FILE NAME: Talc (TALC)

DATE: 1973 Aug 27

DOC#: TALC451

DOCUMENT DESCRIPTION: Memo RE Calculation of Asbestos in Food Grade Talc Proposed by FDA

8/28

CONFIDENTIAL - LIMITED DISTRIBUTION

Johns-Manville **Internal Correspond**

To: R. S. Lamar, R&D Center Date: August 27, 1973

From: V. E. Wolkodoff, R&D Center

Copies:

Subject: PETROGRAPHIC CALCULATION OF CHRYSOTILE AND TREMOLITE FIBERS IN TALCS BY FOOD GRADE TALC SPECIFICATIONS TO BE PROPOSED BY FDA, AUGUST 20, 1973, AS A GOOD MANUFACTURING PRACTICE

(ASB) = TALC

1. The petrographic method is outlined by Schulze and Eisenberg of the U.S. FDA, Washington, D.C., dated February 1, 1973. The method was followed with only two exceptions as follows:
   a. 500X magnification was used rather than the 400X recommended since 400X cannot be employed for direct visual examination on the Leitz Orthoplan.
   b. Square cover slips, 18 by 18 mm, were used rather than circular cover slips with a diameter of 18 mm.

2. As proposed by FDA, the maximum permissable number of fibers are:
   Tremolite - 1,000 fibers/mg
   Chrysotile - 100 fibers/mg

3. The method requires precisely 1 mg of material on a slide for examination. For a frame of reference, the total number of particles in 1 mg of J-M Reeves Jet-Milled talc is 6,720,000.

4. The results are as follows:

Material	Chrysotile Fibers Per mg	Tremolite Fibers Per mg
a. J-M Cyclo-Fil, Standard 70-34	0	47,040
b. J-M Cyclo-Sorb, Standard 70-33	168	16,464
c. United Sierra Mistron Vapor Talc No. C-104	0	0
d. J-M Reeves Talc, Jet-Milled Hazen Concentrate RD-73201-1	504	336

5. In the near future you will be receiving a report on chrysotile fibers in 14 commercial talcs as studied by transmission electron microscopy. Only two talcs, Englehard Emtal 599 and Charles Pfizer, were found to be free of chrysotile and tremolite. The others contain chrysotile in amounts by volume ranging from about one-tenth of one percent (Yellowstone Talc) up to three-tenths of one percent (Italian Talc e Grafite Val Chisone). Johnson and Johnson Baby Powder contains approximately one-tenth of one percent. If TEM is ever introduced as part of the FDA microscopical procedure, then indeed only a very small percentage of talcs could qualify by the proposed new standards. Please keep in mind that the lowest level of particle size that can be determined with reasonable certainty by optical petrographic method is on the order of 0.5 micron, although theoretically it can be read down to 0.25 micron, whereas by TEM chrysotile fibrils of approximately 250Å in diameter can be easily detected and characterized.

6. To the layman, the maximum permissable number of fibers may sound generous. It is not. For example an investigator may settle on 20 fields of view to characterize the microscopical slide (there are at least 40,000 particles in 20 fields) and if one chrysotile fiber is found then by calculation the number of chrysotile fibers per mg is well over 100.

7. You requested my opinion on the microscopical procedure as outlined by Schulze and Eisenberg. There are many drawbacks and weak frames from viewpoints of mineralogy and petrography. The work is essentially a library search, but many of the references are outdated, e.g., nine references are listed for the alpha index of refraction for chrysotile and these range from 1.493 up to 1.559. Technically the paper is correct but weak; also, naive.

8. It may be coincidence, but the first draft by Schulze and Eisenberg is dated February 1, 1973. At about this time Johnson and Johnson had founded a program at the Colorado School of Mines Research Institute to detect very small percentages of asbestos in cosmetic grade talc. We have learned that the program was successful and that asbestos down to one part per million could easily be detected and, it is my understanding, without benefit of TEM.

V. Wolkodoff

V. Wolkodoff

rr

See Distribution on Reverse Side