicative model was made which compared the Stephan curve (Figure 2: Stephan Curve (Wilding 1999)) with the pH increase caused by the pomace extract. From Figure 6, it can be seen that with brushing, the overall pH of the mouth would increase, and it would take more time and sugars for the pH to drop below the critical level (shown by the orange line) than with the control.

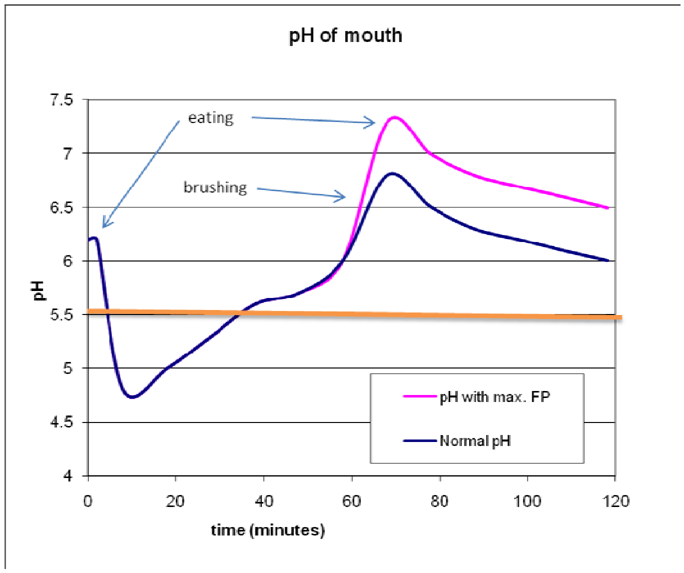


Figure 6: Model of Mouth pH

EXTRACTION PROCESS

One advantage of using grape pomace extract is that the feed ingredient, wine-making waste, is abundant and inexpensive. It is estimated that 13% by weight of the grapes which are processed through wine-making end up in byproduct waste (Torres 2002). In California alone, 3.239 million tons of grapes were grown and harvested for wine-making in 2007 (Ross 2008). This leads to an approximation of 3.82×10^8 kilograms of pomace/year in California. Making the assumptions in Table 2 to reach an order of magnitude estimate about the amount of production and the amount of pomace needed, a very small amount of the total California grape pomace would be utilized for the active ingredient production. This could likely be provided in one area with many wineries, such as Napa/Sonoma, CA.

Table 2: Estimates for Active Ingredient Production

Pomace in California	3.82×10^{8} kg/year
Polyphenols in Pomace (Makris, 2007)	6.7% by weight
Polyphenols in California	2.55×10^{7} kg/year
Maximum Concentration Polyphenolic Extract in toothpaste	500 micrograms/mL
Size of tube of toothpaste	175 mL
Estimated Production (Popovich, 2000)	4.10×10^{7} tubes/year
Polyphenols Needed	3.59×10^{3} kg/year
Percentage of California pomace needed	0.014%
Days of Extraction/year	330 days
Approximate Polyphenolic Production	0.453 kg/hour

The authors of Thimothe, 2007 used a solvent extraction procedure to obtain the polyphenolic extract. This procedure was used in the estimated scale-up of the extraction process in Figure 7.

The steps are as follows:

1. Transport pomace via land from winery to extraction facility.
2. Freeze dry pomace.
3. Mix 1:10 (w:v) freeze dried pomace with methanol/ethanol/water (50/25/25%, v/v) and homogenize.
4. Centrifuge mixture to discard solids.
5. Evaporate solvents at 35° C and reduced pressure until an aqueous extract is obtained.
6. Load chromatography column with extract, elute with 0.01 N aqueous HCl to remove other solutes, then elute polyphenols with absolute methanol.
7. Evaporate methanol at 35° C and reduced pressure to dryness.

From this method, only the operating costs were considered to determine an estimate of the price of the active ingredient, $10.47/g of extract.

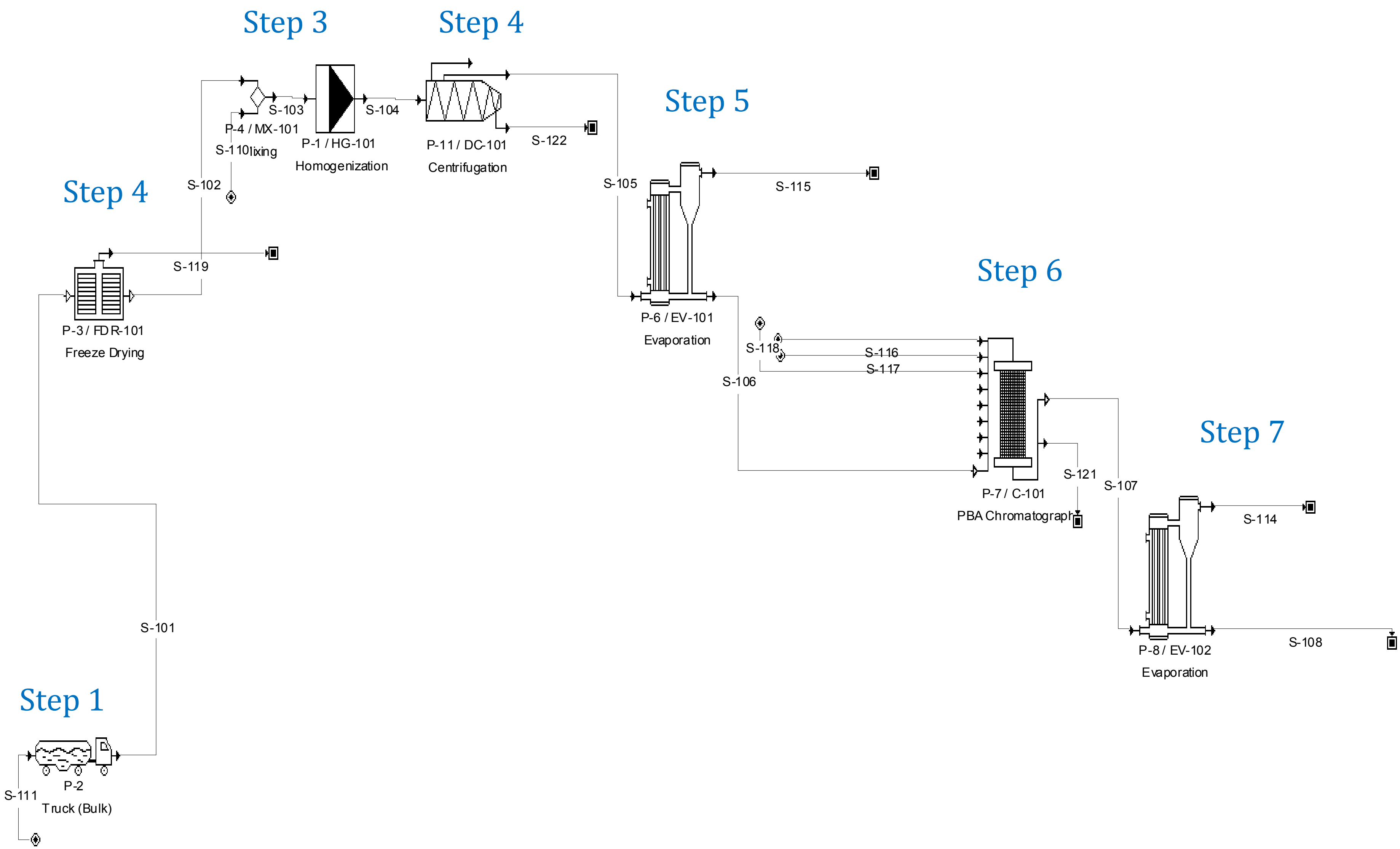


Figure 7: Extraction Flowsheet for Polyphenolic Extract from Wine Pomace

RAW MATERIALS

Toothpaste contains a variety of inactive ingredients which attribute to its unique properties. These ingredients can be broken into ten main categories: abrasives, binders, color, solvent, flavors, flow modifiers, humectants, preservatives, sweeteners, and surfactants. Table 4 and Table 5 summarize the main inactive ingredients in toothpaste and Table 6 (Braun and Rosen 2000) gives the recommended concentration limits. In addition to these main ingredients it may contain special chemicals for functions such as whitening, tartar control, and sensitive teeth. Abrasives remove plaque and other particles that accumulate on the outer surface of the tooth. They affect the toothpaste's consistency and give the paste a gritty texture. Because large quantities of abrasives can cause unnecessary damage to tooth enamel, the American Dental Association (ADA) recommends that the RDA value remain below 200 (See Abrasion). Common abrasives used are hydrated silica, calcium phosphate, calcium carbonate, sodium bicarbonate, and sodium hexametaphosphate. The final product may use one component exclusively or a combination for its desired effect.

Binders are used to thicken toothpastes and prevent separation of the solid and liquid phases. They can affect the speed and volume of foam production, the appearance of the toothpaste on the toothbrush, and the rinse ability of the product (Blanchford 2002). Common binders are bentonite, carrageenan (Irish moss), karaya gum, and methylcellulose (Blanchford 2002), polyethylene, and PEG-12. Color can be attributed to the type of dye used in addition to the amount of titanium dioxide which gives the toothpaste its opacity. Deionized water is used for dilution purposes and comprises the liquid phase of the paste. This type of water must be used in order to prevent undesirable reactions between the naturally occurring ions in water and the other chemicals in the toothpaste.

Flavoring and sweeteners are perhaps the most important components because they give the otherwise tasteless substance marketability and pleasantness. Members of the mint family *Lamiaceae* are commonly used in toothpastes. Examples would include spearmint (*Mentha spicata*) and the hybrid peppermint (*Mentha x piperita)*. These substances give a fresh feeling to the mouth. The synthetic menthol (which is derived from either *Mentha piperita* or *Mentha arvensis*) triggers cold-sensitive receptors in the same manner that capsacin (chemical attributed to heat in peppers) imparts a spiciness and triggers heat-sensitive receptors. A study by Xing, et al. at the University of Florida (2006) describes topical menthol to produce a cooling sensation at low concentrations by acting upon the TRPM8 receptor (a protein ion channel). The introduction of menthol to the rat neural cells caused calcium ions to be released and depolarize the cell, in effect creating an action potential which propagates through the sensory nervous system to give the message of cold to the brain. Other popular flavorings include cinnamon oil which is attributed to killing protein metabolizing bacteria which cause halitosis (University of Illinois 2004). Sweeteners are also used to improve upon the taste of toothpaste. The synthetic sugar-free sweeteners are up to 600 times sweeter than sucrose (table sugar). Table 3 gives a summary of various sweeteners relative to sucrose (Pohlman 2005; Yale-New Haven Hospital 2005; & Koseki 2005).

Table 3: Relative Sweetness

Sweetener	**Relative Sweetness Value**
Acesulfame-K	**200**
Aspartame	**190**
Glycerol	**50**
Mannitol	**0.6**
Saccharin	**300**
Sorbitol	**0.5**
Sucralose	**600**
Sucrose	**1**
Xylitol	**1**

Flow modifiers are the main contributors to the thickness and viscosity of the toothpaste. Common agents which thicken the aqueous portion of the mixture are xanthan gum, cocamidopropyl betaine, carboxymethylcellulose sodium (Cosmeticsinfo.org). The gums increase the viscosity by dissolving in water and swelling to form a more viscous solution (Cosmeticsinfo.org). Preservatives such as sodium benzoate are used to prevent spoilage of the product. The chelating properties of trisodium phosphate may classify it as a preservative because it inactivates metal ions that may degrade the product (Cosmeticsinfo.org).

Humectants are used to retain water in order to keep the solid and liquid phases of toothpaste together. They also can add sweetness and a cooling effect to the toothpaste. Sorbitol, glycerin, and propylene glycol are common humectants. Surfactants reduce the surface tension of water when used in low concentrations (Montana State University 2005). Surfactants are hydrocarbons that have a polar head group (hydrophilic) and a non-polar tail (hydrophobic). In low concentrations, surfactants are suspended in water as individual molecules (Lisensky 2007). It cleanses by creating an interface where water can mix with oil and dirt and remove it from a surface. The surfactant's chemical structure will cause it to form a micelle when its concentration exceeds the critical micelle concentration (Lisensky 2007). Additionally the surface tension and foaming density of a surfactant decreases as its concentration nears the critical micelle concentration. The surface tension decreases linearly while the foaming density decreases logarithmically. The main surfactants used in toothpaste are anionic sodium lauryl sulfate and its derivatives.

Table 4: Inactive Ingredients, Part 1

Abrasives	Binders	Coloring	Flavor
Calcium Carbonate	Carrageenan (Irish Moss)	Titanium Dioxide	**Peppermint Oil**
Calcium Phosphate	Karaya Gum		**Cinnamon Oil**
Hydrated Silica	Methylcellulose		
Sodium Bicarbonate	Polyethylene		
Sodium Hexametaphosphate	**PEG-12**		

Table 5: Inactive Ingredients, Part 2

Flow Modifier (Thickening Agent)	Humectants	Preservative	Solvent	Surfactants	Sweeteners
Carboxymethylcellulose Sodium (Cellulose Gum)	Sorbitol	Trisodium Phosphate	Deionized Water	Sodium Lauryl Sulfate	**Sorbitol**
Xanthan Gum	Glycerin	Sodium Benzoate		Sodium Lauryl Sulfonacetate	**Aspartame**
Cocamidopropyl	**Propylene Glycol**				**Sodium Saccharin**

Table 6: Recommended Concentration Limits of Components (Braun & Rosen 2000)

Type of Ingredient	Min. Concentration	Max Concentration
Abrasive	0.00%	**40.00%**
Binders	1.20%	**3.00%**
Coloring	0.00%	**1.00%**
Flavoring	0.00%	**1.00%**
Flow Modifier	0.40%	**1.00%**
Humectants	20.00%	**75.00%**
Preservative	0.05%	**0.20%**
Solvent	3.70%	**19.45%**
Surfactant	1.50%	**5.00%**
Sweetener	**0.20%**	**1.50%**

Consumer Preference Model

To design an anti-cavity dentifrice that can compete in the toothpaste market, the desires of the consumers must be taken into account. Merely being able to prevent cavities is usually not enough to make a toothpaste overly desireable to a consumer; the physical properties of the toothpaste must be considered. To design a formula with the optimal consumer properties, a linear weighted average of consumer preferences of characteristics is used, in Equation 1 (Bagajewicz, 2007). Although the term satisfaction is used, it merely represents a preference for a certain product or characteristic over other products or characteristics.

Equation 1

$$S_{ik} = \sum w_{ikj} y_{ikj}$$

Where S_{ik} is the consumer satisfaction with product *i* in market *k*, y_{ikj} is the score of consumer satisfaction with characteristic *j* of product *i* in market *k*, and w_{ikj} is the corresponding consumer weight of importance of characteristic *j*. These characteristics can then be related to physical properties and concentrations of ingredients in the product. The final composition for the product can be found by optimizing the consumer satisfaction, *S*. The characteristics chosen to vary for the anti-cavity toothpaste are shown in Table 7.

Table 7: Consumer Weight of Characteristics

Characteristic	Weight
Sweetness	13%
Viscosity	8%
Cooling Effect	18%
Abrasiveness	13%
Foaminess	7%
Creaminess	7%
Effectiveness	33%

Spreadability was another characteristic of toothpaste that was considered. Some toothpaste formulators relate it to the "sag" that the toothpaste experiences when the ribbon sits on the brush for a matter of minutes. However, this quantity was very difficult to predict from only the weight percents of ingredients, and it could be included in future studies.

A group of 15 consumers were given a survey which determined their preferences for and within each characteristic. The age group of these consumers was very narrow (20-24), and a wider sample and a greater number of surveyors would add merit to this study. However, the correlations between characteristics and physical properties hold regardless of the number of surveyed consumers.

SWEETNESS

The sweetness of a toothpaste is an important property because, along with flavor, it is one of the only ways to give the toothpaste taste. Sweetness can be imparted to a toothpaste through multiple ingredients. The common humectants sorbitol and xylitol give the toothpaste some sweetness, and usually the non-nutritive sweetener saccharine is added as well. The consumer survey had the consumers rank the satisfaction with the sweetness of three other food products, as seen in Table 8. Then, these were correlating with their corresponding weight percent of sucrose, or table sugar.

Table 8: Sweetness Consumer Survey

Consumer Option	Equivalent Product	Equivalent wt % Sucrose
1: Low Sweetness	Candy	100
2: Medium Sweetness	Gum	55
3: High Sweetness	Mint	10

The consumer preference was plotted with the equivalent weight percent sucrose to determine the correlation, which can be seen in Figure 8.

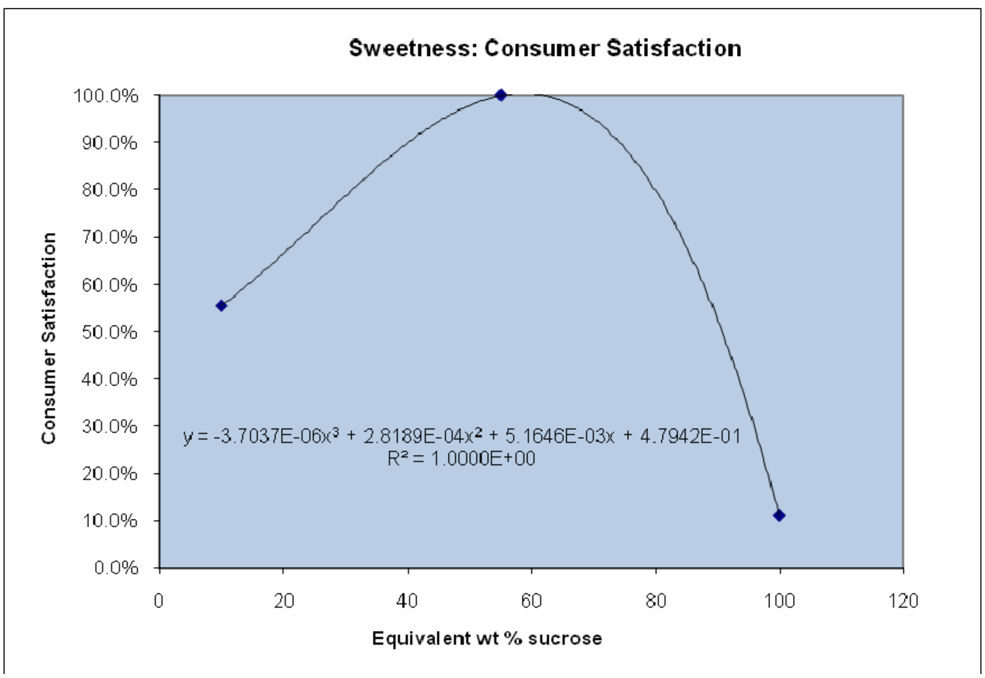


Figure 8: Consumer Satisfaction, Sweetness

To achieve the sweetness for the maximum consumer satisfaction, the effects of sorbitol and xylitol were taken into account, and then additional sodium saccharine was added to the optimal formula, keeping in the equation the relative sweetness of each (**Error! Reference source not found.**).

THICKNESS

Thickness, or the consistency felt in the mouth upon use of the toothpaste, is important to consumers because it directly relates to the usage of the dentifrice. If a toothpaste is too thick, it may be more difficult to spread around the teeth, and it may not all be used. If toothpaste is too thin, it may not feel like it is cleaning as effectively. Additionally, a thick enough paste is required to keep the abrasives properly dispersed throughout the toothpaste (Mason, 2000). This can depend heavily on the amounts of gelling agents in the toothpaste, as well as the fraction of the toothpaste which is solid.

The thickness of a semisolid food is proportional to the shear forces on the tongue. This has been found to be:

$$\{Perceived\ \ Viscousness\} \quad \alpha \quad F = -\mu A \frac{dv}{dy}$$

Equation 2

Where F is the shear forces on the tongue, μ is the viscosity of the semisolid, v is the velocity of the tongue, and h is the height of the initial film layer felt between the tongue and the roof of the mouth (Kokini 1983). This definition would vary slightly for toothpaste because the initial force is felt between the toothbrush, the fluid, and the teeth. Making the assumptions shown below, as made by Cussler (2001), Equation 3 can be arrived at.

$$\frac{dv}{dy} = \frac{v}{h}$$

$$h \ \alpha \ \mu^{1/2}$$

$$\{Perceived\ Thickness\} \ \alpha \ \{Perceived\ Viscousness\} \ \alpha \ \frac{\mu v}{\mu^{1/2}} \ \alpha \ \mu^{1/2}$$

$$\{Perceived\ Thickness\} \quad \alpha \quad \mu^{1/2}$$

Equation 3

Predicting the viscosity of toothpaste means taking into account both the solid and the liquid phases that cause toothpaste to have its consistency. Chosen for this calculation is an empirical correlation, Equation 4, by Barnea and Mizrahi, and explored by Poletto and Joseph (1995). It is considered fairly accurate for suspensions of particles for fluids at low Reynold's numbers, but not for very dilute particle systems.

$$\eta_m = \eta_f * \exp\left[\frac{5}{3}\left(\frac{\phi}{1-\phi}\right)\right]$$

Equation 4

$$\eta_m = mixture\ viscosity$$
$$\eta_f = fluid\ viscosity = \sum \eta_i c_i$$
$$\eta_i = viscosity\ of\ liquid\ i$$
$$c_i = fraction\ of\ i\ in\ liquid\ phase$$
$$\phi = volume\ fraction\ solids$$

As seen in Figure 9, the volume fraction of solids can have a drastic effect on the overall viscosity of the mixture. The regular fraction of solids in toothpaste would be between 10 and 50% (Mason, 2000), which would increase the viscosity of the toothpaste up to 5 times.

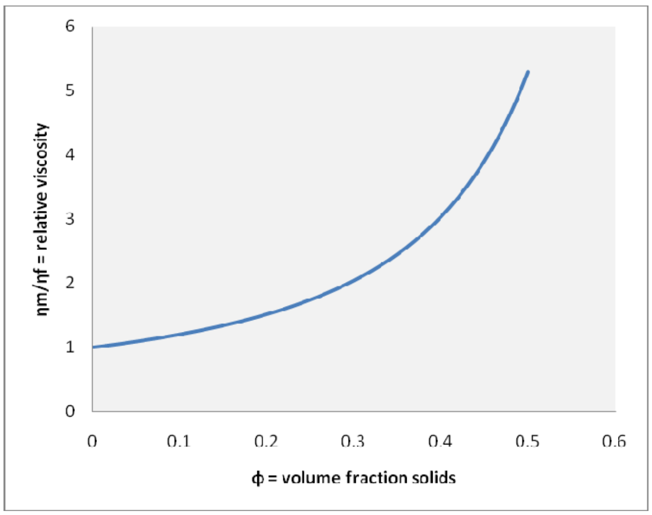


Figure 9: Relative viscosity with different volume fraction solids, according to empirical formula.

The consumer survey had the consumers rank their preference with the thickness of toothpaste by relating it to the thicknesses of other foods, which have definite viscosities (Tiverton-Brown, 2008).

Table 9: Thickness Consumer Survey

Consumer Option	Equivalent Food	Viscosity	Perceived Thickness
1: Little Thickness	Honey	3,000 cp	54.8
2: Moderately Thick	Tomato Paste	150,000 cp	387.3
3: Very thick	Peanut Butter	250,000 cp	500

Then, the consumer satisfaction for the given thicknesses was found. Seen in Figure 10 is the correlation between the consumer satisfaction and the final viscosity (μ_m) of toothpaste.

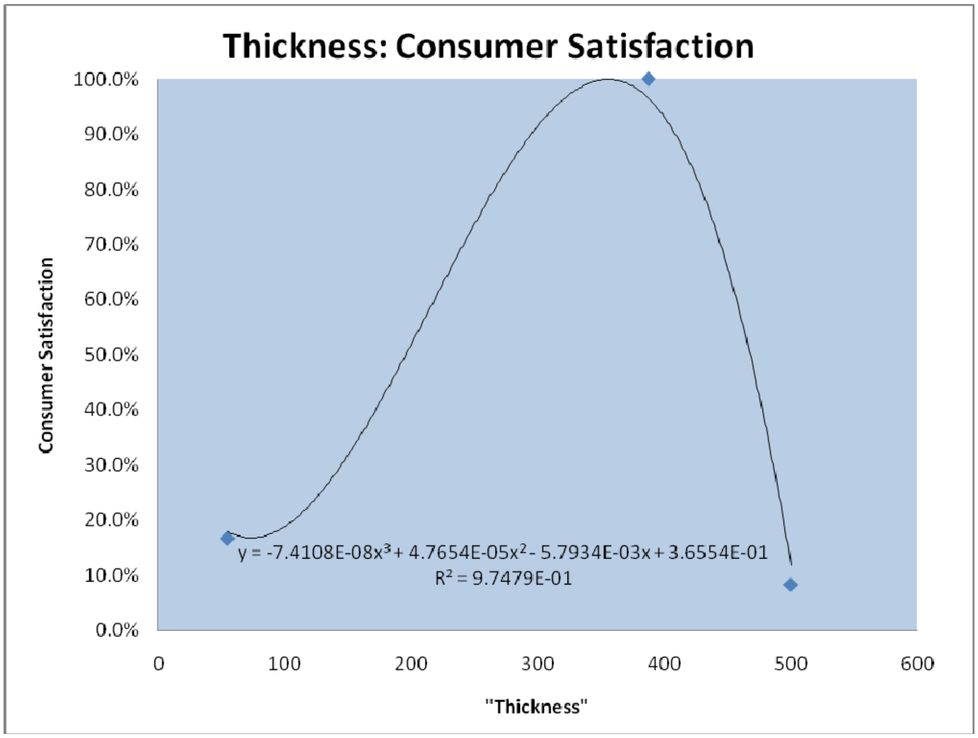


Figure 10: Consumer Satisfaction, Thickness

Cooling Effect

Consumers associate a clean mouth with a cool, minty feeling. Flavors such as oil of peppermint or wintergreen, or synthetic menthol, can impart a minty feeling, and through interactions with the nerve cells as described above, can give the sensation of coolness in the mouth (Blachford 2002). However, two common ingredients in toothpaste, sorbitol and xylitol, also provide a cooling effect in the mouth, but it is due to the negative heat of solution of these polyols (Smith . 2003). However, according to the calculations done in response to the experiments of McKeny et al. (2002), the cooling effect of menthol (such as from flavoring) contributes to the cooling effect of toothpaste far more than the negative heats of solution of the polyols.

The consumer survey had the consumers rank their preference for different levels of cooling effect. However, these were cooling effects produced solely by menthol or related molecules which only produce the sensation of cooling, not an actual change in temperature. Experimentally, a temperature drop was determined for each option that correlated with the sensation caused by the concentration of menthol in each (See Appendix). The experiment resulted in Equation 5.

$$\Delta T = 0.11125 * CO - 0.0675$$

Equation 5

ΔT = temperature drop in degrees Fahrenheit

CO = consumer option number from

Table 10

Table 10: Cooling Effect Consumer Survey

Consumer Option	Equivalent Product	Equivalent Temperature Drop (deg C)
1: Little Cooling	Winterfresh® Gum	3.8
2: Medium Cooling	Extra® Polar Ice Gum	7.8
3: Very Cooling	Altoids® Mint	11.8

From the data in McKemy 2002, the cooling sensation of menthol can be directly related to the sensation of a drop in temperature. Because both sensations are mediated by a Ca^{2+} ion channel, the current of Ca^{2+} ions through the channel correlates to the amount of sensation. The research group at University of California (McKemy 2002) showed how concentration of menthol was related to the calcium ion current in rat neural ganglia cells as shown in Figure 11. However, this was a normalized current, which could be compared to the current at 500 μM, which is around 1400 nA. The actual currents at varying concentrations can be seen in Figure 12, to which was fit a saturation curve.

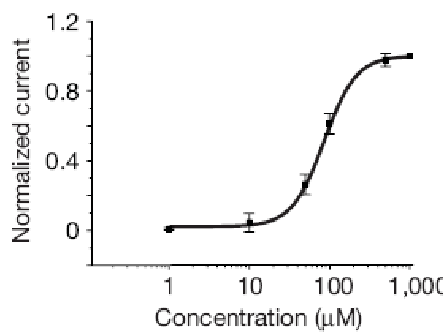


Figure 11: Normalized Calcium Ion Current with Concentration of Menthol

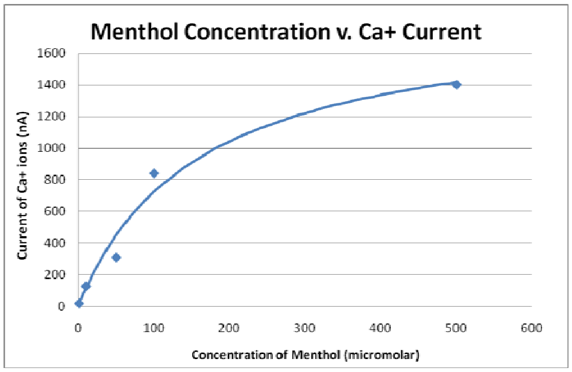


Figure 12: Actual Calcium Ion Current with Concentration of Menthol

In addition, the research group performed the same analysis with a drop in temperature instead of the addition of menthol. Their tests resulted in Figure 13, which shows the current with temperature decrease, both in the presence and absence of menthol. A smooth exponential equation was fit to that data, as shown in Figure 14. The equation resulting was Equation 6.

$$I = 1.17x10^{-7} * e^{(0.230*T+18.77)}$$

Equation 6

I = calcium ion current, nanoamps

T = temperature decrease, degrees C

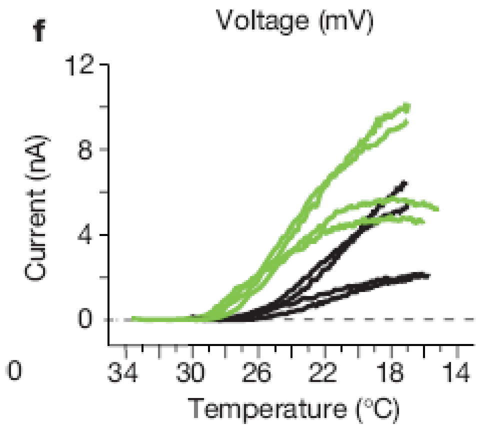


Figure 13: Calcium Ion Current with Temperature Decrease (black shows response in absence of menthol)

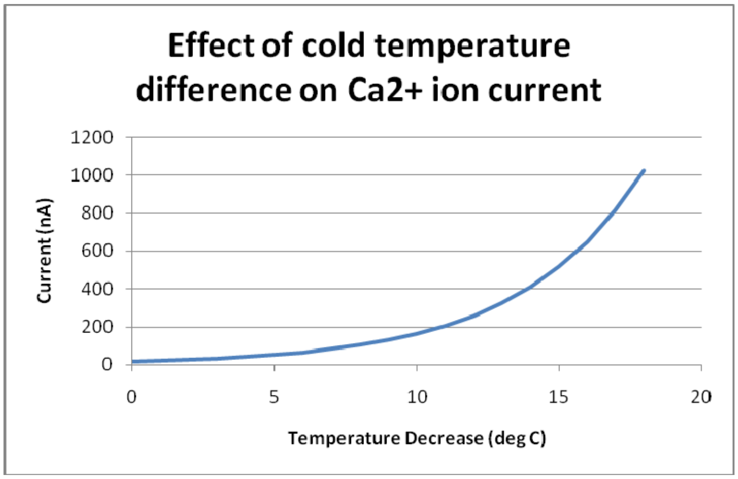


Figure 14: Calcium Ion Current with Temperature Decrease (Smooth Fit to Data)

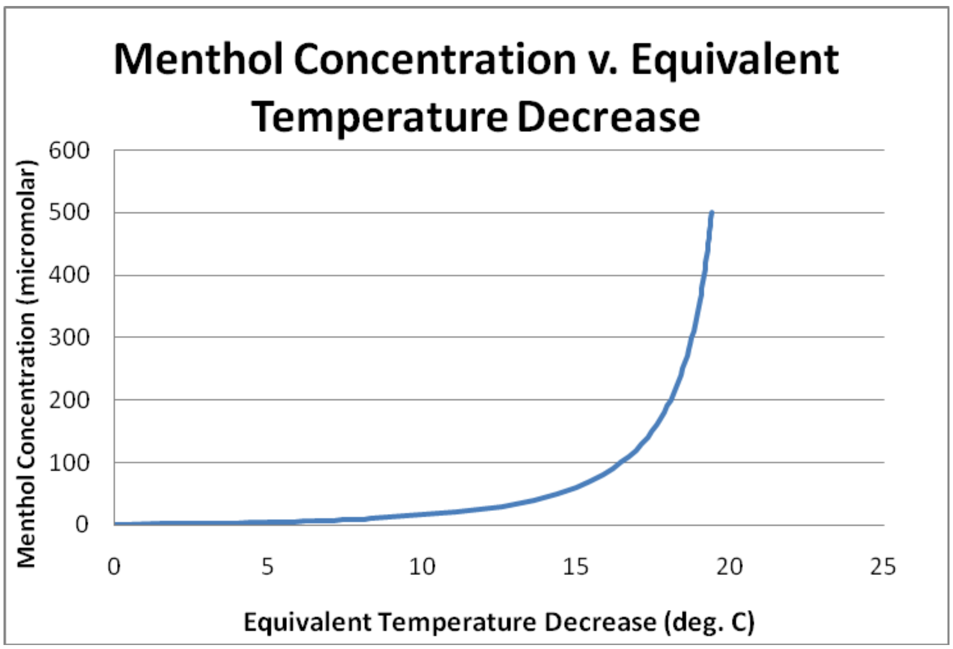


Figure 15: Required Menthol Concentration for Sensation of Equivalent Temperature Decrease

Figure 15 shows the combination of the two equations to finalize the connection between temperature decrease and equivalent menthol concentration. In this way, a menthol concentration was connected to each of the consumer options listed above, as seen in

Table 11. The weight percent of peppermint oil could be determined by assuming that peppermint oil is approximately 50% menthol (Wright 1999).

Table 11: Menthol Concentration with Cooling Effect

Cooling Effect (deg C)	Menthol Concentration (micromolar)	Weight % Peppermint Oil
3.8	3.41	0.08
7.8	8.81	0.21
11.8	24.07	0.58

The consumer satisfaction with the cooling effect as represented by the equivalent products, as temperature drop in degrees Fahrenheit, can be seen in Figure 16.

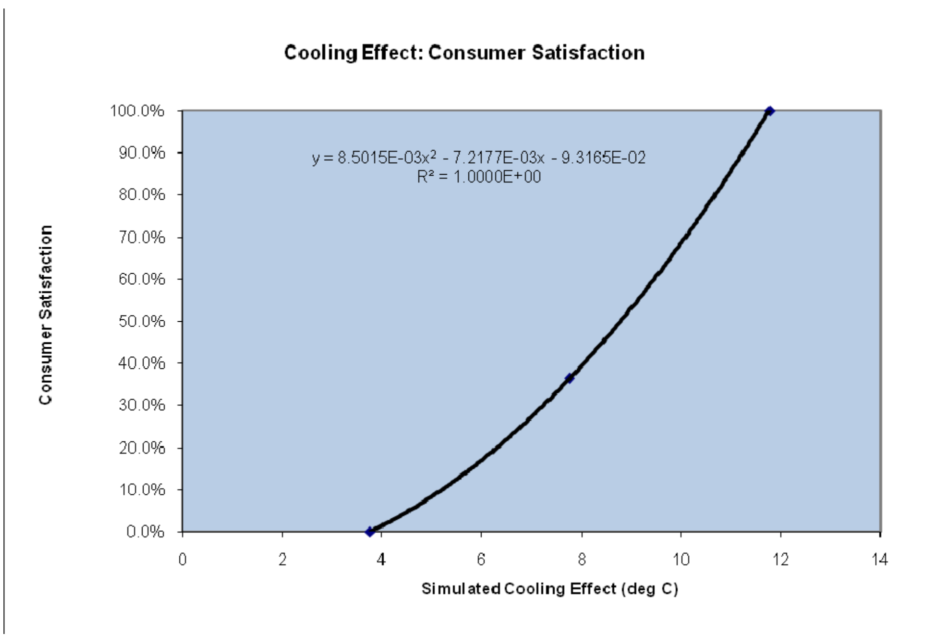


Figure 16: Consumer Satisfaction, Cooling Effect

Abrasion

Abrasion is an important characteristic of toothpaste that allows it to both effectively clean the teeth, and it gives the consumer the feeling of a cleaner mouth. Usually mineral particles are suspended in toothpaste, then brushed against the teeth. Both the concentration and the size of the particles will make a difference in the abrasion. The abrasion of a toothpaste is usually quantified by radioactive dentin abrasion. This is done by taking fresh human teeth (*ex vivo*) and subjecting them to neutrons. The phosphorus in the hydroxyapatite, the main mineral composing the enamel and dentin, converts from P^{31} into P^{32}, which then will be present in the teeth as fairly long-lived radioisotopes. Then, through brushing a human tooth with a dentifrice with a specified abrasive for a certain period of time with a certain load, an amount of dentin is removed which can be measured through radioactivity (Grabenstetter, Broge, Jackson, Radike, 1958). Data were compiled about the different abrasives and their relative radioactive dentin abrasivity, seen in Table 12 (Davis 1980).

Table 12: Radioactive Dentin Abrasion (RDA) for different abrasives, from Davis 1980.

Abrasive	RDA	Multiplier v. Silica
Silica	53	1.00
Dicalcium Phosphate	81	0.65
Calcium Carbonate	100	0.53
Hydrated Alumina	46	1.15

The loading rate of the abrasive also influences the abrasion of a dentifrice. Information about this was obtained from a silica company, INEOS silicas, seen in Figure 17.

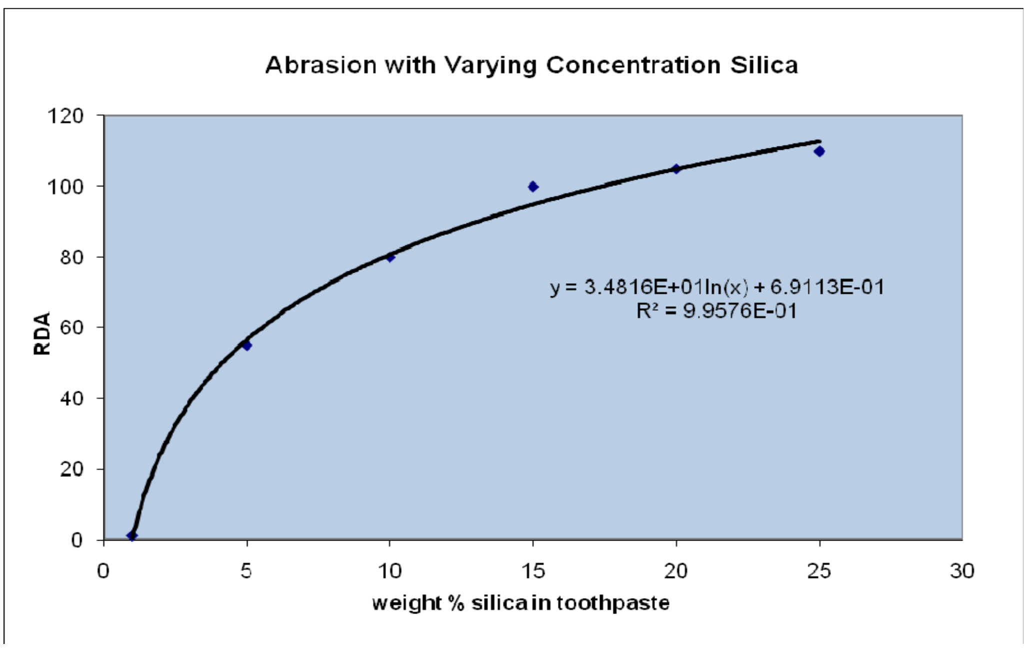


Figure 17: Effect of Silica Loading on RDA

By fitting a line to this information, and by knowing the abrasion forces of other abrasives relative to silica, the RDA can be computed for any formula of abrasives.

In the consumer survey, the consumers were asked to rate their preference for the abrasion of 3 different toothpastes, with three different RDA values (Oral Health Research Institute, 1996).

Table 13: Abrasion Consumer Survey

Consumer Option	Equivalent Dentifrice	RDA value	Weight % Silica	Weight % Calcium Carbonate
1: Little Abrasion	Rembradt® Classic Sensitive (least gritty)	70	7.32	3.88
2: Medium Abrasion	Aquafresh® Extra Fresh	100	17.33	9.18
3: Very Abrasive	Crest® Pro-Health (gritty feeling)	125	35.53	18.83

The consumer satisfaction with RDA was then found, which a formula consisting of one or more abrasives, could satisfy (Figure 18). The abrasives chosen for possible use in the formula were silica, calcium carbonate, and dicalcium phosphate. Only one particle size was assumed for each, although varying the particle size could also have a strong effect on RDA.

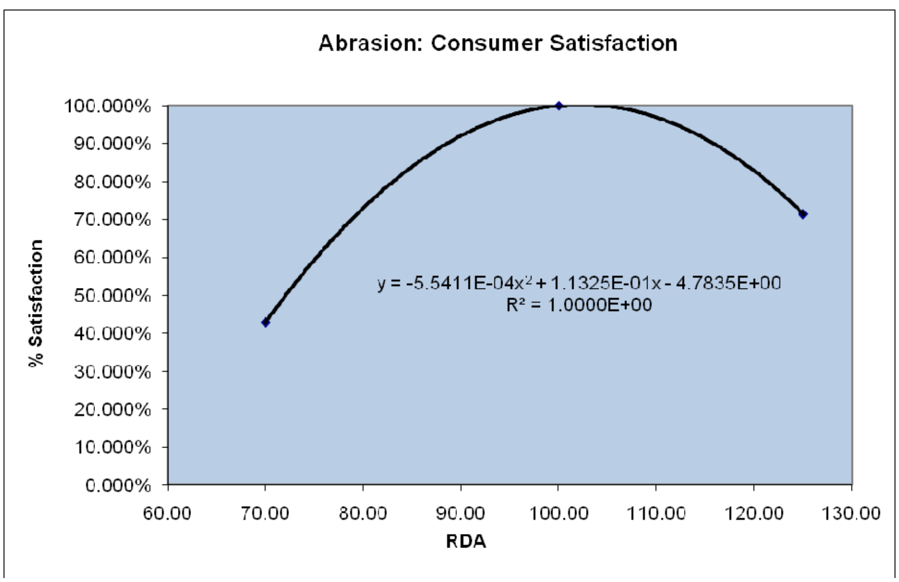


Figure 18: Consumer Satisfaction, Abrasion

FOAMINESS

The foam in toothpaste is essential as a mechanism for suspending and removing the debris, as well as giving a heightened perception of cleaning action (Mason 2000). The quality of the foam, being the volume as well as the foam stability or lifetime, depends on many factors in the toothpaste. Some of these include the amounts and properties of humectants, polymers, and abrasives used in a toothpaste formula (Pader 1997). For simplicity and lack of other available data on the subject, foam volume was connected solely with amount of surfactant. The relationship between amount of surfactant and foam volume can be seen in Figure 19. This represents a best fit line to experimental data from Lunkenheimer 2003. The foam height was produced in a cylinder with 100 cm^3 of gas injected through solutions of different molarities sodium lauryl sulfate (SLS or SDS) in about 20 seconds.

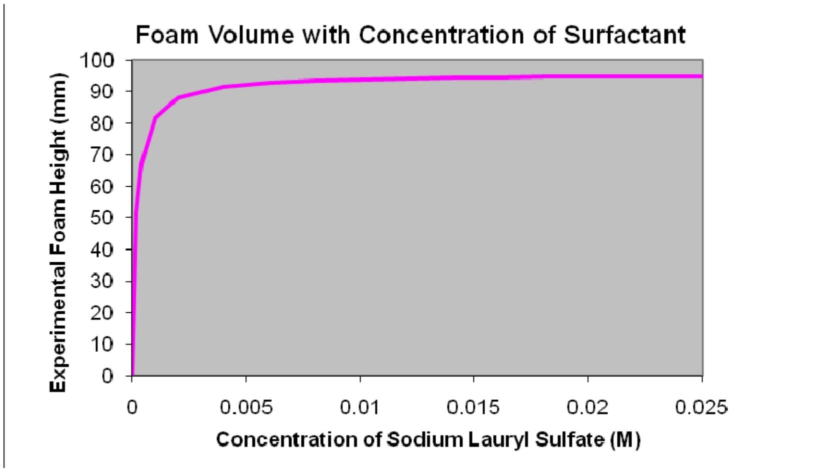


Figure 19: Foam Volume with Concentration of SLS

The consumer survey did not give any other product references to foaminess for the options, mainly because no other food products tend to foam upon use. The options of non-food products (such as other soaps or detergents) might be unsavory for the consumer, and it would bias the preference toward the least foamy side. The options from the survey along with the corresponding properties and concentrations can be seen in Table 14. Foam volumes were then chosen linearly with the consumer options and so that the corresponding concentration limits would be reasonable, or between 0.5% and 2.0% (Pader 1997). The foam volumes were linear between the options, but the concentrations followed the correlation found from the experimental data (Figure 20). It should be noted that the foam volume expressed here is merely hypothetical, and in reference to Lunkenheimer 2003, and does not quantitatively represent the amount of foam that would occur during brushing teeth.

Table 14: Foaminess Consumer Survey

Consumer Option	Foam Height (mm)	Concentration SLS (M)	Weight % SLS Solution
1: Little Foaminess	93.1	0.007	0.50
2: Medium Foaminess	93.9	0.011	0.78
3: Very Foamy	94.8	0.027	2.00

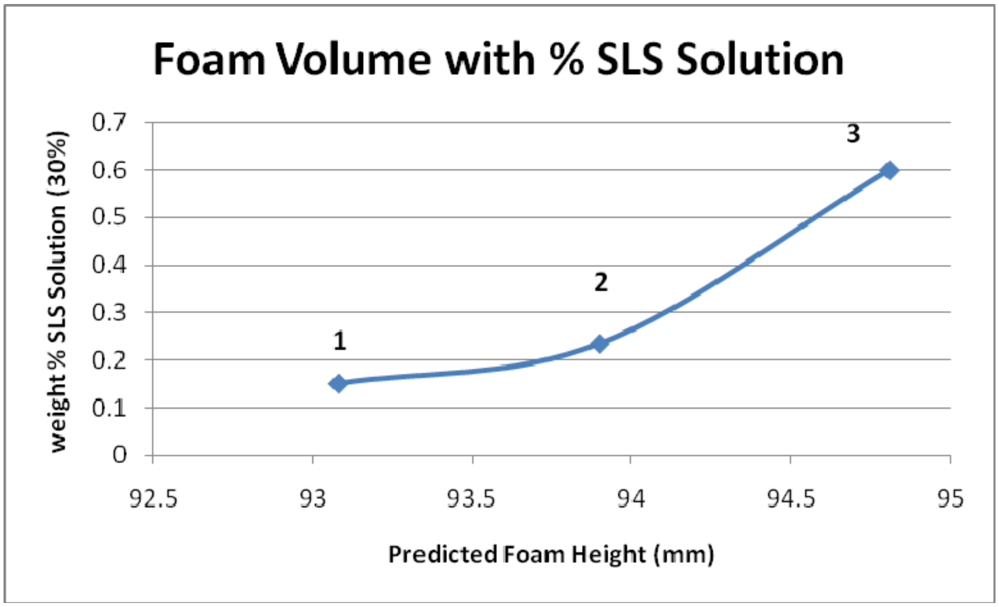


Figure 20: SLS concentration with Foam Height

The consumer satisfaction was then correlated with the hypothetical foam height to yield Figure 21.

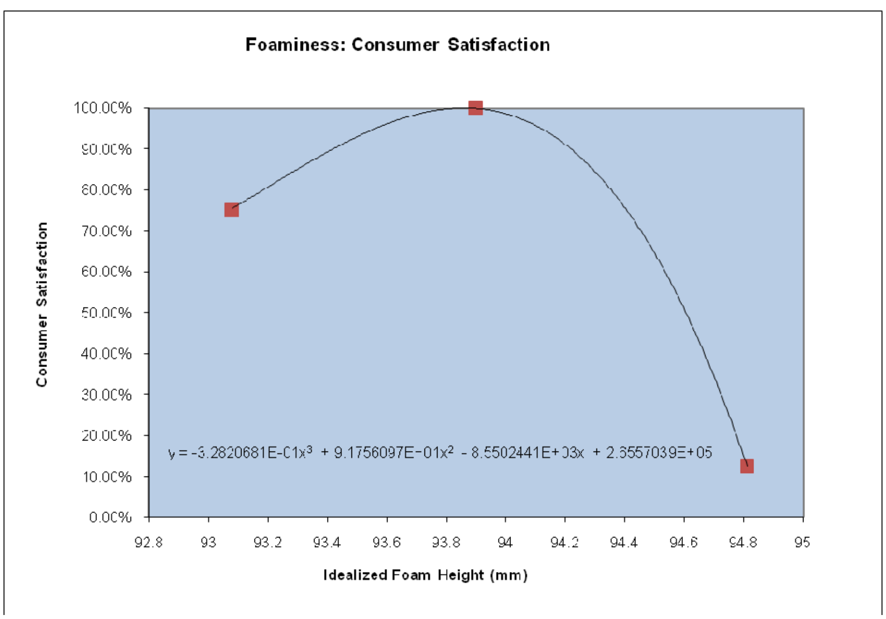


Figure 21: Consumer Satisfaction: Foaminess

CREAMINESS

Creaminess is a physical property of semisolids and liquids that has to do with the mouthfeel of a substance. Equation 7 was determined by surveying consumers and having them arbitrarily assign a value for "thickness", "smoothness", and "creaminess" to a standard and the experimental semisolids and liquids (Kokini 1983).

$$\{creaminess\}\ \alpha\ \{thickness\}^{0.54}\ \{smoothness\}^{0.84}$$

Equation 7

The consumers chose their preference for the creaminess of toothpaste by relating it to other foods, for which the creaminess value was known from the survey by Kokini et al. 1983.

Table 15: Creaminess Consumer Survey

Consumer Option	Equivalent Food	Creaminess Value
1: Little Creaminess	Birdseye Cool Whip®	1.66
2: Medium Creaminess	Ice Cream	1.83
3: Very Creamy	Cream Cheese	2.15

In order to compute the creaminess of a toothpaste, the thickness and smoothness must be known in terms of the parameters from Kokini 1983 to use the empirical correlation. The thickness, as described above, is proportional to the square root of the viscosity of the toothpaste (Equation 3). To convert the viscosity of toothpaste into the thickness value used in the correlation, a conversion factor was obtained using the viscosity and thickness value of cream cheese. The viscosity of cream cheese was fairly similar to that of toothpaste, being around 160,000 centipoise (Hunt, 1997). The thickness value for cream cheese is 2.92, thus Equation 8 is used.

$$\{thickness\} = \eta * 56944$$

Equation 8

η = viscosity of mixture, in centipoises

The smoothness value is slightly more complicated. Kokini claims that smoothness is related to the coefficient of friction of the semisolid, as in Equation 9.

$$\{smoothness\}\ \alpha\ \frac{1}{\mu * W}$$

Equation 9

μ = Friction factor, dimensionless (between 0.67 and 2.00 in experiment)

W = normal load on semisolid

The normal load is considered to be constant with relation to the toothpaste, so Equation 9 reduces to Equation 10.

$$\{smoothness\}\ \alpha\ \frac{1}{\mu}$$

Equation 10

The coefficient of friction of toothpaste is known to be between 0.28 and 0.34 due to the differences in percent solids (Lewis, 2006). This information was graphed to directly determine the coefficient of friction from phi, the volume fraction solids.

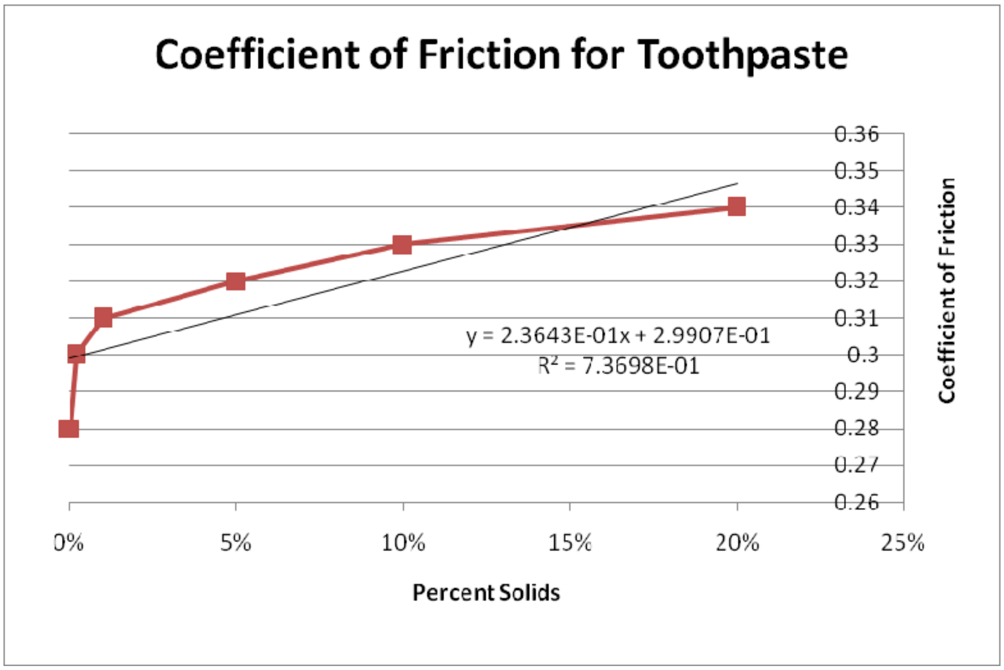


Figure 22: Coefficient of Friction for Toothpaste

With the range of coefficients of friction known for toothpaste, and knowing the range of the smoothness values, the conversion factor was found, making Equation 11 the way to calculate smoothness.

$$\{smoothness\} = \frac{0.412}{\mu}$$

Equation 11

The relation between consumer satisfaction and creaminess can be seen in Figure 23.

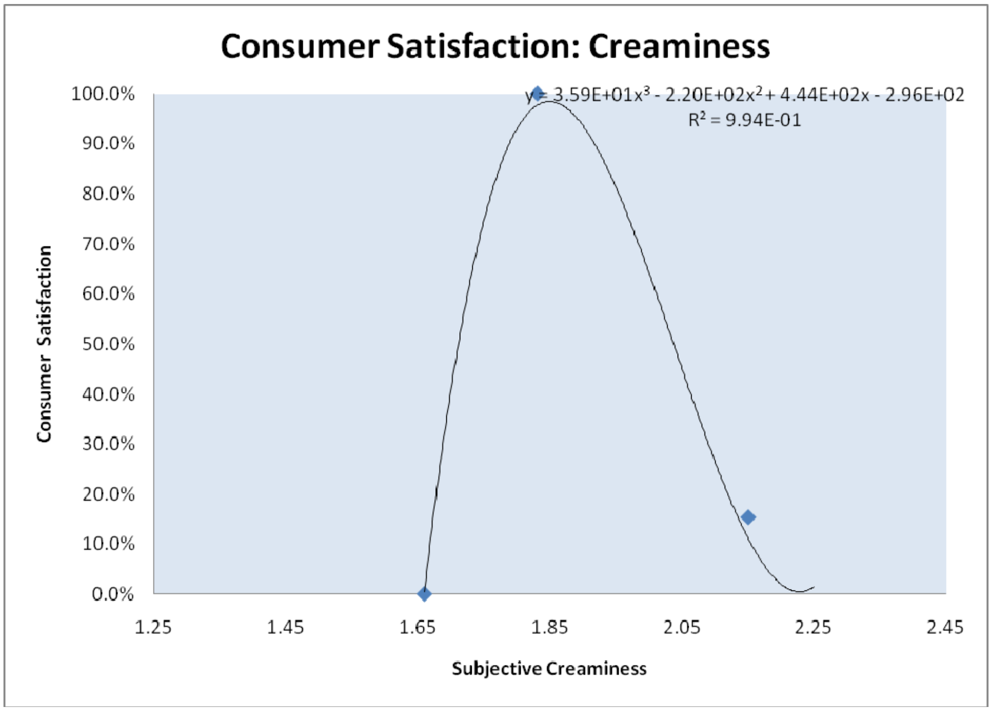


Figure 23: Consumer Satisfaction: Creaminess

EFFECTIVENESS

The efficacy of the dentifrice was determined by the quantity of active ingredient. This could be connected to the consumer through the ranking of preference for percent fewer cavities than average. The percent fewer cavities that would occur with the active ingredient was related to the decrease in virulence of *S. mutans* caused by the polyphenolic extract. This correlation was created from data from *in vivo* experiments with rats. In Koo, 2003, 10 rats' teeth were treated topically with different formulas. One of these contained 0.035% apigenin, which is a polyphenolic compound very similar to catechin, one of the main components of the pomace polyphenolic extract. It was found that apigenin inhibited the glucosyltransferase activity significantly in *in vitro* studies. Then, when rats were treated with the formula, they showed an average of 4.6 smooth surface caries in contrast to the control of 8.1 smooth surface caries. Through logic, the correlation was determined that this percentage of normal GTF B activity (48%) resulted in 43% less cavities than the control. It was assumed that at 0% activity of GTF B, there would be a complete decrease in cavities, of 100%. Also, at 100% GTF B activity (or normal activity), there would be the average amount of cavities, or 0% less. Through this, Figure 24 was developed.

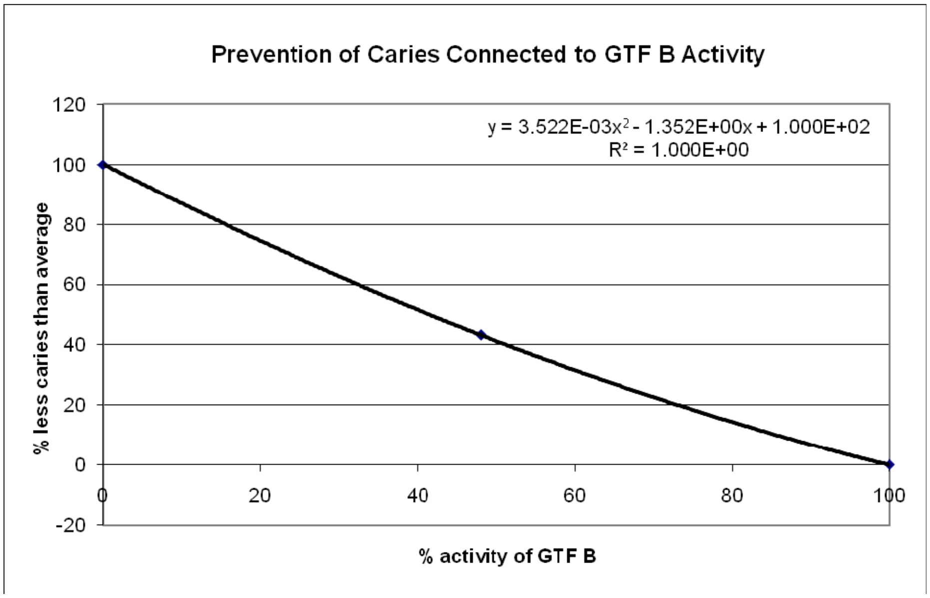


Figure 24: Decrease in Caries Prevalence with GTFB activity

Because the percent activity of GTF B was known for the *in vitro* studies with the wine pomace extract (Figure 4), a correlation was made to connect the amount of Pinot Noir fruit pomace extract with the percent less cavities expected, as seen in Figure 25. The single points are the data from the *in vitro* studies in Thimothe, 2007, using the equation from Figure 24. The line represents the best fit of the data to a Michaelis-Menten type equation to predict the percent less dental caries with varying concentrations of polyphenolic extract.

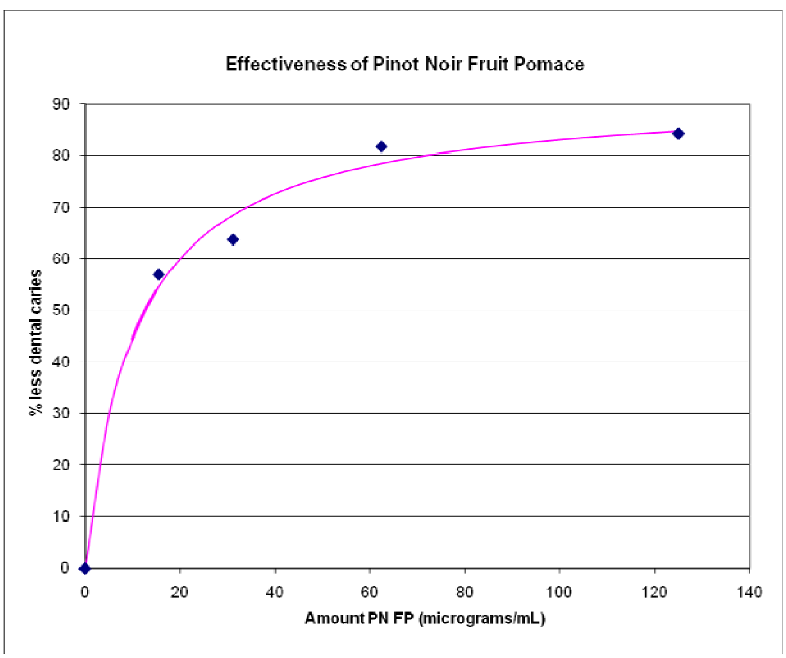


Figure 25: Decrease in Caries Prevalence with Polyphenolic Extract

$$\%C = 92.03\left(\frac{m_{FP}}{10.67 + m_{FP}}\right) \qquad m_{FP} = \frac{10.67 * \%C}{92.03 - \%C}$$

Equation 12

$\%C$ = percent less dental caries than without the polyphenolic extract

m_{FP} = concentration of polyphenolic extract

The consumers were asked to make a judgement of "happiness" for 4 different situations on the consumer survey, keeping in mind that the average cavity prevalence is 1 cavity every 4 years, although that may not be their personal average caries prevalence.

- A. Never having another cavity
- B. Having a cavity (on average) once every 20 years
- C. Having a cavity (on average) once every 10 years
- D. Having a cavity (on average) once every 6 years

These options were calculated into percent less cavities compared to the average, as seen in Table 16. From that point, the necessary concentration of extract to produce the decrease in dental caries was calculated from Equation 12. However, due to the saturation point of the GTF B activity with the increase in polyphenolic extract concentration, option A was estimated to be 90% less cavities instead of 100% less cavities, which was nearly unattainable. The consumer satisfaction with each option can be seen in Figure 26, along with the assumption that the consumer would be 0% satisfied with the efficacy of an "anti-cavity" toothpaste that produced no change in cavities prevalence (0% less cavities).

Table 16: Effectiveness Consumer Survey

	Average	A	B	C	D
Cavities/year	0.25	0.00	0.05	0.10	0.167
% less cavities	---	100	80	60	33.3

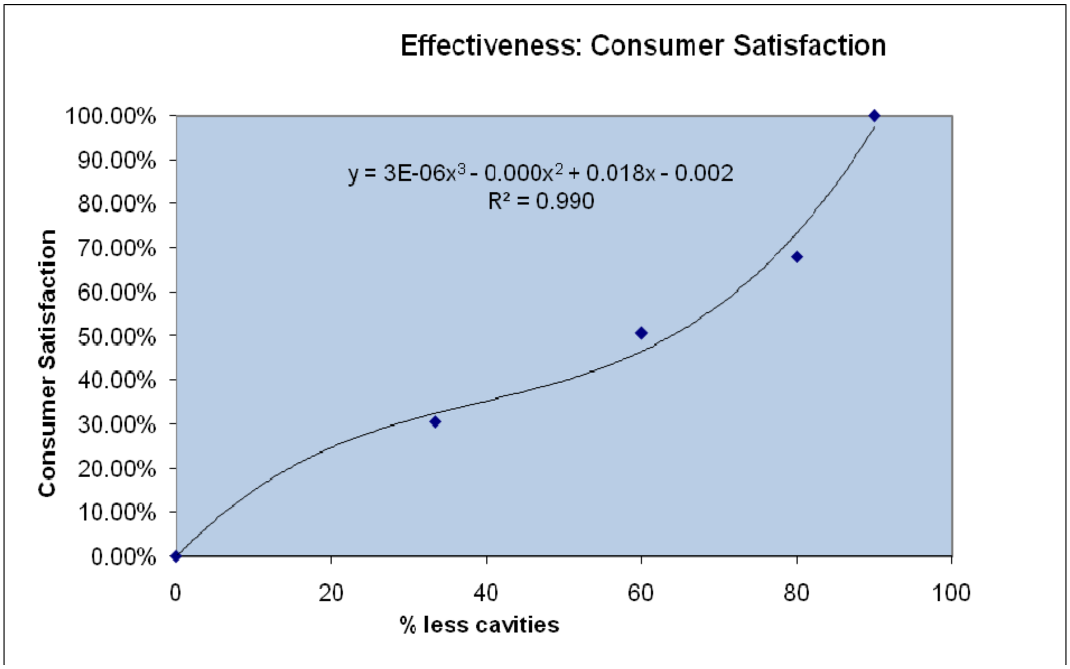


Figure 26: Consumer Satisfaction, Effectiveness

Dentifrice Composition

A toothpaste composition was determined that optimized the consumer satisfaction with the product. The achieved consumer satisfaction was 97.8%, and the composition can be seen in

Table 18. The composition includes ingredients to satisfy each characteristic, as well as a couple that aren't affected by consumer satisfaction: flavoring, sodium benzoate, titanium dioxide, and trisodium phosphate. These were added to the composition in reasonable amounts (Mason, 2000).

Table 17: Maximum Consumer Satisfaction

Characteristic	Property	Consumer Satisfaction	Weight	Total
Sweetness	% sucrose	1.000	0.134	0.134
Thickness	$\text{Viscosity}^{1/2}$	0.878	0.081	0.071
Cooling Effect	Equivalent deg C	1.000	0.178	0.178
Abrasion	RDA	0.966	0.126	0.122
Foaminess	Foam Height	1.000	0.075	0.075
Creaminess	Empirical Equation	1.000	0.074	0.074
Effectiveness	% less cavities	0.977	0.333	0.325
				97.81%

Table 18: Toothpaste Composition Determined from Consumer Satisfaction

Ingredient	Purpose	Weight Percent	Weight (g)	Cost
Deionized Water	Dilution Purposes	**51.9050**	114.19	$0.114
Glycerin	Humectant	**6.4303**	14.15	$0.124
Hydrated Silica	Thickener	**1.1751**	2.59	$0.120
Peppermint Oil	Cooling Effect	**0.5737**	1.26	$0.088
Silica	Abrasive	**23.8037**	52.37	$0.094
Sodium Benzoate	Preservative	**0.0200**	0.04	$0.001
Sodium Lauryl Sulfate (30%)	Emulsifier/ Whipping Aid/ Surfactant	**0.8944**	1.97	$0.005
Sodium Saccharin (10%)	Sweetening	**1.4030**	3.09	$0.150
Sorbitol (70%)	Sweetening / Humectant	**11.6561**	25.64	$0.550
Titanium Dioxide	Opacity	**0.0500**	0.11	$0.001
Trisodium Phosphate	pH adjuster	**0.0500**	0.11	$0.000
Polyphenolic extract	prevent cavities	**0.0386**	0.08	$0.890
Xylitol	Sweetening/Saliva inducing	**1.0000**	2.20	$0.025
Other Flavor	Flavor	**1.0000**	2.20	$0.154
		Total Raw Materials Cost		**$2.317**

This composition results in a tube of toothpaste for which the raw materials cost $2.32.

U.S. Food and Drug Administration Approval Process

The Federal Food, Drug, and Cosmetic Act stipulates that "cosmetics and their ingredients are not required to undergo approval before they are sold to the public," which allows manufacturers to market their product without undergoing governmental review as long as it does not contain a prohibited substance (Lewis 1998). In the US Food and Drug Administration (FDA) article, cosmetics are defined as "articles that are intended to be applied to the human body for cleansing" and it lists mouthwash as one of the many examples. However products that are listed as both a cosmetic and a drug (i.e. fluoride toothpastes) must be scientifically proven safe. A later publishing by the FDA's Center for Food Safety and Applied Nutrition (2002) classified fluoride containing toothpaste as a drug and non-fluoride containing toothpaste as a cosmetic. This excludes our product from having to undergo the FDA's new drug approval process.

American Dental Association Seal of Acceptance

Submission for the American Dental Association (ADA) Seal of Acceptance is a voluntary process that can occur after being cleared by the U.S. FDA as eligible to market to consumers. The product is evaluated by the Council on Scientific Affairs which utilizes technical standards such as ANSI/ADA and ISO specifications (ADA.org 2007). The ADA website outlines the general criteria that are necessary for acceptance. The first is that the generic name "conforms to the requirements of the Federal Food, Drug and Cosmetic Act" and the trade name doesn't suggest a disease, a symptom, or contain a title or its designation (i.e. "M.D."). The second criterion is the composition, nature, and function. An explicit detail of the ingredient properties and concentrations must be submitted along with manufacturing standards that comply with the Good Manufacturing Practices. Evidence that the product performs its given task in addition to test samples must also be presented. Then clinical and laboratory studies are required to demonstrate the safety and effectiveness of the product. The product must also comply with all applicable laws and government regulations and preferably use biodegradable and recyclable materials in its manufacturing and packaging process. Claims of the product's effectiveness must be clear and accurate and its packaging and labeling must be submitted for approval prior to its use. Lastly the ADA sets advertising standards, certification mark guidelines, and prohibits disparaging advertisements of other products. The ADA can at any time withdraw its acceptance and request that the product undergo a renewal process.

Toothpaste Manufacturing Procedure

The mixing procedure requires a slow but efficient incorporation of soluble and insoluble components into the main water phase. One of the most important things to observe during the mixing process is the prevention of incorporating air into the mixture. The following steps are the mixing procedure according to the Personal Care formulation section of the Rheology Modifiers Handbook (Braun and Rosen 2000):

1. Slowly add the binding ingredients with the water and vigorously agitate. Mix the water-binding agent solution until smooth and uniform.
2. Add the sorbitol aqueous solution (70%) into the water-binding agent solution and mix until uniform. Set aside this WBS blend.
3. Mix glycerin (or another humectant) with the thickening agent(s) to create a humectant-thickening blend.
4. Add the humectant-thickening blend to the WBS blend from Step 2. Continue to mix until the thickening agent is thoroughly incorporated.
5. Add the abrasive, flavoring, active ingredient (i.e. sodium fluoride), sweetener, preservative, coloring, and surfactant in the order given one at a time until each component is uniform within the mixture.

Toothpaste is produced with a machine called a contra rotating mixer as seen in Figure 22 below. Contra rotating mixers are ideal for viscous products and have two different shafts. The solid shaft paddle blades rotate in a clockwise manner and the hollow shaft with anchor scrapper blades rotate in a counter-clockwise manner. Homogenous mixing is achieved from the contra rotary motion of the two blades at high speeds. The mixer is jacketed to allow for heating during mixing and cooling after the product has been formed. The mixer should be stainless steel in composition in order to prevent any corrosion issues and it has a homogenizer built in to allow for emulsification.

Figure 27: Contra Rotating Mixer (http://promasengineers.sulekhab2b.com/sell/244819/contra-rotary-mixer.htm)

ECONOMICS

INVESTMENT

The only investment required for this project is the purchase, installation, and other indirect costs associated with the extraction equipment. The total capital investment (TCI) for the extraction process is projected to be $10.1 million. Recall Figure 7 above that illustrates the extraction process determined in SuperPro®. It is possible to eliminate the investment cost of the toothpaste manufacturing process, because this project will utilize an existing process line that will not require any modifications. Table 19 below shows the determination of the total capital investment for this project. It is loosely based upon Price, Timmerhaus, and West (2003) guidelines of certain indirect and direct costs percentage of the required investment.

Table 19: Total Capital Investment

Component	Basis for Estimate	Cost
Purchased Equipment		
Extraction Equipment		$3,257,180
Total Equipment Cost (TEC)		**$3,257,180**
Installation	47 % (TEC)	$1,530,874
Instrumentation and Controls	8 % (TEC)	$260,574
Piping	Stainless Steel Network	$185,146
Electrical	11 % (TEC)	$358,290
Buildings	7 % (TEC)	$228,003
Total Direct Cost		**$5,820,066**

Indirect Costs		
Construction	41 % (TEC)	$1,335,444
Legal expenses	4 % (TEC)	$130,287
Contractor's fee	10 % (TEC)	$325,718
Contingency		$1,000,000
Total Indirect Cost		**$2,791,449**
Fixed Capital Investment	direct cost + indirect cost	$8,611,515
Working Capital	15% TCI	$1,519,679
Total Capital Investment (TCI)		**$10,131,194**

The equipment is based upon the maximum flow rates of the extraction process. The piping costs were also estimated based upon the maximum flow rates of this process and are stainless steel material. The equipment prices and characteristics are summarized in Table 19 and piping costs can be found in Table 20. The piping network cost will be $185,000. This price is largely due to the stainless steel composition of the pipes and valves. There will be 17 streams with an approximate piping length of 73 feet and a maximum flow rate of 28.4 ft3/ hr.

Table 20: Equipment Cost Summary

Equipment Name	Cost
Water deionizer Skid Mounted	$55,804
Homogenizer	$19,000
Freeze Dryer	$2,361,000
Mixer	$105,000
Evaporator (2)	$186,000
Centrifuge	$236,000
PBA Chromatography Column	$293,000
Pumps (2)	$1,376
TOTALS	$3,257,180

Table 21: Piping Network Cost of Extraction Process

STREAM	LENGTH (FT)	ID (FT)	Q, FT^3/HR	Piping Cost	Insulation Cost	Valveing Cost	Total Cost (2007) Ms Index
S-101	7.232197168	5	28.4007719	$ 1,250.00	$ 21.70	$10,000.00	$ 12,716.15
S-102	0.02967626	0.75	0.01748076	$ 187.50	$ 0.09	$10,000.00	$ 11,493.12
S-103	0.418842939	0.75	0.24671886	$ 187.50	$ 1.26	$10,000.00	$ 11,494.43
S-104	0.416420876	0.75	0.24529214	$ 187.50	$ 1.25	$10,000.00	$ 11,494.42
S-105	0.31703688	1	0.24900018	$ 250.00	$ 0.95	$10,000.00	$ 11,564.60
S-106	0.343914879	0.75	0.20258259	$ 187.50	$ 1.03	$10,000.00	$ 11,494.18
S-107	3.079814245	0.75	1.81416034	$ 187.50	$ 9.24	$10,000.00	$ 11,503.44
S-108	0.027386092	0.75	0.01613174	$ 187.50	$ 0.08	$10,000.00	$ 11,493.11
S-110	0.38935253	0.75	0.22934757	$ 187.50	$ 1.17	$10,000.00	$ 11,494.33
S-111	7.232197168	5	28.4007719	$ 1,250.00	$ 21.70	$ -	$ 1,434.66
S-114	3.109406572	0.75	1.83159166	$ 187.50	$ 9.33	$10,000.00	$ 11,503.54
S-115	0.081816549	0.75	0.04819393	$ 187.50	$ 0.25	$10,000.00	$ 11,493.29
S-116	3.052757889	0.75	1.79822283	$ 187.50	$ 9.16	$10,000.00	$ 11,503.35
S-117	6.105515778	0.75	3.59644566	$ 187.50	$ 18.32	$10,000.00	$ 11,513.68
S-118	6.105515778	0.75	3.59644566	$ 187.50	$ 18.32	$10,000.00	$ 11,513.68
S-119	11.98905463	3	28.2485445	$ 750.00	$ 35.97	$10,000.00	$ 12,168.18
S-121	12.52503037	0.75	7.37785188	$ 187.50	$ 37.58	$10,000.00	$ 11,535.41

MARKET

One of the company's existing manufacturing facilities in Northern California will be utilized to create this special toothpaste formulation. This geographic location was chosen because it is close to the active ingredient supplier, the wine production facilities, and will help to keep the grape pomace price low. Table 22(US Census 2007) lists the population of residents in our target area. Approximately 92 million people live in the South-Southwest region of the United States and comprise about a third of the country's population. CDC (2005) reports that a collective 500 million visits were made to the dentist by the American population in 2004. Furthermore Simmons Market Research identified that 93% of consumers use toothpaste.

Table 22: South-Southwest US Population 2007 (US Census 2007)

State Population 2007	People (millions)
Arizona	6.34
California	36.55
Colorado	4.86
Idaho	1.50
Montana	0.96
Nevada	2.56
New Mexico	1.97
Oregon	3.74
Texas	23.90
Utah	2.64
Washington	6.47
Wyoming	0.52
Total S/SW Population	**92.01**

Packaged Facts 2000 reported that toothpaste sells in 2000 totaled approximately $1,846 million and predicted a growth of 3.5%. Using this estimate, it is assumed that retail toothpaste sells in 2008 will total $2,430 million. Sales of toothpaste were then broken down into six different categories: whitening, regular, baking soda and peroxide formulas, multi-benefit, tartar control, and specialty. Whitening toothpaste comprises the majority of sales at 29% and is closely followed by regular toothpaste at 22%. The focus of this product will be on multi-benefit toothpaste which comprised 13.5% of retail toothpaste sales.

The demand assumption used to formulate the beta values assumed that 60% of the population buys toothpaste (55.2 million). Of those people 13.5% will buy multi-benefit toothpaste such as this product. With these assumptions we can assume that 7.45 million people in this market will buy either our product or something similar. The last assumption to determine our market was that the average consumer buys 6 tubes of toothpaste a year. The demand model used is presented by Equation 12 from Bagajewicz (2007) and the constants and variables that the equation uses are in Table 23 below.

Equation 13: Consumer Maximum Utility (Bagajewicz 2007)

$$\Phi(d_1) = p_1 d_1 - \left(\frac{\alpha}{\beta}\right)^{\rho} p_2 \left[\frac{Y - p_1 d_1}{p_2}\right]^{1-\rho} d_1^{\rho} = 0$$ [22]

$$\text{where, } \beta = \frac{H_2}{H_1} = \frac{CompetitorsHappiness}{Our\ ProductsHappiness}$$

α=awareness of existence of new product

p_1=our price

p_2=competitors price

d_1=our demand

ρ=market analysis constant

Y=total market

Table 23: Consumer Utility Maximization Summary

Consumer Utility Maximization	
α	1.00
β	Varied
p_1	Varied
p_2	\$7.00
d_1	Determined by
ρ	0.75
Y	\$358/ yr

In order to determine which product would be the most economical and still have high consumer satisfaction, solver was used to solve the demand equation equal to zero. To solve for the demand, the solver scenario was used to keep the consumer utility equation equal to zero based on the beta range of 0.6 to 0.85. The lower beta values indicate a higher consumer preference for our product than existing products. The product price (p1) selling range varied from \$6 to \$20. The net present worth of each potential selling price at a particular beta was calculated and maximized based upon the demand yielded from Excel® Solver. The largest NPW occurs at the absolute maximum of the each beta curve. The NPW is determined from the cash flow that results from the demand at the particular selling price. The beta curve is presented below as Figure 28 and Table 24: NPW at Various Product Prices (at selected betas)Table 24 gives this information in a tabulated form.

Figure 28: NPW vs. New Product Price

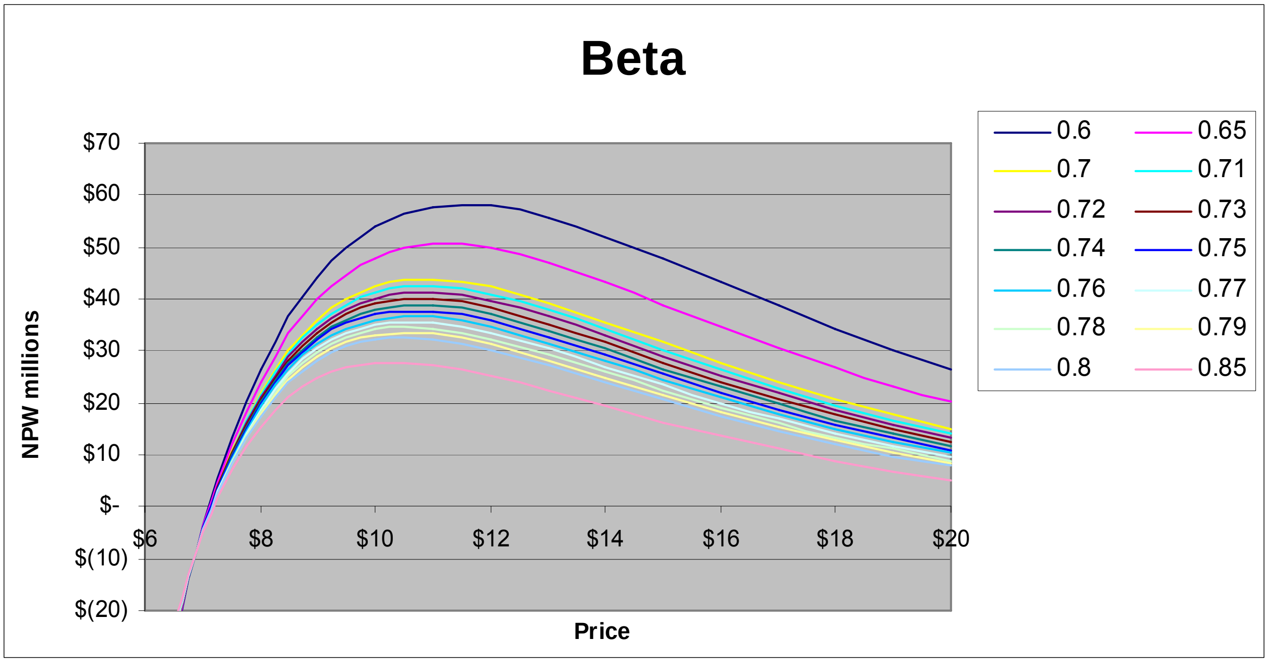


Table 24: NPW at Various Product Prices (at selected betas)

	Net Present Worth ($million)									
	$\beta_{\#1}$	$\beta_{\#2}$	$\beta_{\#3}$	$\beta_{\#4}$	$\beta_{\#5}$	$\beta_{\#9}$	$\beta_{\#10}$	$\beta_{\#11}$	$\beta_{\#12}$	$\beta_{\#13}$
p_1	0.6	0.65	0.7	0.71	0.73	0.77	0.78	0.79	0.8	0.85
6	$ (49.78)	$ (48.49)	$ (47.08)	$ (46.79)	$ (46.19)	$ (44.95)	$ (44.64)	$ 44.32)	$ (44.00)	$ (42.36)
7	$ (3.40)	$ (3.65)	$ (3.91)	$ (3.96)	$ (4.07)	$ (4.28)	$ (4.34)	$ (4.39)	$ (4.45)	$ (4.72)
8	$ 26.29	$ 24.12	$ 21.90	$ 21.46	$ 20.57	$ 18.81	$ 18.38	$ 17.95	$ 17.52	$ 15.43
9	$ 44.25	$ 40.08	$ 35.97	$ 35.17	$ 33.58	$ 30.50	$ 29.75	$ 29.01	$ 28.28	$ 24.80
10	$ 53.91	$ 47.96	$ 42.31	$ 41.22	$ 39.10	$ 35.06	$ 34.09	$ 33.15	$ 32.22	$ 27.85
11	$ 57.84	$ 50.50	$ 43.76	$ 42.49	$ 40.02	$ 35.41	$ 34.33	$ 33.27	$ 32.23	$ 27.43
12	$ 57.96	$ 49.69	$ 42.31	$ 40.94	$ 38.31	$ 33.46	$ 32.33	$ 31.23	$ 30.17	$ 25.28
13	$ 55.69	$ 46.92	$ 39.30	$ 37.90	$ 35.24	$ 30.39	$ 29.27	$ 28.19	$ 27.14	$ 22.38
14	$ 52.05	$ 43.13	$ 35.55	$ 34.18	$ 31.58	$ 26.90	$ 25.83	$ 24.80	$ 23.80	$ 19.30
15	$ 47.72	$ 38.92	$ 31.59	$ 30.28	$ 27.81	$ 23.38	$ 22.38	$ 21.41	$ 20.48	$ 16.31
16	$ 43.15	$ 34.66	$ 27.71	$ 26.48	$ 24.16	$ 20.05	$ 19.12	$ 18.22	$ 17.36	$ 13.54
17	$ 38.63	$ 30.57	$ 24.06	$ 22.91	$ 20.77	$ 16.98	$ 16.13	$ 15.31	$ 14.53	$ 11.05
18	$ 34.32	$ 26.75	$ 20.71	$ 19.66	$ 17.68	$ 14.22	$ 13.44	$ 12.70	$ 11.99	$ 8.84
19	$ 30.31	$ 23.26	$ 17.69	$ 16.72	$ 14.92	$ 11.76	$ 11.06	$ 10.39	$ 9.74	$ 6.90
20	$ 26.64	$ 20.10	$ 14.99	$ 14.11	$ 12.46	$ 9.59	$ 8.96	$ 8.34	$ 7.76	$ 5.19

The highlighted cells of Table 24 represent the profitable range of selling prices and its associated NPW. As evidenced by Figure 8, the beta value of 0.6 produces the best net present worth at each of the product prices. The highest NPW occurs at the product price of approximately $12.00. However in order to be competitive, the $8.00 product is chosen. The $8.00 price corresponds to a demand of 33 million tubes /year and is lower than all of our competitors on a price/ unit basis except Crest®. Table 25 gives a summary of our competitors pricing of their anti-cavity toothpastes. Table 26 summarizes the Rule of Four principle that was used to alter the average product price and product price/ unit basis of our competition.

Table 25: Competitor Pricing and Satisfaction

Brand	price	$/oz	Satisfaction
Clay Bright natural toothpaste	6.99	$2.18	92.1%
Dr. Collins Restore Remineralizing	7.49	$1.87	88.6%
Crest Whitening Exp. Anti-cavity	2.99	$0.50	84.2%
Elgydium Anti-cavity	6.95	$1.99	84.1%
Kiss My Face Anti-cavity Toothpaste	5.99	$1.76	82.0%
AVERAGE*	**6.86**	**$1.95**	**86.2%**
OUR PRODUCT	**8.00**	**$1.39**	**97.8%**

The rule of four is a method that is used to determine whether a questionable value can be discarded. It is determined by calculating the mean and standard deviation for the data set without the outlying value, x. If the outlying value, x, is more than four standard deviations (4σ) away from the new mean then it can be excluded from the data set. This is used because the values for the Crest® brand cause the average value to be under-represented. The summary of the Rule of Four test results are given in Table 24. A returned value of "TRUE" means that the outlying point can be disregarded because it is not within 4σ.

Table 26: Rule of Four Test Results

Rule of Four Test	Competition	$/oz
Average with all data points	$6.08	$1.66
Standard deviation of all data points	1.81	0.67
Outlying point	$2.99	$0.50
Average w/o outlying point	$6.86	$1.95
Standard deviation w/o outlying point	0.63	0.18
4σ	2.51	0.72
Is outlier more than 4σ of new average?	**TRUE**	**TRUE**

Total Annual Product Cost

The annual product cost was determined for the production of the toothpaste to be $4.34 per tube. This calculation is summarized in Table 27 below. It was determined that for each .222 kg tube the raw materials would cost $2.32. The production rate was determined by the demand (3.38 million/

yr) that we projected to have at a product price of $8/ tube. Packaging was assumed to be 147% of the amount of the projected specialty toothpaste demand in the South/Southwest region. Because packaging is very important in attracting consumers in the toothpaste market, this category was over-budgeted, in order to allow for innovative and costly packaging. Three operators are projected to be able to run the process. One operator would be required for the contra rotating mixer and packaging line equipment, one for the evaporation and PBA chromatography column, and the last one for the remaining extraction units. The packaging process will be fully automated so no manual labor will be required. A 15% downtime is forecasted for this production line for preventative maintenance and other necessary repairs and/ or replacements. The utility requirement was determined from Super Pro® for the extraction process and the water requirement for the process was determined to be the water weight percent multiplied by the annual production on a weight basis. The utility determination for the process is summarized in Table 28 below. Straight line depreciation of the total capital investment was assumed to be 10%. The combined taxes and insurance were assumed to be 3% of the fixed capital investment.

Table 27: Total Annual Product Cost

Total Annual Product Cost					
	Rate		**Cost per unit**		**Cost per Year**
Raw Materials					
Active & Inactive Ingredients	7.44.E+06	kg/ yr	$ 10.55	USD / kg	$78,449,110
Packaging	147% of Tubes/yr				$65,733,784
Operating Labor	3 operators at $27/hr				$603,126
Operating Supervision	15% of Operating Labor				$90,469
Utilities	Electricity, Water, Steam				$128,674
Maintenance & Repairs	10% Equipment Cost				$325,718
Operating Supplies	15% Maintenance & Repairs				$48,858
Laboratory Charges	10% of Operating Labor				$60,313
Depreciation	Straight Line Depreciation (10 yrs)				$1,013,119
Taxes	2% FCI				$172,230
Insurance	1% FCI				$86,115
Total Annual Product Cost					**$146,711,516**
Total Annual Product Cost per tube					**$4.34**
Total Annual Product Cost per kilogram					**$19.72**

Table 28: Utility Requirement

Utilities			
Parameter	amount	$/unit	Cost, USD
Electricity (kWh)	2587990	$ 0.05	$116,460
Steam, saturated (kg)	65195710	0.0044	$11,387
Water Cooling (kg)	1239335	0.000396	$491
Water Process (.114 kg/ tube)	849483	0.000396	$337
Total			**$128,674**

ANNUAL CASH FLOW (PERFECT CASE)

The income from sales for our $8.00 product price was determined to be $270 million at the demand projected from the beta analysis. The gross profit or cash flow for each year was determined by subtracting the annual product cost from our income. Gross profit was determined to be $124 million. 34% of gross profit was deducted as taxes in order to obtain a net profit of $81.7 million. Recalling that the initial investment for this process was $10.1 million, a return on investment from the first year is approximately 800%. Additionally the investment for this process would pay out in less than a year. The NPW for the first year is 104 million and increases to $6,540 million over a ten year period. The conditions of the perfect case are summarized in Table 29 below.

Table 29: Annual Cash Flow (Perfect Case) Summary

Parameter	Year 1	Year 10	Cumulative Years
Total Income	$270	$270	$2,710
Gross Profit	$124	$124	$1,238
Income Taxes	$42.1	$42.1	$421
Net Profit	$81.7	$81.7	$817
TCI	$10.1	$10.1	$10.1
ROI, based on yr	800%	800%	8,000%
NPW	$104	$6,540	25,760

ANNUAL CASH FLOW (IMPERFECT CASE, SCENARIO 1)

Modifications were made to the perfect annual cash flow section above that assumed that this toothpaste would capture a demand of 33.8 million tubes/ year. That demand is equivalent to 76% of the target market. The imperfect case assumes that market share will be 7% at its introduction and increase annually at a rate of 3.5% until a maximum of 38.5%. The associated demand with each year is presented below in Table 30 as "#tubes/ yr."

Table 30: Market Share over 10 Years

Year	%market share	# ppl	# tubes/yr
1st year	7%	521,697	3,130,180
2nd year	10.50%	782,545	4,695,270
3rd year	14.00%	1,043,393	6,260,360
4th year	17.50%	1,304,242	7,825,451
5th year	21.00%	1,565,090	9,390,541
6th year	24.50%	1,825,938	10,955,631
7th year	28.00%	2,086,787	12,520,721
8th year	31.50%	2,347,635	14,085,811
9th year	35.00%	2,608,484	15,650,901
10th year	38.50%	2,869,332	17,215,991

This scenario fixes the production rate for the Year 10 value of 17.2 million tubes/ yr (3.8 million kg/ yr of raw materials). This results in a total annual product cost of $68 million / year ($3.94/ tube). The product selling price will remain $8.00/ tube as in the perfect case scenario. Years 1-4 show negative net profits (Table 31) and Years 5-10 show profit (Table 32). The net profit, over the ten year period, of this process is $24 million and results in a 240% return on investment. The projected pay-out time based upon negligible salvage value was 8 years. The NPW doesn't become positive until Year 9. This process would still be profitable but it does not show the immediate success of the perfect case. The summary of Scenario 1 is given in Table 33.

Table 31: Year 1-4 Annual Cash Flow

	Year 1	Year 2	Year 3	Year 4
Total Income	$25,041,442	$37,562,162	$50,082,883	$62,603,604
Production Cost	$67,777,063	$67,777,063	$67,777,063	$67,777,063
Gross Profit	-$42,735,622	-$30,214,901	-$17,694,180	-$5,173,459
Taxes	$14,530,111	$10,273,066	$6,016,021	$1,758,976
Net Profit	-$57,265,733	-$40,487,967	-$23,710,201	-$6,932,435
NPW	-$47,600,233	-$66,558,254	-$153,291,962	-$239,686,651

Table 32: Year 5-10 Annual Cash Flow

	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Total Income	$75,124,325	$87,645,046	$100,165,766	$112,686,487	$125,207,208	$137,727,929
Production Cost	$67,777,063	$67,777,063	$67,777,063	$67,777,063	$67,777,063	$67,777,063
Gross Profit	$7,347,262	$19,867,982	$32,388,703	$44,909,424	$57,430,145	$69,950,866

Taxes	$2,498,069	$6,755,114	$11,012,159	$15,269,204	$19,526,249	$23,783,294
Net Profit	$4,849,193	$13,112,868	$21,376,544	$29,640,220	$37,903,896	$46,167,571
NPW	-$305,571,012	-$324,779,711	-$275,746,247	-$140,818,793	$94,331,743	$441,223,062

Table 33: Cumulative 10 Year Total Annual Cash Flow (Imperfect Case, Scenario 1) Summary

Parameter	$ millions
Total Income	$814
Gross Profit	$136
Income Taxes	$111
Net Profit	$24.7
TCI	$10.1
Pay Out Time	8 years
ROI after yr 10	240%
NPW (yr 10)	$441

ANNUAL CASH FLOW (IMPERFECT CASE, SCENARIO 2)

Since the results from the first scenario were disappointing, this scenario will try to forecast the demand by one period in order to see if positive net profit can be obtained in a quicker time frame by adjusting the production rate accordingly. This scenario differs from the first because it will not keep a constant production rate which was obtained from the maximum market share percentage that is achieved at Year 10. The market share growth and demand assumptions from Table 30 will still apply and the selling price will remain $8/ tube. Table 34 shows the production rate and cost for each year based upon market share assumptions.

Table 34: Market Share, Demand, Production Rate, and Total Annual Cost

Year	%market share	# ppl	# tubes/yr	kg/yr	TAC	$/tube
1st year	7%	521,697	3,130,180	6.89E+05	$16,692,382	$5.33
2nd year	10.50%	782,545	4,695,270	1.03E+06	$22,624,089	$4.82
3rd year	14.00%	1,043,393	6,260,360	1.38E+06	$28,555,796	$4.56
4th year	17.50%	1,304,242	7,825,451	1.72E+06	$34,487,503	$4.41
5th year	21.00%	1,565,090	9,390,541	2.07E+06	$40,419,211	$4.30
6th year	24.50%	1,825,938	10,955,631	2.41E+06	$46,350,918	$4.23
7th year	28.00%	2,086,787	12,520,721	2.75E+06	$52,282,625	$4.18
8th year	31.50%	2,347,635	14,085,811	3.10E+06	$58,214,332	$4.13
9th year	35.00%	2,608,484	15,650,901	3.44E+06	$64,146,039	$4.10
10th year	38.50%	2,869,332	17,215,991	3.79E+06	$67,777,063	$3.94

Scenario 2 shows much better results than scenario 1. Over the course of ten years the cash flow and net profit are consistently positive and are above a million dollars. Year 1 is the only year that has negative net present worth. However at the end of Year 2 the NPW is $8 million. These results were obtained by forecasting the demand and adjusting the production rate. For example, the production rate for Year 1 was based upon the demand that was predicted for Year 2. Year 2 was based upon Year 3 demands and so forth until the maximum demand was reached at Year 9. These results are not as good as the perfect case; however they are more realistic in terms of a new product entering the market and give a good estimate for production scheduling. Table 35 gives the results of Scenario 2.

Table 35: Annual Cash Flow (Imperfect Case, Scenario 2)

	Year 1	Year 10	Cumulative Totals
Total Income	$25,041,442	$137,727,929	$813,846,852
Production Cost	$22,624,089	$67,777,063	$476,702,932
Gross Profit	$2,417,353	$69,950,866	$337,143,920
Taxes	$821,900	$23,783,294	$114,628,933
Net Profit	$1,595,453	$46,167,571	$222,514,987
ROI, based upon year	16%	460%	2220%
NPW	-$6,552,075	$1,599,176,736	$4,809,954,136

CONCLUSION

Tooth cavities are caused by *S. mutans* and are a serious public health issue. Polyphenolic grape pomace extract will inhibit the virulence factors of S. mutans and consequently decrease the risk of tooth cavities when placed in toothpaste with 98% consumer preference. Only the extraction process requires an investment, which totals $10 million and will yield an estimated return on investment of 800% when product is sold at $8/tube. The product with the highest consumer preference is also the most profitable.

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Appendix 1: Cooling Effect Experiment

Participants were used to determine the correlation between true mouth temperature drop and the sensation of cooling provided by three commercial products.

Initial mouth temperature was taken for all participants.

Participants held ice cube in mouth for approximately 20 seconds, and then they took mouth temperature. Then, participants chewed on one Altoid and compared the cooling sensation of the Altoid with the actual coolness from the ice cube. They rated the cooling sensation to the cooling of the ice cube as 1=same cooling.

Next, participants swished with icy water for approximately 20 seconds, and took mouth temperature. Then, participants chewed one piece of Extra Polar Ice gum and compared the cooling sensation to that of the icy water, on the same scale as before.

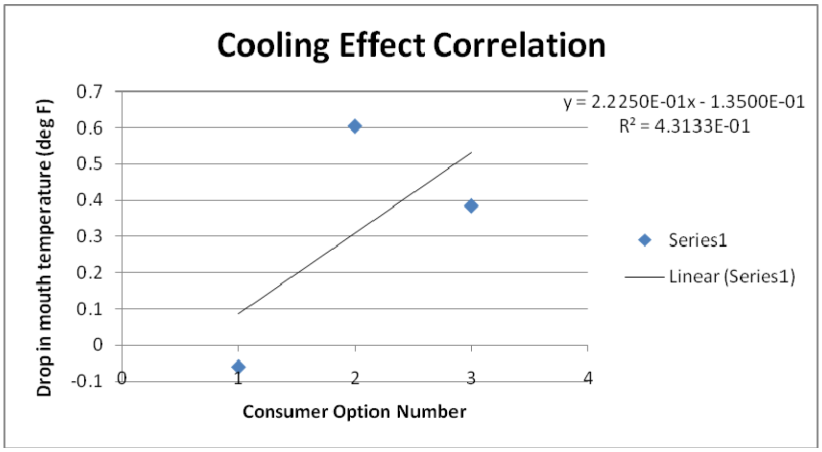
Lastly, participants swished with nearly room temperature water for approximately 20 seconds, and again took mouth temperature. Then, after chewing on one piece of Winterfresh gum, the participants ranked the cooling sensation to that of the regular water.

Results:

The equivalent temperature drops for each consumer option was found by taking the actual temperature drop of the liquid or ice and multiplying it by the fraction given by the consumer.

All temperatures are in degrees F.
Due to equipment malfunction, only 2 participants were used. A standard digital thermometer was used.

Participant	**1**	**2**		
Initial Participant Mouth Temperature	96.9	97.9		
Temp. w/ ice cube	93.8	95.6		
Fraction w/ altoids	0.1	0.2		
Temp w/ cold water	94.9	97.2		
Fraction w/ polar ice	0.5	0.3		
Temp w/ tap water	96.5	99.1		
Fraction w/ spearmint	0.3	0.2		
			average	**consumer option #**
Delt. T Altoids	0.31	0.46	**0.385**	**3**
Delt. T Polar Ice Gum	1	0.21	**0.605**	**2**
Delt. T Spearmint Gum	0.12	-0.24	**-0.06**	**1**


Cooling Effect Correlation
y = 2.2250E-01x - 1.3500E-01
R² = 4.3133E-01
Drop in mouth temperature (deg F)
Consumer Option Number
Series1
Linear (Series1)
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
-0.1
0
1
2
3
4