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Johns-Manville

To: P. A. Martinson, 2 West

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From: R. S. Lamar, R&D Center

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Subject: FDA PROPOSED TALC REGULATION; MORE NUMBER EXERCIZES; HOPE FOR REEVES?

The FDA regulation calls for talc purities of 99.99 percent and 99.9 percent in terms of chrysotile and tremolite, respectively. Their proposed test method, which is completely incompatible with these percent purity data, call for maximum counts of 100 for chrysotile and 1,000 for tremolite in 1 mg of talc. The FDA test method calls for an optical method of counting at 400X.

The FDA requirement states further than only fibers 5 microns or greater in length and having an aspect ratio of 3/1 or greater will be counted.

At a magnification of 400X the lower limit of resolution with an optical microscope using heterochromatic light is 1 x 2 microns. In other words, no particles below this size would be seen or counted by this method. Even at 5 microns petrographic identification is very difficult. Positive petrographic identification becomes more possible at 10 microns and above. The FDA test requires that a petrographic identification be made.

A most significant point here is that the numbers of particles per unit of weight increases enormously as the size of the particles is reduced.

In his report of August 27, 1973, to R. S. Lamar, V. E. Wolkodoff states that J-M Reeves talc, jet-milled Hazen Concentrate RD-73201-1 contains 6,720,000 particles per milligram by direct microscopic count. At 500X with the optical microscope it is most likely that the greatest numbers of particles (below 1 x 2 microns) are not seen and not counted.

This same sample was counted using the Coulter Counter. This is a well recognized procedure now used in most, if not all hospitals and clinical laboratories for blood counts (in place of the older direct microscopic count).

Using the Coulter Counter to count Reeves RD-73201-1 down to 1.19 microns we have determined that 1 mg of this sample has 92,000,000 particles.

Even at 1.19 microns lower limit of detectability the Coulter Counter is ignoring the greater numbers of particles actually present.

Another way of calculating the total number of particles of all sizes down to the very smallest is to work back mathematically from the surface mean diameter. This was determined by air permeability to be 0.50 microns for Reeves RD-73201-1. By this method we estimate that 1 mg of this talc contains 554,000,000 particles. (See memo R. S. Lamar to S. Speil August 29, 1973.) This number is probably closer to the truth than the other two values reported above.

In V. E. Wolkodoff's memo of August 27, 1973, he reports 504 particles of chrysotile and 336 particles of tremolite in Reeves.

It is difficult but very important to put these data in correct perspective.

On the basis of all three counting methods, these calculate as follows:

Counting Method	Total Particles per mg	Percent Tremolite	Percent Chrysotile
Optical; FDA	6,720,000	0.005	0.0075
Coulter Counter	92,000,000	0.00037	0.0005
Surface Mean Diameter (by air permeability)	554,000,000	0.00006	0.00009

Talc purity by the three methods would be as follows:

Counting Method	Percent Talc Purity For Tremolite	Percent Talc Purity For Chrysotile
Optical; FDA	99.995	99.9925
Coulter Counter	99.99963	99.9995
Surface Mean Diameter	99.99994	99.99991

Even under the most difficult counting procedure (optical; FDA) we are talking about purities of 99.995 percent and 99.9925 percent for tremolite and chrysotile in Reeves. This is pretty pure material by any rational standard!

These numbers put this matter in a more rational, sane perspective. Does any sanity yet remain in Washington, D.C?

R. S. Lamar

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