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TO: MEMBERS OF THE CTFA TALC SUBCOMMITTEE & SCIENTIFIC ADVISORY COMMITTEE:

Mr Lee Rasser

Attached herewith and submitted for your reading and comments is a finalized submission of the report of the CTFA Talc Subcommittee which we wish to submit to the Food & Drug Administration.

Please read at once and, likewise, call me at once if you disagree with any of the content matter.

In view of the very short time left to process this submission, your immediate attention is of paramount importance.

Thank you,

George W. Sandland

George W. Sandland
Chairman CTFA Talc Subcommittee

Goodhue WCD 000123

REPORT OF CTFA TALC SUBCOMMITTEE ON METHOD TO DETECT CHRYSOTILE AND TREMOLITE IN TALC.

December 10, 1973

The Scientific Advisory Committee of the Cosmetic, Toiletry & Fragrance Association, 1625 Eye Street, N.W., Washington, D.C. 20006 at a meeting held on September 2, 1973, designated that a subcommittee be set up to study the optical microscopic method proposed by the Food and Drug Administration. This method was published in the Federal Register of September 28, 1973. The present membership of the CTFA Talc Subcommittee is shown on an attached sheet.

At the first meeting of the Subcommittee, it was agreed to submit several samples of talc to members who volunteered to apply the FDA proposed optical microscopic method. The following talc samples were distributed without identification - except for randomly applied and non-duplicated code numbers:

Italian Talc	Grade #1615
Montana Talc	Source P
Montana Talc	Source F
Vermont Talc	Grade #66
Alabama Talc	
No. Carolina Talc	Grade 643

In addition, a sample of Italian Talc spiked w/w with 1% chrysotile and 0.15% tremolite was sent to each participant. The participants were aware that the sample was spiked, but did not know the percentage of spiking.

The attached table summarizes all reports submitted:

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
	Mrs. Lucy McCrone, McCrone Associates for Chesebrough		
Spiked	320	16	Passes
Italian	120	0	Passes
Montana-Pfizer	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No.Carolina	0	0	Passes
Montana-Ferry	0	0	Passes
	Mr. Harold Stanley of Pfizer		
Italian	~100	>100	Fails Chrysotile Passes tremolite
Montana-Pfizer	~100	>100	Fails Chrysotile Passes tremolite
Montana-Ferry	~100	>100	Fails Chrysotile Passes tremolite
Alabama	~100	>100	Fails Chrysotile Passes tremolite
Vermont	~100	>100	Fails Chrysotile Passes tremolite
No. Carolina	~100	>100	Fails Chrysotile Passes tremolite
	Mr. David Hamer of Johnson & Johnson		
Italian	0	0	Passes
Montana-Pfizer	1	0	Passes
Montana-Ferry	25	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	0	0	Passes
	Dr. John A. Reffner (U. of Conn.) for Avon		
Spiked	632	12,930	Fails Chrysotile Passes Tremolite
Italian	220	1,114	Fails Chrysotile Passes Tremolite

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Dr. John A. Reffner (U. of Conn.) for Avon Cont'd			
Montana-Pfizer	0	5,844	Fails chrysotile Passes tremolite
Montana-Ferry	13	9,281	Fails chrysotile Passes tremolite
Alabama	26	15,125	Fails chrysotile Passes tremolite
Vermont	41	165	Fails chrysotile Passes tremolite
No. Carolina	14	11,852	Fails chrysotile Passes tremolite
Dr. Tryggve Baak of United Sierra			
Spiked	3,000	2,000	Fails
Italian	1,000	0	Passes
Montana-Pfizer	0	0	Passes
Montana-Ferry	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	500	0	Passes
Richard E. Stevens of Ernest F. Fullam, Inc. for Whittaker C&D			
Italian	8,250	1,350	Fails chrysotile & tremolite
Montana-Pfizer	18,000	450	Fails chrysotile & tremolite
Montana-Ferry	29,250	5,200	Fails chrysotile & tremolite
Alabama	21,825	6,075	Fails chrysotile & tremolite
Vermont	3,225	675	Fails chrysotile & tremolite
No. Carolina	20,850	6,000	Fails chrysotile & tremolite

Spiked sample was not run.

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Mrs. Lucy McCrone of McCrone Associates for Kolmar			
Italian	53	0	Passes
Montana-Pfizer	0	0	Passes
Montana-Ferry	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
*No. Carolina	0	0	Passes
Spiked Sample	488	16	Passes

*Sample noted to contain some fiber bundles which are rolled up talc plus some non-fibrous tremolite

The following participants examined their samples but were unable conscientously to count particles with confidence, therefore, did not report numbers:

Miss Marie Jones for Dr. G. Cohen - Bristol-Myers Products Research Labs.
Mr. Salvatore DiBianca - The Mennen Company
Liberty Mutual Insurance Co., Research Center - for Kolmar Laboratories
Mr. John Facq - The Colgate Palmolive Company, Research Center

The table reveals strong inconsistency between results obtained by the different scientists applying the method to the same group of coded talc samples. This inconsistency is the result of problems encountered in the methodology.

1. The alpha refractive index of talc - one of the two indices exhibited by talc plates standing on edge - varies in value between 1.539 and 1.550[1]. This in combination with item 2, below, may easily result in the mis-classification of such plates as "fibrous, less than 1.574" and therefore chrysotile.

   Dr. Reffner of the University of Connecticut, in his report to Avon, admits that this factor is paramount - "counts for chrysotile are high since (talc) edges will often be mistaken for fibrous particles".

2. The immersion method for the determination of relative refractive index becomes unreliable when applied to extremely small (ca. 1 μm)particles. This is due in part to the fact that particles around 1μm in width approach the limit of resolution of the human eye when both size and contrast are considered, especially when applying the Becke line technique prescribed. This will

2. cause eye fatigue and resulting errors. Thus, a fine talc shard or plate on edge may be easily mistaken for an asbestos fiber. This applies to both the chrysotile and amphibole portions of the test.

3. It is quite likely that chlorite - a mineral of varied composition commonly found in pharmaceutical grade talc - would be incorrectly identified as tremolite. Refractive indices for chlorite vary in the range 1.57-1.66[2].

4. The examination of a sample of one milligram dispersed on a single microscope slide presents the investigator with a preparation which is too dense for a petrographic study.

5. The method is laborious and time consuming. Dr. Reffner quotes an analysis time of about five hours per sample and at JOHNSON & JOHNSON the investigator (D. H. Hamer) estimated at least two or three hours.

6. Dr. Walter C. McCrone in an earlier letter to the FDA suggested that there were relatively few scientists in the country who could use the method effectively. Scientists at Bristol-Myers, The Mennen Company, Liberty Mutual and Colgate-Palmolive had great difficulty in following the method to conclusion.

7. The proposed FDA method implies that all fibrous particles in talc having optical properties similar to those of asbestos minerals are in fact asbestos. This is probably an unwarranted assumption.

REFERENCES:

1. Deer, W.A., Howie, R.A., and Zussman, J., Rock-Forming Minerals, Vol. 3, p. 121 (1962).

2. Ibid, p. 131.

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We have concluded that the method published in the Federal Register does not provide a truly reliable means for the detection of asbestos in talc. It results in both false-positive and false-negative findings. It is also tedious and may consume as much as one half day per sample.

The subcommittee urges that the Food and Drug Administration defer finalizing the proposed optical microscopic method and proceed into a Phase II program which would combine FDA and Industry in a strong effort to develop a truly reliable method for measuring chrysotile content in talc. We are confident that the detection and estimation of fibrous tremolite can also be done, if necessary, as a fringe benefit, at the same time.

We estimate that a satisfactory method will take at least six months to a year to develop. We suggest a close liaison between FDA and industry in this all-out effort with updating reviews to take place as frequently as necessary.

Review of Alternate Methods

The CTFA Talc Subcommittee has reviewed several methods to detect chrysotile and tremolite in talc, including modifications of the optical microscopic method. These are listed with comments.

1. Optical Microscopic Method - may be used with some modification. Possibly better selection of R.I. liquids and reduction of sample size per slide.

2. X-ray Step Scanning - A good method for detecting tremolite if we could accept about 0.2% as the threshhold of detection. It does not distinguish fibrous from non-fibrous tremolite. The simultaneous detection of chlorite makes method impractical for chrysotile.

3. X-Ray Step Scanning + Optical Microscopy - Acceptable as in #2 above but the optical method continues to present the dilemma in reliable identification of chrysotile. However, this does not rule out a major revision of the optical method to do the chrysotile identification and counting.

4. X-Ray Scanning - The problem of chlorite interference in the detection of chrysotile is present in all x-ray procedures thus far available. It is reliable for the detection of 1% tremolite (both fibrous and non-fibrous).

5. Differential Thermal Analysis - This procedure is capable of detecting chrysotile at the 1% level, however, it will not detect tremolite.

6. Scanning Election Microscopy - This procedure is not capable of identifying asbestos. Even with energy dispersive analysis, completely satisfactory identification is not possible.

7. Transmission Electron Microscopy + Electron Diffraction - This appears to offer the best, most reliable method and is probably capable of detecting chrysotile and tremolite (fibrous), both at a level of 0.1%. It is estimated that an installation would cost about $130M +, and is obviously prohibitive for the small manufacturer who uses talc. The amount of talc sample examined by this procedure is miniscule.

Summary

The CTFA Talc Subcommittee has completed its review of the Optical Microscopic Method for the Estimation of Chrysotile and Fibrous Tremolite in Talc, which appeared in the Federal Register, vol. 38 (No. 188), (p. 27076, September 28, 1973). It recommends postponement of the finalization of the proposed regulation on talc. In addition, a collaborative effort between FDA & industry to resolve a satisfactory method of estimating chrysotile and tremolite in talc, is recommended, with periodic liaison reviews to monitor the project status. A task force of industry experts has been designated to pursue alternate methods. We invite FDA to participate in collaboration with the task force.

George W. Sandland
Chairman CTFA Talc Subcommittee

GWS:dd

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