HFF-40

MEMORANDUM OF VISIT

September 28, 1976

BETWEEN: Ms. Rachel Scott, Correspondent
The Washington Post

and

Heinz J. Eiermann, Director
Division of Cosmetics Technology

Ms. Scott inquired about any progress the FDA had made in regard to the "asbestos problem". She was doing a follow-up story and wanted to know whether the agency proposed, or is about to propose, regulations concerning asbestos as a contaminant of talc.

I informed her that no regulatory action had been taken concerning asbestos in cosmetics. We were continuing our work on the development of instrumental methods for the determination of asbesti-form minerals and examined several samples of commercial cosmetic talc products. Once the methodology has been worked out to our satisfaction we may propose regulations on asbestos. Our investigations of talc products demonstrated that none of the talcs used in these products contained asbestos as a contaminant. She wanted to know whether their was still concern regarding the asbestos program. I answered her that since asbestos had been identified as a potential carcinogen, the agency would always be concerned about this matter and its potential health hazard.

Heinz J. Eiermann

10-5-76

Lee Auerbach

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Chemsec

TO : George H. Boone
Director of Science, HFR-2160
New York District

DATE: October 5, 1976

HFR 2161

FROM : Product Composition Branch, HFF-446
Division of Cosmetics Technology

SUBJECT: Asbestos in Talc ~~Yes.~~ You approved at last ~~4t. res.~~ meeting. ~~WMP 10-14-76~~

This memorandum is in reply to your telephoned offer to provide us with assistance in the development of analytical methods for the detection and determination of asbestos in cosmetic talcs.

It is my understanding that you expressed interest in the development of methods for the detection of chrysotile and tremolite by optical microscopy and that you would like to receive some samples for analysis. Per your request we are sending you, under separate cover, the following samples:

~~DCST-77-1371~~ ~~16 hrs approved per 4th Board Meeting Notes.~~
DCST-77-1372
DCST-77-1373
DCST-77-1374
DCST-77-1375
DCST-77-1383
DCST-77-1384
DCST-77-1385

These samples consist of talc with known amounts of added chrysotile or tremolite. The talc used to prepare these samples is a commercial product which was analyzed by x-ray diffractometry and differential thermal analysis. The analysis indicated the absence of tremolite, chrysotile and chlorite at the limit of detection. To make the samples as uniform in composition as possible, the talc and asbestiform mineral were mixed in a blender using alcohol as a mixing aid. The alcohol was then removed by evaporation and the sample remixed.

We would appreciate receiving the results of your analyses when you have completed the examination of these samples. We would like to know the identity of the asbestos in each sample and, to the extent possible, the amount present. We would also appreciate receiving a copy of your methodology or a reference.

Enclosed are some reprints of material dealing with the microscopic identification of amphibole and serpentine minerals.

Thank you for your cooperation, assistance and interest.

Ronald L. Yates

Ronald L. Yates

Dr. J. Stuart

TO: Members of the CTFA Task Force on Methodology for the Detection of Asbestos in Talc

At the September 11, 1974, meeting of the CTFA Task Force on methodology for the detection of asbestos in talc for cosmetic use, the results of our round robin analysis were discussed. The two "cookbook" procedures for the detection of chrysotile and asbestiform amphibole in cosmetic grade talc have now been modified as a result of this evaluation. The two methods would assure that a talc is 99.0 to 99.5% free of asbestiform minerals.

A shortcoming of the round robin analysis for chrysotile in talc is that no one performed the necessary optical microscopy-dispersion staining back up method to the DTA procedure. This method is of great importance since the primary method (DTA) is specific only to the serpentine class of minerals; that is, antigorite, chrysotile, etc. which have different morphologys.

Enclosed you will find three coded talc samples possibly containing chrysotile. Would you please examine these samples strictly in accordance with our proposed optical microscopy-dispersion staining test method, a copy of which is attached.

I will contact you by telephone on or around October 31, for your results and comments.

Thank you,

F. Robert Rolle

F. Robert Rolle, Ph.D.
Chairman, Task Force on
Methodology for the Detection
of Asbestos in Talc

FRR/gm
Attachment

Optical Microscopy and Dispersion Staining

Having failed the DTA test for serpentine minerals, the sample must next be tested by optical microscopy/dispersion staining or by transmission electron microscopy.

The following optical method uses the Becke line procedure for determining relative refractive index.

1. Prepare a microscope slide by dispersing approximately 0.3 mg. of talc in Cargille refractive index liquid 1.550, under a 22 x 22 mm. cover glass.

2. On examination with the polarizing microscope any chrysotile fibers or fiber bundles in the prepared slide will exhibit:

   a. in the crossed polars mode, low order (first order, grey-white) retardation colors and straight extinction characteristics.

   b. distinctive fibrous morphology - in most cases a length: diameter ratio of several hundred to one.

   c. in the plane-polarized light mode a refractive index match when the long direction of the fiber is parallel to the plane of polarization. In the plane perpendicular to this the fibers will exhibit a refractive index less than that of the liquid.

3. Repeat 1 and 2 using Cargille refractive index liquid 1.544. Under these conditions for 2.c. (above) the refractive index match will occur when the short (diameter) direction of the fiber is parallel to the plane of polarization. The other index exhibited will be greater than that of the liquid.

4. Using the slide prepared in 1, examine the sample in the dispersion-staining mode with central stop (dark-field).

   Any chrysotile fibers present will exhibit blue colors, distinctly separating them from the non-chrysotile particles.

   If this test is carried out with plane polarized light as the illuminating source the color exhibited will vary with fiber orientation, so that as the stage is rotated the chrysotile fibers will change color: blue → blue-purple.

Again, for positive confirmation, both color and morphology (fibers, large l:d) criteria must be satisfied.

5. If optical microscopy/dispersion staining gives negative results, chrysotile may be present with a diameter too small to be detected by optical microscopy, thus, transmission electron microscopy with SAED must be employed.

Following is the transmission microscope procedure. If chrysotile serpentine is detected at the same level found by DTA by either microscopical method, then the talc fails.