J+J testing was inadequate (frequency + sample size)
Opinion: The frequency of and sample size for asbestos content evaluation by J&J was inadequate to assure the absence of asbestos.

Basis: Asbestos is often present in talc.

1. See Longo testing
2. See summary of positive results for asbestos in talc
3. PCPC0080760 - 65

- They also state: "Mineralogically, there are two forms of talc: Nonasbestiform, also called platy or nonfibrous, and Fibrous, also called tremolitic."

- Their paper contains the following paragraph: "A different study [from the 1971 Henderson et al. report] reported in mid-1971 by the Environmental Sciences Laboratory, Mt. Sinai School of Medicine, The City University of New York, revealed that significant amounts of asbestos were present in two brands of commercial, household-use fibrous [sic] talc dusting ("talcum") powder. As a result, the US Food and Drug Administration announced that if such results were to be corroborated by an independent expert panel, it would ask the manufacturers to recall such "talcum" powders. It is of interest that independent geologists informed the FDA that talc and asbestos can appear in the same mines, and that contamination could be caused at that source."

The two citations given at the end of the above paragraph were: “18. Trade and government memos, in F-D-C Reports 33:1, July 12, 1971.”; and “19. Trade and government memos, in F-D-C Reports, 33:12, July 19, 1971.”
Mineral Content of Post-1976 Cosmetic Talc

*Blount AM and Vassiliou AH. 1983. Identification of chlorite and serpentine in cosmetic or
Authors, affiliated with Cyprus Minerals, emphasized that there is a great variety in talc compositions, with, for example, New York talc having high asbestos content, while Montana talcs are of unrivaled purity.

The most commonly occurring asbestos fibers in talc are tremolite and anthophyllite, with some occurrences of chrysotile.

Scanning electron microscopy is the most reliable detection means. Optical microscopy has a definite potential for distorting the analysis. The authors illustrate how a typical curled-edge platelet of talc would be identified as two particles, one fibrous, and the other plate-like, due to limited depth of focus. SEM also has advantage over TEM-SAED for initial screening (ability to examine a 10x larger sample), the latter of which can positively confirm the identity of fine particles. X-ray diffraction is of limited value, as it will not detect a large number of fibers, though it is valuable for screening and characterization of deposits.


Abstract in English states: "Nineteen industrial, pharmaceutical and cosmetic talc samples sold on the Italian market were examined by optical microscopy techniques (phase contrast and dispersion staining) in order to assess their mineral fibre content. The percentage by count of asbestos fibres respect to total particles was in the range of 0.2-3.2. Chrysotile and amphiboles (tremolite and/or anthophyllite fibres) were found in most samples. The amphibole particles were often present in fragment form. Chrysotile fibres nearly always showed diameters of 0.3 μm and aspect ratios of ≥ 10:1; most of the amphibole fibres had diameters between 0.5 and 2 μm and aspect ratios between 3:1 and ≤ 10:1. In the majority of samples an asbestos weight percentage considerably less than 1% was found."


Examined talc powders used as excipients and in cosmetics from Italian and European sources to ascertain asbestos content. Overall fibrous particle percentages ranged from 2 to 30 percent in all of the powders analyzed. 8 out of the 15 Italian samples showed asbestos via electron microscopy. In 7 samples there were fibers of tremolite, and in sample there fibers of chrysotile. There was asbestos in 6 out of the 14 samples provided by the European Pharmacopoeia. In 3 of those samples there was chrysotile; in 2 the amphiboles tremolite and anthophyllite were present; and in 1 there was tremolite and chrysotile. In the 2 samples with amphibole asbestos, the amount reached about 20 percent of the total particle mass. Table 9 shows percentage of six samples identified as cosmetic talcs. In those talcs, the percentage of total fibrous content ranged from about 3 to 21; and the percentage of asbestos ranged from about 1.5 to <0.1. At 231. The authors noted that the only regulations existing on the international market were those promulgated by CTFA in the U.S.


"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 and Langer, 1974; Krause and Ashton, 1978; Parmentier and Gill, 1978), the idea that asbestos is commonly and intimately associated with talc is simply incorrect. 225

- While serpentine asbestos can be located in proximity to pure talc in mineral deposits, appropriate selection of mine sites, careful mining processes, and utilization of modern beneficiation techniques allow avoidance of the serpentine portion of the deposits, and safeguarding against asbestos contamination. In addition, companies are able to confirm the absence of asbestos minerals in the finished product by using X-ray diffraction, optical microscopy, and electron microscopy techniques. 225-26.


Observed that talc deposits may contain considerable amounts of asbestos, and that optical microscopy and x-ray diffraction would leave undetected very large numbers of asbestos fibers which might be present in talc end products.


Explains the properties of cosmetic talc and the mineral deposits they come from, and how cosmetic talc "bears no resemblance to the many industrial talcs that have fallen under investigation recently for a variety of reasons." 33

Discusses identification of various chlorite minerals in cosmetic or pharmaceutical talc via X-ray diffraction, and notes the difficulty in distinguishing chlorites from hazardous chrysotile asbestos variety of serpentine. Suggests need for more detailed examination via optical and electron microscopy when serpentine is identified in talc.


Blount examined 10 U.S. samples (5 from deposits in MT, 3 from VT, and 1 each from AL and NC), and 4 foreign samples available in the U.S. using a centrifuge microscopy method. All samples were well below an amphibole particle count which the FDA has equated with 0.1 percent.


- Discusses results of studies of fibrous content of talc mined in New York, apparently principally at the Gouverneur Talc Co. mine. Maintains that NIOSH studies of the New York mining and milling operations showed the presence of asbestos. Mining operations showed fibrous content in the range of 0.8-9.8 TWA; milling showed a range of 0.2-16.0 TWA. “Of all the fibers analyzed, 12-19% were identified as tremolite, 38-45% as anthophyllite, 1-2% as nonasbestos fibers and the remaining 38-39% not identified as asbestos.”

- “many of the fibers which we did not identify as amphiboles by electron diffraction are in a state of alteration between amphiboles and talc and actually may not belong to any given mineral category. These fibers are also very fine in diameter and may not be specifically identified by optical microscopy alone.”

- “[T]hese talcs do contain fibrous talc, they also contain up to 15% anthophyllite as stated in our [earlier] letter.” [No citation to earlier letter.]

- “Rohl found abundant fibrous particles in all samples analyzed. Many of these fibers were identified as amphiboles by electron diffraction. Rohl identified the long, then amphibole fibers as anthophyllite while the shorter prismatic amphiboles were identified as tremolite.”

- Table II shows percentage of fibers ≥ 5 µm analyzed by electron microscopy as 7 percent tremolite, 65 percent anthophyllite, and 25 percent not positively identified.

- “…New York talcs do in fact contain asbestos fibers.”


4. J&J testing frequency and sample size inadequate

**MATERIAL SPECIFICATION**

**BABY PRODUCTS COMPANY**

**SUBJECT:** WINDSOR 66 TALC

8. **FREQUENCY OF CHARACTERISTICS TO BE TESTED**

<table>
<thead>
<tr>
<th>No.</th>
<th>Characteristic</th>
<th>T.M.</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>2A.</td>
<td>Asbestos(a)</td>
<td>CTFA/41-1</td>
<td>Per Note 1A</td>
</tr>
<tr>
<td>2B.</td>
<td></td>
<td>TH 7024</td>
<td>Per Note 1B</td>
</tr>
<tr>
<td>3.</td>
<td>Moisture</td>
<td>7164</td>
<td>Certified per 2</td>
</tr>
<tr>
<td>4.</td>
<td>Sulubility by Acid</td>
<td>7165</td>
<td>Certified per 2</td>
</tr>
<tr>
<td>5.</td>
<td>Magnesiu (MgCO3)%</td>
<td>7171 or 7077</td>
<td>Certified per 2</td>
</tr>
<tr>
<td>6.</td>
<td>Bulk Density</td>
<td>7166</td>
<td>Certified per 2</td>
</tr>
<tr>
<td>7.</td>
<td>Color</td>
<td>7170 or 7071</td>
<td>Certified per 2</td>
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<tr>
<td>8.</td>
<td>Finessness</td>
<td>7167 or 7070</td>
<td>Certified per 2</td>
</tr>
<tr>
<td>9.</td>
<td>Heavy Metals</td>
<td>7168</td>
<td>Certified per 2</td>
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<tr>
<td>10.</td>
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<td>7169</td>
<td>Certified per 2</td>
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<tr>
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<td>Water Soluble Iron</td>
<td>USP</td>
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<tr>
<td>12.</td>
<td>Microbal requirement</td>
<td>7807</td>
<td>Every lot-See 3</td>
</tr>
</tbody>
</table>

**NOTE:**

1A. A composite sample is made from every two completed silos, labeled with silo numbers and production dates and forwarded to J & J Baby Products for x-ray diffraction. Results are reported to Windsor Minerals.

5. **ITA-Sabatelli-999. 1988 Due diligence**

"Asbestiform Testing"

West Windsor Mill - No asbestiform testing is conducted by Windsor Minerals. Samples of ore and finished product are sent to J & J labs and McCrone for testing and certification. The samples sent to J & J (Skillman, NJ Lab) are composite samples from two, 300 ton silo composites (approximately two samples per month). J & J analyzes the samples according to CTFA J 4-1 methodology.

The McCrone sample is comprised of a monthly composite of the flotation feed material. All records indicate that no asbestiform minerals have ever been detected in the flotation feed material.

Columbia Mill - Monthly composite samples are analyzed by McCrone. The samples represent a composite of products produced from a specific mine or a blend of crudes. All records indicate that their products are free from naturally occurring asbestiform minerals.”

**ITA-Sabatelli-524. 1988 due diligence**

There are references to both "random process samples" and "two week composite" samples.
A detailed analysis of the quality of crude ore and finished products processed by The Vermont Talc Company revealed one potential quality issue which may have a significant future economic impact on the Chester/Hamm operation.

The mineral actinolite was detected in two products manufactured at Chester on March 29, 1988. Multiple XRD scans detected from 0.03%-0.4% actinolite in products V-8 and V-15. The average of 3 scans for each product was 0.05% in V-8 and 0.17% in V-15. Both samples were random process samples, not production composites.

A two week composite sample of product V-10 milled November 1-15, 1987, also exhibited trace levels of actinolite. The average of 3 scans was 0.02%.

The next memo place quotation marks around the word asbestos in describing "asbestos" testing indicating that the author did not think the testing was of questionable quality.

"The "asbestos" testing conducted for Vermont Talc by Shelbome Laboratories has not reported the presence of actinolite in Chester/Hamm products. We attribute this condition to the following:

1. The actinolite contamination is at trace levels and is most probably sporadic.
2. Shelbome analyzes a monthly composite sample (dilution effect).
3. Shelbome runs long scan XRD is on these samples which reduces the detection sensitivity to approx. 1-1.5% for amphiboles.
4. By not detecting actinolite by XRD, SEM analysis would not specifically be utilized as a confirmation tool.

Aside from this potential problem, no other significant quality related problems were uncovered which might warrant the delay or termination of our intended purchase agreement with Vermont Talc.

Overview Summary

- Quality control testing of all production is minimal and infrequent.
- Process control testing is virtually non-existent.
- The Material Safety Data Sheets utilized by Vermont Talc are lacking information required by OSHA. They are not in full compliance.
- The bag labeling utilized by Vermont Talc lacks information required by the Hazard Communication Standard. They are not in full compliance.
- Vermont Talc "certifies" that their products meet certain quality criteria (i.e. USP) but they neither test for all the required parameters nor do they have sufficient historical data to substantiate their certification without testing.