Handbook on Cosmetics (Processes, Formulae with Testing Methods)
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Cosmetics products are created for application on the body for the purpose of cleansing, beautifying or altering appearance and enhancing attractive features. It is not similar like medicines in addition to it cannot be used to modify the physique function or performance. The cosmetic Industry has witnessed rapid growth over the last couple of decades. Now a day the range of cosmetic and beauty products has widened tremendously. The use of cosmetics has increased exponentially not only among in females but the male population also indulges in their use. A wide range of chemical and natural materials is used in the formulation of cosmetic and toiletry preparations. Cosmetics like creams, gels, face powder, eye makeup, shaving cream, and colognes are used on a daily basis by both women and men. The Indian cosmetic Industry has witnessed rapid growth over the last couple of decades. In that time the range of cosmetic and beauty products in India has widened tremendously. Beauty products manufacturers in India mostly cater to the great demand for cosmetics and toiletries that fall into the low or medium price categories as the greatest demand in India has always been for these economically priced products. Bearing a long glowing heritage of cosmetic and beauty, aesthetic makeup products is being used since olden days and nowadays it appear like a booming economy in India which would be the largest cosmetic consuming country in a next few decades. While the demand of beautifying substances are growing day by day, a large number of local as well as international manufacturers gradually extend their ranges and products in different provinces of India. Industry sources estimate a rapid growth rate of 20% per annum.

Some of the fundamentals of the book are regulation of cosmetic products, the relationship of cosmetic products to drugs, preservation of cosmetics, factors affecting preservation, organisms found in cosmetics, antiperspirants and deodorants, cleansing creams and lotions, baby toiletries, face powder manufacturing process, aerosol cosmetics, shaving preparations: soaps, creams, oils, and lotions, advantages and disadvantages of natural dyes, packaging cosmetic preparations, etc.

The book covers formulae, manufacturing processes of various types of cosmetics like antiperspirants and deodorants, cleaning creams, lotions, emollient creams, baby toiletries, face powder, eye makeup and many more along with testing methods. This book will be great asset to new entrepreneurs, existing units, technocrats and technical institutions.

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Sample Chapter:
regulation of cosmetic products

Historical development

The modern day mass market toiletry and cosmetic industry began in the US in the early years of the 20th century and particularly between the two world wars. Whilst the industry record for in use safety of its product was good this rapid expansion in consumer exposure gave rise to calls for action to preempt possible problems that could arise. Consumer pressure and advances in the science of toxicology added to the general concern.

In the US the Pure Food and Drugs Act of 1906 enacted to extend formal federal controls over foods and drugs did not include cosmetics reportedly as the result of a political compromise. Not until passage of the Food Drug and Cosmetic Act in 1938 were cosmetics included in the general prohibitions against manufacturing and marketing adulterated or misbranded products. The 1938 Act also made it possible for products previously unregulated to come under Food and Drug Administration (FDA) control as drugs if they were intended not only for medicinal and therapeutic purposes but also if they were intended to affect the structure or function of the body. The 1938 Act has since been amended to control the safety of cosmetic colors. Regulations under both the FDC Act and the Fair Packaging and Labeling Act (FDCA) administered by FDA restricted or prohibited cosmetic ingredients found to be unsafe and required extensive informative labeling of cosmetic packaging.

Other national and regional governments have likewise sought to govern cosmetic products. In Japan cosmetics are included in the Pharmaceutical Affairs Law administered by the Ministry of Health and Welfare. The law requires that cosmetic manufacturers and importers be licensed and that each cosmetic placed on the Japanese market either be in conformance with the monographs that make up the Comprehensive Licensing Standards of Cosmetics or have obtained direct individual approval from the Ministry.

In Europe prior to 1976 there was no comprehensive control of cosmetics and local legislation varied widely. Some countries e.g. Germany already had a highly developed regulatory system whilst other relied almost solely on rather antiquated rules for poisons control. With the development of the then European Economic Community later the European Community and now the European Union (EU) with its twin aims of free movement of goods between member states (MS) and consumer safety this situation was unacceptable. In 1976 the then MS agreed a Directive on Cosmetic Products which would be applicable to the Community as a whole. In the pursuit of adaptation to technical progress this Directive has in the meantime been amended no less than 24 times.

Other countries have developed their own regulatory styles but in the main these are based on those of one of the three major markets Japan USA or Europe.

Self regulation

In many areas of the world and especially in the US the cosmetic industry has embarked on voluntary programs aimed at improving the safety and effectiveness of cosmetics and at the same time at avoiding more intrusive government regulation. These activities have included codes of good practice and self regulatory programs such as voluntary registration of cosmetic manufacturing establishments cosmetic products and ingredients and voluntary reporting of adverse reaction experiences. In addition in the US the industry has undertaken a program [the Cosmetic Ingredient Review (CIR)] to assess the safety of cosmetic ingredients through an independent panel of scientific experts which meets deliberates and publishes its findings. CIR reports on specific cosmetic ingredients are used by industry and government to establish the safety of these materials. In addition the perfumery industry set up the international organizations IFRA
(International Fragrance Research Association) and RIFM (The Research Institute for Fragrance Materials) to examine and review perfumery materials and to control their use. The aerosol industry published a code of practice for manufacture of aerosol products while the European Chemical Industry set up ECETOC as a review body to control information on the safety of chemical substances. COLIPA (Comite de Liaison des Associations Europeennes de l’Industrie de la Perfumerie des Products Cosmetique et de toilette) the representative body for trade associations within the FC published Advisory Notes of Manufacturers together with a number of other advisory documents covering the safety of cosmetic and toiletry products. These included the Education and Training of Personnel, Product Safety Verification during Marketing and Avoidance of Nitrosamine Formation in Cosmetic Products.

Although much of the voluntary activity described eventually led to legislation there still remains a wealth of voluntary activity and the legislation imposed has been maintained at realistic levels. Industry continues to adjust its voluntary controls in the light of consumer pressures, environmental concerns, and legislation in other areas that impinges on the products manufactured and sold as cosmetics and toiletries. Constant vigilance and awareness of these issues is imperative for all scientists aspiring to create new approaches and new products in this area.

Regulation in the United States
Federal Regulation of Cosmetics
The Federal Food Drugs and Cosmetic Act (FDC Act) is the primary food and drug law in the United States. The FDC Act prohibits the distribution or importation of cosmetic products that are adulterated or misbranded terms that have been interpreted by Congress the Food and Drug Administration (FDA) and the courts to include certain characteristics. However in general the term adulterated includes products that are defective, unsafe, filthy or produced under insanitary conditions. A cosmetic may be adulterated if it or its container is composed of a deleterious substance that may render it injurious to users under customary or labeled conditions. A cosmetic may also be adulterated if it contains any filthy, putrid or decomposed substance or if it has been produced, packed or held in insanitary conditions under which it may have become contaminated. Finally a cosmetic may also be adulterated if it contains an unapproved color additive.

The term misbranded refers to statements, designs or pictures in cosmetic product labeling that are false or misleading or which fail to provide required information and to the use of deceptive or improper containers. A cosmetic may be misbranded if it fails to bear all of the information required under both the FDC Act and the provisions of the Fair Packaging and Labeling Act (FPLA) which sets forth the content and placement of information required on all consumer packages.

The FDC Act also requires that companies maintain certain records and authorizes FDA to inspect cosmetic products and establishments including manufacturing and packaging plants, warehouses and other storage facilities, vehicles used for transporting cosmetic products and containers of imported goods held at US ports of entry.

The Food and Drug Administration, an agency within the Department of Health and Human Services administers and enforces both the FDC Act and the FPLA. FDA conducts routine and regular inspections of cosmetic establishments in the United States to determine that products produced, packed and stored are neither adulterated nor misbranded. The FDA has not issued good manufacturing practice (GMP) regulations for cosmetics although cosmetics that are also drugs are subject to the pharmaceutical GMPs.

In practice the same inspection team generally conducts inspections at both over the counter drug and cosmetic facilities. In addition to its routine inspection activities, FDA will also investigate products and establishments on the basis of consumer complaints or because a company has filed a trade complaint concerning a possible violation of the law by one of its competitors.
Persons and firms responsible for violations may be subject to civil and criminal sanctions. Products found to be in violation may be seized and their further manufacture or distribution may be enjoined by orders obtained by FDA in the Federal court. If the offense is egregious deliberate or repeated FDA may bring a criminal suit against the company and its responsible officials. Imported products that appear to be in violation of the law may be detained at the port of entry by FDA inspectors and if found to be in violation may be destroyed if they cannot be brought into compliance or are not re exported.

Although FDA brings many formal cases against violators and products each year it also works with domestic companies toward voluntary recall or correction of illegal goods and practices. This in part is due to the scarce resources of the FDA and because the FDA has the burden of proving that a product is either adulterated and/or misbranded. The first step in the FDA’s enforcement procedures is therefore usually a warning letter to the responsible company or individual from the FDA charging a violation of the Act and regulations and providing a limited time usually 15 days for the company to correct the violation.

Despite the formidable enforcement tools at the disposal of the FDA cosmetics remain the most lightly regulated products within the FDA’s jurisdiction in large part because more stringent restrictions have not been needed. Cosmetic products may be placed on the US market without FDA premarket clearance as long as the products do not contain any prohibited or unsafe ingredients (not adulterated) and are properly labeled and promoted (not misbranded). There exists no Federal requirement for cosmetic establishment registration or for listing cosmetic products or ingredients with the FDA. The regulations do include procedures for voluntary registration and listing of cosmetic establishments products ingredients and many industry members participate in this voluntary program.

**Cosmetic Composition**

*Safe ingredients* Each cosmetic manufacturer is responsible for using only safe and suitable ingredients in its products and for substantiating the safety of the finished product. Products whose safety has not been substantiated must bear a warning statement on the label. Although to this author’s knowledge no cosmetic product has ever been so labeled in the event that a product is shown to be unsafe and is marketed without such a warning FDA could charge the responsible company with failure to warn under this provision. This use of the misbranding provisions of the statute together with the adulteration prohibitions in the statute encourages voluntary testing of cosmetic products and ingredients prior to marketing.

The FDA has published a short list of restricted or prohibited substances including items such as bithionol hexachlorophene mercury compounds for all but preservative use in eye area products vinyl chloride halogenated salicylates zirconium in aerosols chloroform methylene chloride and chlorofluorocarbon propellants.

*Color additives* The FDA has also published regulations stipulating the color additives that may be used in cosmetic products including the product categories in which they may appear any restrictions in the concentration level of the colors and any required label warning statements. The list of color additives is divided into those that must be certified by the FDA prior to their sale (all FD&C and D&C colors) and so called *natural* colors for which no certification is required.

In contrast to some other color additive regulatory schemes most synthetic coal tar colors (the colors identified by FD&C and D&C nomenclature such as FD&C Red 6) have not been authorized for use in products intended for the eye area. The exceptions are FD&C yellow 5 FD&C Green 5 FD&C Blue 1 and FD&C Red 40.

*Hair dyes* The FDA’s prohibition against the use of poisonous or detritious substances in cosmetic products does not apply to coal tar hair dyes as long as the statutory warning statement appears on the product containers. In addition coal tar hair dye colors are not subject to the regulatory requirements for cosmetic color additives. The warning statement required by the FDC Act is as follows

**Caution**-This product contains ingredients which may cause skin irritation on certain individuals and a
preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows to do so may cause blindness.

Cosmetic Labeling
The FDA has issued detailed rules for the labeling of cosmetic products. These rules are issued under both the FDC Act and the FPLA. Because the FPLA applies only to the outermost containers of retail cosmetic packages some labeling requirements such as the ingredient declarations product identity statements and placement and type size of net content declarations only apply to the outermost retail container. Cosmetics must be labeled with the information detailed in sections 1 to 6.

*Product identity* This statement should appear on the principal display panel (PDP) of the outer container in bold type and in lines parallel to the bottom of the package. The law does not require a product identity statement on the inner container of cosmetics that are packaged in an inner and outer container. However the inner containers of most products are labeled with a product identity statement to avoid consumer confusion and potential misuse that could result in a product liability suit.

The name used may be the common name of the cosmetic a descriptive name or of fanciful name (if the nature of the cosmetic is otherwise obvious) or the cosmetic may be identified by an appropriate illustration of the cosmetic's intended use.

Products sold to beauty salons for professional use by beauticians gifts of free samples testers or demonstrators and theatrical make up for professional use only are exempt from product identity labeling requirements. However in practice these products generally are labeled with an identity statement to avoid user confusion and potential misuse that could result in user injury.

*Name and address of the manufacturer packer or distributor* The name and address of the manufacturer packer or distributor must appear on both the inner and outer containers. The street address may be deleted if the company appears in the local telephone or city directory. If the name that appears on the container is not the manufacturer it must be prefaced by an explanatory phrase such as Distributed by Manufactured for Packaged by or a similar description. The name and address must be placed conspicuously on the product although specific type size and placement are not required. Labeling the bottom panel is not generally considered to be conspicuous. The actual corporate name of a corporation must be used. Partnerships individuals or associations may be identified by the name under which they do business.

*The net content in American (ounces/fluid ounces) and metric measures* this statement should appear in American units within the lower 30% of the PDP in lines parallel to the bottom of the package. If the PDP is less than 5 inch² (32mm²) the declaration may appear anywhere on the PDP. If there is more than one PDP the declaration must appear on each. The required type size for the net quantity of contents varies with the size of the PDP.

If a cosmetic is sold in an inner and outer container the inner container must also bear a net quantity of contents statement. However the type size and placement requirements for the net quantity of contents do not apply to the inner container as long as the statement appears in a conspicuous location.

4. *A statement of ingredients in the product in descending order of predominance* The ingredients are only required on the outer container and generally are listed in order of predominance in the product. The minimum required type size for product ingredient statements is 1/16 inch (1.6 mm) except that 1/32 inch (0.8 mm) may be used if the total surface area available for labeling is less than 12 inch². Placement must be on an appropriate information panel (bottom panel labeling is not generally considered appropriate). Products sold to beauty salons for professional use by beauticians gifts or free samples testers or demonstrators and theatrical make up for professional use are exempt from ingredient labeling requirements. Special ingredient labeling rules exist for certain cosmetic products such as lines of shaded products assortments products sold by mail order and products displayed in cases and display units.
Any warnings required by regulation (such as the warnings required for aerosol products and bath foam products) Warning statements must be conspicuous and prominently displayed on both the inner and outer containers and in typesize no smaller than 1/16 inch (1.6 mm). Warning statements have been prescribed in the US for foaming bath products hair dyes aerosol products feminine deodorant sprays and for products without adequate safety substantiation.

Country of origin if imported Us Customs Service regulations require that cosmetic product containers be marked with the country of origin of their contents. Expiration dating and lot or batch codes are not required by specific regulation. Most companies do include an expiration date if the products are not likely to be sold and used within its period of stability. Lot and batch codes are commonly added to cosmetic product labeling to facilitate recall and identification of products in the marketplace when necessary.

sensitivity testing
Tests for sensitivity to cosmetics are divided into two general categories
Diagnostic testing. The establishment of the cause of dermatitis produced by cosmetics in general use. Prophetic or predictive testing. The ascertainment of the irritant and sensitizing potential of new cosmetics before they are permitted to be used by the general public.

DIAGNOSTIC SENSITIVITY TESTING
The establishment of the diagnosis of cosmetic dermatitis and the proof that a cosmetic is producing a particular dermatitis is usually determined by patch tests.

Technique of Diagnostic Patch Testing
Patches should be placed on grossly normal nonhairy skin. It is preferable to utilize areas that are usually covered by clothing so that strongly positive patch test reactions which may persist for several days or even for a week or so will not embarrass the tested patient. In rare instances hyperpigmentation depigmentation and even slight scarring may occur at the patch tests site.

For routine covered patch tests a small amount of cosmetic is applied to 1 cm² of cotton fabric gauze or Webril. This square may be backed with polyethylene to obtain occlusion and is held in place with a plastic adhesive tape such as Dermicel. Dermicel is a nonrubber acrylate mass adhesive which is nonirritating and nonsensitizing. Blenderm is a similar acrylate mass adhesive.

Most investigators feel that the back is a reliable site for patch tests since the pressure to which this area is subjected in sitting and laying enhances patch test reactions. However the skin of the upper inner aspect of the arm may also be employed for testing. The use of this site enables the patient to readily remove any patch that itches or burns excessively. In general if it is suspected that a test substance may cause a severe reaction that substance should be tested at a site separate from the main body of the patch tests. This will enable the patient to remove readily the reacting test patch without disturbing the other patches.

Patients should be given the following instructions after the test patches have been applied
Remove any patch that causes severe itching or burning but if possible do not disturb the other patches. Keep the patch test areas dry.
Avoid rubbing or scratching any test site. Should you have to remove a patch the application of cold water compresses will help allay itching or burning and will not affect the reading of the reaction provided that you keep the other patches dry. You may take aspirin or a sedative if necessary.

The patch test reaction depends on the sensitivity of the patient the concentration of the substance used for patch testing and the length of time that the substance is permitted to remain on the skin. Usually the patch test is kept in place for 48 hr then removed and a reading made. When the patch is removed it is wise to mark the exact location of the test material on the skin with a skin marking pencil or pen for future
reference. This is especially true if the results of the test are slight or doubtful and may have to be reread the next day or at some later period. Readings should be made after an interval of 20 to 60 min from the time of the removal of the patch. This time interval is necessary so that the skin may recover from the effects of pressure of certain patch test substances which may produce a mild erythema or even dermographia which is usually transient. The true erythema of the specific reaction to the test agent persists for hours or days. The pressure of solid cosmetics may produce a temporary blanching that may stimulate a negative reaction and that may become positive only when the effect of the pressure wears off and allows edema and the eczematous response to come through the cutis into the epidermis.

**The Interpretation of Patch Test Reactions**

Significant reactions to patch tests present changes in the skin characteristic of eczema. As a rule the site of a positive patch test reaction itches. A typically significant positive reaction consists of vesicles on an edematous red area. When a single bulla occurs it is usually due to a primary irritant but there are exceptions to this rule. When there is a questionable reaction such as a mild erythema it is wise to reexamine the patch test site the following day. Redness which persists or increases in intensity is probably significant for an allergic reaction. Erythema at the test site which fades in 24 hr is probably not associated with an allergic reaction of clinical significance.

A positive patch test reaction with a cosmetic usually means that that particular cosmetic is capable of producing allergic dermatitis provided the test has been properly performed and interpreted. However it is possible on rare occasions for a cosmetic to give a negative patch test reaction when the test is performed on the usual sites such as the arm or back but give a positive reaction when applied closer to the site of the eruption particularly if the thin skin of the eyelids or neck is involved or if the cosmetic is a weak sensitizer. Stronger sensitizers such as hair dyes or nail lacquer resins usually give a positive reaction at the conventional sites of patch testing. However when a suspected cosmetic gives a negative patch test reaction the trial and error method of reapplication will usually establish its guilt or innocence.

Whenever a number of patches are performed that cosmetic that is under strongest suspicion and may produce a reaction should be placed away from the other patches so that its early removal if necessary will not disturb the remaining patches and so that a strongly positive reaction will not spread and produce false reactions at adjacent sites.

**Uncovered versus Covered Patch Test Technique**

Cosmetics suspected of being photosensitizers should be tested both covered and exposed to sunlight or artificial light. Cosmetics which contain volatile chemicals may be primary irritants under a closed patch. These include hair lacquers nail polish and some perfumes. Such cosmetics should be allowed to remain uncovered on the skin at the site of the patch test until the volatile substances have evaporated (usually for 10 to 15 min). After this period of time has elapsed the patch test site may be covered.

Certain cosmetics which in actual use do not cause dermatitis may give false positive patch test reactions with the covered patch test technique since they are primary irritants when occluded. The following should be tested uncovered: depilatories, permanent wave preparations, soaps, shampoos, detergents, hair tonics, alkaline hair dye mixtures, caustic agents (cuticle removers), oxidizing agents (certain freckle creams), mascaras containing volatile elements, shaving creams and tooth pastes that contain soapy bases. The interpretation of covered patch test results with solutions of soaps, shampoos and detergents is difficult. When these substances are suspected as the cause of allergic dermatitis testing should preferably be performed with such ingredients as preservatives or antibacterial agents by both the covered patch test method and open for photosensitization.

Another technique for testing cosmetics by the open method is to employ the use method in which the
cosmetic simply is massaged gently into the forearm three times a day for 3 days and the forearm is inspected for evidence of any reaction.

In general primary irritants burn rather than itch and produce reactions on the skin sooner than do sensitizers. A primary irritant may cause a reaction in a few minutes to an hour or so while a sensitizer usually requires 24 to 48 hrs to produce its effect. A primary irritant reaction tends to remain confined to the site of the application of the cosmetic and usually fades rather rapidly after the patch test site has been uncovered. Many allergic reactions tend to spread beyond the site of application of the cosmetic and to persist and even become more marked for several days after the patch is removed. It is however sometimes admittedly very difficult to distinguish between a primary irritant effect and a true allergic eczematous reaction.

Features of Patch testing with Paraphenylenediamine

Federal legislation requires that oxidation dyes such as paraphenylene diamine (PPDA) bear a warning to the effect that a patch test should be performed prior to each and every application of the dye. In actual practice it is the custom in many beauty parlors to do a patch test prior to the initial hair dyeing procedure but to omit the test on subsequent applications.

Patch testing for allergic sensitivity to PPDA may be performed by either the uncovered or covered patch testing method.

Uncovered Patch Test Method for PPDA Sensitivity

This is the routine technique for testing hair dye sensitivity. Instructions for such testing are included with every package of hair-dye preparation. The test may be performed as follows five drops of the solution from the bottle containing the dye should be mixed in a small glass with a similar amount from the bottle containing the oxidizing agent. The mixture is allowed to stand for 5 min and is then painted on the skin at the bend of the elbow or behind the ear with a cotton tipped applicator. The application should cover an area not less than the size of a 25 cent piece and should be allowed to dry and remain on the skin uncovered for 24 hr. If at the end of this time there is no itching or sign of irritation at the site of the application the dye can usually be safely used on the hair. If there is any sign of irritation at the site of application such as redness swelling papules or vesicles the dye should not be used.

The two bottle mixture should always be tested by the open method since the alkali and oxidizer of the mixture are primary irritants under occlusion.

Covered Patch Test Technique for PPDA Sensitivity

A 2% concentration of PPDA in petrolatum is standard for such testing. This preparation darkens by slow oxidation and should be freshly prepared every 3 months. Staining of the skin from a patch test with PPDA should not be confused with an irritant or allergic reaction. Such staining is due to the oxidation of PPDA on the skin. PPDA for testing should be dispensed in a dark bottle and should be kept tightly closed at all times. Unoxidized PPDA and the black or colored end product of the union with the hair probably are not sensitizers. The intermediate partially oxidized quinone chemicals are said to be the actual sensitizers.

Evaluation of Patch Test Reactions to PPDA

Experience has shown that a 1 + to 2 + reaction to the PPDA hair dye mixture by the open method is of clinical significance and usually dermatitis will develop if the hair dye mixture is used.

On the other hand many individuals have been observed who show a similar mild reaction to 2% PPDA in petrolatum by the covered method and who continue to use PPDA containing hair dyes without difficulty. However a stronger reaction (3 + to 4+) by the covered patch test technique precludes the use of PPDA hair dyes. Such strongly positive patch test reactions to PPDA are usually accompanied by allergic dermatitis if the dye is used.

In medicolegal cases the open patch test should be performed with the actual dye mixture that was
employed. If a positive patch test reaction is obtained the open test should be supplemented by testing with PPDA alone by the covered technique. A positive patch test reaction by both methods proves that the PPDA was the cause of the dermatitis. Unless such a supplementary test with PPDA alone is performed one cannot be certain of the actual cause of the dermatitis since the patient has been exposed to several chemicals in the hair dyeing procedure.

A patch test with PPDA after 48 hr is rarely positive. After an interim of 3 to 5 days a reaction occurs. Such a delayed reaction may indicate that the test procedure itself has sensitized the individual. The application of the hair dye in the interim produces a dermatitis despite the original negative reaction. Fortunately such an occurrence is extremely rare. At any rate performing a patch test before application of a PPDA hair dye is a legal mandatory requirement.

Patch tests with PPDA should be postponed until the dermatitis is under control. In the acute phase of a dermatitis the skin may give a false positive reaction and a strongly positive patch test reaction may cause a severe flare of the dermatitis.

Patients with hair dye dermatitis should also be tested with 2% para toluylene and 2% ortho nitro paraphenylenediamine which may be present in certain oxidation type hair dye preparations.

Features of Patch Testing with Nail Polish

Patch tests with nail polish may be performed by the covered technique or by the open method. Where the closed patch test method is used the lacquer is painted directly on to the skin which is not covered for about 15 min to allow evaporation of any volatile solvents that may be present. The test site may then be covered. The sulfonamide formaldehyde resin the most common cause of nail polish dermatitis is tested at a concentration of 10% in petrolatum.

In the rare instances where photosensitivity to the dye in the nail polish is suspected because of a history of flaring of dermatitis following exposure to sunlight it is mandatory to perform an open patch test on an exposed portion of the skin or to perform photopatch tests.

Patch Testing with Lipstick

Lipstick should be tested by both the open and the covered method. The open site is tested for photosensitivity. Should the covered patch test be positive a nonphotosensitizing azo dye the oils fats waxes perfumes flavors or antioxidants (preservatives) used in the lipstick may be found to be responsible. Upon request the manufacturers of hypoallergenic cosmetics will send a raw material testing set containing individual lipstick bases and dyes for patch testing. To confirm the results of the testing set these companies will also supply a clinical testing set consisting of sample lipsticks of various colors for clinical trial and will prepare special lipsticks if necessary.

Testing with Permanent Wave Solutions

Most modern permanent waving are cold processes with ammonium thioglycollate as the active agent. Added are perfumes gums synthetic resin opacifiers lanolin and emulsifying agents. Ammonium thioglycollate rarely sensitizes. It may be patch tested in a 10% aqueous solution. Permanent wave solutions should be diluted with five parts of water before being applied under a covered patch. A nonspecific irritant erythema is often obtained by such testing particularly when the pH of the solution is high. Mild erythematous patch test reactions should not be considered allergic unless at least three controls show no reaction from the test.

quality assurance

QUALITY CONTROL

Quality assurance serves the purpose of making sure by means of planning direction and inspection that every preparation meets the promises of the producer. Every effort must be made to ensure that the
consumer receives what he or she expects on the basis of advertising catalogue descriptions or directions for use. Consumer expectations must not be let down. Preparation quality must already be established in the development phase of a preparation. Legal guidelines regarding quality determine the development of a preparation. In order to ensure that a preparation meets these guidelines quality must be controlled. Quality control remains indispensable under even the most modern technical conditions. Personnel and material expenditures for quality control count as part of the normal conduct of business. They usually account for about 5% corporate turnover.

Modern strategic planning concepts is a company such as the just in time inventory can lead to ever higher production costs. For example if a cosmetic ingredient or package component is as a result of this reduced inventory procedure no longer purchased four times per year but rather six times per year and if every delivery is inspected as always the necessary control expenditures will rise by 50%. This is of course not justifiable. Even quality assurance must adhere to modern planning criteria.

The Analytical Laboratory Its Significance for Raw Materials/Active Ingredients and the Finished Preparation. All the raw materials and ingredients needed for cosmetic preparations are tested for usability in an analytical laboratory. The finished cosmetic preparations are also tested here. The prerequisites for optimal chemical control (optimal is used here to signify the lowest expenditure that provides the highest degree of protection) are the most modern technical aids such as IR UV AAS spectrometers as well as gas chromatography and personal computers. Qualified and experienced technical personnel are also indispensable.

The Microbiological Laboratory Assurance of Purity and Hygiene. Without technical aids molds or bacteria in cosmetic preparations are usually only recognized when it is too late. It is the task of a microbiological laboratory to control their presence in cosmetic preparations. During production of a cosmetic preparation it must already be known which microorganisms the preparation is exposed to the germs discovered must be analyzed and tested to ensure that a precisely fixed germ count is not exceeded. Sterile working conditions are not required for cosmetic preparations but hygiene regulations must be observed during the production process. The GMP and GLP guidelines are generally regarded as the applicable regulations. Cleaning and disinfecting are just as essential as the provision of hygiene education to personnel. Only informed employees guarantee that all regulations are adhered to. Disinfecting machines and machine component are normally cost and time intensive. The clean in place system is an example of innovative attempts in this area which no business can ignore.

Clean in place refers to washing cleaning and disinfecting machines by an installed system of pipes without having to take apart machine components or pumps.

Raw Material Inspection
Specification is the foundation for the inspection of cosmetic ingredients. It takes into consideration the specific requirements of the company as well as legal guidelines. Each detail of the specification must be coordinated with the producer of the raw materials. An inspection certificate which is given to the user with each delivery makes it easier for laboratory administrators to decide which properties of the specification need to be subjected to chemical analysis. It is not necessary to analyze every property of each delivery. The decision regarding how often to test is dependent upon the frequency of delivery coordination of all specification properties between supplier and buyer the inspection certificate accompanying each delivery the history of the raw material in question the degree of trust between buyer supplier and the complete documentation of all data. A sensory test of smell color and/or appearance together with an IR spectrum is often sufficient to identify a delivery accurately. The decision as to whether a full analysis of all specific values needs to be carried out on every third fourth or fifth delivery is made by the laboratory.
administration. It is also absolutely necessary to store all analytical data in a personal computer. An
evaluation of the raw material or supplier can be made at any time with the help of this data.

Inspection of the Finished Product
Specific manufacturing instructions are essential for the production of the finished preparation. Instructions
regarding temperature mixing speed instruments or the order in which ingredients are incorporated make it
easier to keep to the specification. Here too an in process control which registers the actual values
(temperature mixing speed etc.) in relation to the specified values should be adopted.

A particular risk can be bound up with the weighing of the individual raw materials. However great the
inspection expenditures are (for example the additional presence of a specialist from the analytical
laboratory while weighing in active ingredients) mistakes by personnel cannot be excluded. For example
too much of an active ingredient (such as a preservative) could cause fatal effects. For this reason active
ingredients are often inspected again by the analytical laboratory as to their proportion in the final
preparation. This doubled or tripled safeguarding is cost intensive and hence not justifiable according to
modern conceptions of quality. In the search for preventative test characteristics the use of computerized
weighing controls has therefore become prominent. A preparation manufactured under these conditions will
generally meet the prescribed standards.

Inspection of Containers and Packaging Materials
It would not be possible to inspect each of 10 000 bottles delivered for packaging purposes. Yet it must be
guaranteed that they are all in flawless condition. Breakage and structural faults which would lead to
leakage or glass splinters must be totally excluded. It is impossible to compromise on this issue. The
problem can be resolved with the help of statistics. Probability statements regarding the specific quality of a
delivery can be made through the use of spot tests and fault evaluation methods that practically eliminate
error. The result of tests on a small representative sample of a total delivery is used to decide whether an
entire delivery of an item should be accepted or rejected. In terms of cost benefit analysis this is the only
practicable system for inspecting large lot quantities from the viewpoint of both buyers and manufacturers
of packaging materials.

Modern business planning ideas such as the previously mentioned low level inventory method have had a
decisive influence on current conceptions of quality for packaging materials. Statistics remains the
foundation of quality controls but checking systems have been developed which will be discussed here in
some detail namely skip lot inspection source inspection vendor certification and computer assisted delivery
testing. All these inspection systems are related to the need to reduce control expenditures without there by
incurring greater risk.

Skip Lot Inspection. The cosmetics industry also makes use of packaging materials which are relatively
simple to produce. They have therefore retained consistently good quality over the years but each delivery
must nevertheless be thoroughly inspected. If the history of the packaging component has remained
unchanged it is sufficient to inspect every third fourth or fifth delivery (hence the term skip lot). Precise
knowledge of the packaging components and the supplier are however essential pre requisites for using
this method of inspection. For deliveries which are not inspected an identity check (appearance potential
transport damage code number and so on) will suffice.

Source Inspection. Packaging materials that are produced in large quantities and ordered in partial lots
also do not require comprehensive inspection of each delivery. This is especially important when using the
just in time inventory method where small quantities of the materials are ordered with greater frequency.
Source inspection requires that the total amount be statistically checked once by the producer. An identity
check is then sufficient for all deliveries of partial lots. In this case too cooperation between supplier and
buyer is necessary especially regarding the lot size per order. A cost benefit analysis (expenditure on
controls by the producer transport costs versus savings) must be carried out to determine whether to use
source inspection procedures.

**Vendor Certifications.** There are suppliers whose preparations have proved themselves over the years to be of exceptional quality. Packaging components supplied by them do not need to be routinely checked with every delivery since the risk remains small. A control can be made via skip lot or source inspection methods at any time.

**Computer Assisted Delivery Testing.** An exact record and evaluation of all available data is an essential prerequisite of the above mentioned tests employed in less frequent quality inspection methods. A computerized system of measurement at the packaging delivery point makes this possible. Such a system is organized so that it contains all the basic data regarding a supplier and a component and the data from every further test procedure regardless of whether it is a skip lot or routine test method is fed into its memory. This happens automatically with every technical measurement test because the measuring devices are linked to the computer. The results of attributive tests (of appearance color and so on) are entered manually. The analysis of a number of these tests shows immediately whether there is a tendency towards deviation from the norm or whether the values remain constant within the specification. The computer is queried every time goods arrive. It provides the decision on whether to test that particular delivery. This system has proved its reliability in practice and can therefore be recommended for use in every business.

**In Process Control**

Quality control that is oriented towards testing after the fact does not meet the criteria of a modern conception of quality. Prevention is the only possible means of recognizing and correcting errors and cutting costs. In process controls are preventative technical operational procedures which monitor the work process by means of measurement devices integrated into that process. An example of this is the computerized weighing control of ingredients. In this system the quantity of an ingredient which is given in the formulation instructions is stored in memory and automatically compared with the actual amount weighed. Each deviation is communicated immediately by a signal or a printout. The sum of the individual weight readings must correspond exactly to the quantity of the formulation. Projections of the actual amount of a basic ingredient used in relation to the target amount with reference to the amount in stock provides additional security.

**Integrated Inspection Processes in the Manufacture of the Finished Product.** Different companies offer memory programmed management and inspection systems. Their purpose is to automate a mixing process with computer assistance according to predetermined specifications. This optimizes effective time management of a facility and consistent reproducibility of the finished preparation as well as the storage of formulation data. Control systems continually monitor temperature mixing speed and process duration. These systems also help in prevention or advance inspection (in process control procedures). The check weigher belongs to this group of systems for example this is a weighing system which is integrated into the production line and automatically checks the weight of each individual preparation. A computer evaluates the measurement results. In production facilities which cannot implement a check weigher weight inspection takes place during the production process by means of spot checks (computer assisted inspection of fill quantities). The evaluation and projection of individual results at a central point provides certainty that the proper fill quantities are always contained. Torque measurement an ongoing check for container leakage and inspection of the finished product with automatic removal of faulty items those with missing labels or lot codes empty containers containers without lids or insufficiently filled containers are also possible in this way.

**Finished Goods Control**

The systematic prevention of error encompasses errors related to machines on the one hand and to human error on the other. In production of the finished product this is especially important because it is the last
opportunity to spot and rectify errors before the product is released. Specification features for the packaged preparation are prescribed by the Cosmetics Decree the finished Package Decree and the Guidelines for Aerosols as well as by the internal company specifications. The manufacturer must establish the extent of inspection activities in such a way that every preparation which reaches the consumer fully meets all legal requirements.

raw materials
Introduction
A wide range of chemical and natural materials is used in the formulation of cosmetic and toiletry preparations. It is outside the scope of this book to give a complete overview therefore only those materials of primary importance will be stressed. This chapter deals with the basic raw materials for the production of hair, skin and oral care products. It does not include special additives such as herbal extracts nor raw materials such as pigments for decorative cosmetics. An overview of herbal extracts is given by Nowak. The materials described are listed by application rather than by chemical classification which is difficult to follow. This means that some products are described twice for example the alkyl sulfates as basic surfactants and as oil in water emulsifiers but makes it easier to provide an overview of a specific field and allows the direct comparison of possible ingredients. For each material the chemical pathway of production and special precautions regarding stability and compatibility with other ingredients are also described.

Basic surfactants
The purpose of a shampoo or shower bath is to clean the skin and hair. Customers also expect a dense and luxurious lather although this effect is not essential for the cleansing. To fulfill these requirements the so called basic or primary surfactants which are the backbone of the cleansing products are necessary.

Alkyl ether sulfates
Alkyl ether sulfates are the most widely used surfactants for cosmetics and toiletries due to their well balanced properties. The alkyl moiety usually consists of a mixture of C12 C16 chains. The degree of ethoxylation is between 1 and 4 (x=1-4). M is either sodium ammonium or magnesium.

In former times chlorosulfonic acid was used in a batch process. Today however the most common process for the production of alkyl ether sulfates is the continuous SO3 sulfonation of ethoxylated fatty alcohols in a thin film reactor followed by a neutralization step. The typical products called lauryl ether sulfates or sodium laureth sulfate (CTFA Cosmetic Toiletry and Fragrance Association nomenclature) are based on alcohol mixtures. Well accepted and approved for use in cosmetics and toiletries are the products based on natural alcohols derived from the coconut palm (C12 approx. 70% C14 approx. 25% C16 approx. 5%), the semi natural alcohols from the Ziegler process (C12/C14 approx. 50/50%) and the partly branched SHOP alcohols (C12 C13 C14 C15 approx. 20 30 30 20).

The properties of alkyl ether sulfates are largely determined by the number of ethylene glycol units in the starting ethoxylated alcohols. Figure 1 shows the influence of the degree of ethoxylation on skin compatibility as measured by the Zein number (an in vitro measurement of the irritancy of surfactants). The presence of 2 to 3 ethylene glycol units leads to ideal behavior regarding foam and detergency. Such alkyl ether sulphates are easily thickened with salts and show good water solubility even at low temperatures. The skin and eye compatibility is acceptable for most applications but is usually improved by combination with mild secondary surfactants. Higher degrees of ethoxylation up to 8 or 12 can significantly reduce irritation. Combinations of these highly ethoxylated ether sulfates especially the magnesium form with normal ether sulfates are recommended for baby shampoos.

Alkyl ether sulfates have been found to be a source of relative high levels of 1,4 dioxane. Up to 600 ppm of
this impurity has been found in shampoos. The impurity at this level presents little or no health risk but improvements in the sulfonation process have resulted in lowering of the dioxane level below 20 ppm (calculated on active matter). This level of dioxane is now standard for ether sulfates.

Water based and salt free alkyl ether sulfates are commercially available in two forms (i) low concentrate (27-30% active matter) a low viscosity clear solution and (ii) high concentrate (70% active matter) a translucent paste with pseudoplastic flowing behavior. In low concentrations the ether sulfates form spherical micelles which are transformed into rod like micelles when the concentration increases. At around 50% active matter these rods are tightly packed and form a hexagonal structure a stiff gel. At 70% active matter a sandwich like structure the liquid crystalline lamellar phase appears. The layers can glide on each other and the product is easily pumpable. Advantages of the 70% form are (i) reduced transport costs (ii) increased storage capacity and (iii) microbiological safety without the need for preserving agents. The concentrate must be stored above 20°C and needs special equipment for dilution because the gel phase between 30 and 65% must be passed through. Technology is available for both batch and continuous dilution. The principle is always the same to increase the speed of dilution a large surface has to be formed using colloid mills or a spray process.

**Alkyl sulfates**

Alkyl sulfates were the first synthetic surfactant to be used in large quantities in cosmetics and toiletries and in some countries including the USA they are still the most popular. The alkyl sulfates used for cleansing products are usually lauryl derivatives (alkyl=C12 to C16). As in the case of the ether sulfate the starting alcohols are seldom pure. Sodium ammonium mono and triethanolamine magnesium and other salt forms are present in concentrations of 30-40% active product diluted in water.

Alkyl sulfates are excellent foamers producing a rich and creamy foam but are unstable in hard water. This is not a problem for shampoo or shower applications but means that they cannot be used as the main component in foam baths. Instead they must be combined with surfactants such as olefin sulfonates or sulfosuccinates which are stable in hard water. The sodium forms of fatty alcohol sulfates are not very soluble at low temperatures and formulations with high amounts of sodium lauryl sulfate often cloud up at temperatures below 5°C. Triethanolamine (TEA) salts show much better cold temperature stability but relatively higher amounts must be used since TEA represents nearly one third of the molecular weight and does not contribute greatly to foaming and cleansing properties of the surfactant. The TEA is a type of solvent. With respect to solubility the ammonium form is somewhat better than the sodium form but the formulation must have a pH of 5-6.5 since at alkaline pH ammonia will be liberated.

A negative point of the alkyl sulfates is their high irritation value although an exception is magnesium lauryl sulfate which combines the mildness of a secondary surfactant with the good cleansing and foaming properties of the primary surfactants. Figure 3 gives an overview of the irritation index of several surfactants as determined by the Zein method. This laboratory test correlates well with *in vivo* test results. The high irritancy of the sodium alkyl sulfates is one reason why alkyl ether sulfates are often preferred in liquid formulations while sodium cocoyl isethionates are preferred in the field of *syndet* (synthetic detergent) bars.

A very important application of alkyl sulfates is their use in toothpastes. Sodium lauryl sulfate is available in very pure form with low amounts of unsulfated matter. This results in a very neutral taste compared to the bitter taste of other surfactants.

Chemically both alkyl sulfates and alkyl ether sulfates are esters of sulfuric acid and are therefore unstable at acidic pH values. In this case the hydrolysis is an autocatalytic process where the velocity of hydrolysis increases with decreasing pH. This is mainly a problem regarding storage at elevated temperatures but should also be taken into account during the development of formulations with low pH values.

**Olefin sulfonates**

Olefin sulfonates are a mixture of alkene sulfonates and hydroxy alkane sulfonates prepared by sulfonation
of a olefins followed by alkaline hydrolysis. Contrary to most other surfactants where the C-12 alkyl chins show the highest surface activity olefin sulfonates show maximum activity when C14 and C16 olefins are used. In the first step of production which is the sulfonation in a thin film reactor alkene sulfonic acid and sultones are formed. These sultones are then hydrolysed into alkene sulfonates and hydroxy alkane sulfonates. The mixture usually contains approx. 60 65% of alkene sulfonates 35 40% of hydroxy alkane sulfonates and up to 10% of disulfonates. The olefin sulfonates are commercially available as solutions with approx. 40% active matter.

From Figure 3 it can be seen that olefin sulfonates are milder than alkyl sulfates and of similar irritation to the alkyl ether sulfates. An in vivo test did not differentiate betweenolefin sulfonates and ether sulfates. Olefin sulfonates also produce an excellent flash foam when used in cold water and are therefore particularly recommended for liquid hand soaps. They are stable in hard water and show hydrotropic properties. This results in low cloud points on cooling and high solubilizing power for superfatting agents. The difficulty of thickening can be overcome by combination with other surfactants. For example a mixture of 60% olefin sulfonate and 40% sulfosuccinate which are individually very difficult to thicken shows a thickening behavior comparable to alkyl ether sulfates. Contrary to the alkyl sulfates and the alkyl ether sulfates olefin sulfonates are stable at both acidic and alkaline pH values.

Olefin sulfonate is a well established basic surfactant particularly in the US and Japan. Regarding toxicology it is one of the best known anionic surfactants besides alkyl sulfate. Today's technology allows the production of light colored sulfonates without bleaching.

Other Basic Surfactants
Linear alkyl benzene sulfonate and alkane sulfonate are very powerful surfactants with good detergency and foaming properties. However due to their strong defatting action they leave a harsh and dry feel on skin and hair. For very cheap formulations small amounts can be used to reduce the costs of raw materials. Their main use is in dish washing liquids and all purpose cleaners.

Mild anionic surfactants
Compared to the basic surfactants a much wider group of mild anionic surfactants is used in cosmetics and toiletries. The purpose of mild or secondary surfactants is to improve skin and eye compatibility of the formulation. On the other hand mild surfactants usually show reduced foaming and cleansing compared with basic surfactants. Fortunately there are many synergisms for combinations of surfactants which are known to compensate or partially compensate for this behavior.

Sulfosuccinates
Sulfosuccinates represent a diverse group of derivatives of sulfosuccinic acid. Both mono and diesters are known. The diesters particularly the sodium diethylhexyl sulfosuccinate are very effective wetting agents for industrial use while the monoesters are mild surfactants with good foaming properties and are widely used in cosmetics and toiletries. Sulfosuccinates are prepared in a two step process. The first step is the esterification of maleic anhydride with an alcohol. This can be for example a fatty alcohol an ethoxylated fatty alcohol a fatty acid monoethanolamide or an ethoxylated monoethanolamide. The second step is the sulfonation of the resulting half ester with sodium sulfite.

The most popular derivative used in Europe is disodium laureth sulfosuccinate where laureth refers to an ethoxylated lauryl/myristyl alcohol with approx 2 3 moles ethylene oxide. In the USA sulfosuccinates based on amides particularly the disodium oleamido sulfosuccinate are more important.

The sulfosuccinates have good skin compatibilities compared with the basic surfactants. In general the amine based sulfosuccinates are better than the alcohol based types. Sulfosuccinates are good formers and are relatively cheap. A disadvantage is their instability at both low and high pH values. The highest stability is obtained at pH values between 6 and 6.5. The ethoxylated forms are stable in hard water and
are useful lime soap dispersants. They are mainly used in liquid formulations. The non ethoxylated forms are
good co surfactants for syndet bars. Sulfosuccinates are relatively poor solubilizers for perfumes.

**Cocoyl isethionates**
The cocoyl isethionates can be prepared in two ways (i) by the direct esterification of sodium 2
hydroxyethansulfonate with coconut fatty acid and (ii) by condensation with fatty acid chloride which leaves
small amounts of sodium chloride in the product.

Cocoyl isethionate is mainly used as a surfactant in syndet bars. In normal soaps it improves skin
compatibility and acts as a lime soap dispersant. The extraordinary mildness of this surfactant has been
proven by more than 30 years experience. For syndet bar production plasticizers such as stearic acids fatty
alcohols or waxes are used. Cocoyl isethionate is relatively insoluble in these plasticizers but has to be
dispersed. Consequently cocoyl isethionates are usually offered as extremely fine powders with a particle
size below 40 m. Ready made premixes in noodle form which are combinations or plasticizers with cocoyl
isethionate and other surfactants are also available to the cosmetic formulator.

At room temperature cocoyl isethionate shows only limited solubility in water. This permits its use in syndet
bars but can lead to crystallization in liquid preparations that are not properly formulated. Due to its
excellent skin compatibility and emolliency properties the use of sodium cocoyl isethionate in baby products
and in facial wash formulations has been reported. Since it is an ester cocoyl isethionate shows maximum
stability in the pH range 5 7.

**preservation of cosmetics**
The adequate preservation of a cosmetic product is a very difficult and complex task. Preservation is the
retarding or prevention of deterioration of the product from the time of manufacture until the time that the
consumer completely uses up all of the product in the container. The cosmetic manufacturer would of
course like to see all products manufactured sold to the consumer and used up in the shortest possible
time. However he cannot assume that this will be the case. Because of this he must try to stabilize products
and prevent them from changing over long periods of storage and under exposure to many varying
conditions of climate.

In any product there are many changes that may occur. Emulsion products may change viscosity cream or
completely break down. Clear products may become cloudy. The package may react with the product or
conversely the product may react with the package. The color of the product may change with time
temperature or light conditions. The actives in the formulation may break down and the perfume or dye
system may deteriorate. The oils in the product may become rancid. Microorganisms may suddenly overrun
the product. Many types of reactions and interactions may occur at the same time. The cosmetic chemist
must anticipate as many of these problems as possible and try to eliminate them by good formulating
manufacturing and packaging techniques.

Stabilization and preservation are really one and the same. The term preservation as can be seen from the
above means more than just stabilizing the product against attack by various microorganisms.

There has always been some tendency to confuse the terms preservative antiseptic disinfectant and
germicide when referring to antimicrobial properties. Preservative in this sense means any material that
would react with prevent the growth of or destroy microorganisms that might harm products or grow in
products. Antiseptic refers to substances that prevent the growth of or destroy microorganisms when these
substances are applied to living tissue. Disinfectants destroy disease producing microorganisms on
inanimate objects. Germicide is a more general term meaning any substance that kills microorganisms. It
must be remembered that none of these terms refer to compounds that have the ability to sterilize
completely. The reason is that none of the compounds in any of these classes can destroy all spores.
Preservatives generally do not make good antiseptics or disinfectants but the reverse is not necessarily
The changes that occur in products are due to physical chemical microbial or enzymatic reactions. During accelerated and normal stability testing studies a continual watch must be kept for any change that might occur. Physical changes such as increasing or decreasing viscosity changes in surface tension changes in the feel of the product changes in color changes in odor package distortion corrosion or permeation of the container must be noted investigated and prevented. Chemical changes such as degradation of active ingredients interactions of ingredients and reaction of ingredients with packaging materials or with manufacturing equipment (materials of construction) must be prevented. Microorganisms may grow in the product and add color or their enzyme systems may break down emulsifier systems destroy active ingredients use up all of the antimicrobial preservative and as a result destroy the product.

Most microorganisms need water present to grow. There are however a number of organisms that will thrive in completely anhydrous systems. Because of this every cosmetic preparation should have a preservative in it. If the product contains vitamins hormones mucilages fatty acids lipids or albumins it will be particularly sensitive to microorganisms as many of them will break down these compounds. If oils or fats are present in the product the problem of stability is increased even more because these materials can be oxidized. Emulsions having oil as the continuous phase are much less subject to microbial attack but can still suffer from problems caused by oxidation of the oil.

Preservatives such as formaldehyde alcohol boric acid salicylic acid and its derivatives and benzoic acid and its derivatives all have drawbacks to their use. To be effective the acids and their derivatives can only be used in a limited pH range. Alcohol cannot be used in the presence of proteins and many other substances and formaldehyde is odoriferous and can easily react with many dye and perfume systems. Numerous investigators shared the opinion that of the preservatives in general use the esters of p-hydroxybenzoic acid are the preservatives of choice since they approach the requirements of the ideal preservative most closely. Of course these investigators had no way of knowing that many years after they made this statement these same esters would react with a new class of emulsifying agents the nonionics which would then decrease their effectiveness. Also these investigators could not possibly have known that at an even later time people would prove sensitive to these same compounds.

There is no right preservative or wrong preservative for every situation as there is no right or wrong stabilizer for every formula. The choice of ingredient that is used is even today largely empirical. Because when preservation is mentioned microorganisms come to mind those that are found in cosmetics as contaminants are gone over in detail.

ORGANISMS FOUND IN COSMETICS

Molds

Molds are filamentous fungi and are widely distributed throughout the world in soil and water and as parasites in plants and animals. They are unicellular or multicellular fungi. Their average size is about 30 in diameter. They may be black brown green yellow or white. Molds can have thread like long filaments called hyphae. These hyphae may be branched or unbranched or may be divided into cells (then called septate). These cells in the hyphae have one nucleus in each cell or if you have a nonseptate hypha you can have more than one nucleus.

The molds due to the appearance of their matted hyphae (called mycelia) are usually velvety in appearance or perhaps cottony. Their hyphae burrow into the substrate and large upright spore heads that are usually pigmented are grown. These spore heads eventually drop the spores or open (in the case of sporangia) the spores fall and if they reach a moist surface they begin to germinate. Molds may reproduce by budding or sexual means (zygospore formation) as well as by spore formation.

Molds grow best at room temperature. They require moisture and darkness to grow. The pH must be
between 2 and 5.5 but the best pH for them is 4.5 to 5.5. They will not grow in an alkaline or neutral environment. Molds like a media with high osmotic pressure such as liquids with high concentrations of salts or sugars. The molds that contaminate cosmetic products are mainly saprophytic. They grow best on broken down decaying organic matter.

It is only within the past 10 to 15 years that we have started to get more extensive information in the literature regarding the identification of organisms found in spoiled cosmetic and drug products. In 1954 de Navarre pointed out the need for more work being done in this area and in 1957 he published a report on the isolation and identification of a mold Paecilomyces varioti that was found growing in an emulsion system. Paecilomyces varioti is a mold that is very similar in appearance to Penicillium and Aspergillus. Its sterigmata are short and tubular tapering into long conidium bearing tubes mostly curved or bent slightly away from the axes of the main sterigmatic cells. This mold was found contaminating a cap liner and contaminated the product while it was in use. The spores of this organisms are fairly resistant which may account for their presence in the closure liners the material of which is subjected to heat and chlorine treatment. This mold grew well on the emulsion and was a brown gray almost green color. Galloway in 1952 described the contamination of cosmetic products by molds. The following are probably the most frequent molds found in cosmetics.

Penicillium is an extremely widespread genus of fungi most often seen as a green velvety growth. Its mycelia are a network of fine branching tubular threads with cross walls marking off cell limits. Some of the branches are characterized by a tuft of fingerlike branches at the tip at the end of which long chains of microscopic single celled spores occur. It appears colored green blue green or yellow and will grow on almost anything with an acid pH. This fungus is able to decompose proteins fats and carbohydrates. Aspergillus can be green yellow brown or black. The spores are borne in chains as with the Penicillium but in this case the tip of the mycelial branch bearing them is club shaped. Aspergillus also needs slightly warmer growing conditions and more nutrients than Penicillium. It will grow on many crude drugs such as rhubarb because of the presence of acids and anthraquinones. Rhizopus and Mucor have mycelia that show no cross walls and their spores are produced inside a globe or sporangium. These fungi also produce thick walled resting cells (zygospores) by a rudimentary sexual process. Rhizopus nigricans occurs commonly as the black bread mold. Its large black sporangia can be distinguished with the naked eye on the surface of a fluffy white network of mycelia. This mold requires more moisture to grow than either Penicillium or Aspergillus. Mucor mucedo grows as a silvery gray turf of mycelia. Its sporangia are grayish and are borne on single long threads branching off the main mycelia. It too is widespread and may be found on a great variety of decaying organic matter. Its moisture requirements are the same as those of Rhizopus nigricans. Botrytis cinerea is commonly found on decaying organic material and is commonly associated with plant disease. Vegetative growth is fluffy gray white to dark with small single celled spores borne on crowded fine warty swellings along the rounded tips of upright branches somewhat in the manner of bunches of grapes. It is rarely found in cosmetics but Nowak has reported finding it in creams where it subsists on the fatty acid residues of soap substances. Alternaria is usually dark in color greenish black with creeping vegetative mycelia which send up short unbranched threads at the ends of which chains of large many celled dark spores are formed. These spores are usually pear shaped and have numerous cross walls with the cells arranged like irregular bricks in a wall. In 1946 Holt and Carroll found this mold contaminating creams and lotions. This mold was found growing in the sealer of the caps that were used on the product. Stemphylium resembles Alternaria in occurring as dark spreading mycelia with club shaped muriform spores. However these spores are borne singly at the tips of short upright branches rather than in chains.
The fungus is found as a saprophyte on decaying organic matter or as a very mild secondary parasite on plant lesions caused by stronger pathogens.

Cladosporium is a soil fungus with dark greenish black mycelia. Its spores are usually olive green and they appear in chains which branch in a tree like fashion on upright mycelial threads. They are small oval bodies at first one celled but often forming one cross wall as they mature.

Cladosporium herbarum has been isolated by Cox and Sewell from a hydrocortisone cream where it was found to be metabolizing the steroid.

Yeasts

Yeasts are unicellular organisms containing no chlorophyll but they may contain pigments (yellow pink red green or black). They do not form hyphae are ovoid or spherical in shape and average about 5 m in diameter but they can be anywhere from 5 to 30 m in length. They have a nucleus and they reproduce by budding fission or ascospore formation. It is believed that yeasts are degenerate forms of fungi that have lost their ability to produce hyphae. They are nonmotile have a thick cell wall and their cytoplasm may contain granules of glycogen and volutin as well as small vacuoles of fat. Yeasts cannot manufacture their own food and therefore must depend on higher plants and animals for their energy. They obtain energy by aerobic oxidative dissimilation or by anaerobic fermentation. Most yeasts will grow best on any medium containing fermentable sugar will grow over a pH range of 2.2 to 8 (although most yeasts prefer acid conditions) and usually grow best at room temperature. They usually require an abundant amount of oxygen to grow.

Saccharomyces are usually small celled yeasts. They reproduce by budding and they can easily ferment sugar solutions as long as the minerals that they require for growth are present. Saccharomyces ellipsoideus contains some strains of yeast that will not contaminate by fermentation but will in the process cause the production of aldehydes and ketones that will completely destroy the flavour of the product.

Cryptococcus (formerly known as Torula) reproduces by budding forms little or no hyphae (when hyphae form they are very short) are never dark or brown but can in some cases form carotenoid pigments. These organisms are important because one species will ferment lactose and another Cryptococcus neoformans (formerly known as Torula histolytica) is pathogenic to man. Yeasts of this genera have been reported in the literature as being found in cosmetics or in the plant where cosmetics or pharmaceuticals were being manufactured.

Candida (formerly known as Monilia) is also a yeast that reproduces by budding. At times it may form very short hyphae. Members of this genera have been reported found in cosmetics. This is very important because these organisms can be pathogenic to man. Candida albicans is the usual culprit and can infect the skin nails mucous membranes of the oral and vaginal cavities and can occasionally be found as a secondary invader in lung abscesses and other chronic pulmonary diseases.

Bacteria

The bacteria are much more difficult to generalize about than are either the molds or the yeasts. The reason is that there are so many different known species (more than 1600) many of which thrive under very unusual conditions. Most bacteria are quite small around 0.5 to 3 but there are species that are as large as 100. Bacteria are single celled organisms that reproduce by binary fission are affected by osmotic pressure and surface tension and are usually killed by high temperature (although some spores can survive in boiling water for as long as several hours). The optimum temperature for the growth of most but not all bacteria is 37°C. Bacteria do best on a media that is slightly alkaline pH 7.2 to 7.6. At a pH of 6.5 most yeasts and molds will thrive but many types of bacteria will be killed. Bacteria need moisture to grow although spores will resist the lack of moisture. Many bacteria are killed by exposure to ultraviolet light or x rays.
Many different bacteria have been reported at one time or another as contaminating cosmetic products. Baker reported finding Aerobacter aerogenes Pseudomonas aeruginosa Bacillus pyocyaneus Alcaligenes viscosus and Pseudomonas fluorescens. Also reported by Babicka and referred to by de Navarre were Bacillus subtilis Staphylococcus albus Bacillus mesentericus Achromobacter lipolyticum Bacillus mycoides Staphylococcus roseus Escherichia coli Sarcina lutea Serratia marcescens Bacillus mesentericus Staphylococcus citreus Escherichia paracoli and Bacillus astrosorus. This by no means was to be considered an attempt to find every report of every case of microbial contamination in a cosmetic product. Many other cases of contamination are listed and discussed in other sections. It is important that the reader have some idea as to the number and variety of microorganisms that can grow in cosmetic products if extreme care is not taken during formulation manufacture and packaging of the product.

antiperspirants and DEODORANTS

INTRODUCTION

Based on a historical perspective antiperspirants and deodorants are relatively new personal care products covering a 100 year span of development and use. One can appreciate the technological advancements of these compositions considering that over 300 generations have passed during which some kind of cosmetology was crudely practiced. Botanically extracted oils fragrances and metallic based ointments were extensively used for skin care eye and facial décor.

In the early 20th century the antiperspirant active choices available to consumers were few. This undeveloped cosmetic science together with poor product delivery forms applied to the axillary body region was considered nothing less than crude in the extreme.

The earliest known marketed deodorant product was a zinc oxide based cream composition introduced within the United States in 1888. Through the years zinc in various salt forms has been evaluated for its antiperspirant and deodorant properties. The incorporation of zinc halides into basic aluminum and zirconium chloride complexes has resulted in salt complexes described as useful antiperspirants possessing good alcohol solubility. Zinc metal complexes however were never adopted into the Category I antiperspirant active listing. Other zinc based compounds known to have deodorant potential were zinc peroxide zinc salicylate zinc sulfocarboxylate and zinc sulfide.

In the early 1960s zinc phenolsulfonate was introduced in aerosol form and was coupled with hexachlorophene. The effective antimicrobial action of the two ingredients quickly led to high consumer acceptance and some cannibalization of the decade old roll on antiperspirants. Today zinc phenolsulfonate is one of the few clinically accepted zinc salts that can be found in deodorant compositions.

Hexachlorophene however has banned in the mid 1970s due to potential skin penetration and neurotoxicity. The earliest antiperspirant was a non formulated product consisting of a dilute aqueous solution of aluminum chloride. The application was simply one of cotton swabbing the axillary area and waiting for the sting and water to disappear in that order. Aluminum chloride despite its strong acidity is perhaps the most effective active to this day. It can be found in pharmacies in a regulated dosage of not greater than 15% on a hydrated basis in non aerosol form.

Since the early 1900s aluminum salts were primarily the only active ingredients recognized as effective in reducing sweat and controlling odor. Efficacy was not quantified until 1916 the first published report appearing in the journal of the American Medical Association. At the same time promotional campaigns were under way leading to national popularity from aluminum chloride solutions.

Esthetics were clearly lacking from the simple solution forms of anti perspirant but by 1930 cream compositions were introduced containing aluminum sulfate in wax bases. Compared with current standards
the esthetics may appear to have been derived from poor cosmetic science but were in fact elegant to the consumer of that era. By 1945 88% of the US antiperspirant market was in the form of creams the greatest share of an antiperspirant from ever to exist.

In the 1950s hand squeezed aerosol and roll on antiperspirants made their way onto the market representing unique delivery forms. The package technology was not perfected however leaving the consumer with convenient but often faulty delivery systems. The attractive features were the fact that the antiperspirants could now be applied without the use of fingers. Popularity grew slowly but as early as the next decade or roll ons dominated the market over creams for a short period of time. During the same era phenomenal changes occurred in the way aerosols were designed. Deodorants and antiperspirants were incorporated into pressurized propellant systems in metal containers leading once again to high consumer acceptance. Valve perfection coupled with anhydrous suspension compositions dramatically reduced the rate of clogging. By 1973 aerosol forms achieved greater than 80% market share. The huge success of aerosols sparked interest in many countries. Currently approximately two thirds of the UK antiperspirant and deodorant market is in the form of aerosols.

The mid 1970s in the United States can be remembered as an era of growing environmental safety awareness which hit hard on aerosol compositions. Both fully halogenated chlorofluorocarbon propellants and aluminum zirconium complexes were prohibited from use in aerosols and sprays leading to the fastest market decline in an antiperspirant/deodorant category ever witnessed.

The greatest formulary ingredient ever recognized for esthetic improvements came about at the same time that aerosols were under fire. The generic name for this miracle additive was cyclomethicone. It possessed high esthetic and lubricative properties which led to rapid technological advancements in suspension roll ons and sticks. These anhydrous suspension systems have become consumer favorites and today more than 80% of all antiperspirant formulations contain cyclomethicone. In Europe and other parts of the world aqueous based roll ons and sprays dominate suspensoid stick compositions. The existing antiperspirant/deodorant market comprises roll ons sticks aerosols gels and creams. Since 1985 consumers have had the choice of conventional and enhanced performance types. The US market history of antiperspirant and deodorants is graphically illustrated in Figure.

REGULATIONS

Unlike most cosmetic products antiperspirants have been regulated more stringently by the US food and Drug Administration both with respect to the active raw materials and the finished product compositions. Up until 1938 there were no regulations relative to cosmetic materials. The Food Drug and cosmetic Act which was enacted in 1938 by the federal government clearly stipulated that deodorants which did not alter a bodily function were viewed as cosmetics but antiperspirants which affected the operation of the sweat glands were considered drugs. This physiological concept is interpreted in basically the same way today through out the world however labeling and testing requirements for cosmetic drugs do vary from country to country. The United States has initiated the most specific labeling requirements and Canada probably leads in the most conservative testing programs.

Antiperspirants as classified as over the counter (OTC) drugs and deodorants are designated as cosmetic products. The regulatory control tightens specifically when claims are made by the manufacturers of such products. The proposed rules for classifying OTC drugs were drawn up in the Federal Register in 1972 by the FDA. The last final tentative drug monograph CFR 21 part 350 was published in 1982 and since then it has been regarded as the only document to spell out rules regarding safety clinical testing and active categorization. Labeling of OTC drugs is discussed in CFR 21 part 201.

In addition to the tentative final document Category I antiperspirant actives which were effective in January
1995 were adopted by United States Pharmacopoeia (USP) as drug compounds assuming identity standards and test methods consistent with USP requirements. Currently, additions and modifications are underway to provide full coverage of Category I actives. The specifications will include the total range of elemental atomic ratios, solvents, and concentrations. The changes are consistent with the industry's use or intended use with the specifications already permitted in CFR 21 Part 350. For commercial considerations, only those actives listed in Category I should be of interest to the formulator, as shown in Table 1.

**Mechanism of sweating**

Antiperspirants are intended for use in the axilla region of the human anatomy. This area contains apocrine, eccrine, and sebaceous glands. These glands generate fluids and chemical substances which lead to the development of body odor. The eccrine glands average about 200 per square cm and produce the majority of sweat. The eccrine secreted fluid is composed of a hypotonic solution of sodium chloride, urea, lactates, and other metabolic wastes. The sebaceous gland is a sub-surface gland evidenced by a hair follicle. It excretes lipids and fatty acid substances which are responsible for the generation of coryneform bacteria. The apocrine gland, also a sub-surface gland with a protruding hair follicle, secretes lipids, cholesterol, and steroids. The biological degradation of certain steroids by coryneform bacteria is mainly responsible for the development of odiferous compounds. The total mechanism is still not fully understood.

The production of sweat by the eccrine glands is initiated by both emotional, thermal, and sensory stimuli. The actual mechanism is somewhat complicated in the sense that water is not just pumped through the sweat duct to the surface. The transfer of sweat fluid results from the enzymatic degradation of Na+/K+ ATPase within the basal membrane. The movement of Na+ ions across the luminal membrane in the secretory coil causes an osmotic pressure gradient. The relief of this gradient condition is accomplished by the movement of water across the cells of the sweat gland secretory coil into the lumen. This movement of water continues under either stimuli increasing luminal hydrostatic pressure. The excess fluid carries over to the absorptive duct in the secondary coil and proceeds to the pore opening on the skin.

There are a number of theories about how antiperspirants affect the sweat gland to diminish the flow of fluid. One of the earliest investigations by Shelly and Horvath suggested that protein plugs were created when aluminum chloride was used to treat the axilla. This was challenged as being more of an injurious effect causing a cell transformation to restrict flow. Papa and Kligman theorized that aluminum chloride damaged the sweat duct causing cell erosion thus allowing for sweat to leak from the inner duct into interstitial spaces rather than flow to the skin surface. Others postulated that the pores swell shut when contacted by antiperspirant materials.

The most respected theory, which has been substantiated by many scientific evidences, is the hydroxide plug development by aluminum and other metallic salts. This theory best coincides with the hydrolysis chemistry of aluminum chloride and its basic salt complexes. These complexes are polymeric in nature and possess a high degree of cationic charge relative to the average molecular weight of the polymer distribution. Aluminum chloride has the highest charge and lowest molecular weight compared to the lower charges of higher molecular weight basic aluminum halides. Table 2 illustrates the charge to weight relationship in polymer development. One should conclude that the smallest polymer size spices with high charge will enter the sweat duct by some migratory movement perhaps assisted by charge attraction. During this journey in a very diluted state neutralization followed by hydrolysis occurs causing the hydroxide plug to form in the intracorneal and intraepidermal ducts thus restricting flow. These plugs in fact have been confirmed using electron microscopy and aluminum fluorescence techniques to detect the presence of the gel.

Studies by Quatrale have been conducted on the antiperspirant action of aluminum chloride aluminum...
chlorohydrate (ACH) and aluminum zirconium glycinate (AZG) during application. By performing cellophane stripping of the applied axilla region it was demonstrated that hydroxide plugs from aluminum chloride were found to be the deepest and most difficult to remove. The restoration of the affected sweat glands back to normalcy was slow. ACH hydroxide plugs were next easiest to restore followed by AZG. One would have expected AZG hydroxide plugged glands to be deeper and restore slower than ACH because AZG typically demonstrates 40% relative higher sweat reduction than ACH. It should also be recognized however that under dilute conditions as would be the case in underarm applications polymer growth for most AZG compounds exceeds that for ACH. This faster more extensive superficial hydrolysis at an earlier stage of migration into the duct makes an AZG an effective antiperspirant.

Currently there are numerous polymeric versions of ACH and AZG with enhanced or activated properties. Most types of the enhanced salts are offered in dry powder form but there are aqueous and propylene glycol complexes that are stable as well.

It is advisable for the formulator to have a polymer finger printer for each particular batch of an active to ensure that the physical properties are consistent with those used during the developmental stages of formulation. A chromatographic analysis of an enhanced active is the only means of verifying potential performance. Figure 2(a) (f) illustrates various polymer distributions of the aluminum complexes. The formulator should also be familiar with other physical properties of the active found during the research and development stage so that scale up can be better understood. Process variables can impart changes to the active itself.

The hydrolysis of trivalent aluminum is extremely complicated. The formulator who incorporates these polymer blends should be aware that solvated forms of BAC will in fact reach a different polymeric equilibrium under certain conditions of use. Such conditions would include the dilution of active with polar solvents freezing process temperature time and the use of pH altering additives. Most marketed forms of concentrated basic aluminum chlorides will show a shift both in the molecular size distribution and structural coordinates during the formulation process. This can be lead to reduced efficacy.

Conventional aqueous ACH is the most popular form of BAC which is normally supplied as a 50% hydrated salt solution. It is fully miscible with anhydrous ethanol propylene glycol glycerine and most low molecular weight polyols. The typical polymeric distribution for ACH 50% aqueous solution shows 35% peak 2 polycations of about 8000 gm^{-1} 60% peak 3 intermediate polycations of about 5000 gm^{-1} 1.3% peak 4 Al13 polymers of about 3000 gm^{-1} and 2% peak 5 oligomers and monomers of less than 2000 gm^{-1}. The nominal empirical formula for ACH is Al2(OH)5Cl2 2 H2O and and the anhydrous active content of a 50% solution is 40.5%. BACs are permitted in all types of formulations not to exceed a maximum anhydrous dosage of 25%. A formula containing ACH 50% solution should not comprise greater than 61.6% of the total composition. Aqueous ACH is primarily used in roll on emulsions pumps creams and gels.

ACH is also marketed as a dry powder that is available in various particle size distributions. ACH powder corresponds to the same nominal empirical formula as the aqueous solution except that the anhydrous active content is 81%. The balance is both free and hydrated water.

Variation in particle properties can impart different characteristics to a formula. Discretion is often necessary to match the right powder form with the application.

In an unmicronized state ACH is basically spherical in nature. This form is sometimes referred to as crystal powder or bead. ACH can be used in this form with some economic advantage because the micronizing process stage is not exercised. The formulator should make certain that the random distribution is 100% less than 100msince this is the critical size at which the consumer can begin to detect grittiness during application and use. One advantage of using unmicronized powder is that the particle density can be readily controlled during manufacturing. This affords the formulator better control of the suspension
characteristics in lower viscosity systems. Apparent bulk densities can vary between 0.2 -0.9 g cm$^3$ with typical values of about 0.5 g cm$^3$. The critical particle density in cyclomethicone is about 0.24 g cm$^3$. Unmicronized ACH with higher density and narrower distribution has some utility in aerosol sprays because it tends to deliver a better controlled spray pattern. Such distributions contain a smaller fraction of particles below 10µm.

Micronized ACH is available in various particle size distributions depending on the application. The industry standard grade more often than not will be found suitable for use in most suspension systems. The standard particle size specification for controlling distribution is 97% minimum less than 325 mesh. The mean particle size is about 10µm. Extra fine ACH is sometimes required for ultimate suspension capability. The standard grade generally contains 80% minimum less than 10µm and mean particle size of 5µm.

The pH of a 15% ACH solution is 4.3 compared with 3.9 and 3.5 for a nominal metal/chloride ratio ASC and ADC respectively. Since pH is logarithmic function of acidity/basicity it is likely that ADC and the lower range of ASC will show more irritation at the same dosage levels as ACH. This is the predominant reason why highly basic ASC and ACH nearly always have an exclusive presence in the marketplace. A basicity index range for antiperspirant actives relative to their metal/chloride specifications is shown in Figure 3. ACH can be polymerically optimized with higher scores 3 and 4 to impart a greater efficacy potential over the conventional version. These salts may be referred to as enhanced or activated because they can reduce sweat by 30-50% relative to the conventional type. As those experienced in the field of antiperspirants have sometimes recognized other formula ingredients do not always behave in the same way in the presence of enhanced salts as they do with conventional forms. These interactions can impart rheological changes to the formula as well as diminish the potential difference of the anticipated clinical result. It is the writer's contention that some non ionic surfactants in particular those with strong emulsifying characteristics will selectively seek out the most available coordinated water in anhydrous formulations. This water can be found in the lower molecular weight bridged polycations of the enhanced polymer group. Once this bound water is drawn into phase equilibrium with the emulsifier migratory movement of the enhanced species to the sweat duct is impaired.

cleansing creams and lotions

The purpose of a cleansing cream or lotion is the removal of facial makeup surface grime and oil from the face and throat. A properly formulated cleansing cream or lotion will quickly and efficiently remove such applied cosmetics as face powder rouge foundation bases cake makeup and lipstick. The large increase in the use of eye cosmetics has created a need for cleansing products specially formulated to remove such makeup. Although adequate washing with soap and soft water will perform the same function a cleansing cream has certain advantages. The chemical nature of facial makeup allows more ready removal by a cleansing cream which is specifically formulated to dissolve or lift away the greasy binding materials holding pigments or grime on the skin. Latven investigated the effects of cleansing creams and other products upon a specific type of natural skin oil sebum which had solidified over the sebaceous or pilosebaceous orifices. These plaques were surprisingly resistant to removal by scrubbing with soap and water but they were removed by the use of various commercial cleansing creams polyethylene glycol 400 and olive oils. A series of fat solvents such as acetone chloroform glycerol kerosene white gasoline dioxane trichloroethylene and ethanol (95%) although effective in removing the surface oil layer were ineffective in removing the solid sebum plaques. Latven suggested that the presumed superior efficacy of cleansing creams may lie in their ability to dislodge and remove these plaques from the orifices of the sebaceous ducts.

A cleansing cream is conveniently applied and used. Another important consideration is the low irritation factor in the use of a cleansing cream. A well balanced modern cleansing cream will leave an emollient
residual film on the skin which is protective in a dry skin condition. This property would suggest the avoidance of such a cleansing cream for oily skins. However it is a common practice with many women to use a cleaning cream first for makeup removal and then to complete the cleansing process by using soap. Cleansing preparations specifically designed for oily skin have acquired more importance. These are based on detergent or solvent action or they may be washable. They are designed to remove surface oil and leave a minimal deposit on the skin.

In addition to the primary function of cleaning a multipurpose character can be given to a cleansing cream by appropriate formulation. By the addition of modifying ingredients such properties as the abilities to soften lubricate and protect are obtained and claimed for some modern cleansing creams.

Frazier and Blank adequately describe the process of cleaning the skin. Much foreign material reaches the skin. This exogenous soil includes that which reaches the skin unintentionally and that which is intentionally applied such as ointments or cosmetics. Autochthonous soils are the products of excretion of the sebaceous eccrine and apocrine glands. Cells and flakes of the cornfield epithelium are being shed continuously. Both society and health demand that these soils be removed from time to time. For the abnormal skin pus blood cells serous exudates and crusts must be removed. Water solvents such as gasoline and turpentine mineral oil soap and synthetic detergents are agents used for cleaning the skin. Water alone is a good cleaning agent. In acute or chronic dermatitis a war dressing removes serous and purulent exudates and accumulation of crusts. Water removes water soluble soils from the skin. The skin surface normally carries a negative electrostatic change. Many particles including bacteria are also negatively charged. In water these particles are repelled from the skin with resulting cleansing action. Water alone however is seldom sufficient to clean the skin. The oily soils on the skin require a solvent or an emulsification process for removal.

Soap and synthetic detergents aid water in emulsifying the oily soils permitting their removal as an emulsion by rinsing with excess water. Solvents such as gasoline and turpentine also remove the oily soils by dissolving them but their use may leave the skin deficient in natural oils. Mineral oil has solvent action on the oily soils but its use may leave the skin greasy if a film is left behind although it will leave the skin degreased if it is removed completely with a tissue.

The modern cleansing cream is based on the solvent action of mineral oil on the oils and grease binding either grime or makeup to the skin. The removal of the pigments of rouge lipstick and face powder from face and throat is a daily problem for most women. Cleansing cream is an ideal agent to perform this function.

Properties Sought
The following properties are required of a good cleansing cream
As a cosmetic product it should be stable and have a good appearance.
It should melt or soften on application to the skin.
It should spread easily without too much drag. During application it should not feel greasy or oily. After evaporation of any water the cream residue should not become viscous.
Its physical action on the skin and pore openings should be that of flushing rather than absorption.
A light emollient film should remain on the skin after use of the cream.
The directions for use of a cleansing cream or lotion are standard. The general practice is to apply the cream to face and throat with fingertips. A rotating upward stroke of the fingers is used to spread the cream.
A tissue or soft cloth is then used to remove the residue.
In the case of the so called washable cleansing creams the cream residues may be removed using tap water with or without prior use of tissue.

History
Most emulsified cleansing creams can be considered as cold creams modified to enhance their property of removing makeup or grime from the face. Physically a cold cream has heavier body and application than most cleansing creams.

The evolution of the cleansing cream took place over a period of centuries. The Greek physician Galen about A.D. 150 is considered to be the inventor of the first cold cream. The skin preparations of the ancients consisted of animal and vegetable fats and oils. Beeswax and olive oils were used. Galen conceived the idea of incorporating water into a molten mixture of beeswax and olive oils. In the resulting product the emollient effect of the oil was accelerated and a pleasant cooling effect was obtained from the evaporation of the water. The process of manufacture was slow and laborious. The product was unstable and subject to development of rancidity. In time sweet almond oil replaced the olive oil of the older formulations and borax was introduced. The introduction of the borax cut down the time of manufacture and a whiter and more stable emulsion resulted. Subsequently spermaceti was added with a resulting softening of the product.

Rose water Ointment USP XV shown in Formula 1 was the direct descendant of the preceding formulations. This cold cream was known for many centuries by the name of Unguentum or Ceratum Refrigerans. It changed but little in proportions or method of preparation throughout many centuries. This cream is readily absorbed by the skin and produces a feeling of coolness. It has the disadvantage of being subject to rancidity.

Until around 1900 druggists compounded such a cream as needed and stored it in the icebox to inhibit deterioration. The manufacture of such a cream on a commercial scale was not feasible. At about this time a cold cream using mineral oil was developed and accepted because of its stability and other desirable properties.

The Rose Water Ointment USP XV of Formula 1 although listed in National Formulary XII is not longer listed in the current U.S. Pharmacopoeia. It had been replaced by Petrolatum Rose Water Ointment USP XVI which differs in formula only in the substitution of liquid petrolatum for the expressed almond oil of Formula 1. Subsequently the rose water in this ointment was eliminated and this ointment is officially listed as cold Cream in USP XVIII.

The use of vanishing type creams as greaseless foundation bases and the increase in use of face powder and rouge during World War I stimulated the development and sale of cleansing cream which today rank among the top selling cosmetic products.

Types of Cleansing Cream

Traditionally cleansing creams are classified into two categories. One is the usual white emulsified or cold cream type often referred to as the beeswax borax type of cream. The other is the translucent liquefying type usually anhydrous in character and consisting of a mixture of hydrocarbon oils and waxes. As a result of the development of the newer emulsifying agents many cleansing creams of the emulsion type are made without using either beeswax or borax.

Beeswax Borax Emulsion Type

The beeswax borax emulsion represents a most important formulation among cleansing creams. The typical creams are usually white of high luster and free from graininess. The creams have a firm consistency on application to the skin they liquefy and spread with ease. These creams contain a high percentage of mineral oil for cleansing efficacy. Physically many of these creams belong to the oil in water type of emulsion. After the creams are rubbed on the skin sufficient water evaporates to permit phase inversion to the water in oil type. With oil as the external phase the solvent action of the oil for cleansing purposes is facilitated.
In the beeswax borax emulsion type the minimum basic ingredients required for a satisfactory product are beeswax, mineral oil, borax, and water. Other ingredients are normally added to modify or improve the properties of the basic formulation. A generally accepted basic preparation (5) is illustrated by Formula 2.

**Basic Materials**

For intelligent formulation a knowledge of the elementary principles involved in the formation of the emulsion and the properties of the raw materials is essential.

**Beeswax** is an important factor in determining the quality of the cream. Beeswax is a raw material of natural origin. For cosmetic formulations it is defined as the purified honeycomb of the bee free from all other waxes. The chemical composition of beeswax is complex and cannot be expressed by a specific formula. It consists of approximately 71% esters of wax acids mainly myricyl palmitate and other myricyl esters 10.5 to 13.5% hydrocarbons mainly C31H64-C29H60 and C30H60 13.5 to 14.5% free wax acids referred to as ceroic and melissic acids 1 to 1.25% free higher alcohols 1% cholesteryl esters of fatty acids 1 to 2% moisture and mineral impurities approximately 0.3% coloring matter mainly 1 3 dihydroxyflavone.

Its color range is from light yellow to dark brown and it is easily bleached either by sunlight or by chemical means. The melting range of the material is 62 to 65°C and its acid number is from 17 to 24. Beeswax does not develop rancidity. It is not a primary irritant or a sensitizing agent. The commercial beeswax normally used for cleansing cream is the bleached white grade.

The following are some of the considerations involved in the use of various grades of beeswax.

Beeswaxes with the lowest melting points generally form the softest emulsions.

There is little relation between the acid number of beeswaxes and the quality of emulsion.

Chemically bleached beeswaxes develop the least odor in the final product. However there is little difference in the quality of creams made from sun bleached beeswaxes or from chemically treated beeswaxes.

The use of cheaper grades of beeswax may be economically unsound since proportionately far larger amounts of the cheaper grades may be required to form an emulsion as compared with standard grade.

There are considerable differences in emulsifying power of various grades of beeswax but these differences at present cannot be explained on the basis of physical or chemical properties.

Once a formula has been established the quality and source of the beeswax should be standardized and the supplier should be required to deliver equivalent material.

**Mineral oil** is a hydrocarbon that is stable, inexpensive, not subject to rancidity and odorless. When purchased in accordance with specifications a very uniform product can be obtained. Owing to its uniformity and freedom from rancidity the substitution of mineral oil for the vegetable oils of the older cleansing cream formulations was an important step in the development of cleansing creams meeting consumer acceptance.

Mineral oil is a good solvent for the oils and greases binding either grime or makeup to the skin. The cleansing power of a cream is related to its mineral oil content. Mineral oil also has the advantage of remaining on the skin long enough to allow its mechanical removal by tissue.

Although all viscosity ranges of mineral oil are used in cosmetic creams the most suitable for cleansing cream are the light and medium viscosity grades. These grades produce a film that does not become viscous on the skin.

In the basic Formula 2 the mineral oil to water ratio can be varied widely from 2:1 to 1:2 with satisfactory products being obtained. The higher percentage of mineral oil are related to better cleansing efficiency. However when the mineral oil content exceeds 60% the creams show signs of instability. Increase of the mineral oil content results in a stiffening effect on the creams. Increase of water content softens the creams and results in finer grained and more lustrous creams at the expense of cleansing efficiency. The basic reactions involved in the manufacture of the beeswax borax cleansing cream are the hydrolysis of the borax and subsequent reaction with the free acids present in beeswax to form the corresponding soaps. These
soaps emulsify the mineral oil in the water. Other components of beeswax such as myricyl alcohol are considered to have a stabilizing effect on the emulsion. The amount of borax used is a critical factor in producing a satisfactory cream. The theoretical quantity of borax to be used is the stoichiometric quantity necessary to neutralize the free acids present in beeswax.

The acid number of beeswax should range from 17 to 24. Since 1 mg of potassium hydroxide is equivalent to 3.4 mg of borax (Na₂B₄O₇·10H₂O) the theoretical quantity of borax required to react with 1 g of beeswax varies from 57.9 to 81.5 mg. For formulation purposes 5 to 7% of the weight of beeswax is considered the correct amount of borax to be used.

An insufficient quantity of borax will result in a dull grainy cream. The emulsion may be unstable and of indeterminate character. An excess of borax can cause formation of hard sharp crystals of boric acid resulting from limited solubility of the boric acid in the water phase.

The creams represented by Formula 2 although adequate can be modified and improved by the addition of other ingredients. Among the ingredients frequently added to produce variations of the basic formulation are spermaceti, cetyl alcohol, paraffin, petrolatum, ozokerite, ceresin, vegetable oils, cocoa butter, and lanolin.

Since mineral oil may remove appreciable quantities of natural oils from the surface of the skin emollients are often added. Spermaceti, cetyl alcohol, cocoa butter, vegetable oils, and lanolin serve this purpose. Spermaceti in addition to its emollient effect acts to make the cream more opaque and lighter in appearance. Cetyl alcohol in a proportion of about 1% acts as emollient and as an emulsion stabilizer. Cara must be taken not to use too much since the cream may soften and become less opaque.

Cocoa butter to the extent of 1 to 2% serves as a skin softener. Higher percentages should not be used since a grainy textured cream may result.

Vegetable oils if used should be in a formula in which at least half of the total oil content is represented by a light viscosity mineral oil. Otherwise the cream is apt to be sticky and of poor luster. A firm cream that has the property of quick melting on application to the skin is desirable. A small proportion of paraffin will produce this result. Petrolatum will behave in a similar fashion but will not harden the cream to the same extent as the paraffin. Petrolatum will serve to increase the body and help stabilize the cream if a high percentage of oil is used.

Ozokerite and ceresin serve to stiffen the cream and prevent bleeding of oils when the oil content is high. Generally when other waxes are added the amount of beeswax is correspondingly lowered. Formulas 3 to 8 represent creams with some of the ingredients just mentioned.

Liquefying Cleansing Creams

The translucent liquefying anhydrous type of cleansing cream consists of a mixture of oils and waxes designed to liquefy when gently massaged and to cleanse in the same manner as the beeswax borax emulsion creams. A physical mixture of mineral oil, paraffin, petrolatum, and other waxes is melted, mixed, and poured while warm. This type of cream is easier to make but its formulation must be controlled carefully. Hardness of the cream is obtained by a thixotropic effect produced by a wax such as paraffin. The mineral oil to be used must be carefully selected. A mineral oil of heavy viscosity produces an oily feel on the skin upon application. Too high a quantity of crystalline waxes is undesirable because it may result in separation, sweating, and a granular appearance. A common difficulty is the formation of a crusty surface. This condition can be corrected by substituting amorphous materials such as ozokerite and petrolatum for the crystalline ones. The petrolatum also aids in preventing bleeding of the mineral oil particularly when a light viscosity oil is used.

Emollient ingredients such as lanolin or its derivatives cetyl alcohol, spermaceti, and cocoa butter are added to leave an oily film on the skin.

The normal cream of this type is translucent in appearance. A more opaque appearance can be obtained by adding ozokerite and ceresin.
by incorporating such ingredients as zinc oxide titanium dioxide magnesium stearate zinc stearate or hydrous lanolin. A smoother application is obtained in such creams with a diminution of the greasy feeling characteristic of this class of creams. Approximately 2% of zinc oxide titanium dioxide magnesium stearate or zinc stearate can be used. These can be incorporated into the product by milling preferably with a roller mill. Formulas 9 to 13 are representative of this type of cleansing cream.

The liquefying cleansing creams are used particularly by women with dry skin although many women with oily skins find them effective for degreasing.

Miscellaneous Emulsion Types
Emulsion type cleansing creams which do not contain the beeswax borax system can be made using such emulsifiers as the sorbitan fatty acid esters and their polyoxyethylene derivatives glycerol monostearate diethylene glycol monostearate sodium cetyl sulfate and the various absorption bases.

Sorbitan Fatty Acid Ester Emulsions
The sorbitan fatty acid esters and their polyoxyethylene derivatives represent an important series of surface active agents which are being used increasingly in modern cleansing cream formulations. They can be used with or without the beeswax borax emulsion system. Both water in oil and oil in water emulsion types can be made using these agents. The resulting cleansing creams are stable easily manufactured and effective.

baby toiletries
The constantly increasing sales volume of baby toiletries in the overall cosmetic market indicates their relative importance to the consumer manufacturer retailer and pediatrician. These products include powders oils lotions creams diaper rash preparations shampoos and soaps. In 1970 the combined retail sales of baby powders oils lotions diaper rash ointments and shampoos amounted to $87,970,000. Despite the declining number of births from its peak in 1957 the sales increase for baby powders in the 1957 1970 intervals was 57.8% for oils and lotions the increase was 77.1% and for baby shampoos the increase was 159%. Part of the increase in baby powders and baby shampoos can be attributed to adult usage. This appears to be due to the focusing of advertisements especially in the late 1960s on the adult as well as the baby market.

The steady sales growth pattern when viewed in marked contrast to the decreasing births from 1957 through 1968 is indicative of the intensive and successful educational and promotional efforts of manufacturers retailers and pediatricians who have emphasized the need for special products for babies. The decline in birth rates since 1957 is considered by government population experts to be temporary. These experts believe that within the decades from 1965 to 1975 and from 1975 to 1985 the tremendous birth rate increase that followed the end of World War II in 1945 will show up in a new birth rate increase as the babies born in the late 1940s begin raising families of their own.

The market potential for baby toiletries is indicated in the Census Bureau's projected population growth of children under 5. The Census Bureau presented four principal series of population projections (Series A B C and D) which offer the user a fairly wide choice of assumptions as to the course of future population changes. The Bureau stated that the uncertainty with respect to future fertility rates (annual number of births per 1000 women 15 to 44 years of age) accounts for a fairly wide range in the population projections. The Bureau indicated the Series A and Series D projections are not regarded as probable upper and lower limits and that it is even more likely that actual population changes will not follow any particular series very closely.

Faust presented an interesting and thought provoking discussion of the legal interpretations of formula
composition function and implied claims for baby toiletries. Faust considered the relationship between cosmetics and drugs particularly in baby toiletries and described a pediatric cosmetic as...one which usually contains old components makes no therapeutic claims is used more or less to prevent rather than cure undesirable skin problems and is one which possesses little pharmacologic action. The spectrum between these extremes is broad and the large gray area in the middle emphasizes the difficulty in differentiating sharply between the pediatric cosmetic and the pediatric pharmaceutical. We do know however that a formulation can be judged to be a cosmetic or a drug solely on the nature of its labeling and claims.

In the sections to follow we first discuss epidermal physiology skin care of the newborn care of the diaper area and care of the hair and scalp. This will be followed by specific formulations designed to accomplish the desired effects.

**Epidermal Physiology**

We use the term newborn to refer to the first 2 weeks of life infant (baby) designates children up to the end of 1 year and young children include the group from 1 to 4 years of age. The skin of the child and more particularly of the infant and newborn differs from that of the adult both histologically and physiologically in many fundamental respects. It is thinner less cornified and less hairy. Chemical analysis shows a higher proportion of water and of extracellular fluid minerals. The stratum corneum is thin and lacy in its histological structure because the supporting structures (elastic reticulum) are only partially developed.

In late intrauterine life the stratum corneum is thought to be protected by the vernix caseosa from maceration in the amniotic fluid. The vernix is a complex water in oil mixture containing sebum peridermal cells lanugo hair and other debris. The immature fetus has extensive deposits of vernix whereas the postmature infant has less with distribution mainly in the flexures groin and axillas. Many functions including bacteriostasis have been attributed to the vernix but none convincingly. There is evidence that it has a high content of estrogenic substances. It is rubbed off at the first bath or on the clothing during the first 24 to 48 hours of life leaving varying degrees of erythema. Within the first few days of life the erythema diminishes and a fine scaling occurs. There is a tendency toward peeling and flaking (desquamation) during the first three weeks of life.

After removal or disintegration of the vernix caseosa the skin is pink soft and silken to the touch and very delicate in texture. It is in all likelihood more permeable to substances approaching it from within and without. All these structural differences probably influence both the incidence and manifestation of particular dermatoses in early life.

Sebaceous glands are present in the newborn and are prominent on the nose cheeks and chin. The sweat glands are fully developed anatomically at birth and begin to function very early probably within a few days after the vernix has gone. At about 3 years of age the component structures of the skin begin to resemble more closely those of the adult. Before puberty however the sweat and sebaceous secretions are decreased.

Children’s hair is on the average finer rounder less frequently medullated and lighter in color than adults hair.

The transepidermal water loss of human newborns was studied by Wildnauer and Kennedy and Hey and Katz. Wildnauer reported that the average transepidermal water loss from upper back skin of newborns in the first 10 days was slightly but significantly lower (30%) than that of comparable adult back skin. The mean transepidermal water loss for human newborn upper back skin was found to be 0.18 + 0.06 mg/cm2/hr as compared with 0.27 + 0.04 mg/cm2/hr for the adult. The effect of relative humidity on the production and loss of heat in the newborn baby was evaluated by
Hey and co-workers.
The skin of infants in general and of the newborn in particular is highly susceptible to irritation and infection especially since the immunologic functions are poorly developed. Potter and Abel reported that few babies display surface sterility at birth the majority showing contamination principally with *Staphylococcus albus* (formerly called *Micrococcus pyogenes var. albus*) and *Escherichia coli*. In contrast however it has been stated that the skin of the newborn is remarkably sterile for the first 4 to 5 days and that organisms begin to appear after that. The normal flora of the skin is essentially saprophytic but it must be regarded as including facultative pathogens for disease of the skin is produced when the latter is damaged or its defense mechanisms are in some way impaired. Because of its exposed position it is surprising that the skin does not suffer more from infection than is the case. However it is protected from infection by a number of factors (a) the marked acidity (*pH* 4 to 6) of its surface (b) the physical armor of its keratinized layer (c) its excretory functions and continuous desquamation which tend to remove microorganisms mechanically and (d) its generally dry surface which impedes bacterial growth.

Skin Care of the Newborn

A very important problem in pediatrics is the proper care of the skin of the newborn during the stay in the hospital nursery and after reaching home. That there is little unanimity of opinion regarding such care states Perlstein seems largely due to a lack of understanding of the physiology and pharmacodynamics of the skin of the newborn. The care of the newborn's skin during the 4 to 5 days in the nursery has been the subject of many research papers characterized by the many variations and contradictions in recommended procedures all of which reflect the ever changing approaches in pediatric dermatology.

This lack of unanimity was further brought out in a survey of 83 large hospitals on Current Practices in the Care of the Newborn. In this report it was noted that in reply to the question concerning the initial bath 5 hospitals reported no bath 3 bath only after 12 hours 20 that the entire body was cleansed 22 a shampoo plus the entire body bath and 4 the removal only of obvious soil. In reply to the question concerning the solutions used on the skin for this initial procedure 20 hospitals reported the use of oil 16 soap and water alone 2 water followed by oil 5 lotion 6 dry technique and 20 a substance not specified. In reply to the question concerning the material used for a daily cleansing after the initial bath 35 reported the use of plain water 24 the use of oil 18 the use of soap and water 10 the use of lotions and the others used various preparations such as alcohol alcohol or oil boric acid cetyl pyridinium chloride 1 1000 penicillin ointment pHisoHex benzalkonium chloride and only 1 the dry technique.

This multitude of methods of skin care was even more striking upon consideration of The Standards and Recommendations for Hospital Care of Newborn Infants published by the Committee on Fetus and Newborn of the American Academy of Pediatrics in 1949. In the section on Care of the Skin it was stated The proper care of the skin in the newborn infant is important in preventing infection. At present the consensus seems to be that the less manipulation the less danger of infection. It is recommended that no water or oil bath be given during the first week or 10 days after birth. The buttocks may be gently wiped away from the folds of the infant's skin with warm sterile mineral oil on sterile cotton or soft sterile gauze. Each time the diaper is changed sterile oil should be applied to the soiled or wet areas of the skin.

The 1971 edition of *Standards and Recommendations for Hospital Care of Newborn Infants* stated Bathing. Blood and excess vernix caseosa not removed in the delivery room may be removed for esthetic reasons with sterile cotton after the infant arrives in the nursery. Hexachlorophene bathing reduces the rate of skin and nasal colonization by staphylococci and possibly lowers the incidence of staphylococcal skin infection in newborn infants. Surgical gauze is not recommended for any phase of the routine skin care of the newborn infant because it is more irritating to the infant's skin than cotton.

Care of buttocks. The buttocks may be satisfactorily cleansed with a cotton ball moistened with fresh warm
tap water or a hexachlorophene solution. There should be as little rubbing as possible. If oil is used for the diaper area it should be kept in a separate sterile glass container for each infant however it should be recognized that pathogenic organisms may contaminate such containers.

The prevention of epidemics of impetigo nconatorum has been a major problem in hospital nurseries for many years and its complete elimination has not been achieved. It is a pyogenic infection due mainly to a *Staphylococcus* and is very contagious. *Streptococcus* impetigo is encountered at times and is contagious although less so than the staphylococcic form. Bullous impetigo is also caused by a *Staphylococcus* but is especially found in newborn babies and infants (often called pemphigus of the newborn). Any outbreak of skin infection among newborn in the nursery results in a costly and unpleasant interruption of maternity service and is often difficult to eradicate.

Some of the products and procedures used in the nursery to be discussed in greater detail include the following

- One to five percent ammoniated mercury ointments.
- Mineral and vegetable oils containing antiseptics.
- Mineral oil lotions.
- Cationic acidic lotions.
- Sulfonamide ointments and emulsions.
- Cod liver oil ointments.
- Detergent petrolatum cholesterol emulsion.

The dry or no bath technique where no treatment is given the newborn’s skin until the seventh day after birth (except for removal of excessive blood with sterile cotton at birth).

Some researches have emphasized the benefits derived from the last method of protecting the newborn’s skin by the simple elimination of chemical and mechanical trauma caused by daily cleansings. This method is based on the premise that the vernix caseosa is a necessary covering which serves as a lubricant for the baby’s skin. While it has been considered as a barrier against bacterial infection Lubinski and Benjamin demonstrated the inability of the vernix to protect against staphylococci or *E. coli* in vitro. Sprunt and Redman also demonstrated that vernix caseosa tested *in vivo* and *in vitro* showed no evidence of antibacterial activity. Removal of this covering has been shown to be unnecessary and Apfel has recommended that it be preserved. After it has served its purpose it will dissolve at normal body temperature absorb or dry up then fall off within a few days if left undisturbed. By leaving it intact microscopic abrasions and breaks in the superficial layers of the skin and contamination incident to its removal are avoided. But if desired by the doctor the larger masses of vernix may be wiped away with sterile cotton dipped in sterile vegetable or mineral oil.

In the group of external antiseptic applications the preparation most commonly used was ammoniated mercury ointment in varying strengths (1 to 5%) selected because of its known value in the treatment of impetigo. Fischer pointed out that this procedure possessed several recognized disadvantages. It involved a time consuming technique at least one and frequently several complete inunctions during the neonatal period being required. There was always the not inconsiderable danger of sensitivity reactions and even possible nephritic damage. The statistical evidence clearly indicated that complete protection was lacking. Another method in the prevention and treatment of skin infection of the newborn is the use of various sulfonamide ointments. Fischer maintained that this method possesses the same disadvantage as the use of ammoniated mercury or other ointments plus the very real danger of skin reactions and sulfonamide sensitization. In contrast to this viewpoint however are the excellent results reported by Weymuller and Ittner with a 5% sulfathiazole ointment in an oil in water emulsion base. No instance of sensitization to sulfonamide compounds was encountered in 3205 newborn infants.

Another comparative study reported by Heimer and co workers was on the treatment of alternate newborn
infants with local applications of sterile mineral oil or a cod liver oil ointment. There was an incidence rate of 1.35% of rashes in the mineral oil group and 0.85% in the cod liver oil ointment group. A subsequent study by the same authors indicated that a cod liver oil ointment and cod liver oil lotion were effective in the topical treatment of several skin disorders including contact dermatitis (due to diaper rash) and chafing in opposing skin areas. Behrman and co workers recommended the use of cod liver oil ointment for infantile intertrigo (diaper rash) because of the rapidity of its healing action. Turell and Marks found the cod liver oil ointment to be effective in the therapy of proctological disorders. All of these cod liver oil ointments and lotions are based on Norvegian cod liver oil lanolin petrolatum zinc oxide and talc. Marks stated that absorption of both vitamins A and D is known to take place in abraded areas. The saturated and unsaturated fatty acids in the oil also play an unknown part in maintaining the reparative process. The physiologic effect of cod liver oil appears to be primarily to promote anabolic action.

Baby Oils

During the 7 to 10 days in the nursery care of the diaper area varies tap water sterile water baby oil or lotion being used for the removal of fecal soil. Skin folds are cleansed with water oil alcohol or are left alone. There are several references in the literature to the use of antiseptic oils. These preparation are based on mineral oil and vegetable oils (peanut sesame olive cottonseed) used either separately or in admixture. Some oils contain hexachlorophene as the antiseptic and an antioxidant (tocopherol or butylated hydroxyanisole) to retard development of rancidity of the vegetable oils. Fischer stated that with the use of these antiseptic oils there still exists the disadvantage of possible irritation sensitivity reactions and only partial protection.

Antiseptic baby oils are far less irritating than ammoniated mercury ointment and have enjoyed wide usage for many years. In 1949 the Committee on Fetus and New born of the American Academy of Pediatrics recommended the use of oil for wiping the folds of the infant's skin in the buttocks area with application of sterile oil to the skin at each diaper change. Holt and McIntosh recommended during the first few days of life the newborn may be cleaned with oil and cotton the full bath being deferred until after the cord has separated. After the bath the skin of most infants requires nothing further than careful drying others particularly very fat infants benefit by the application of a small amount of oil or lanolin or by some bland absorbent powder in the folds of the skin. If plain water produces an undue amount of irritation salt may be added to the bath water to bring it to the approximate concentration of physiologic saline.

An opposing point of view concerning the use of oils applied to the newborn skin during the first weeks of life was expressed in 1951 at a Round. Wrong stated that oils coat the skin and seal off the glands in that way. He continued if there are organisms in the area there is more tendency for them to invade the oil and sweat glands. Oils which contain perfume and various antisectics may act as sensitizers and produce an eruption. The tendency in the past has been to overdo the use of skin oils. The new born's skin is better if it is cleaned with plain water and if soap is used sparingly certainly the skin should not be covered with grease or oil which may contain some perfume or substance which will in itself be a sensitizer.

At the same symposium on Pediatric Dermatology Ross stated in newborn infants overzealous cleaning of the baby and too much anxiety on the part of the nurse following birth are apt to do far more harm than good. Antibacterial preparations are not to be used often and probably are not advisable. Up to 4 or 5 days the skin of the newborn is remarkably sterile and organisms begin to appear after that. There are a number of institutions that have substituted a new regime of leaving the vernix on for a period of from 2 to 5 days then gently removing this material with lukewarm water and no use of soap what ever. For a period of 3 or 4 weeks at home no soap should touch the baby's skin when soap is used later it should be a super fatted soap and the child should be bathed not more than
2 times a week. The horny layer on a newborn baby's skin is exceedingly thin and is very sensitive to the
alkaline soap. Since alkali has a marked effect on a newborn baby's skin the use of soap in the early weeks
of life should be stopped.

Again concerning the contraindications of soaps and oils Gaul and Underwood stated
Overcare of the skin... produces a high incidence of minor rashes and irritations. A good example is the
care of the newborn skin. The daily soap bath defats the skin causing erythema dryness roughness and
disturbance in keratogenesis subthreshold vascular injury. A baby oil is substituted for the natural skin
lipids. It further dissolves out the lipids that the soap and water missed. This overcare perpetuates the
pinkness of the newborn skin and accentuates dryness and redness. Minute fissuring and chafing of the
epidermis is the result. The skin that has had overcare is susceptible to heat rashes and secondary
infections and weather changes to lower temperatures and humidities stress the vascular bed to the point
of eczematization. The end result of overcare is that the skin is less able to withstand the sudden
exigencies of weather changes.

In Apfel's opinion the occasional occurrence of skin infection in the newborn in spite of diligent application
of antiseptic oils is due to the fact that it is difficult not to injure the baby's skin in the act of massaging it
with the oil and inasmuch as the skin is never quite sterile the break of the superficial layer of the skin is an
invitation for the bacteria to bring about impetigo.

**face powders**

From the masklike effect in ancient times to the natural look which has blossomed during the current
decade face powders have been and still remain one of the basics of the cosmetic industry.
Changes in face powder fashions during the last twenty five years have far surpassed those made in any
previous period of time. The matt (dull) look in makeup is passé the natural look shows no sign of waning.
Transparency is the word a woman's real skin should show through. Tinted shiny enhanced by our modern
cosmetics the woman of today is able with only modest effort to be more attractive than she has ever been
in the past.

Along with these transformations in fashion have evolved modifications in the formulation and manufacture
of face powder. Contemporary concepts of makeup and the array and diversity of products have brought
with them numerous technical innovations.

It is hoped that this chapter will present guidelines that will be helpful in the creation of good present day
face powders.

A face powder is basically a cosmetic product which has as its prime function the ability to complement skin
color by imparting a velvetlike finish. It should enhance the appearance of the skin by masking the shine
due to the secretion of the sebaceous and sweat glands. A powder should achieve its effect by being
opaque enough to mask minor blemishes but it must not impart a masklike effect. In addition the powder
must possess reasonable lasting properties so that frequent repowdering is unnecessary.

Since there is no one ingredient that possesses all the properties desired in a face powder a blend of
constituents is employed which imparts the following essential characteristics of a good product
Covering power. The ability to mask skin defects such as skin shine enlarged pores and minor blemishes.
The faculty of spreading over the skin without dragging and the characteristic smooth feeling.
Adhesiveness. The ability to cling to the face.
Absorbency. The capability of absorbing skin secretions (perspiration oiliness) without showing evidence of
such absorption.
Bloom. The ability to impart a velvety peachlike finish to the skin.

**LOOSE FACE POWDER**
Raw Materials
The primary consideration in the manufacture of face powder is the selection of the raw materials. The spectrum of basic ingredients used is rather narrow thus the quality of each is all the more important since it will be a most significant role in the ultimate powder formulation.

A face powder must be a blend of specific raw materials if it is to be a product which exhibits the particular characteristics desired. Therefore would be well to list the basic ingredients normally employed as well as the properties each may impart to the finished powder formulation.

The first and foremost ingredient to be considered in the formulation and manufacture of face powder is talc. The variety of tals which are available is ostensive.

Chemically talc is a magnesium silicate (3MgO·4SiO₂·H₂O). It is a basic ingredient of virtually all modern face powder formulations. Its outstanding properties are easy spreadability (slip) and low covering power. Talc is the softest material on the Mohs scale of hardness and should be judged on the basis of slip smoothness fineness grit density color and odor. For face powder use talc should be white and virtually odorless with a smooth greasy feel. Of course excellent slip properties are the fundamental necessary. The highest quality talc are the softest material on the Mohs scale of hardness and should be judged on the basis of slip smoothness fineness grit density color and odor. For face powder use talc should be white and virtually odorless with a smooth greasy feel. Of course excellent slip properties are the fundamental necessary. The highest quality talc have been mined in France and Italy a great deal of talc is now available in the United States. Proper grading by the producer will greatly influence the final quality of the talc.

Particle size of a talc is one of the criteria for its standard of quality. At least 98% should pass through a 200 mesh screen (no larger than 74µ). Micronized talcs are now readily available in which the particle size may be reduced to several microns. The use of micronized talc is desirable in cases where an even particles size and high bulking value is required. Bulk density (degree of fluffiness) is of extreme importance in talc since variations will greatly affect the quality and packaging of the final product.

The proper selection of micron size is very much dependent on the type of face powder desired. A coarse talc will not adhere to the skin as well as one that is considerably finer and may result in abrasiveness on powder application. On the other hand the fineness of talc may reach the stage where the material may lose some of the basic structure and characteristics. Certain talc possess a transparency not attainable with any other face powder constituent and if the particles of such talcs are too finely divided they scatter light and appear to be of higher opacity. Thus excessive division of particles may result in the destruction of valuable properties of a talc.

Dermatologically talc is an innocuous material.

Kaolin
Kaolin or China clay is a generic term which is applied to several hydrated aluminum silicates. Kaolin is a naturally mined product derived from feldspar it excels as a face powder adjunct. It possesses good covering power and adhesion as well as certain grease resistant and perspiration absorbent properties. Kaolin helps to remove the shine of talc and has certain soothing effects on the skin. Since it is a compound of high density it is used in formulations to adjust fluffiness and control bulk.

The color of the kaolin used should be as light as possible (slightly off white to pale cream colored). The raw material should be highly purified to entirely remove gritty impurities and coarse particles.

All aluminum silicates cannot be classified as kaolin. There are however three distinct groups of clay which have essentially the same formula (Al₂O₃·2SiO₂·2H₂O) and may be called kaolin nacrite dickite and kaolinite.

Since kaolin is hygroscopic its use in face powders does not normally exceed 25% (more may result in streaking during damp weather).

Kaolin like talc is a dermatologically innocuous material.

Precipitated Chalk (Calcium Carbonate)
In face powder formulation and manufacture a good cosmetic grade of precipitated chalk which is not used in excess serves to preserve a certain balance between slip and adhesion covering power and...
transparency.
A grit free calcium carbonate reduces the shine of talc and has good covering power. It helps to absorb the perfume and is also grease resistant and perspiration absorbent. Precipitated chalk is also excellent for developing the bloom effect when face powder is applied.
Precipitated chalk is a mildly alkaline white odorless microcrystalline powder it is quite dull and has a chalky feeling. When this raw material is used in excess the powder may acquire a dry feel but moderate usage is most helpful to face powder formulas.

**Magnesium Carbonate**
The valuable characteristics of magnesium carbonate make it a commonly ingredient in face powder. Magnesium carbonate has fine absorbent properties and has been proven satisfactory as a means of distributing perfume. Its density is a fraction of that of precipitated calcium carbonate quality which may contribute to the development of a fluffy type of power.
The magnesium carbonate used should be of as fine a quality as possible and free from contamination by impurities. As in the case of calcium carbonate magnesium carbonate should be employed in moderation since use in excess may result in a drying effect on the skin.

**Metallic Stearates**
Zinc and magnesium stearates are by far the most widely used of the metallic stearates. For face powder the stearates must be of the highest quality to avoid the development of rancid disagreeable odors. The most important characteristics of zinc and magnesium stearates are their adhesive and waterproofing properties. Zinc stearate the most commonly employed also possesses a soothing quality. Used in excess stearates may create a smeared blotchy effect on the skin. In moderate amounts (4 to 15%) however zinc stearate in particular contributes to the adherent qualities of a face powder.

**Zinc Oxide Titanium Dioxide**
Since one of the primary functions of a face powder is to mask minor skin blemishes covering power must receive careful consideration.
There are two basic opacifiers employed in face powder formulas zinc oxide and titanium dioxide. Too much coverage by either may produce a masklike effect which is undesirable too little gives a powder with insufficient body.
It is well known that zinc oxide has certain therapeutic properties and helps to clear up minor skin disorders. However excessive use of this material may result in a drying effect.
Zinc oxide possesses moderate adhesive properties and is comparatively inert. When employed in face powders it should be of high quality as white in color as possible odorless uniform fine and free from grit. To avoid any drying effect and yet allow for sufficient coverage a formulation may consist of as much as 25% zinc oxide. In present day face powders however such a high proportion of this opacifier is seldom required.
Titanium dioxide is three to four times better as a covering agent than zinc oxide but it has less adhesion and does not blend quite as well. For a face powder in which an appreciable quantity of covering power is desirable the judicious use of titanium dioxide zinc oxide or a blend of the two is necessary. Variations in the properties of titanium dioxide and zinc oxide allow for fluctuation in talc and other ingredients of the formulation which change all of the basic characteristics of a face powder.
Used alone or in conjunction with zinc oxide 10 to 15% titanium dioxide will allow for sufficient coverage in any powder formulation.

**Rice Starch**
Several decades ago the use of rice starch as a basic ingredient in face powder was widespread its current activity is limited.
The use of rice starch has brought into play bacterial decomposition problems since it is an ideal nutrient for bacteria. The bloom and absorbent properties that were contributed by the use of rice starch are now
provided by calcium carbonate and other materials in face powder formulas.

**Silicas and Silicates**

Silicas and silicates may be found useful in face powder to maintain free flowing characteristics even with high humidity. Silicates have also been employed as perfume carriers. The use of fine silicates such as magnesium trisilicate is helpful in face powders since they have extremely high water and oil absorption properties.

**Frosted. Look Materials**

In face powder as in all modern cosmetics the use of materials to give a frosted appearance has very much come into vogue. This trend to the translucent and shiny look has given birth to the widespread use of raw materials which help create this effect.

For a number of years natural pearlessence (guanine) served the cosmetic industry well. Guanine consists of needlelike colorless and transparent crystals which by the simultaneous reflection and transmission of incident light on their platelets impart a pearl luster. Pearlessence exhibits extreme light stability. Due to its cost uncertain supply and inherent natural characteristics guanine could not be adapted to certain uses in the cosmetics and toiletry field.

The synthetic pigment bismuth oxychloride was developed to replace guanine. Although photosensitive bismuth oxychloride is quite adaptable for use in frosted face powders to impart a metallic pearl like luster. Metallic powders (mica aluminum bronze) are widely used to formulate powders with a sheen. Since these powders reflect all rather than a portion of the incident light the luster is harsher than that produced by the pearl. However the cost is very much lower than the synthetic pearl and these metals may be judiciously blended with bismuth oxychloride to create fine pearly looking face powders.

Mother pearl (thin layers of calcium carbonate which are bound together) has also been found useful in face powders to produce the frosted effect. It should be noted that synthetic pearl mother of pearl and mica must not be milled since milling would destroy their optical lustrous effects.

**Color**

The use of color additives is basic to the art of creating face powder which display the subtle nuances of shading required for the discriminating female population. The colors invariably employed are either the inorganic pigments or the organic lakes and toners. Since there is a possibility of color bleed due to their solubilization by perspiration and fatty secretions the water or oil soluble dyes are not used to any degree.

Under the provisions of the Federal Food Drug and Cosmetic Act the organic color additives must be government certified inorganic pigment do not require such certification.

The quantity of color required depends to a great degree on the type of base used in the formula. The opacity of the oxides and transparency of the talc greatly influence the quality of color needed. There are a large variety of synthetic iron oxides available for use in face powder manufacture. The natural oxides such as umbers siennas and ochres like the synthetic iron oxides are in themselves of a dull nature and the coal tar colors are often needed to add brilliance to their color tones. The use of fine quality inorganics blended with a smattering of organic lakes allows for a broad variety of face powder shades the number of colors employed must always be kept to a minimum.

It must be remembered that lakes do have varying degrees of instability to light a factor not encountered with the use of inorganic pigments. The light fastness of a lake therefore must be carefully considered since it does play an important part in a formulation. The added brilliance of lakes makes them indispensible to the enhancement of the inorganic pigments.

In passing it would be well to stress the importance of color grinding to bring out maximum shade development. Poor pulverization of color extenders will result in underdevelopment of shade intensities and in tones that differ from those obtained by efficient pulverization. To bring out the maximum color in each batch of a face powder the pigments used must be of uniform particle size.
**Perfume**

The selection of the proper perfume and its most efficient manner of dispersion within the face powder is of extreme importance since the odor of a powder plays an important role in the sales potential of the product. Proper dispersion of the perfume is not a simple procedure because of the extremely large surface area of the cake and the possibility of reaction of the perfume with impurities in the raw materials employed. If the raw materials are of a fine cosmetic grade the fragrance selected will be that much less of a problem in the finished face powder formulation.

It is of vital importance that the perfume used be nonirritating stable to mildly alkaline conditions and that it not undergo oxidation or volatalize too easily. The fragrance must be compatible with all of the powder ingredients since problems with rancidity heterogeneity of odor and discoloration may result from improper odor selection.

The concentration of the perfume in the product is variable but if this concentration is too low it may not be perceptible and will not properly mask raw material odors. On the other hand too high a perfume concentration may result in an overpowering odor and it may cause lumping of the powder. It may also cause skin irritation. As a rule between 0.2 and 1.0% is a reasonable perfume range in a face powder.

The manner of introducing the fragrance in the face powder can be varied. The fragrance may be mixed into one of the raw materials which has good absorbent powers (magnesium carbonate) or it may be sprayed into the entire batch. In either case it is of importance that the perfume be homogeneously dispersed in the face powder.

Odor selection is at best subjective and based on the olfactory characteristics desired by the manufacturer. The fragrance should undergo scientific scrutiny and tests should be run to determine that it is actually compatible with the particular powder formulation. Perfume manufacturers can help and advise in any problems that arise with the fragrance.

In summary the basic ingredients covered and their associated outstanding characteristics are listed in Table 1.

A face powder is as dependent on the quality of the raw materials as it is on the skill of the formulator and the manufacturing procedures outlined. There can be no compromise on ingredient quality if a superior face powder is to be ensured.

**FORMULATION**

A face powder formula should be adapted to the characteristics desired and the type of skin to be covered. In general the skin to be powdered will fall into three categories dry normal or moderately oily and very oily. On the basis of these skin variables loose face powders have been classified as light medium and heavy. These designations do not refer to the density of the powder but rather to the quantity of powder necessary to cover the same area of the skin the covering power.

Since a dry skin will secrete virtually no oil and little moisture it requires a powder of slight covering power a light powder. Normal or moderately oily skins which are shinier due to skin secretions require a somewhat higher coverage a medium powder. Extremely oily skins which have a great deal of shine require great covering power a heavy powder. Formulas 1 to 9 represent the various types of loose face powder.

The quantity of perfume to be incorporated in a formula will be based upon the aesthetics of fragrance characteristics and the intensity of odor desired. Generally 0.5% would be a satisfactory starting point for the evaluation of a perfume in a powder base.

The amount of pigment to be employed will depend on the shade opacity and color intensity of the product to be manufactured. Pigments in the form of dilutions may vary from the 1% level to the 5% range in the finished product.

**COMPACT FACE POWDER**
Compact face powder which was introduced in America in the 1930s has surged in popularity due to its extreme ease of application and storage convenience. A compact powder is a dry powder which has been compressed into a cake and is usually applied with a powder puff.

**shaving preparations soap creams oils and lotions**

The origin of shaving that is some form of cutting the hair on and about the face undoubtedly predates recorded history. One of the earliest records attesting to the existence of barbers is mention of them in the Bible and some have been traced back as early as 400 B.C. in Greece. Shaving soaps or aids as such were first described over 125 years ago and as would be supposed were prepared by the saponification of cooking fats with potash and soda lye. Since these early attempts man has been trying to make this process of shaving a more pleasant convenient and comfortable necessary ritual.

The total shaving cream market has been constantly growing because of an ever expanding population and also especially in the last decade a vastly growing awareness of personal appearance as evidenced by the fact that more American men are shaving more frequently now than they did in the last century. Even though many men look upon shaving as a chore and at best a necessary evil they are rather particular about the shaving preparation they will use. Although some men have definite preferences and will use only one brand or type of shaving soap or cream most are willing to try another product or type of preparation if it can offer any advantages such as greater speed or more comfort. This can be seen by the evolution of various types of products offered by manufacturers and the fact that they are constantly working to improve their existing products and create new ones which will appeal to or satisfy the shaving male.

Preferences in shaving preparations have undergone definite changes. For the longest time soap dominated the market first in the form of the cake or bar then in the mug stick or powdered form. These in turn gave way to the cream type products both lather and brushless. Again these products encountered competition from the invention of the dry electric shavers with their claimed advantage over the old fashioned wet methods. Then the advent of the aerosol age and the aerosol shaving creams caused another change in men’s shaving preferences one that to this day accounts for the majority of shaving preparation sales.

In the year 1965 aerosol shaving cream accounted for over one half (57%) of all shaving cream sold in the United States. By 1966 this figure was increased to almost two thirds (65%). Interestingly the profile of users shows that convenience was the biggest factor in the growth of aerosols and that the greatest users of the brushless and lather type of products were mostly men in the age bracket of 45 and over. Regardless of the type of product chosen most must possess certain attributes which will make them useful necessary and salable. Some of the more important properties of shaving preparations are the easy and rapid production of a copious lather resistance to rapid drying or collapse while on the face during the normal length of time needed for shaving freedom from the possibility of causing skin irritation especially to the mucosa of the eyes nose etc. rapid softening of the beard and sufficient viscosity to hold the hairs erect to facilitate cutting the individual hairs and lubrication to make the razor glide over the face more easily and painlessly. Also as with any consumer product the stability of the preparation must be adequate at all temperatures corresponding to all possible geographical areas where one might be expected to use it. These preparations should not cause rusting or dulling of razor blades although with the advent of the stainless steel blades this is no longer as important a consideration.

The evaluation and testing for many of these criteria are largely subjective and ultimately rest with the user and shaver. However some researchers have attempted to devise methods of evaluation. Hair softening studies were conducted by Valko and Barnett and by Hollander and Casselman. These were primarily measurements of the swelling of hair by water and its effect on the softening or cutting strength. Hollander...
and Casselman determined that with the use of 120°F water for pre softening the beard a minimum of 2 ½ to 3 min would be needed to attain satisfactory softening prior to shaving. This preparation time increased with a decrease in water temperature.

Ross and Miles devised an apparatus and published a method for measuring the foaming capabilities of soaps and detergents and Scott and Thompson were able to measure the consistency or viscosity of foams.

Many shavers have found that the passage of the razor edge across the face was invariably accompanied by the production of superficial cutaneous abrasion of the skin. These abrasions more often than not were invisible but resulted in subsequent irritation. A study of the skin trauma caused by shaving was made by careful examination of the scrapings and residues obtained from the faces of men who had shaved. The skin scrapings were found to be composed of hair with large amounts of varied epithelial components both nucleated and non nucleated. This localized trauma could be increased with the factors that tend to promote a closer shave. These factors would be the use of sharp new blade the use of thin lathers or plain water excessive stretching of the skin or the raising of the hair follicles as after the use of a pilomotor agent or shortened preparation times. It is to prevent or at least reduce this trauma that the use of thicker lathers is preferable and that emollients lubricants and other additives are added to most shaving preparations.

Shaving Soaps Sticks and Powders

Shaving Soaps

Shaving soaps originally were prepared in bar or cake form then in the shaped mug or bowl form. They all had to be applied with a shaving brush to produce a sufficient quantity of lather. Although the bar shaving soap may appear physically to resemble some ordinary bar toilet soaps there are changes that must be made in the formulation in order to meet the requirements of a shaving soap.

A shaving soap must lather quickly and copiously which is a property of the coconut oil soaps. However the lather must be thick or dense in texture and reasonably long lasting which is more characteristic of the fatty acid soaps of palm oil or tallow derivation. Soaps of this second group lather more slowly than the coconut soaps but have better lathering properties and so some combination will usually give a better product than will the soap of any single fatty acid or oil alone. The ease of lathering also depends on the solubility of the soaps and potassium soaps in general are more soluble than the corresponding sodium soaps.

Nevertheless potassium soaps alone are usually softer and a certain proportion of sodium soap must be present to give body to the mixture. In addition various soaps have different potentials for causing irritation. Emery and Edwards conducted a study based on the production of pure soaps and the use of patch testing and classified them in their order of irritancy. Emery and Edwards concluded that in general the potassium soaps are more capable of producing irritation than are the sodium soaps but that the differences may not be due to alkalis alone but also may be associated with solubility double bonds and pH.

Many additives and modifications have been suggested to improve upon the basic soap type of system. Doran has suggested the use of triple pressed stearic acid in place of tallow provided it is used in conjunction with a vegetable oil to enhance lathering. Myers on the other hand claims that a 70 30 mixture of palmitic/stearic soaps instead of coconut oil soap is less irritating and lathers as well. German patent 421 490 claims the use of superfatting agents for soap of the type of monodecyl dodecyl tetradecyl or hexadecyl ethers of diglycerol amines such as dodecyl ( dihydroxy propyl) amine. Albumen decomposition products of high molecular weight such as lysalbinic acid and protalbinic acid acylated at the nitrogen with higher fatty acids of carbon length 12 to 18 are claimed to aid in lime soap dispersion and also to help retain moisture in the lather thereby retarding dry out. Smith claims that alginic acid or its salts of potassium or sodium added to shaving soap at 0.1 to 20% will soften the fatty material or oils in the hair better than soap and because of their high viscosity will create in conjunction with soap a firm lasting foam.
Styptic or hemostatic materials such as the lipid soluble fraction of soybeans and adrenalin and its salts have been incorporated into shaving soaps so that they give the shaving preparation a mild astringent action which is sufficient to prevent or stop bleeding caused by accidental cutting by the razor blade. Also the addition of 10 to 15% talc is said to increase the persistence of the lather and reduce the danger of scratching and cutting by aiding the razor to glide over the face more readily than when ordinary shaving soap is used. In 1937 before the advent of the stainless steel razor blade a United States patent recommended as an additive to shaving preparations oxidizing compounds such as chromic acid chromates dichromates chlorates perchlorates and perborates. The purpose was to produce a passive condition of the iron or steel of the blade so that the blade would efficiently resist corrosion thereby prolonging its usefulness through more shaves.

In order to obtain closer cleaner appearing shaves the use of pilomotor agents has been suggested. These materials when applied to the skin in concentration of 0.1 to 10% are supposed to cause contraction of the hair follicle muscle (arrectus pilorum) thereby projecting the hair fiber further out of the follicle by about 0.2 to 0.3 mm. If the beard hair is shaved off while in the extended position the hair stub will withdraw lower into the skin after relaxation of the muscle and give a cleaner appearance. Several patents for alkali stable materials have been granted. These are for the types 2 (phenyl amino) 1 3 diazocyclopentene (2) such as 2 (2 6 dichlorophenyl) amino diazocyclopentene (2) 2 (3 hydroxyphenyl) morpholine and its acid addition salts and 2 aminoimidazolines and its salts such as 2 benzyl aminoimidazoline hydrochloride.

Shaving Sticks
Shaving sticks are usually produced in a very dry firm form which is rubbed onto the moistened skin then worked into a lather with a brush. This product is not significantly different from the bar shaving soap and is much like the mug or bowl soap.

An example of a shaving stick is Formula 2.

These products usually possess only small amounts of glycerol are composed mainly of stearic acid and contain larger percentages of potassium stearate than the bar soaps.

A nonsoap containing non lathering shave stick was patented in 1939. This product was to be applied directly to the moistened skin at which time oxygen was released from an alkali peroxide such as magnesium peroxide. This peroxide was claimed to be capable of conditioning the beard for shaving by its depilating ability in the decomposition or dissolution of the hair substance.

Shaving Powders
This type of product is relatively unknown now but at one time was popular with barbers. This was because the powder could easily be dispensed into a shaving mug prior to the addition of water and the production of a lather using a shaving brush. The product was also more sanitary in that a fresh quantity of powder was used for each application. A typical product of this type is Formula 3.

Lather Shaving Cream
Essentially a lather type shaving cream contains ingredients similar to those of the bar shaving soap. However because of the inclusion of a greater amount of water and the creamy or pasty consistency desired this type of product is subject to all of the usual stability problems associated with bar soaps and in addition the problems of viscosity stability and product separation.

As with the bar soap the type of fatty acids and their ratio as both the potassium and sodium soap greatly affect the foam which is subsequently produced. In the lather creams these ratio affect not only the foam qualities but the consistency and stability as well. Small changes in these ratios can greatly change the viscosity or consistency of a cream. Sodium soaps for example tend to product a stringy and firmer cream and potassium gives a cream that is softer and better lathering but possibly not as stable. Here it is for the formulator to decide which qualities are most important to the product he wishes to make. A typical starting
The addition of borax in minor amounts of 0.1 to 1.0% has been found to have a marked effect on the viscosity of the creams and is sometimes employed for this purpose. Other ingredients can be added to the lather cream to help improve the lather make the face feel better retain moisture or make the lather more lubricating. Most creams contain super fatting agents which serve a twofold purpose first to neutralize any free alkali that might be present and second to help stabilize both the cream and the lather. The most common super fatting agents are free stearic acid free coconut oils or other vegetable oils mineral oil or lanolin. However lanolin or its derivatives are normally used in lesser amounts for their emollient properties. Significant quantities of glycerol (5 to 10%) are usually used to help keep the cream soft and pliable and improve the lather by retaining moisture. Propylene glycol or sorbitol may be substituted for glycerol if it is preferred. Menthol is sometimes added for the apparent cooling effect it imparts or because the odor is preferred by some men. Hexachlorophene has been added by some manufacturers for its contribution as a germicide. Triethanol amine is usually avoided in lather creams because it will often discolor with age and upon hydrolysis can produce ammonia.

The use of fractionated acids from coconut or palm kernel oil has been claimed to make nonirritating soaps with good lathering properties. The soap of almost completely hydrogenated vegetable oils or animal oils (such as cottonseed peanut soybean sesame corn sunflower olive and linseed) and tallow lard oleo etc. have been recommended for their improved high temperature stability in preference to soaps made with commercial stearic acid or unhydrogenated oils. As mentioned previously alkali stable pilomotor agents such as derivatives of 2 aminoimidazoline have also been utilized in lather creams. Since many lather creams today are packaged in collapsible aluminium tubes 0.1 to 0.4% sodium silicate can be added to prevent corrosion.

**Brushless Shaving Cream**

The brushless shaving cream resembles lather shaving cream in appearance. There the similarity ends. Whereas the lather cream is a soap which is intended to produce foam the brushless cream's purpose is not to produce a foam. Brushless shaving creams are in essence oil in water emulsions of the vanishing cream type. The possess certain possible advantages over shaving soaps such a greater convenience and speed since they do not require a brush for application and they give a more comfortable shave because of their greater lubricating ability and subsequent reduction in razor pull or drag. They also leave the face with a thin coating of oil or grease after shaving which makes the skin feel less irritated and softer.

Since the brushless creams do not contain any major amounts of soap they do not of themselves soften the beard and this function must be accomplished by first washing the beard with soap and water before application of the cream. The brushless cream does keep the hairs of the beard erect retains moisture well and above all provides a maximum of lubrication between the razor blade and the skin.

A simple starting formula for the manufacture of a brushless shaving cream is found in Formula 5. Many additives may be incorporated to improve upon the product's consistency lubricity wetting ability or feel. Borax in concentrations of 0.1 to 0.5% may be used to vary consistency or viscosity. Humectants such as glycerol propylene glycol or sorbitol may be used for their moisturizing ability and their effect on softening the cream. Emollients such as lanolin and its derivatives or fatty alcohols such as cetyl alcohol may be added for the unique feel that they impart to the skin. The use of various wetting agents such as the sulfonated aromatic hydrocarbons sulphuric acid esters of lauryl alcohol fatty acid amides and phosphatides such as lecithin has been suggested to increase beard softening. Gums such as methylcellulose tragacanth alginates and carragheenates have been suggested. These materials add stiffness or body to the cream help retain moisture and possibly provide more slip to the face.

**Shaving Oils and Lotions**

Another class of shaving preparations has existed which is neither soap nor brushless cream in the
classical sense. These products are various compositions of oils and lotions which are applied before another shaving preparation as a pretreatment or may be used alone for the purpose of shaving with a razor blade. Some are merely intended to improve the shave by performing the function of beard softening. One of the earliest of this type was patented in 1927 and suggested the use of a mixture of sugar borax turpentine and water for treating the beard prior to the application of a shaving soap. A more up to date version of this is one based upon a 0.5% solution of a polyoxyalkylene derivative of sorbitan monolaurate in witch hazel.

Other products have been claimed which depend on gums or other mucilaginous substances to provide additional lubrication on the skin other than that obtained with the regular soap type shaving preparations. These materials are intended to act as primary lubricants usually in combination with additives such as surfactants mineral oil and lanolin derivatives. The most often employed have been starch and gelatin sodium carboxymethyl cellulose acrylamides and acrylates and alkyl cellulose ethers as in Formula 7.