Asbestos Victim’s Family Wins $3M from Mining Co. (2012)

J&J Hit With $110M Verdict In Latest Mo. Talc Cancer Trial

Colgate Defense Win in Talc/Meso/Asbestos Trial in LA

Jury awards woman $13M for exposure to asbestos in talcum

Talc/Meso/Asbestos

55 million

Verdict follows $72 million award in February; plaintiffs say talcum powder caused
Outline

> What is talc?
  - Deposits/accessory minerals
  - Industrial, cosmetic and pharmaceutical

> Product testing – past and present

> Analytical considerations

> Exposure studies

> Benchmarking potential exposures
What is Talc?

> Crystalline, hydrated silicate of magnesium
  - Typically platy (platiform); rarely found in fibrous form

> Composition varies depending on geological deposit
  - Industrial vs. cosmetic uses

> Talc deposits may contain additional minerals
  - Silicates (incl. chrysotile/tremolite*)
Cosmetic Uses of Talc

Select Cosmetic Uses:

- Baby products
- Eye Make-up
- Perfumes
- Fragrance
- Shampoo
- Conditioner
- Hair dye
- Face powder
- Foundation
- Lipstick
- Nail polish
- Oral hygiene products
- Deodorant
- Shaving products
- Foot-powder
- Sunblock
- Lotion
What is Tremolite?

- Naturally occurring, non-commercial amphibole
- Not intentionally mined for any specific purpose
- Occasionally found with substances (talc, chrysotile) used in commercial products

### Asbestos (Asbestiform) vs. Non-Asbestiform

<table>
<thead>
<tr>
<th>Asbestos (Asbestiform)</th>
<th>Non-Asbestiform</th>
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<tbody>
<tr>
<td>Crocidolite</td>
<td>Riebeckite</td>
</tr>
<tr>
<td>Amosite</td>
<td>Cummingtonite-Grunerite</td>
</tr>
<tr>
<td>Tremolite Asbestos</td>
<td>Tremolite</td>
</tr>
<tr>
<td>Anthophyllite Asbestos</td>
<td>Anthophyllite</td>
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<tr>
<td>Actinolite Asbestos</td>
<td>Actinolite</td>
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</tbody>
</table>
Definitions

**Asbestiform**
- Rare
- High length-to-width aspect ratio
- Long, thin, flexible fibers

**Non-Asbestiform**
- Common
- Low length-to-width aspect ratio
- Short, thick, brittle fibers
- *Cleavage fragments*
Initial concerns raised in the late-1960s/early-1970s

A handful of historical studies and newspapers reported asbestos in cosmetic talc powders

Did not distinguish between asbestiform and non-asbestiform

Addison and Langer (2000):
“…in the 1960s and 1970s were carried out using X-Ray Diffractometry, a method which is incapable of differentiating between the asbestos form and the normal forms of amphiboles”
Analytical Methods Required?

**XRD** (X-ray Diffraction)  
**PLM** (Polarized Light Microscopy)  
**TEM** (Transmission Electron Microscopy, w/ SAED)

Cosmetic, Toiletry and Fragrance Association (CTFA, n/k/a Personal Care Products Council) (1976)
- Detection limit of 0.5%
- Recommends using XRD, PLM, and TEM
### Recent Research

#### Results of Bulk Analyses of Cosmetic Talcum Products

<table>
<thead>
<tr>
<th>Product</th>
<th>Product Type</th>
<th>Years of Manufacture</th>
<th>Laboratory A</th>
<th>Laboratory B</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>XRD</td>
<td>PLM</td>
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<tr>
<td>A</td>
<td>Baby Powder</td>
<td>1961</td>
<td>Peaks of Monoclinic Amphibole</td>
<td>Tremolite cleavage fragments</td>
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<tr>
<td>B</td>
<td>Beauty Dust</td>
<td>1969-1970</td>
<td>Peaks of Monoclinic Amphibole</td>
<td>Tremolite cleavage fragments</td>
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<tr>
<td>C</td>
<td>Facial Powder</td>
<td>1940-1941</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>D</td>
<td>Body Powder</td>
<td>1970s</td>
<td>ND</td>
<td>Tremolite cleavage fragments</td>
</tr>
<tr>
<td>E</td>
<td></td>
<td>1962-1963</td>
<td>ND</td>
<td>ND</td>
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<tr>
<td>F</td>
<td></td>
<td>1973-1977</td>
<td>ND</td>
<td>ND</td>
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**Laboratory B**

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<th>Laboratory B</th>
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<td></td>
<td>PLM</td>
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<td></td>
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The survey found no asbestos fibers or structures in any of the samples of cosmetic grade raw material talc or cosmetic products containing talc.
FDA’s Recent Testing (Claire’s/Justice Products & Beauty Plus)

> Ongoing testing and reporting since 2017

> FDA issued a consumer warning and requested a recall of specific Claire’s and Justice products
  - Make-ups

> Source mines are unclear
JOHNSON & JOHNSON CONSUMER INC. TO VOLUNTARILY RECALL A SINGLE LOT OF JOHNSON'S BABY POWDER IN THE UNITED STATES

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15 New Tests from the
Previously
Over 60 New Tests of the
Labora

NEW BRUNSWICK, NJ, (OCTO
Inc. (the Company) today announ
Johnson’s Baby Powder previous
Administration (FDA) found no a
samples from the single lot of J
voluntarily recalled on October 1

Company Investigation Confirms No Asbestos in Johnson’s Baby Powder

More Than 150 Tests Show No Asbestos

Current Analytical Considerations

> What analytical methods should be used?

> What limit of detection is acceptable? Feasible?

> What counting criteria should be followed?

> What is the significance of the particles observed?
Toxicological Considerations

> Cosmetic talc exposure does not cause mesothelioma
  ▪ Miner and miller epidemiology (Italy, Vermont, North Carolina)
  ▪ Animal studies

> Cleavage fragments
  ▪ Vast majority not respirable (>1µm diameter)
  ▪ Biopersistence
  ▪ Animal studies
Airborne Exposures From Consumer Use of Cosmetic Talc

Several studies have evaluated airborne concentrations associated with consumer use of talcum powder (n=7)

Typical use scenarios evaluated:

• Diapering
  – Infant exposure
  – Adult exposure

• Face powdering
  – Adult exposure

• Body powdering
  – Adult exposure
Evaluation of Airborne Exposure Data

> Conversion factors are used to describe the relationship between different units of measure
  - Identified historical data relating measured airborne talc dust to talc fiber concentrations
> Allows for inclusion of all available exposure data in standard units of PCM (f/cc)
Diapering Scenarios

Infant Exposure

Airborne Concentration (f/cc)

Adult Exposure

Measured Fiber Data
Converted Fiber Data
Adult Use Scenarios

Face Powdering

Body Powdering

Airborne Concentration (f/cc)

- Measured Fiber Data
- Converted Fiber Data
FDA (1985) – Risk Assessment

> Evaluated potential infant exposure to asbestos in talcum powder
  ▪ Assumed that 0.1% of fibers found in talc were asbestos

> Cumulative exposure: 0.0001 f/cc-years
  ▪ Assumes 43.8 min exposure/week, for 2 years

“We conclude that the added human risk of lung cancer and mesothelioma from possible asbestos in talc is less than $10^{-8}$ [1 in 100 million] lifetime risk and quite possibly orders of magnitude less.”
Consumer Exposure Potential from Cosmetic Talc Use

Average Cumulative Asbestos Exposure (f/cc-year)

Cumulative Background Asbestos Exposure
0.00002-0.00008

0.002-0.4 f/cc-year

0.00007-0.010

Diapering

Adult Use
Final Thoughts

> Findings of historical and current testing should be interpreted carefully

> New product testing methods should differentiate mineral habit

> Risk assessment practices can be used to understand significance of potential exposures
Thank you

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