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TALC:
A Basic Review of Its Safety and Usefulness
Professional Information for Physicians, Nurses
and Other Health Professionals

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FOREWORD

Talcum powder has been used for many centuries as a cosmetic. Baby powder, which contains cosmetic talc, has been used as a safe and effective product for over 80 years. Baby Powder is effective in providing lubricity to prevent chafing. It is also an adsorbant and drying agent in body areas susceptible to collection of moisture. The safety of baby powder is substantiated through exhaustive studies.

The purpose of this document is to comprehensively review the data from the carefully designed and performed work on cosmetic talc in order that professionals in the medical area can be made aware of the most recent developments in the field. Recent work in the sense of touch in infant development has shown tactile responsiveness and sense of protectiveness to have important impact on emotional growth of a child. Application of baby powder can mediate this unspoken conveyance of reassurance.

It is hoped that physicians, nurses, and other health professionals will find this review informative, and that it will assist them in answering any questions about baby powder that may be encountered in course of contact with their patients and other lay individuals.

TALC OVER THE CENTURIES

Over the centuries talc has been known by many other names: steatite, stella terrae, talq, Katzensilber, lardstone, soapstone, and hydrous magnesium silicate. Talc, the name now well established in everyday use, is a chemical compound, a natural mineral, and a commercial product with a wide variety of applications.¹

A Chemical Compound

Pauling² formulated the structure for talc in 1930 and suggested that a layered configuration accounted for its smoothness and softness to the touch. The diagram of talc's atomic structure in Figure I illustrates the manner in which the three layers, two silica sheets and a central "brucite" sheet of magnesium ions, are loosely packed together in a lattice-like arrangement. This molecular configuration allows the talc layers to slide across one another giving the very useful characteristic known as "slip".²

(Insert Figure I)

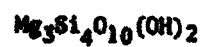
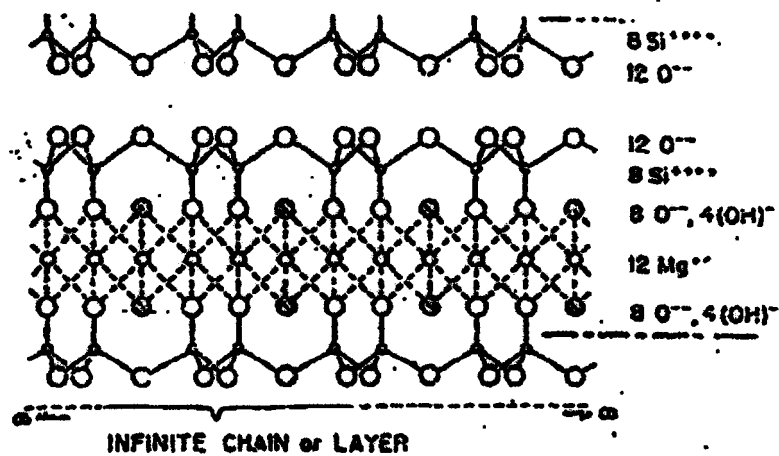
A Mineral

Talc (hydrous magnesium silicate) is a member of the silicate family of minerals; it is most often found, naturally, in metamorphic rocks. This means that it is essentially a

Figure I.

Atomic Structure Formula of Pure Talc Compound

(from Chudzikowski, R.J.¹)



"secondary type of mineral -- one formed as a result of environmentally caused changes in its "parent" rock.¹

The country that mines and processes the largest amount of talc is the United States, followed in order by China, France, Italy, India, and Canada.¹ Large quantities are available in many locations. Talc is often white to light green, but it may be yellowish to reddish in color.³ It is lustrous, soft, and chemically inert.¹

A Product

The Ancient Chinese, Assyrians, and Egyptians used cosmetic grade talc rock for carving.¹ Over the centuries, talc in a variety of grades has played a part in the production of an increasing number of manufactured items, including ceramic tile, cosmetics, health care products, leather goods, machinery, paint, paper, pharmaceuticals, processed food, roofing, and rubber goods.³ However, talc probably is most familiar to the majority of people in its role as "one of the oldest, most important, and most commonly used ingredients of cosmetics and toiletries".¹

COSMETIC TALC EFFECTIVENESS

In the classic, The First Five Years of Life, Gesell⁴ makes the oft-quoted remark that "Of all infants, the human infant is at birth the most helpless." Gesell points out that a 4-week-old infant is, except for its crying, "almost inarticulate," and that although sounds are heard, they cannot be discriminated. It is as though the infant were "staring" at sounds in the same way it simply stares at the objects and people in its environment.

Infants and Touch -- Psychological Aspects

As early as 4 weeks, however, Gesell says that there is a tendency for the infant to be soothed when it is picked up and wrapped up warmly and snugly. He comments that the infant "probably feels a dim sense of security from calm and assured handling."⁴ Gesell believes that the infant's "tactile responsiveness and sense of protectedness" have "social import."⁴

For a baby, bath time can be one of the highlights of the daily routine. The picking up, wrapping up, and cuddling that occur after the bath appear to be particularly pleasurable for both infant and parent. Diaper changing can also provide important opportunities for contact between parent and child. At these times the mother or father has the ability to bring love and physical comfort to the child by making sure that he or she is clean, warm, and dry. As Leboyer has said in Birth

Without Violence. "It is through our hands that we speak to the child, that we communicate. Touching is the primary language... It is a language of skin-to-skin..." 5

Effects of JOHNSON'S Baby Powder on the Skin

The use of JOHNSON'S Baby Powder for infants has become a tradition in the United States since it was introduced to physicians, midwives, and mothers in 1894. Over the years, the popularity of this product has spread throughout most of the rest of the world.

There are some functional reasons for this wide acceptance. The soft platy talc from which JOHNSON'S is made enables it to adsorb residual moisture that coats an infant's skin even after towel drying and helps the skin stay dry afterward, even in hot weather. When JOHNSON'S Baby Powder has been dampened by a wet diaper, its platy crystals retain their lubricity, minimizing chafing from the diaper. After careful powdering with JOHNSON'S, an infant's skin is well lubricated, even in the folds and creases. It feels smooth and is protected from rubbing and chafing.

Use in Adults

Many adults have long recognized that the benefits of JOHNSON'S Baby Powder need not be restricted to babies. Adults, too, can suffer from rubbing and chafing, especially in warm weather, and their skins can retain a thin film of moisture after toweling. The same silky talc platelets adsorb excess moisture from adult skin and lubricate, protect, and impart a smooth feeling.

HISTORY OF JOHNSON'S BABY POWDER

JOHNSON'S Baby Powder is an institution. For many years it has been a familiar sight in millions of homes, used by millions of parents in caring for young children. Its sweet-smelling fragrance has become associated with freshness, comfort, and cleanliness.

Johnson & Johnson was aware of a need for a powder that could be used upon tender skin. In 1894, the new powder was added to the Maternity Kit then sold to doctors and midwives. New mothers liked the powder. Finally, in 1895, it was named JOHNSON'S Baby Powder and made commercially available.

HOW JOHNSON'S BABY POWDER IS MADE

JOHNSON'S Baby Powder is made from a cosmetic grade talc that contains an unusually high proportion of smooth platelets. This talc comes from a mine at Windsor, Vermont, that is owned and operated by Windsor Minerals, Inc., a subsidiary of Johnson & Johnson.

The talc used in JOHNSON'S Baby Powder is processed by means of a unique refining method.

(Insert Figures II, III, and IV, which are various outside summer color pictures of Windsor Minerals Buildings.)

After it is mined and milled to fine particle size, the purity of the talc is assured by a unique flotation process that selects the platy-shaped talc particles for the final manufacturing process. In a froth of talc, water, and air bubbles, the best of the platy particles rise to the top and are skimmed off. This process effectively washes out non-platy particles, because the flat sides of the tiny talc plates adhere to the bubbles and float. Non-platy particles sink to the bottom. The flotation process is repeated several times until the non-platy impurities have dropped out and the purified talc can be dried by exposure to intense heat and stored in a large silo. From there, the talc is piped into a tank truck that takes it to a manufacturing plant at North Brunswick, New Jersey, or shipped in bags to another manufacturing facility at Sherman, Texas. Within these plants, the pressure of filtered air is used to propel the talc through the mixing process in which the fragrance

is added, and on to the packaging lines.

The resulting product is platy, soft, and free from impurities. Because of its platiness, the product also has very good "slip". Pure talc content of the product is approximately 97%. A light fragrance is the only added ingredient.

An enormous amount of effort goes into the manufacture of JOHNSON'S Baby Powder. Quality control is complex and costly. Throughout the processing and packaging of JOHNSON'S Baby Powder, from the flotation process until the package is opened by the consumer, no one touches either the talc or the finished product. Samples of the talc are analyzed chemically and mineralogically at Windsor, Vermont, and microbiologically and mineralogically at New Brunswick, New Jersey. When the talc reaches the manufacturing plants, additional samples are removed for further analysis. The last sampling for analysis is done at the end of the finishing line, where packages of the product are pulled from the line for a final check. Only after it has been positively determined that the product meets established high standards and that no potentially harmful contaminants are present, packages of JOHNSON'S Baby Powder are released for distribution.

(Insert Figures V and VI which are microbiological and mineralogical examination photos)

The first statement in the official Johnson & Johnson credo is: "We believe that our first responsibility is to the doctors, nurses, hospitals, mothers, and all others who use our products. Our products must always be of the highest quality." Attitudes of this kind and the practices that spring

from them are part of the long tradition of concern with
safety in the health field at Johnson & Johnson.

SUMMARY OF SAFETY ASPECTS

It is clear in the following sections of this review that in normal consumer use of baby powder in infants, exposure levels are relatively low compared with currently permissible industrial levels. Epidemiologic and animal studies presented revealed no toxic effects from cosmetic grade talc or from the talc variety contained in JOHNSON'S Baby Powder. In light of these findings, normal consumer use of JOHNSON'S Baby Powder must be considered safe.

SAFETY ASPECTS OF TALC

Cosmetic talc-based consumer products, including baby powder, have been in widespread use for generations. Yet only recently did the need arise to review the effects, if any, of talc exposure, especially with respect to new information on possible trace contaminants and to share these findings with interested health care professionals. Interest in such a review has been stimulated by several developments. One was that small amounts of asbestos fibers had been detected in some samples of lesser known baby powders. Another was the misconceptions that grew out of the presence of the trace metals in baby powder. A third was that in a number of studies recently reported, the safety of cosmetic talc itself in products intended for consumer use was questioned. It is important, therefore, to explore these topics, to examine some new studies dealing with the biologic effects of talc, and to clarify the situation so far as baby powder is concerned.

In considering epidemiological and other evidence relating to the safety of talc and talc-based consumer products, at the outset it is important to recognize two distinctions, one qualitative and the other quantitative. The first is that there are two kinds of talc: industrial and cosmetic; the second is that there are two types of talc exposure; industrial (or occupational) and consumer.

Types of Talc

The composition of industrial grades of talc varies. One grade or another is selected because of properties specific to the purposes for which it is to be used. An industrial "talc" may be composed of talc and a number of other mixed minerals that may include asbestos. Some materials classified as industrial "talcs" may actually contain little or not talc. In contrast, the grade of talc commonly used in cosmetic and health care products today contains no less than 90% talc, limited amounts of other minerals, and no asbestos.³ Johnson & Johnson talc never has been found to contain asbestos and JOHNSON'S Baby Powder is 97% talc.

The presence or absence of asbestos (a fibrous material) is certainly of great importance from a health standpoint. According to an extensive recent review of the literature on talc,³ a number of studies have shown that inhalation of asbestos is a health hazard and can be carcinogenic above certain threshold levels. Thus it is important to recognize that although industrial grades of talc may contain asbestos, cosmetic grade talc does not.*

*
At one time, prior to full realization of the importance of the source of talc selected for eventual cosmetic purposes, asbestos was found in occasional samples. Since then, sources which have no asbestos contamination have been used exclusively. Tests of several hundred samples collected recently by the Food and Drug Administration from a number of different sources have revealed no asbestos. Cosmetic grade talc today, in fact, is extremely pure.

Types of Talc Exposure

Vast quantitative differences exist between talc exposure in talc workers and some other industrial workers exposed to mixed mineral dusts, and exposure in consumers using normal amounts of cosmetic talc and talc-based health care products.

Prior to implementation of modern environmental controls, some mine and industrial workers were exposed for lengthy periods to very high concentrations of mixed mineral dusts.³ Pulmonary morbidity in some such situations was high, with some workers developing pneumoconiosis. As a result, dust concentration limits were set by the Federal government with current threshold limit value (TLV) in the United States for talc in industry being 20 million nonfibrous particles per cubic foot (20mppcf) and 56,632 fibers per cubic foot.⁸ Available data³ indicate that the establishment of such TLV's have been effective in reducing the incidence of cancer among miners and millers to that level observed in the general population, and also in reducing the incidence and severity of pneumoconiosis.

Consumer exposure to cosmetic talc is limited greatly by two important conditions: its normal short duration of use and its low concentrations during and following use.

Figures for consumer exposure were obtained from a study designed to pinpoint, as precisely as possible, the extent of exposure associated with use of baby powder. Product use was studied in 76 mothers caring for their infants. In 62% of

applications, only the diaper area was powdered; in 20%, the whole body except for the head, and in 18%, other body sites. Powder was applied either by direct application to the infant's skin or by putting the powder in the mother's hand before application. Powdering of infants occurred one to nine times daily, with duration of powdering ranging from 3 to 25 seconds. Median frequency was five powderings of the diaper area per day. Median duration of powdering was 10 seconds.

From these experiments, it was estimated that during an application lasting 10 seconds, median concentration for both mother and child was 0.243 mppcf and that during the subsequent 1.08 minutes, when the powder was settling, median concentration was 0.124 mppcf.⁶ These data are summarized and compared with the government-established TLV in Table 1.

(Insert Table 1: TLV, etc.)

Calculation of the ratio of the TLV to infant and maternal exposure ($800/0.1024$) reveals that the permissible exposure in industry is approximately 7800 times greater than the median exposure of infants and mothers during and after use of JOHNSON'S Baby Powder.⁶

A controlled study⁷ was made of the biologic effects on Syrian golden hamsters of inhalation of test samples of JOHNSON'S Baby Powder. These animals were exposed to aerosols containing excessive levels of talc for up to 300 days (Figure II). There

Table 1.

TLV (U.S.) for Talc Compared with Median Infant and
Maternal Exposure During and After Powdering of Infants.⁶

	mppcf	Hours per week	Weekly mppcf - hours	Weekly mg-hours/m ³
TLV (Talc Mining)	20	40	800	4000
Infant and Maternal Exposure During Powdering	0.243***	0.10*	0.0243	0.122
Infant and Maternal Exposure After Powdering	0.124***	0.63**	0.0781	0.391
Infant and Maternal Exposure During and After Powdering			0.1024	0.513

* 10 seconds (median), 5 times a day for 7 days: $10 \times 5 \times 7 = 350$ seconds
= 5.83 minutes = approximately 0.10 hours.

** 65 seconds (median), 5 times a day for 7 days: $65 \times 5 \times 7 = 2275$ seconds
= 37.9 minutes = approximately 0.63 hours.

*** Estimated from F.D. Pooley Laboratory Powdering Experiments.⁶

was no effect on mean body weight, morbidity, mortality (Figure III) or type and incidence of histopathologic changes in the exposed group, and it was concluded that treatment had no effect on occurrence of neoplasms.

Results of a subsequent study⁶ in 48 human mothers and 48 babies under 16 months of age showed that powdering time (in a subgroup of 35 mothers and babies) ranged from 2 to 10 seconds (average, 4.6), amount of powder used from 0.11 to 2.10 grams (average, 0.79), and average concentrations during three trials from 0.07 to 0.39 mg/m³ (average, 0.21 mg/m³). In another subgroup of 13 mothers and babies, average concentrations was 0.15 mg/m³. Based on these results, it is estimated that maximum exposure to JOHNSON'S Baby Powder among the Syrian golden hamsters was approximately 1700 times greater than the average exposure of infants diapered by their mothers on a five-times-daily basis.

(Insert Figure VII)

Following a more recent hamster study⁶, it was estimated that in animals receiving a single two-hour, nose-only exposure to a talc aerosol of JOHNSON'S Baby Powder 6% to 8% of the inhaled material was deposited in the alveoli. Alveolar clearance was reported to be essentially complete four months post-exposure. After clearance from the lung the talc appeared to have been swallowed and passed through the gastrointestinal tract. No translocation of JOHNSON'S Baby Powder to liver, kidneys, ovaries, or other parts of the body was found.

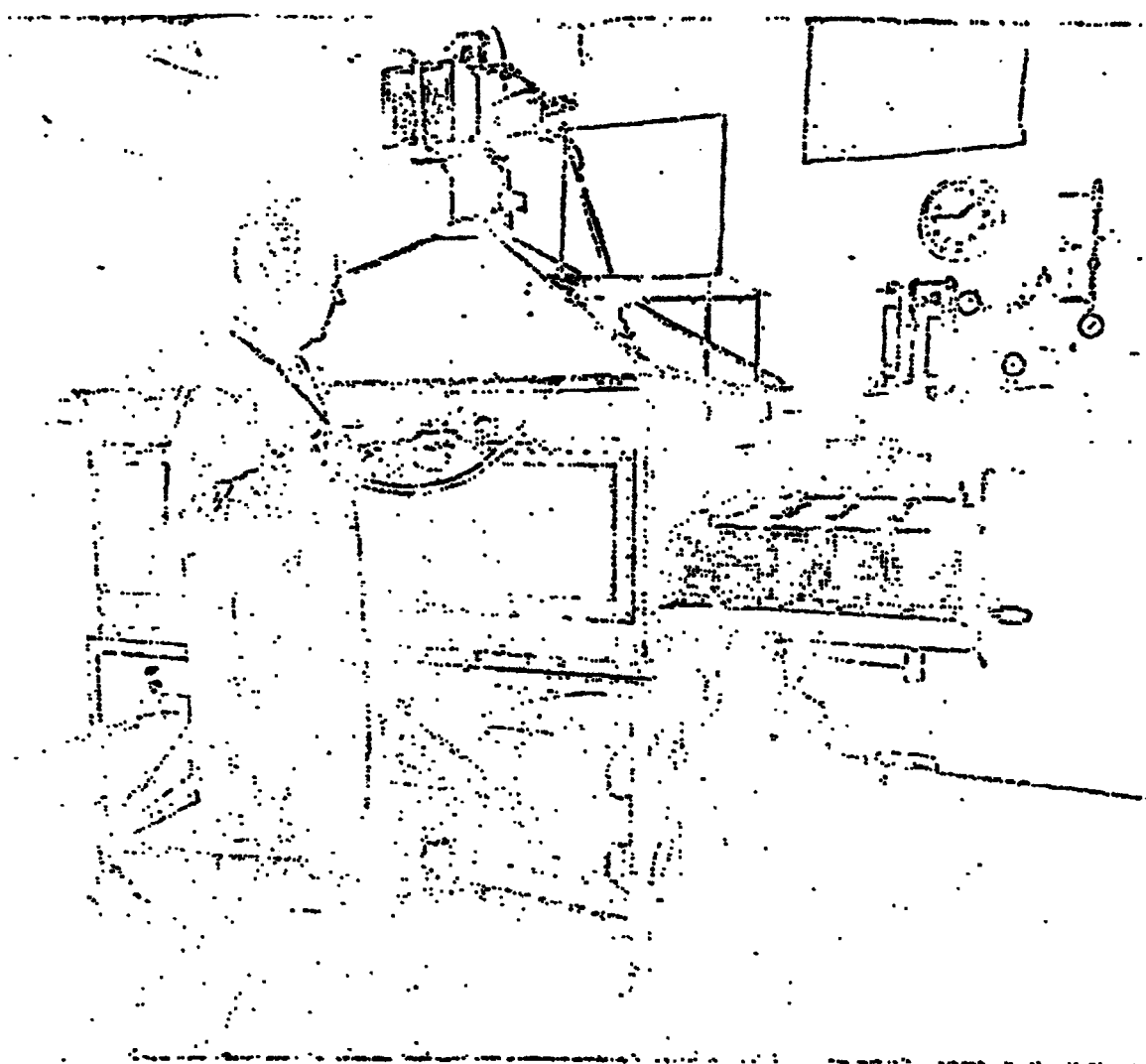


Figure VII

Aerosol exposure system used in a controlled study of the effects on animals of inhaled test samples of JOHNSON'S Baby Powder.⁷

From
Wehner,
1975

Trace quantities of naturally occurring metals can be found by sophisticated chemical analyses to be bound within the talc lattice structure. This particular chemical configuration does not usually allow the metals to be biologically available. It has been calculated⁶ that if all the metals in talc were available to be taken into a child's body, it would represent only a small fraction of the metals that are normally ingested by a child from its normal food diet.

Other Studies of Talc Exposure

Although human exposure to talc is the focus of this brief safety review, studies of cellular response and mutagenic, teratologic, and other animal studies reveal additional significant data in support of the safety of cosmetic talc.

Cellular Response

After reviewing cellular response studies,³ it was concluded that cosmetic grade talc is not an allergen and that, when introduced into the body, platy talc alone produces minimal cell toxicity. Platy talc is generally inactive, in contrast with a number of fibrous materials.

Mutagenic Studies

The mutagenic potential of cosmetic grade talc has been assessed by host-mediated assay, dominant lethal assay, and cytogenetic study techniques in vitro and in vivo.⁶

Talc dose levels of 2, 20, and 200 mcg/ml were compared in the in vitro tests with 0.1 mcg/ml of the positive control triethylene melamine. Host-mediated assay results were negative,

Other Animal Studies

Animal studies of talc administered orally, intra-tracheally, or injected into the peritoneum or pleural space also showed no evidence of tumor production. These animal data indicated that talc is not carcinogenic.³

IN CONCLUSION

JOHNSON'S Baby Powder is probably much better known and liked than understood. Johnson & Johnson is anxious, however, that consumers should not only know and accept the product but understand some important facts about it as well.

As medical professionals, the physician and nurse are prime sources of guidance and factual information for many individuals and families. That is one of the reasons Johnson & Johnson is pleased to have had this opportunity to share some background information and scientific data concerning JOHNSON'S Baby Powder.

Many of the mothers who seek professional advice today concerning child care or other matters were themselves cared for, as infants, with JOHNSON'S, and will tend to trust it instinctively. As intelligent parents and consumers, however, they may be interested in learning about some of the key points discussed in this review. In particular, they will want to know...

- that JOHNSON'S Baby Powder can provide an effective medium through which conveyance of touch to an infant is made. This sense of touch in infant development has been shown to have an important impact on a child's emotional growth;
- that JOHNSON'S Baby Powder is an adsorbent and drying agent in body areas susceptible to collection of moisture;

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- that JOHNSON'S Baby Powder can provide an effective medium through which conveyance of touch to an infant is made. This sense of touch in infant development has been shown to have an important impact on a child's emotional growth;
- that JOHNSON'S Baby Powder is an adsorbent and drying agent in body areas susceptible to collection of moisture;

- that JOHNSON'S Baby Powder contains no asbestos;
- that any naturally occurring trace amounts of heavy metals in JOHNSON'S have been shown to have no biologic effect whatsoever;
- that talc exposure in normal powdering of infants is approximately 7800 times less than the permissible exposure for talc workers in the United States;
- that the normal use of cosmetic and health products containing cosmetic grade talc is not a hazard to health.

In short, Johnson & Johnson is firm in its belief that JOHNSON'S Baby Powder is today, as it has always been, effective, useful, and safe.

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