

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

94-TA-43

E. EDWARD KAVANAUGH
P R E S I D E N T

September 9, 1994

Donald C. Havery
Office of Cosmetics and Colors
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Dear Mr. Havery,

Thank you for your letter of inquiry dated June 7, 1994. I have responded previously (June 8, 1994) by forwarding you a copy of the manuscript entitled *Talc: Occurrence, Characterization and Consumer Applications* (Zazenski et al., 1994). We have since made some minor revisions to the manuscript (enclosed).

The answers to the specific questions in your letter are as follows:

[It was] mentioned at the [IS RTP] Talc Symposium that cosmetics grade talc is 200 mesh, and that it goes through a process to give 90-95% pure talc. In the CTFA Compendium Specifications, talc is defined as "..... containing no detectable fibrous, asbestos minerals". Is this the specification for cosmetic grade talc presently used in the industry?

Answer: Yes.

Does the cosmetic industry run QC tests for asbestos in the talc they use?

Answer: Yes, both suppliers and manufacturers of finished talc-containing products run QC tests to confirm the absence of asbestos.

Do talc producers certify batches of talc for composition and fiber content? If so how long have they been doing this? Do they use x-ray diffraction as suggested by the CTFA?

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702
202.331.1770 FAX 202.331.1969
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Answer: The CTFA talc specification to which you refer (enclosed), was issued in 1976. The specification includes testing for the absence of fibrous minerals (fiber content). Although the specification was not issued until 1976, major talc producers and users instituted tests for the absence of asbestos as early as 1972. At least one major U.S. producer had instituted microscopic tests of their talc products which would have identified fibrous particles as early as the late 1940s. As referenced in the CTFA specification for talc, X-ray diffraction is widely accepted as the preferred test to screen samples for amphibole (including asbestos) or serpentine minerals. A copy of CTFA Method J4-1 (Asbestiform Amphibole Minerals in Cosmetic Talc) is also enclosed for your information.

Does industry conduct... quality assurance testing and mineral surveys of promising mines... in the US? Is there any way this can be documented? (For example, has there been any industry-wide publications or mandates that this be done which ... can [be] reference[ed]?) [Have] British standards ... been published anywhere so they can be referenced?

Answer: We are not familiar with British standards. The U.S. Bureau of Mines and the U.S. Geological Survey has explored and documented the existence, mineralogical make-up and geology of all mineral deposits in the U.S., including talc. In addition, individual companies conduct more detailed investigations of any specific mineral deposits they consider viable for their business. As discussed in the paper by Zazenski et al., contamination by any other mineral in cosmetic grade talc is not desirable so careful assessment of mining sites is a business prerequisite no mining company can afford to ignore.

Would asbestos survive the talc refining process you described? Is there a reference to document this? How long has industry been using the purification procedure?

Answer: Wet beneficiation of talc is conducted primarily to remove naturally associated minerals such as carbonates. Wet beneficiation (froth flotation) does have the processing potential to remove the asbestos from the talc; however the simplest and safest method of mining/processing is to use talc ore that is free from asbestos.

In your presentation at the Symposium, I thought I heard you say that talc and asbestos materials were not formed under the same geological conditions therefore the careful selection of mining sites results in asbestos-free talc. In a paper by Rohl, A.N., et al. (J. Toxicol. Environ. Health (1976) 2, 255-2-4) the authors said "They [asbestos materials and talc] form in the same as well as similar geological processes. Consequently, many talc deposits contain asbestos minerals, so that in industrial and commercial use, such talcs always contain varying amounts of asbestos fibers." Which is true?

Answer: It is important to note that, to our knowledge, Dr. Rohl and his co-workers were not geologists. In contrast to Rohl et al's unsubstantiated assertion, the U.S. Geological Survey has confirmed (see attachment) that the conditions under which talc forms are geologically distinct from those associated with the formation of talc. Careful mining procedures and careful beneficiation by modern methods ensure minimal, if any, contamination by asbestos.

I trust that these answers adequately respond to your questions. Should you have any further questions, or wish to discuss this matter further, please do not hesitate to contact me at (202) 331-1770.

Sincerely,



Stephen D. Gettings, Ph.D., D.A.B.T.
Director - Toxicology

cc: JBailey (FDA)
GNMcEwen (CTFA)

Enclosures