

FILE NAME: RT Vanderbilt (RTV)

DATE: 1971 Aug 3

DOC#: RTV149

DOCUMENT DESCRIPTION: FDA Asbestos & Talc Discussion Session Minutes

DIVISION OF COLORS AND COSMETICS TECHNOLOGY
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C.

ASBESTOS AND TALC

Discussion Session, August 3, 1971, Room 1409, 200 C Street, S.W.
Moderator: Dr. Alfred Weissler

Discussion Topics

1. Asbestos and Talc Mineral Deposits - Dr. Malcolm Ross
U.S. Geological Survey
2. Fibrous Content of Cosmetic Talcum Products - Dr. L. J. Cralley
NIOSH
3. Biological-Medical Significance of Asbestos and Other Fibers -
Dr. I. J. Selikoff, Mt. Sinai School of Medicine
Dr. C. Hildick-Smith, Johnson & Johnson
Dr. Paul Gross, Medical University of S.C.
4. Current FDA Interests in Asbestos - Dr. R. E. Bazilal, Bureau of Drugs
Dr. J. K. Brock, Bureau of Drugs
Dr. H. P. Mayhill, Bureau of Foods
5. Consumer Interest in Asbestos - Morris Kaplan
Consumers Union
6. Cosmetics Industry Interest in Asbestos - Dr. Norman Estrin
CTA
7. Analytical Methods for Asbestos - William Eisenberg, FDA
Dr. S. Essi, Johns Manville
S. R. Mountsier, Jr., Whittaker, Clark & Pacific
Dr. A. M. Tager, Mt. Sinai
Dr. Harwood, Chas. Pfizer & Company
Dr. G. Hildick-Smith, Johnson & Johnson

MEMORANDUM OF A SYMPOSIUM
August 3, 1971

ASBESTOS AND TALC

Held at the Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204

Moderator: Dr. Alfred Weiseler, Director
Division of Color & Connection Technology

SUMMARY

The amount of asbestos fibers in talcum powder products, and the potential health hazards associated with their presence, are subjects of current interest but differing reports.

At a symposium held on August 3 at the Food and Drug Administration attended by over 40 scientists, physicians and consumers, it was generally agreed that most talcum powders of major manufacturers are relatively free of asbestos.

Nevertheless, on behalf of consumers, FDA is working on the details of a laboratory procedure for the analysis of asbestos in talcum powder which will give consistent meaningful results.

Accurate analyses for the amount of asbestos in talcum powder will be obtainable, according to many of the participants, only through the use of a battery of specialized instruments and techniques, including x-ray diffraction, polarizing optical microscopy, electron microscopy, and electron diffraction of isolated particles.

In addition to extensive discussions of the analytical methods for asbestos used by various laboratories, the topics considered such topics as the medical significance of asbestos and other fibers, and the removal of asbestos and talc are expected.

INTRODUCTION

Dr. Weiseler opened the meeting by outlining some of the events which had brought the question of asbestos particles in talc to the attention of FDA. He indicated that in response to a letter from Jerome Kretschmer (Administrator, Environmental Protection Agency, New York City) to HEH Secretary Richardson, on June 28, 1971 the FDA was taking steps to investigate the problem of asbestos particles in talc.

CRMC-HT-TALC-000143

As a first step the FDA would like to establish a laboratory procedure for the determination of asbestos in talc. This will give meaningful and consistent results. Once the methodology is agreed upon FDA would be in a position to determine if such products on the market contain asbestos fibers.

The format of the meeting consisted of short presentations by each participant followed by informal discussions which served to pool the knowledge of the experts present. A list of the discussion topics is attached.

GENERAL DISCUSSION

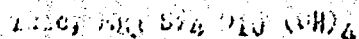
1. Dr. Rose of the U.S. Geological Survey made the first presentation. Dr. Rose, a mineralogist, outlined the various characteristics of asbestos mineral species with talc. During this presentation and the discussion which ensued the following salient points emerged:

a. Definition: Asbestos is a generic term for a variety of hydrated silicate minerals which have one common attribute, the ability to be separated into relatively soft, flexible fibers. Although the term is ordinarily associated with those varieties which have technologic importance, it is applicable to all minerals which fit the above description. The term "asbestos minerals" is perhaps most descriptive (1).

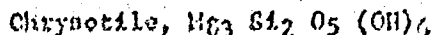
b. The known varieties of asbestos-forming minerals can be divided into two main classes on the basis of their crystal structures: serpentine and amphibole. The sole member of the serpentine class is chrysotile asbestos, which is by far the most common of the asbestos-forming minerals. It accounts for more than 95% of the asbestos fiber produced today.

There are five amphibole asbestos-forming minerals: actinolite, hornblende, anthophyllite, tremolite, and crocidolite. Although the amphiboles are common rock-forming minerals, the asbestos-forming varieties are much less abundant than chrysotile (1).

c. The empirical formula of talc and other asbestos-forming minerals can be represented as follows:

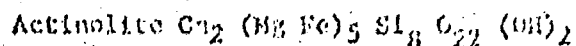
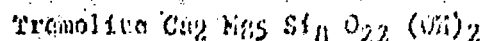
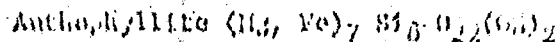


Serpentine Class



(1) Spall, S. and Lafucueber, J.P., Environmental Research 2, 166-203 (1969)

Ampibole Class



- d. It is not unusual to find large variations in the composition of a mineral within a relatively small area of a given deposit. The differences depend to a great extent on the mineralogy involved.

2. Dr. Gailley, of the National Association for Occupational Safety and Health spoke on the fibrous content of cosmetic talcum products. His presentation, centered in part on a paper he co-authored entitled "Fibrous and Mineral Content of Cosmetic Talcum Products," Am. J. Industrial Hygiene Association Journal, 22, 350-4 (1963). The following conclusions were made in this paper:

"With the exception of 4 of the 22 cosmetic talcum products analyzed, the levels of free silica, lead, nickel, chromium, and manganese were generally of a low magnitude and within a narrow range. It is not known whether the four products represent a significant proportion of sales in the industry or to what extent the sources of the talc in these four formulations are the same as sources of talc specified for use in other talcum products in the competitive market. The levels of silica, chromium, and nickel in these four products are sufficiently high, however, to be of concern in their potential to cause disease.

All of the 22 talcum products analyzed have an appreciable fibrous content, ranging from 6 to 34% by weight of the total talcum particulates, and averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile as these are often present in talc. These talc products should be included as a source of the fibers from which may be derived ferruginous bodies observed in the lungs of humans. The meaning of the presence of these ferruginous bodies, however, is uncertain."

The third discussion topic on the program dealt with the biological and medical significance of asbestos and other fibers. Three speakers addressed themselves to this topic.

a. Dr. Selinger of Mount Sinai School of Medicine spoke on the biological

problem presented to the general population with regard to asbestos. It was considered at that time to be mainly an occupational problem. He reported that recently acquired knowledge has greatly increased his concern over the whole question of asbestos fibers in the environment. He felt that the new dimension added to the problem was the possibility that lung cancer may result even from exposures at less than occupational levels.

- b. Dr. Hildick-Smith, Director of Clinical Research for Johnson and Johnson (J&J), outlined briefly the medical aspects of talc production and uses. He reported that J&J has been in the talc business for over 70 years. Talc, along with asbestos, is one of the few materials that can give rise to a biological response. J&J has not noted any adverse effects from the use of talc in either their employees or reported in the literature.

Talc manufactured by J&J is highly refined to produce a "platy talc." Available data indicates that there is no health hazard associated with the use of cosmetic grade talc. It was also pointed out that talc introduced surgically does not apparently cause mesotheliomas.

- c. Dr. Gross of the Medical University of South Carolina reported that there is very little if any data on the effects of talc in man or animal. Intratracheal injection of talc in hamsters caused no ill effects. In these animals no lung cancer has been seen. Asbestos particles less than 5 microns in length reportedly do not cause lung damage. This point, however, has not been definitely confirmed.

4. Dr. Kraybill of FDA's Bureau of Foods reported that the subject of asbestos in food and the environment had been evaluated within the past few years and that no need for regulatory action was indicated. Recent events, however, may require that the problem be re-evaluated.

Dr. Barzilai of the Bureau of Drugs reported that particulate matter in drug products and in the environment could be very dangerous in looking for the analytical methodology which can be used for the identification of such particles.

5. Morris Kaplan of Consumers Union indicated that we always seem to be looking at problems after they occur rather than anticipating them. He hoped that existing knowledge on the subject of asbestos and talc would be researched in the interest of the consumer rather than in the interest of the producer.

Dr. Estlin of the Cosmetics, Toiletry and Fragrance Association reported that the Association was ready to join with FDA and the academic community to determine if there is a consumer safety problem with talc.

ANALYTICAL METHODOLOGY

The afternoon session was devoted to a discussion of analytical methods that could be used for the identification and determination of asbestos in talc. Six presentations were given outlining methods used in various laboratories.

1. Mr. Eisenberg of the Division of Microbiology reported on optical methods, such as the use of the polarizing microscope, for the detection of asbestos minerals in talc.
2. Dr. Spall of Johns Manville Research Center reported that tremolite and chrysotile could be determined in talc at a level of about 0.5% by x-ray diffraction. Dr. Spall said, however, that the important question to be answered is: How much gets into the lung of the person who is exposed? He suggested that a model be set up to determine the real exposure values.
3. Dr. Lavin, a consultant for Whittaker, Clark and Fernald reported that x-ray powder diffraction would be an ideal screening technique for rapidly determining which samples of talc contain asbestos minerals. He indicated that there are talcs on the market which appear to be objectionable.
4. Dr. Langer and Dr. Maggiore of Mount Sinai reported that they use the following techniques to detect and determine asbestos minerals: light microscopy, x-ray powder diffraction, electron microscopy, electron microprobe and electron diffraction. During the discussion that followed Dr. Langer's presentation he was asked if he had ³⁴⁴² found asbestos in talc. He said that he had and that it was a high quality talc. He added that all the talc producers represented at the meeting produced a high quality talc product.
5. Dr. Horwood of Claxton Fibers and Company agreed that x-ray diffraction would be used as a screening technique of asbestos in talc. ^{using step scanning} other sophisticated techniques you could probably detect down to 0.1% of chrysotile in talc.
6. Dr. Nash of Johnson and Johnson introduced Dr. Rolfe who made available a table which outlined "Methods of Analysis of Fibers in Talc." (Copy attached). Dr. Rolfe recommended that optical microscopy be used as a first step in detecting fibers in talc. If very few or no fibers are seen, electron microscopy with electron diffraction should be used. If many fibers are seen x-ray diffraction should be used.

7. In closing the meeting Dr. Belouar thanked the participants and summarized the most promising approaches which might be used to determine the presence of asbestos in talc. Detailed procedures on analytical methodology will be sent to FDA by some of the participants at the meeting, and these will be synthesized by FDA and circulated for comments.

John A. Weininger
 John A. Weininger
 Assistant Chief, Chemical Branch
 Division of Color & Cosmetic Technology

The following people attended the symposium:

Lewis J. Grelley, Ph.D.	National Institute of Occupational Safety and Health, Cincinnati, Ohio
Irving J. Selikoff, M.D.	Rt. Stand. School of Medicine
Arthur H. Singer, Ph.D.	"
William J. Nicholson, Ph.D.	"
C. J. Maggiore, Ph.D.	"
Malcolm Ross, Ph.D.	U. S. Geological Survey
Wilson Hsieh, Ph.D.	Johnson & Johnson
Gavin M. Jick-Schick, M.D.	"
R. P. Kelle, Ph.D.	"
T. H. Shelley, Ph.D.	"
A. Gaudin, Ph.D.	"
Prof. F. B. Pooley (Consultant)	"
W. T. Conner (Consultant)	"
Ion H. Stewart, Ph.D. (Consultant)	"
G. R. Grieger, Ph.D. (Consultant)	"
Dr. F. J. ...	Chas. I. ... Co.
Harold D. ... Ph.D.	"
Commr. Harold Rosen	N.Y.C. Dept. of Air Resources
D. R. ...	Whittaker, Clark & Daniels
Prof. S.Z. Levin (Consultant)	"
Paul Green, M.D.	Medical University of South Carolina
Sidney Spell, Ph.D.	Johns-Manville
Morris ...	Consumers Union
Norman ... Ph.D.	Cosmetic, Toiletry & Fragrance Assoc.
Murray ... Ph.D.	"