

MEMORANDUM

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

DATE: August 20, 1973

FINAL DRAFT

The Acting Commissioner
THROUGH: Associate Commissioner
for Compliance
Director, Bureau of Foods _____

OM : Director, Office of Technology (BF-400)

SUBJECT: Asbestos in Cosmetic Talcs - ACTION MEMORANDUM

Issue

To recommend an Agency position concerning the possible health hazard associated with the use of cosmetic talcs containing asbestos in amounts of less than 1%.

Background Information

Talc, a magnesium silicate mineral mined at many locations in the United States and other countries is widely used as a principal ingredient in body dusting powder and face powder cosmetics. As mined, it can contain some asbestos, which is a closely related magnesium mineral. Pure talc deposits frequently occur in association with dolomite and marble.

Asbestos exists in six major varieties of which chrysotile and tremolite occur most commonly as cosmetic talc contaminants. Analysis of about 200 samples of the talcum powder types of cosmetic talcs by x-ray diffraction showed chrysotile in approximately 10% of these samples and tremolite but no chrysotile in another 10% (1). A small number of these samples analyzed in other laboratories by means of optical microscopy, x-ray diffraction and differential thermal analysis, generally agreed with the tremolite results but showed significant differences with the chrysotile. One of these investigators postulates (2) that the chrysotile found in the commercial talcs differs from that found in the natural geological deposits. In his judgement the chrysotile contaminant showed significant differences from the "classical" variety in the location of its x-ray diffraction peaks, in its appearance under the microscope, in its reactivity toward dilute acid, and in its behavior with respect to differential thermal analysis.

The difficulties involved in analyzing talc and other samples for small amounts of asbestos have been pointed out by many

investigators. It is not surprising that the results of different laboratories disagree sometimes, especially in the presence of transitional or altered mineralogical species. Moreover, with regard to the two varieties of asbestos of concern here, it is unfortunate that the one which is a clear inhalation hazard to man, namely chrysotile, poses an intrinsically more difficult analytical problem than the other, tremolite, which has not yet been shown to present a biological hazard.

Talc in itself is not considered carcinogenic. The impairment of pulmonary function which it can cause comes only after prolonged years of heavy industrial exposure, and then it may be due to the presence of tremolite (3) rather than to the talc itself (4).

An exact determination of the biological no effect level for talc dusting powders and face powders containing asbestos above 1 percent cannot be made at this time. There is a long latent period between asbestos exposure and the appearance of the various adverse effects. This makes it difficult to determine the relative degree of hazard due to different types of asbestos or levels of exposure. Asbestosis usually requires 10 to 20 years after the exposure period to develop, while carcinogenesis is rare before 20 years but is found quite regularly after 40 years (5).

? On the basis of available information, it is established that the number of asbestos fibers inhaled as a result of normal use of body dusting powder or face powder several times daily, if the powder contains no asbestos detectable by an analytical method sensitive to 1%, is well below the number resulting from occupational exposure to air containing 5 fibers per cc (See Tab A). Important to our considerations are the conclusions of a recent National Academy of Sciences study that there is a gradient effect in asbestos exposure and "... there is no evidence that persons in the general population -- without occupational, household or neighborhood exposure -- have any increased risk of neoplasm, even though there may be ferruginous bodies or fibers in their lungs." (6)

Options

We may, therefore, take any of the following courses of action:

1. Take no further action.

Pro: The bulk of cosmetic talc marketed today contains less than 1% of talc and cosmetic talc manufacturers are becoming increasingly aware of the desirability of marketing "asbestos free" talcs. Also, there is no evidence that these talcs have produced real problems to the consumer, nor have great potential of doing so under ordinary use conditions.

Con: Such an approach is a violation of this Agency's mission and to fundamentals of preventive medicine and public health practices.

2. Study the problem in greater depth on the basis of the literature and direct laboratory investigation.

Pro: a) literature

Increasingly sophisticated laboratory investigations and epidemiology are being done on the biological effects of asbestos. The results of these studies are gradually beginning to appear in the literature. Much of our present thinking could be changed in the next year or two by published results.

b) FDA intramural and extramural laboratory investigation

Present analytical methodology relating to chrysotile determination is not established. That shows any chance of widespread application is confined to optical microscopy. Other methods (electron microscopy, differential thermal analysis and x-ray diffraction) should be pursued with the prospect of developing more sensitive and rapid methods by themselves or in combination. Proposed extramural FDA supported research will include talc as one of the substances to be investigated. This study will greatly increase our knowledge about theoretical and actual talc depositions in the lung, in conjunction with lung retention, and local and systemic effects of the material.

Con: Completion of the above investigation may take longer than public needs allow.

3. Based on present knowledge, issue a regulation specifying acceptable levels of asbestos contamination in cosmetic talcs and the determining analytical methodology.

Pro: A stated standard, as low as present manufacturing and analytical technology allows, will have the positive

5. Selikoff, I.J.; Bader, R.A.; Bader, M.E.; Chung, J. and Hammond, E.C., Editorial, Asbestosis and Neoplasia, Am. J. Med., 42, 487, 1967.
6. Asbestos, The Need For and Feasibility of Air Pollution Controls, National Academy of Sciences, 1971, p. 19.

Tab A

Present federal occupational standards (29 cfr 1910.93 a) state "The 8 hour time-weighted average airborne concentration of asbestos dust to which employees are exposed shall not exceed 5 fibers per milliliter greater than 5 microns in length, as determined by the membrane filter method at 400 - 450 X magnification (4 millimeter objective) phase contrast illumination. Concentrations above 5 fibers per milliliter but, not to exceed 10 fibers per milliliter, may be permitted up to a total of 15 minutes in an hour for up to 5 hours in an 8-hour day." Elsewhere the Food and Drug Administration had proposed a standard for food grade talcs permitting 1,000 amphibole and 100 chrysotile fibers per milligram of talc.

For purposes of estimating the number of fibers that could be inhaled by a young adult female applying talc to the body of an infant, (see Table 1) it is assumed she would be an average height of 5'4", working at a table height of 30 inches, contaminating a cylindrical area of approximately 4 feet in diameter, and shaking out a generous application of talc (3 grams). It is also assumed that there would be about 6 applications per day, and the individual would be in the contaminant zone about 3 minutes at a time for a total exposure each day not exceeding 20 minutes. Using the above FDA talc standard not exceeding 1100 fibers per milligram, the average adult inhalation volume of air of 6 liters per minute, and the extreme assumption that all three grams of talc at each application became airborne, and evenly dispersed, the woman would inhale 0.4×10^6 fibers per day. This is in great contrast to occupational limits designed for a working lifetime which allow a time-weighted exposure of up to approximately 14×10^6 fibers per day. These occupational limits, set for a lifetime of work, have not been to date related to development of malignancies. Exposure to talc under the above conditions is 1/40 of the allowed occupational exposure per day. A proportionate value to an occupational lifetime exposure should be even less or about 1/30 of the suggested housewife value above.

Table 1

1. Table height	30 inches
2. Height of mother	64 inches
3. Potential diameter of contaminated area	48 inches
4. Dimensions of area in inches	34 x 48
5. Dimensions of area in centimeters	86 x 122
6. Assumed shape of area	cylindrical
7. Formula for calculating cubic capacity of a cylinder	r^2h
8. Volume of contaminated area $3.14 \times 24^2 \times 34 = 61,494$ cu. inches or $3.14 \times 60^2 \times 85 = 960,840$ cc or about	961 liters <i>~ 1,000 l.</i>
9. Average inhalation volume of adult	6 liters/min.
10. Proposed FDA limit of amphibole & chrysotile fibers/mgm talc	1100 <i>in talc for food</i>
11. Occupational limits 5 fibers/ml per 8 hr. day 6 liters/min. = 30,000 fibers/480 min. equals about	14×10^6 fibers/day
12. Home a) mother - 961 liters in area & 3 gms — <i>5 gms</i> used or about 3 mg. talc/liter = 3300 fibers/16 liters/min. x 3300 x 20 min. total exposure per day = about	0.4×10^6 fibers/day
b) Infant on table - Inhales 1/2 liter/min. so that value should not exceed 1/12 of above or about	0.03×10^6 fibers/day

5 gms talc = 5,000,000 fibers

5 MM fibers / 1,000 l volume

1 MM ml volume

= 5 fibers / 1 ml volume

= OSHA standard