

For CTFA Talc Meeting
March 11, 1976

March 8, 1976

COSMETIC TALC STATUS

The safety of consumer talcum products has been under continued attack, primarily led by the Mt. Sinai group, because of three alleged concerns. These allegations are as follows:

1. Commercial talcs often contain asbestos as naturally occurring contaminants.
2. Talc contains other impurities, minerals and metals which may have potential biological significance.
3. Talc as a mineral itself may be hazardous.

I. FACTS ON TALC

A. Asbestos and Cosmetic Talcs

- chrysotile asbestos has never been detected in cosmetic talcs or finished talcum products.
- amphibole asbestos, e.g. tremolite and anthophyllite, has been found in a few U. S. consumer talcum products (by Mt. Sinai and confirmed by a very reliable expert consultant).
- disagreement existed between Sinai scientist and an expert consultant in recent analyses for asbestos in British OTC talcum products. This resulted in withdrawal of highly controversial allegations of asbestos in British talcum products intended for presentation at the 4th International Symposium on Inhaled Particles & Vapours.
- Mt. Sinai disclosed statements in February '76 during private interview with the Canadian Broadcasting Corporation that their analysis of U. S. products has found asbestos.

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B. Biological Testing of Cosmetic Talcs

- extensive animal testing data is only available for Windsor 66 talc and Italian 00000 talc.
- Battelle hamster inhalation testing on Windsor 66 talc with chronic exposures up to 185 times median baby dosage has demonstrated no exposure-related pathology.
- MRC (British Medical Research Council) testing with Italian 00000 talc indicated no tumours resulted from intrapleural inoculation or ingestion.
- MRC testing with Italian talc showed fibrosis at high and very long exposures (up to 1000 times median baby dosage).

C. Human Medical Studies

- Pubino Mortality Study indicated no excess deaths due to cancer amongst talc miners and millers exposed to Italian cosmetic talc.
- Green prospective Pulmonary Study with Windsor talc miners and millers have shown no respiratory disease.
- Kleinfeld has published that deaths were due to cancer of lung and pleura amongst talc workers receiving high exposure to industrial talcs mixed with appreciable amounts of tremolite, anthophyllite and small amount of silica.

D. Conclusions

- all of the data which argues strongly that cosmetic talcs are not a hazard to health under normal-use conditions are based on studies with Windsor 66 and Italian 00000 talcs, both of which have a talc purity of better than 90%, and no asbestos content.
- amphibole asbestos contaminants have been observed in finished talcum products. Tight specifications should be written to preclude sources which are marginal as to potential contaminants.

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II. FDA/OTC PANEL REVIEWS OF TALC

FDA - LEWIN PRODUCT ANALYSES

- Professor Lewin's mis-identification of chrysotile in store shelf talcum products highlighted to FDA the need to develop analytical methodology for talc.

OTC CONTRACEPTIVES & VAGINAL PRODUCTS PANEL

- After a brief look at the safety of talc, the September 18-19, 1975 meeting decided to defer definitive action on talc to the OTC Antiperspirant Panel.

OTC SEDATIVE PRODUCTS PANEL

- This panel originally proposed that talc, a non-essential ingredient be banned from OTC products that are meant to be ingested. Because of a J & J response, this Panel altered its position to urge that talc containing asbestos not be permitted to be formulated in OTC products meant to be ingested.

OTC ANTIPEPSPIRANT PRODUCTS PANEL

- Talc was cleared for use in antiperspirants only on the basis of the low exposure in use. This panel has stated that it has not cleared talc for other uses.

OTC MISCELLANEOUS EXTERNAL DRUG PRODUCTS PANEL

- Because all three of the above Panels have not issued an unequivocal conclusion in the safety of talc, this fourth Panel will be required to provide an ultimate and definitive safety review on talc. With the previous history of attacks in the public media and the erosion of consumer confidence, all means should be taken to obtain a Category I for cosmetic grade talc. The publicity of category III would do irreparable harm to talc's already tarnished image.

PRESENT PROBLEM FOR CTFA & INDUSTRY

- Present allegations from Sinai that they have analyzed and found asbestos in a substantial number of U. S. talcum products is particularly damaging to CTFA's Panel presentation testimony that means are presently being taken by industry to self-regulate.

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Unless this Sinai data is refuted, it will adversely influence the Miscellaneous External Panel's forthcoming safety review for talc and undermine the tenet that safe cosmetic grade talcs are now being responsibly utilized by the industry.

III. RECOMMENDATIONS FOR CTFA ACTION

- CTFA should immediately provide refuting data by organizing a test of current talcum products and conduct examination for asbestos by the best method through independent experts. These same product samples should be offered to the FDA and the Mt. Sinai Laboratory for verification of analyses.
- to support an effective and persuasive presentation to the OTC Miscellaneous External Panel, CTFA should issue a strict revised talc standard which would very clearly distinguish cosmetic from industrial grades of talc. Such a specification will be credible to the consumerist advocates only if it fulfills the following requirements:
 1. It must specify the absence of asbestos constituents by the most sensitive method.
 2. It must adhere to a talc purity level which is closely similar to that already used in toxicological studies; namely, at least 90% talc.
- CTFA should identify conforming sources of talc as CTFA Cosmetic Grade Talcs and encourage manufacturers using this grade to label their finished products with this designation.