

94-TA-47

TALC: OCCURRENCE, CHARACTERIZATION AND CONSUMER APPLICATIONS

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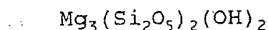


ABSTRACT

Talc is a mineral compound with unique attributes and significant commercial importance. As used in consumer products, talc has a long and proven history of safe use. Direct consumer applications include body powders, other cosmetic formulations, pharmaceutical tableting, and some confectionery food products. Production, characterization and consumer applications of FDA-regulated talc products, particularly cosmetics, are described. The implementation of stringent safety and quality control measures designed to ensure the absence of asbestos fibers from consumer talc products is discussed. Consumer exposure from talc-containing products is at least 350 times lower than permissible industrial exposure.

INTRODUCTION

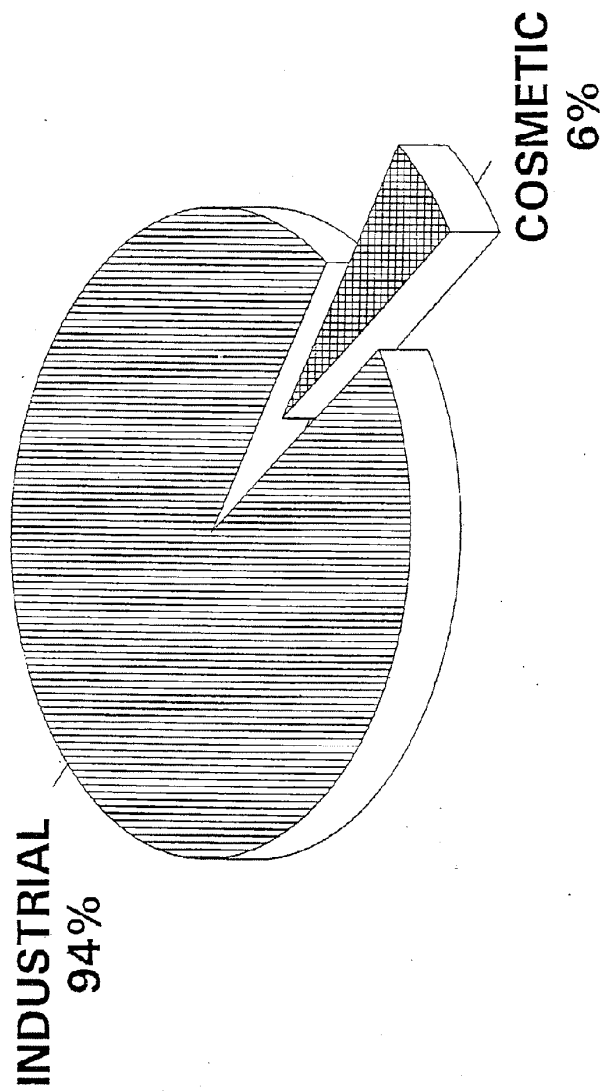
Talc (CAS No. 14807-96-6) comprises pulverized, natural, foliated, hydrous magnesium silicates (Harvey, 1988). As a pure mineral compound, talc is mineralogically defined as hydrous magnesium silicate, with the approximate chemical formula:

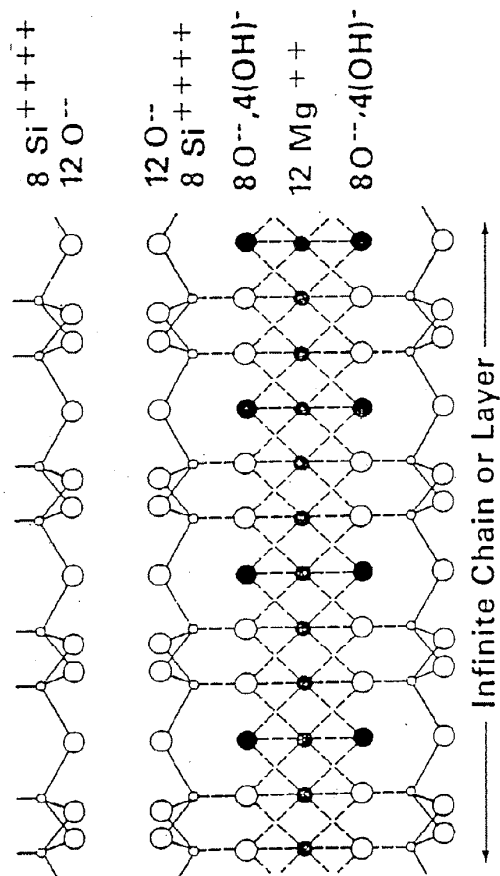


The largest commercial uses of talc are in industrial applications such as paint, plastics, paper, ceramics, and construction materials (Roskill, 1990). Approximately 850,000 tons of talc are consumed annually in the United States alone for industrial applications (Virta, 1993). The quality assurance requirements for talc utilized in industrial applications generally focus on the performance characteristics of the product. In some instances, the presence of specific non-talc impurities is a desired feature because of additional benefits associated with particular applications (e.g., presence of non-asbestiform tremolite in talc utilized in ceramic and paint formulations). Talc utilized in direct cosmetic applications accounts for a relatively small percentage of the overall talc market (Figure 1). In 1992, approximately 48,000 tons of talc were used in the United States for cosmetics, pharmaceuticals, and food products (American Westmin, Inc./Luzenac America, unpublished data).

Presented, in part, at the International Society of Regulatory Toxicology and Pharmacology/U.S. FDA Workshop on Talc: Consumer Uses and Health Perspectives, NIH, Bethesda, MD, January 31 - February 1, 1994.

U.S. TALC CONSUMPTION





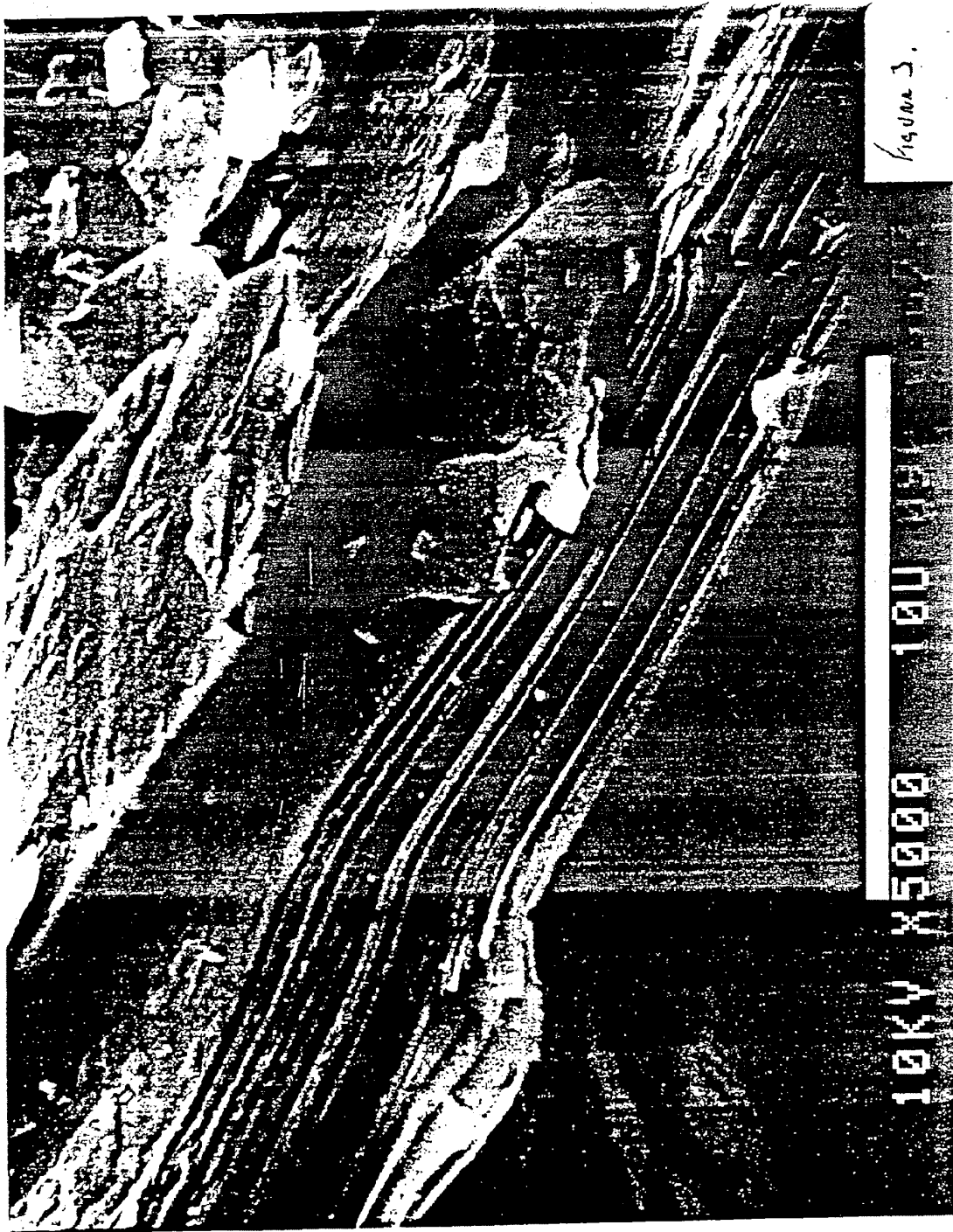


Figure 3.

OCCURRENCE AND MINERALOGY

Talc is mined throughout the world; primary deposits are found in almost every continent. Talc commonly forms by hydrothermal alteration of rocks rich in magnesium and iron (ultramafic rocks) and by low-grade thermal metamorphism of siliceous dolomites (see Ross, 1984). Due to the variety of ways in which the geological formation of talc is manifest, virtually every talc deposit is unique with regard to both chemistry and morphology (Piniaskiewicz et al., 1994). This accounts for the fact that certain deposits are valued for their cosmetic attributes, while others are prized for their industrial functionality. Factors which characterize the commercial viability of a talc deposit include (i) brightness and color; (ii) platiness and crystallinity; and (iii) type and presence of non-talc minerals associated with genesis of the deposit.

Pure talc is a translucent mineral that appears white when finely ground. The crystal structure of talc is characterized by composite sheet arrangements lying parallel to a common plane (Figure 2). These sheets consist of three sublayers comprising a layer of edge-linked $\text{MgO}_4(\text{OH})_2$ octahedra sandwiched between two identical layers of corner-linked SiO_4 tetrahedra. The apical oxygen atom positions of the tetrahedral layers are shared with one of the oxygen atom positions of the octahedral layer.

Off-white or discolored talc is indicative of elemental substitution within the talc crystal, usually by iron or other metals (Pooley & Rowlands, 1977). Small amounts of aluminum can substitute for silicon in the tetrahedral positions, and small to moderate amounts of aluminum, Fe^{3+} , Fe^{2+} and manganese for magnesium in the octahedral positions (Ross, 1984). Heavily discolored talcs can sometimes be bleached to an acceptable color and brightness, but most often are of little commercial value.

As seen under the electron-microscope, talc is made up of stacks of the triple-sheet crystalline units held together by weak Van der Waal's forces (Figure 3). The sheets slide past one another to produce the smoothness associated with talc. The natural platiness and crystallinity of a talc deposit defines its suitability for specific commercial applications. A *macro-crystalline* talc is one in which the natural platelets are large and well defined. Macro-crystalline talcs are considered ideal for cosmetic applications such as body powders. *Micro-crystalline* talcs are characterized by a small, irregular plate structure, and are used primarily in industrial applications and in some cosmetic applications such as pressed powders.

Non-talc minerals associated with commercial talc vary from deposit to deposit and may include calcite, magnesite, dolomite, chlorite, serpentine, and quartz (Piniakiewicz et al., 1994). The ease with which talc can be mined and separated from such impurities is very important in determining the commercial

viability of a deposit. The purity of commercial talc product is thus a function of the talc deposit from which it is obtained, the mining and manufacturing processes employed in its production, and the quality requirements of the commercial application for which it is intended.

MINING AND MANUFACTURING

Talc is typically mined in open pit operations (over 90% of the United States talc production is from open pit mines). Selection of an appropriate mine is based upon consideration of the factors described previously. The talc deposit is mined by first uncovering the talc (i.e., removal of the overburden); once exposed, the talc is removed by drilling and blasting. Since talc deposits of commercial significance generally contain other non-talc minerals, it may be necessary to sort (beneficiate) desirable from non-desirable material (Piniakiewicz et al., 1994). The talc ore may be beneficiated at the mine site by utilizing both physical and visual sorting techniques. The most common technique is hand-sorting. Operators stand next to a moving belt that is conveying crushed talc ore; by visual and physical inspection of the rock, the operators sort-out either obvious impurities or the talc, whichever operation is more efficient. While hand sorting is labor intensive, it is capable of producing talc ore that is >95% pure talc.

Although not always necessary (i.e., depending upon the nature of the talc deposit), wet beneficiation processing may be utilized in the production of high purity talcs such as those required for cosmetic, pharmaceutical, and food applications. Wet processing offers a number of advantages over dry methods including (i) the capability of achieving 99-100% talc concentrates; (ii) repeated washing (acid, water) removes soluble impurities; and (iii) facilitates reduction of microbial content. The talc ore is first crushed and ground to a fineness which liberates it from other associated non-talc minerals. Grinding can be performed on talc ore which is in a wet or dry state. A dilute talc/water slurry is then conditioned for flotation by the addition of a small amount of frothing agent, (typically a low molecular weight alcohol). This slurry is then processed through a series of cells through which air is pumped. This action causes bubbles to form and rise to the surface. As they rise, the talc particles attach to the bubbles due to the organophilic nature of talc. Because the hydrophilic non-talc impurities do not preferentially attach to the bubbles, the float (or "froth") collected from the top of the cells is much richer in talc content than the ore entering the cell. The process is then repeated until desired purity levels are achieved. The talc particles can be further processed by magnetic separation or acid washing to remove discoloring iron-bearing minerals, soluble salts and metals. Ultimately, the talc is filtered, washed, and dried. Depending on the commercial application for which it is intended, the dried talc may be ground to a finer particle size if required.

CHARACTERIZATION

Comminution, or grinding, of talc is performed to achieve particle size distributions required for specific commercial applications. Size reduction is achieved using conventional grinding equipment (e.g., crushers, hammer mills, roller mills, high energy air classifying mills, etc.). The commercial attributes of the final talc product are a direct function of the purity of the talc, its mineral crystallinity, and its particle size distribution. Several common terms (based upon U.S. Sieve Series and Tyler equivalents; Perry, 1984) are used in the talc industry to characterize the general "fineness" of a product:

- *200 Mesh.* Particle size distribution which allows 95-99% of the product to pass through a 200 mesh (74 micron) screen when wet-out with alcohol and dispersed in water. The use of 200 Mesh talc is preferred for body powders due to the physical attributes which are retained at this relatively coarse particle size.
- *325 Mesh.* Degree of fineness which allows 95-99% of the product to pass through a 325 mesh (44 micron) screen when wet-out with alcohol and dispersed in water. 325

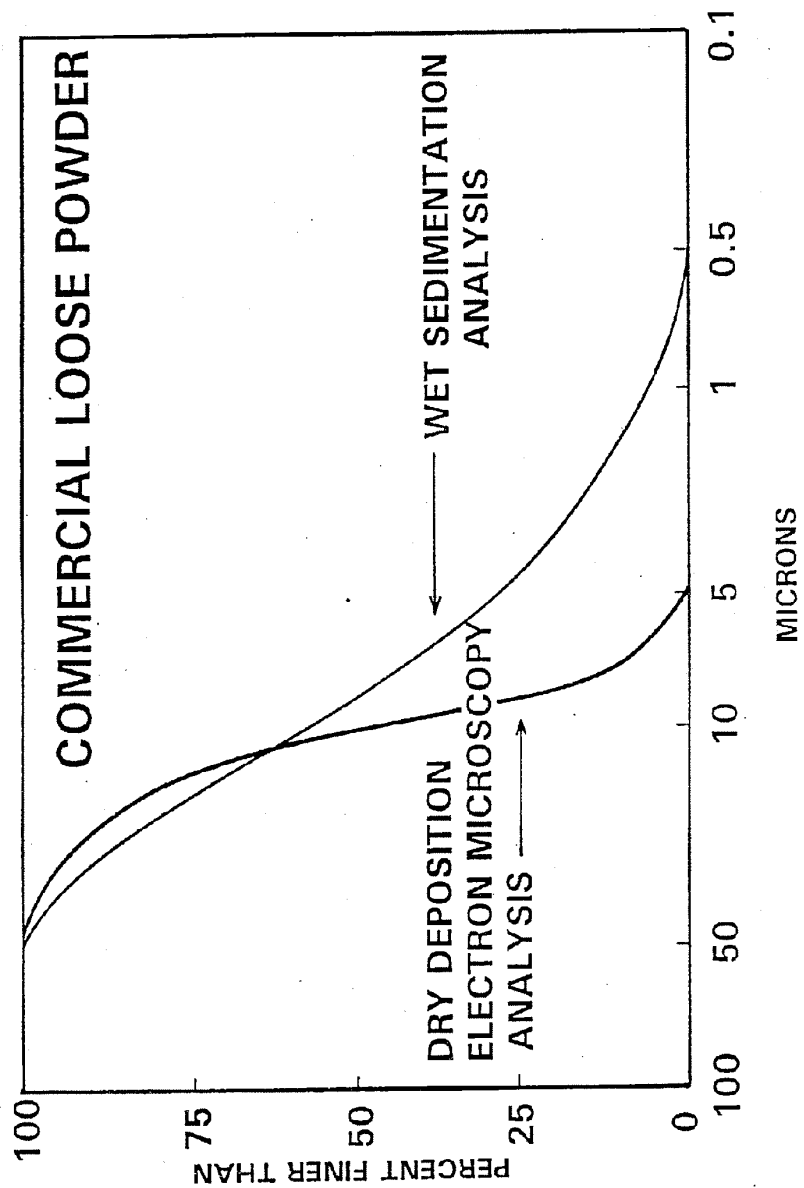
Mesh products (or finer) are generally used in all other cosmetic, pharmaceutical, and food grade formulations.

- 400 Mesh. Degree of fineness which allows 95-99% of the product to pass through a 400 mesh (37 micron) screen when wet-out with alcohol and dispersed in water. 400 Mesh products are used for some specialized cosmetic applications such as pressed powders.

Particle size distribution of talc products may be determined using several techniques of which the most commonly used is wet sedimentation. Particle size distribution is determined by measuring the Stokes settling velocity of a dispersed sample in water and calculating its equivalent spherical diameter (Orr and Smithwick, 1987). However, due to their platiness, talc particles tend to settle at a rate slower than that of an equivalent mass of a cubic or spherical particle (Allen, 1981). Consequently, wet sedimentation particle size analysis artificially *inflates* the mass attributed to particles of small diameter resulting in over-estimation of the number of small particles in any given sample. Wet sedimentation is therefore useful for comparing *relative* particle size distributions (e.g., in talc process control), but has distinct limitations with regard to *absolute* determination of particle size distribution.



Figure 8.



A newly emerging technology which has proven useful for determination of particle size distribution is computer-controlled scanning electron microscopy (CCSEM) (Schwoeble et al., 1988). CCSEM has the advantage that it is performed using dry powder and thus the results of such analyses are more applicable to determination of particle size distributions of talc products under actual use conditions. While use of this analytical technique is not practicable for routine process control purposes, CCSEM enables the automated characterization of the size and shape (Figure 4), as well as the elemental composition of large numbers of individual particles. Figure 5 illustrates the particle size distribution of a typical cosmetic talc product as analyzed by both wet sedimentation and CCSEM. Comparison of the two particle size distributions of the same commercial loose powder illustrates how wet sedimentation analysis results in overestimation of the relative proportion of small (e.g., ≤ 10 microns) talc particles. These data strongly suggest the importance of proper interpretation of particle size distributions based upon wet sedimentation analysis, particularly if inferences are to be drawn with regard to determination of the respirable fraction of a particular sample.

CONSUMER APPLICATIONS

In 1992, approximately 48,000 tons of talc were used in direct consumer applications in the United States. Pharmaceutical tableting and various food applications account for approximately 8% of direct consumer uses of talc products; the greatest



proportion (approximately 92%) is used in cosmetic applications (Table 1).

Table 1. Direct Consumer Applications of Talc

<i>Application</i>	<i>Estimated Percentage of Total Usage</i>
Loose Powders.....	71%
Pressed Powders (Eye & Face Make-up).....	18%
Pharmaceutical Tableting.....	5%
Chewing Gum and Other Food Applications.....	3%
Antiperspirants.....	3%

(American Westmin, Inc./Luzenac America, unpublished data)

Pharmaceutical and OTC Tableting

Talcs are used for various purposes as processing aids in the tableting of pharmaceutical and over-the-counter (OTC) products (APA, 1986; Dawoodbhai and Rhodes, 1989; Dawoodbhai et al., 1987). As a *glidant*, talc helps as a processing aid (flow agent) for the other active and inactive ingredients. In this application, the quantity of talc used may range from 0.5 to 2.0% by weight of the tablet. As a *lubricant*, talc helps to ensure that, as the tablet is released from the die wall in the tablet press, it will remain smooth and not crack. Lubricants are synonymous with "*mould release agents*" and utilized in the range of 1.0 to 2.0% by weight of the tablet. As a *dusting agent*, talc prevents the tablet from sticking to surfaces.

Talc is also used as an excipient in pharmaceutical applications, particularly as a *coating aid*. Many tablets are coated with films that can be sugar, solvent, or aqueous-based. The coating helps the consumer to swallow the tablet and helps disguise unpleasant tastes. Talc is added to ensure that the coating or film will affix to the tablet without showing cracks or ridges. Talc also adds strength and helps brighten the pigments or colorants used in the coating. Talc, used in this application may range from 1.0 to 5.0% by weight of the formulation; particle size requirements are generally similar to those described below for use in cosmetic pressed powders.

Confectionery Food Products

Approximately 3% of total talc usage is utilized in the production of chewing gum and selected hard candy (American Westmin, Inc./Luzenac America, unpublished data). As with other applications, the talc serves as a detackifying agent as well as a general filler and stabilizer. When used as a filler, the volume of the talc can be as much as a third of the base used. The particle size requirements for talc used in this application range from a 200 to 400 mesh (74-37 micron) product, depending on the performance attributes desired by the manufacturer.

Cosmetic Applications

Talc is used for cosmetic or "comfort" applications because of its unique combination of natural attributes:

- Talc is one of the softest minerals known (Pough, 1991). This characteristic is due to the delicate nature of the thin talc platelets which can yield and bend without fracturing (Figure 6). This phenomenon is responsible for the emollient sensations perceived when high grade platy talc is applied to the skin.
- The sheet-like layers of talc are held together by weak Van der Waals forces. Upon the application of shear, the talc platelets begin to slide upon one-another resulting in lubricity or "slip".
- The platelet structure of talc allows it to lie across the surface of the skin; its stratified layers assist in covering unwanted blemishes while its translucent character minimizes cover thickness.

Talc is used as an ingredient in several types of cosmetic formulations which may best be described as constituting a solid, semi-solid, or liquid matrix. The particle size of the talc raw

material used in these products varies widely by product type and by manufacturer. While important with regard to product performance attributes, the raw material particle size has no practical significance with regard to human exposure since encapsulation by the other ingredients in the product matrices (consider a lipstick or antiperspirant stick, for example) render the talc constituent essentially non-respirable. In contrast, the majority of cosmetic talc is used in loose-matrix products (e.g., baby powder or after-shower talcs) which contain much larger diameter talc particles than are used in other cosmetic talc applications.

Solid-Matrix Formulations

By definition, a solid structure is achieved when all of the individual ingredients of a formulation are completely bound and form a solid mass. Typical examples of such a solid structure are stick anti-perspirant products. The incorporation of talc in antiperspirants is somewhat different from other cosmetic talc applications. Binder systems, comprising viscous and heavy materials such as waxes, act to keep the formulation solid. Anti-perspirant active ingredients (e.g., aluminum chlorohydrate) are mixed with binding agents and talc at high temperatures, and processed into molds while still hot; thus the purity of the talc used is critical to ensure that unwanted chemical reactions (which may cause undesirable odors in the finished product) do not occur.

A typical stick antiperspirant formulation is shown in Table 2. In general, 200-400 mesh talcs are used for antiperspirant formulations. Talc is used as an inexpensive filler or bulking agent, as well as to give additional glidant properties and increased emolliency. In the finished product the talc particles are completely agglomerated by the other ingredients; commonly used solidifiers or gellants include stearyl alcohol, PEG-8 distearate, glyceryl stearate, PEG-100 stearate, steareth-100, stearamide MEA, stearic acid, paraffin, ozokerite, synthetic waxes, polyethylene, cetyl alcohol, arachidyl alcohol and hydrogenated castor oil. The solidifying agents comprise approximately 90-95% of the formula.

Table 2. Typical Stick Anti-Perspirant Formulation

	Weight Percent
Active Ingredient	20-25%
Solvents (ethyl alcohol, cyclomethicone)	20-40%
Waxes	20-25%
Clays	10%
Talc	4-10%
Fragrance	1-2%

Other examples of solid structures which incorporate talc include lipsticks and concealing makeups. In lipstick formulations, talc is sometimes used as a carrier for pigments or as a pigment extender. Solidifying agents (e.g., triglycerides, mineral oil, beeswax, carnauba wax, castor oil, etc.) comprise approximately 95% of typical formulations and completely encapsulate the talc. The percentage of talc used in lipstick formulations is approximately 2-4%.

Semi-Solid Matrix Formulations

Semi-solid talc-containing structures (typically, pressed powders such as blushes, eyeshadows, pressed finishing powders and base powders) incorporate binder systems which are not as viscous as those found in solid structures. Binding or compressing agents include stearic acid, glycerol monostearate, sesame oil, olive oil, isopropyl monostearate, cellulose gum, and propylene glycol. Typical pressed powder formulations are shown in Table 3. For cover-up or blemish-concealing make-ups, the use of talc with a fine average particle size distribution (300-400 mesh) is desirable. In contrast, a fine "translucent" talc with a larger average particle size (200 mesh) is often preferred for use in blushes, eyeshadows, and finishing powders.

Table 3. Typical Pressed Powder Formulations

Finishing Powder	Weight Percent
Talc	50-60%
Other Powders (clay or oat flour)	10-15%
Colors (pigments and titanium dioxide)	2-20%
Binders (oils and waxes)	15-20%
Fragrance	1-3%
Preservatives and Antioxidants	0.1%
Eye Shadow	Weight Percent
Talc	30-40%
Other Powders (clay or oat flour)	20-30%
Colors	2-10%
Anti-caking Agents	3-4%
Binders (oils and waxes)	5-30%
Preservative and Antioxidants	0.1-0.3%

Liquid Matrix Formulations

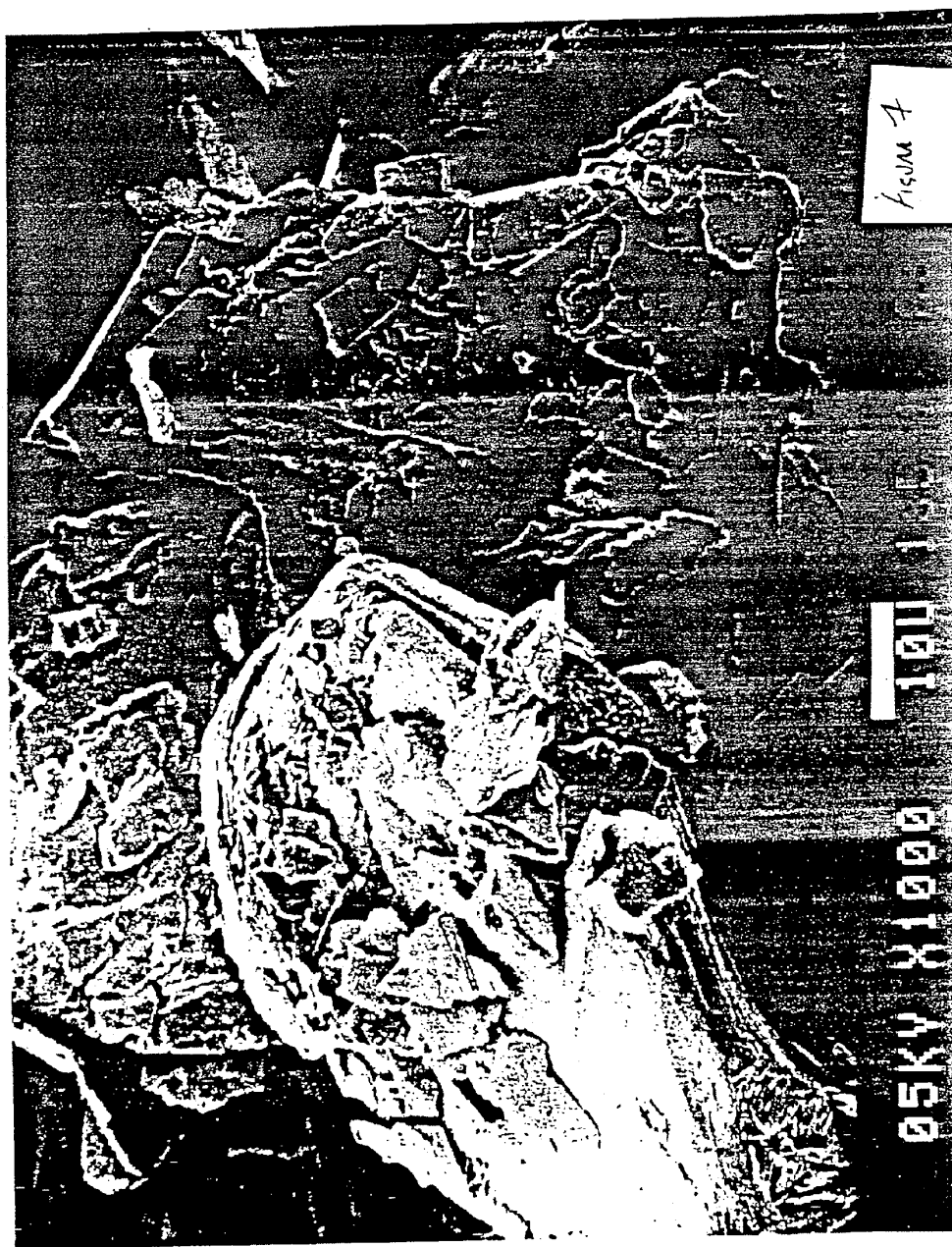
Liquid formulations containing talc (e.g., cream and liquid makeups, moisturizing creams and lotions) incorporate binder systems with considerably less viscosity than semi-solid structures. Viscosity will vary from product to product (e.g., if the product is a moisturizing cream the viscosity of the binder system will be considerably thicker than if the product is a liquid makeup). Typical liquid formulations are shown in Table 4.

Table 4. Typical Liquid Formulations

Liquid Make-Up	Weight Percent
Water	50-75%
Oils or Esters	15-20%
Talc	2-10%
Colors	1-3%
Emulsifiers	3-5%
Preservatives	0.5-1.0%

Foundation Cream	Weight Percent
Talc	2%
Water and Oils	50%
Thickeners	20-50%
Emulsifiers	5-10%
Preservatives	0.5-1.0%
Colors and Opacifiers	2-10%
Perfume	<1.0%

In liquid makeup formulations talc is primarily used as a pigment, or as a carrier of pigments. The percentage of talc used in liquid makeup formulations ranges from 2-10%. Thickening or binding agents include light oils and esters. In general, creams



have a higher viscosity than do lotions or liquid makeups. Thickening agents include glyceryl stearate, tricaprin, caprylic-capric triglyceride, propylene glycol dicaprylate dicaprate, oleyl erucate, stearic acid, cetyl alcohol, and trilaureth-4-phosphate. Typically, thickening and gelling agents account for 20-50% of the formulation. As a result, glidants such as talc are used to promote the spreadability of the cream across the skin. If used as a pigment or pigment extender, talc is used to add whiteness (or, in some cases, another color) to the cream. If used as a glidant, the percentage of talc in the formulation used may be as high as 7-8%; if used as a pigment, the percentage of talc is approximately 2-4%.

Loose Matrix Products

Loose talc-based formulations do not include a binder system. In body powder applications, talc is used as a lubricant and as an emollient. Talc also acts as a carrier for fragrances (or active ingredients in the case of medicated products) which are coated onto the talc. In fine fragrance body powder applications the degree of purity of the talc is critical so as not to interfere with individual fragrance characteristics. Addition of fragrance oil increases the bulk density of the talc powder without affecting the free-flowing characteristics of the product. Examples of loose powder systems containing talc include medicated foot and body powders, fragranced body powders, loose finishing makeup powders,

baby powders, and body powders. In baby powder applications talc acts as a skin-lubricant, prevents moisture from chaffing the skin, and acts as a tactile stimulant. Baby powder is also used by adults either as an after-shower lubricant or as a foot-powder. Typical loose powder formulations are shown in Table 5.

Table 5. Typical Loose Powder Formulations.

Baby Powder	
	Weight Percent
Talc (200 Mesh).....	99%
Fragrance.....	1%
After-Shower (Body) Powder	
	Weight Percent
Talc (200 Mesh).....	65-70%
Corn Starch.....	15-25%
Sodium Bicarbonate.....	1-5%
Fragrance.....	<5%

The two most important criteria for body talcs are their fragrance retention and slip characteristics. Fragrance retention is defined as the ability of the talc to retain the purity of the fragrance with the least amount of deterioration, change in fragrance characteristics (odor), or loss of fragrance potency. Slip characteristics are synonymous with platy or flaky talcs. A large platy structure provides a smoother surface than a granular talc and consequently, glides across the skin surface more easily. The larger the platelet, the better the softness and lubricity. For loose powders, a 200 mesh (74 micron) talc is used almost exclusively. This relative coarseness allows for (i) maintenance

of large platelets (hence good slip); (ii) low surface area (hence good fragrance retention); and (iii) minimization of dust during application due to large particle size. A scanning electron photomicrograph of a typical body powder is shown in Figure 7. In particular, note that (due to electrostatic and crystalline charges on the talc particles) substantial agglomeration occurs. In some circumstances the addition of fragrance oil may act as a minimal binder system causing the talc to agglomerate further. The amount of fragrance added to body powders can range from 0.05% to 5% by weight. Additional additives such as magnesium carbonate, synthetic silicas, corn starches and other ingredients are often included in the formulation to help improve the flow characteristics and fragrance retention of the finished product.

QUALITY ASSURANCE

The talc industry has a moral and legal responsibility to supply products that can be used safely. Quality assurance programs established by talc producers engaged in the production of talc used in food, pharmaceutical or cosmetic applications are influenced by (i) FDA regulations and guidelines; (ii) specifications issued by the Food Chemical Codex (FCC), the United States Pharmacopeia (USP), and the Cosmetic, Toiletry and Fragrance Association (CTFA); and (iii) customer specifications and requirements. Product quality assurance criteria fall into two general categories: (i) performance specifications; and (ii) health

and safety specifications. *Performance specifications* focus on the physical characteristics of the talc such as particle size, bulk density, color, and brightness. These specifications are adhered to so as to ensure that talc supplied for specific applications will meet customer requirements. *Health and safety specifications* focus on chemical purity and absence of potentially harmful micro-organisms.

As defined in the Federal Food, Drug, and Cosmetics (FD&C) Act (and the regulations published under the authority of these laws), talcs used in pharmaceutical, food and cosmetic products are categorized as drug components, food additives, and cosmetic raw materials, respectively. Regulations published by the Food and Drug Administration (FDA) are codified in Title 21, Code of Federal Regulations (21 CFR). Talc facilities engaged in the manufacture of USP, FCC, or CTFA-grade talc products are subject to the general provisions of the FD&C Act and are prohibited from introducing adulterated articles into interstate commerce. Under empowerment of the FD&C Act, the FDA has published Current Good Manufacturing Practices (CGMP's) for food, drugs, and medical devices. Talc facilities engaged in the manufacture of FCC talc products must comply with the FDA's CGMP's for manufacturing, packing, or holding human food as detailed in 21 CFR 110. Talc facilities engaged in the manufacture of USP talc products are regarded as "Bulk Pharmaceutical Producers" and must comply with FDA's CGMP's for manufacturing, processing, packing, or holding of drugs as detailed in 21 CFR 210.

Talc quality assurance specifications focusing on health and safety criteria have been issued by CTFA (1990a), USP (1990), and FCC (1981). The focus of all three specifications is similar in that they place limits on certain extractable elements and other potential chemical contaminants. Only relatively pure talc products are capable of meeting these specifications. All cosmetic, pharmaceutical, and food companies utilize raw material specifications based on CTFA, USP and FCC criteria.

The historical association between talc and asbestos is an extremely unfortunate one. Precipitated in large part by the use of overly broad definitions of asbestos and nonspecific analytical techniques (Rohl, 1974; Rohl & Langer, 1974; Krause and Ashton, 1978; Parmentier and Gill, 1978), the idea that asbestos is commonly and intimately associated with talc is simply incorrect. As a retrograde mineral, talc may be found in association with chrysotile in serpentinites and other hydrous minerals. However, the geologic conditions under which talc and asbestos form are dissimilar. Many talc-bearing rocks form from ultramafic rocks, the central core of which is composed of serpentinite surrounded, successively, by shells of talc-carbonate rock and talc-bearing steatite (steatite is synonymous with soapstone). Usually a thin wall schistose rock, composed essentially of chlorite, separates the steatite from the country rock. The serpentinite is composed mostly of non-fibrous serpentine minerals (lizardite and antigorite), but small amounts of chrysotile asbestos may also occur within the serpentinite. The talc-carbonate and steatite shells which surround the serpentinite core contain abundant talc

but do not contain asbestos. In the mining of the talc ore the serpentinite core is avoided, thus preventing asbestos contamination.

Appropriate selection of mine site, careful mining procedures and the utilization of modern beneficiation techniques further safeguard against asbestos contamination. Confirmation of the absence of asbestiform minerals in the finished product is established using x-ray diffraction, optical microscopy and electron microscopy techniques (CTFA, 1990b).

CONSUMER EXPOSURE TO COSMETIC TALCS

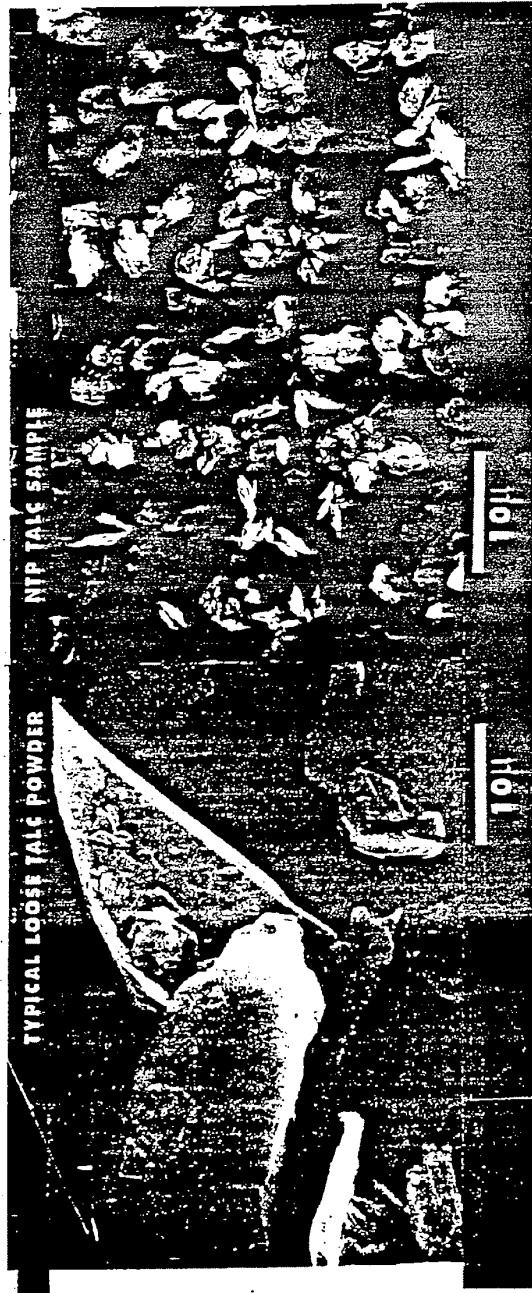
In the United States, the safety of cosmetic ingredients and finished formulations must be substantiated by manufacturers. Raw material suppliers also bear a responsibility for the safety substantiation of ingredients they supply to the cosmetic industry since Section 201(i) of the FD&C Act defines "cosmetic" to include articles used as components of cosmetic products (21 U.S.C. 321(i)). The available safety information on cosmetic talc has recently been reviewed (Wehner, 1994). Of particular concern has been the suggestion that perineal exposure to talc may increase the risk of ovarian cancer (Harlow et al., 1992), and that inhalation exposure to high concentrations of talc particles can lead to pulmonary tumours in rodents (NTP, 1993).

Critics of the supposed association between talc and ovarian cancer highlight the reported weak associations and the numerous confounding variables (e.g., interview case/control comparisons, failure to adequately address key independent risk factors, etc.) which characterize much of the epidemiological research in this area (Gross, 1994). Further, experimental studies in which neutron-activated talc was repeatedly introduced into the vagina of cynomolgus monkeys (*Macaca Fascicularis*), failed to demonstrate translocation to the cervix, uterus or ovaries (Wehner, et al., 1985; Wehner et al., 1986). The results of these studies in monkeys suggest that any increased risk of ovarian cancer following perineal exposure to talc is biologically implausible. While deserving further study, a causal association between perineal talc application and ovarian cancer appears improbable at this time.

Consumers are exposed to talc during the application and use of body powders. In this regard, human exposure to cosmetic talc occurs principally via the dermal route, but primary concern has focused on exposure via the respiratory tract. Talc miners and millers are exposed to long-term, relatively high concentrations of airborne talc; the results of human cohort studies involving cosmetic grade talc miners and millers thus provide a useful basis against which pulmonary risk to consumers may be estimated (Scansetti et al., 1963; El-Ghawabi et al., 1970; Rubino et al., 1976; Gamble et al., 1982; Wegman et al., 1982; Leophonte et al., 1983; Wergeland et al., 1990). These studies show that a pneumoconiosis (talcosis) risk does exist but only when respirable

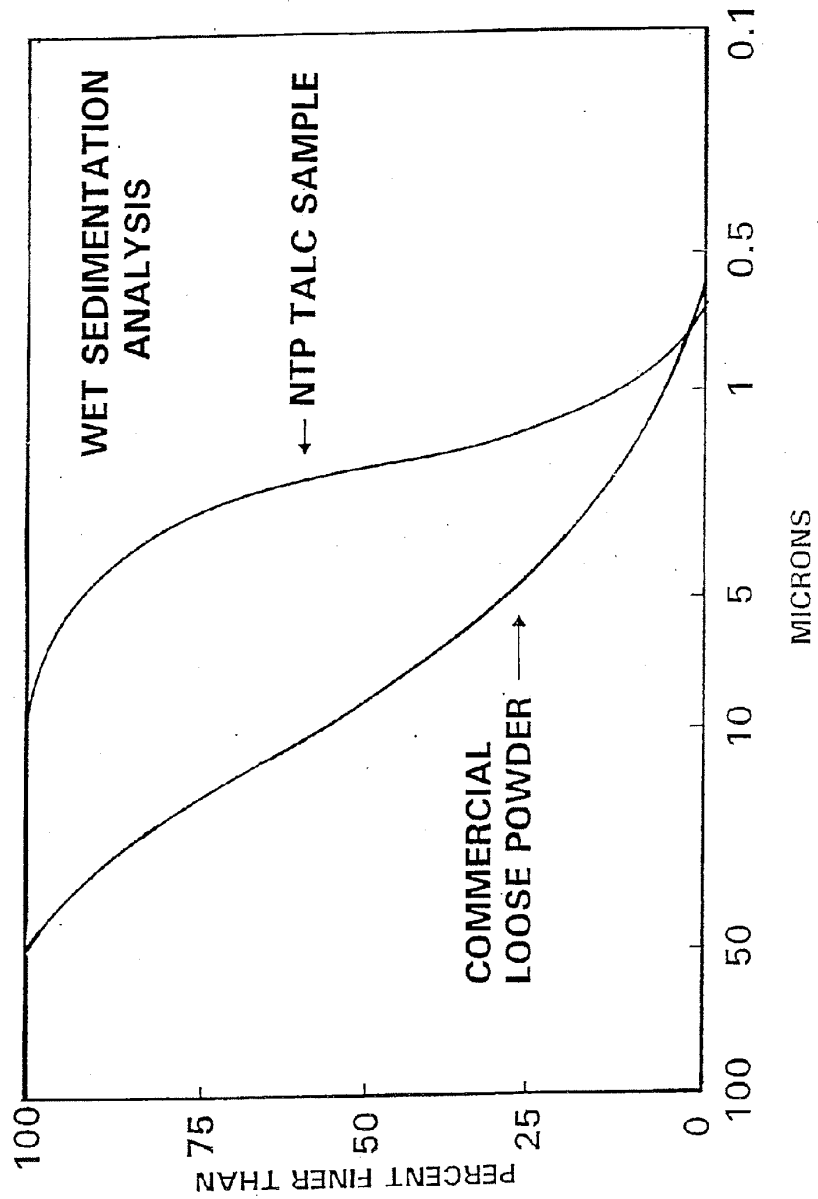
talc dust levels are significantly greater than worst-case consumer exposures (described below) and exposure is over an extended period of time (several years). While there may be disagreement over the amount of exposure required to induce pneumoconiosis, such studies suggest that talc poses a low to moderate pulmonary risk in an industrial setting. For example, in a mortality and morbidity study of Italian talc miners and millers, radiographic abnormalities consistent with pneumoconiosis were found among talc workers after an average duration of exposure for 22 years, with an average respirable dust concentration of approximately 11 mppcf (Rubino, et al., 1976); in contrast, in a study involving French talc workers, no cases of pneumoconiosis at a level of 15 mppcf were reported (Leophonte, et al., 1983). Although, it is difficult to reliably convert respirable particle count data (mppcf) into respirable gravimetric data (mg/m^3), such levels typically fall into the 1-2 mg/m^3 range (e.g., in a study of Vermont talc miners and millers (Boundy et al., 1979), pneumoconiosis was observed when respirable dust levels ranged from 0.5 to 2.9 mg/m^3). Despite the incidence of pneumoconiosis at high industrial exposure levels it is important to note that an excess prevalence of lung cancer in talc mining populations has not been observed (Selevan et al 1979; Leophonte et al., 1983; Wergeland et al., 1990; Rubino et al., 1976).

Electrostatic, Van der Waals and valance charges present on the particulate surfaces of a dry powder such as talc result in substantial particle-to-particle agglomeration (see e.g., Figure 4), thereby increasing effective mass, diameter, and settling



hsm 8

Figure 9



velocity (Carta et al., 1981; Gajewski, 1990). Two studies have been conducted to evaluate exposures to respirable particles during application of talc as an adult body powder and as a baby powder (Russell, et al., 1979; Aylott, et al., 1979). In both studies, respirable particles (≤ 10 microns) were collected using a cyclone particle fractionation system operating at an air flow rate of 1.7-1.9 liters/minute. Adult exposure was assessed during normal face/body powdering practices by placing cyclone collection units on shelves at appropriate face height, or by positioning a cyclone attached to a headband near the nose (i.e., in the subjects' breathing zone). To evaluate the exposure of babies to talc, sampling units were placed on the changing table near a baby's (or doll's) head during normal powdering practices (i.e., while changing a diaper). Talc was dispensed using common twist-top, sprinkle-type containers, or in the case of face powder, powder puffs. Exposure of adults to respirable particles during application of talc ranged from 0.48 to 2.03 mg/m³, while the exposure to babies ranged from 0.19 to 0.21 mg/m³ (Table 6). When these numbers are extrapolated to 8-hour time weighted average exposures, they range from <0.001 to 0.005 mg/m³. For comparison purposes, the current OSHA/ACGIH permissible industrial exposure limit for talc is 2.0 mg/m³ as an 8 hour time weighted average (ACGIH, 1992), i.e., the industrial permissible limit is approximately 350 times greater than the worst case consumer use of cosmetic grade talc.

Based upon the determinations reported in the literature, human exposure to respirable talc particles during normal product

use are approximately 2,000-20,000 times lower (Table 7) than those used to expose rats and mice in inhalation studies conducted by the National Toxicology Program (NTP) (NTP, 1993). Although a direct comparison of the dosimetry of inhaled materials between rodents and humans is far from simple (Dahl et al., 1991), such a broad difference in exposure level is quite striking. The incidence of tumors resulting from massive exposures such as those involved in the NTP talc inhalation study are more likely to reflect a particle overloading effect in the experimental animals (Morrow, 1988; Morrow, 1992; Oberdorster, 1988) than any genotoxic effect associated with the test material (Endo-Capron et al., 1993). Moreover, it should be emphasized that the talc sample utilized in the NTP study was not a product that would be used in a cosmetic powder application because of its extreme fineness. SEM Photomicrographs comparing the NTP sample with a typical body powder are shown in Figure 8. The test material used by NTP is an industrial grade product typically used in specialty coatings and high performance polymeric applications. The median particle size of the NTP talc sample (sedigraph analysis) was approximately 1.2 microns; 100% of the particle size distribution was below 10 microns (Figure 9). Further, the NTP talc aerosol was exposed to Kr-85 gamma radiation immediately prior to its introduction into the exposure chambers containing the experimental animals. Use of ionizing radiation was intended to neutralize the electrical charge imparted on the talc particles during aerosolization. Charge neutralization tends to decrease agglomeration and results in deposition of particles in the deep lung of exposed animals. Thus, while selection of an ultra-fine talc product combined with

procedures designed to maximize particle dispersion may be entirely appropriate from a toxicological perspective, such an artificial environment has questionable relevance with regard to actual human exposure from commercial cosmetic talc products under use conditions.

CONCLUSIONS

Used for decades in a wide variety of cosmetic and other applications, talc has proven to be among the safest of all consumer products. The talc industry has adopted stringent quality assurance standards set by the Food Chemical Codex, the United States Pharmacopeia and the Cosmetic, Toiletry and Fragrance Association (FCC, 1981; USP, 1990; CTFA, 1990a). A thorough review of the literature provides no convincing evidence that cosmetic talc, when used as intended, presents any health risk to the consumer (Wehner, 1994). Although all dusts in sufficient quantity and form (i.e. size, durability, physicochemical properties, etc.) are capable of causing adverse pulmonary effects (Morrow, 1992), consumer exposure to talc is minimal (Aylott, et al., 1979; Russell, et al., 1979). The most frequently applied talc dust standard in the United States for industrial exposures is 2 mg/m³ of respirable talc dust averaged over an 8 hour work day (ACGIH, 1992). This permissible exposure level is approximately 350 times greater than the consumer use of talc likely to result in greatest potential exposure.

ACKNOWLEDGMENTS

The authors wish to thank Dr. Malcolm Ross (U.S. Geological Survey) for his critical review of the manuscript, and Pandora Dennis (CTFA) for careful manuscript preparation.

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Figure 1. U.S. Talc Consumption. Talc utilized in direct cosmetic applications accounts for a relatively small percentage of the overall talc market (900,000 tons/year) (American Westmin, Inc./Luzenac America, unpublished data).

Figure 2. Talc: Molecular Structure.

Figure 3. Talc Mineralogy. SEM of typical talc body powder (original magnification 5000X) showing the laminar nature of talc, consisting of stacks of individual sheet-like, or "platy", crystals held together by weak Van der Waal's forces.

Figure 4. Talc Characterization. Typical talc body powder (original magnification 500X). Computer-controlled scanning electron microscopy (CCSEM) enables automated characterization of the size and shape of large numbers of individual talc particles. The existence of electrostatic, Van der Waals and valence charges present on the surface of individual talc particles results in substantial particle-to-particle agglomeration.

Figure 5. Particle Size Distribution. Comparison of the particle size distribution of a typical cosmetic talc product as determined by both wet sedimentation and Computer Controlled Scanning Electron Microscopy (CCSEM).

Figure 6. Cosmetic Talc Applications: Physical Attributes. SEM of typical body powder talc sample (original magnification 5000X). The sheet-like, or "platy", layers of talc are held together by weak Van der Waals forces. Application of shear causes individual plates to slide over each other; individual talc platelets can yield and bend without fracturing.

Figure 7. Cosmetic Talc Applications: Body Powders. SEM (original magnification 1000X) of a typical commercial body powder (200 Mesh). Note the substantial agglomeration of small particles.

Figure 8. Comparison of a Typical Loose Powder with NTP Talc Sample. SEM's (original magnification 500X) of a typical loose body powder with the talc sample used by the National Toxicology Program (NTP) in 2-year rodent inhalation studies (NTP, 1993). Particle size distributions of the two samples are shown in Figure 9.

Figure 9. Comparative Particle Size Distribution. Particle size distribution of typical commercial loose powder compared to NTP talc sample (NTP, 1993) as determined using wet sedimentation analysis.

Table 6. Consumer Exposure Data

	AVE. RESP. DUST mg/m ³	SINGLE EXP. DURATION (Minutes)	DAILY FREQ. OF ACTIVITY	EQUIV. 8 Hr. TWA RESP. DUST mg/m ³
ADULT FACE APPLICATION ⁽¹⁾	0.48	0.30	1	0.0003
ADULT BODY APPLICATION ⁽¹⁾	1.13	0.75	1	0.0018
BABY DIAPERING ⁽¹⁾	0.21	0.345	5	0.0008
ADULT BODY APPLICATION ⁽²⁾	2.03	1.38	1	0.0058
BABY DIAPERING ⁽²⁾	0.19	0.50	5	0.0010
ACGIH TWA ⁽³⁾				2.0000

Assessment of consumer and baby exposure to respirable talc particles during application of adult body powder/baby powder under normal conditions of use. Data from ⁽¹⁾Aylott et al (1979) and ⁽²⁾Russell et al (1979). ⁽³⁾Actual exposures have been recalculated as equivalent 8hr time-weighted average (TWA) exposures to allow for comparison with permissible industrial exposure limits (ACGIH, 1992).

Table 7. Comparison of Consumer Exposure During Normal Conditions of Use with NTP 2-year Inhalation Rodent Exposures.

STUDY	DAILY EXP. mg Hrs/m ³	DAILY RODENT EXPOSURES (NTP) EXPRESSED AS MULTIPLES OF DAILY ADULT/INFANT EXP.	
		6 mg/m ³ 36 mg Hrs/m ³ **	18 mg/m ³ 108 mg Hrs/m ³ **
ADULT ⁽¹⁾ FACE	0.0024	15000	45000
ADULT ^(1,2) BODY	0.014-0.046	782-2571	2347-7714
BABY ^(1,2) DIAPERING	0.0058-0.008	4500-6206***	13500-18620***

Ratio of measured exposure concentrations of respirable talc particles (Aylott et al., 1979; Russell et al., 1979) with rodent exposures in the NTP 2-year inhalation studies on talc. Actual chamber talc concentrations; calculated daily talc exposures (mg hrs/m³) based upon 6hr exposure interval. Ratio of rodent: consumer exposure for baby diapering based upon 5 applications/day.