

SHM

D R A F T

TO: Mr. Anthony Romero
Criteria Manager
Division of Criteria Documentation
& Standards Development
NIOSH - 8A-37
5600 Fishers Lane
Rockville, Maryland 20852

Dear Mr. Romero:

The Cosmetic, Toiletry and Fragrance Association, Inc. (CIFA) is a national trade association representing the cosmetic industry. CIFA ~~is comprised of~~ ^{includes} more than two hundred Active member companies which manufacture or distribute finished cosmetic products in the United States. In addition, CIFA includes more than two hundred Associate member companies from related industries, such as manufacturers of cosmetic raw materials and packaging materials. We estimate that CIFA members are responsible for more than 90% of the cosmetic products manufactured and distributed in the United States.

The CIFA Talc Subcommittee read with concern the first draft of the Stanford Research Institutes' Talc ~~Recommendations for~~ ^{Recommendations for} ~~Members of the Talc Subcommittee~~ ^{a Talc Subcommittee}, which is composed of industry scientists, including mineralogists, ~~wish to offer~~ the following comments which we hope will be helpful ~~to you~~ in the preparation of subsequent drafts:

- I. The Stanford Research Institute is apparently unaware that CIFA has developed voluntary purity standards for cosmetic grade talcs (Attachment 1). These standards distinguish ~~between cosmetic grade talcs and industrial grade talcs~~ ^{between cosmetic grade talcs and industrial grade talcs}. The information provided by the standards should be of importance to you in distinguishing cosmetic grade talcs from the industrial grade talcs ~~for which you are considering development of occupational hygiene standards.~~ ^{which}

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EXHIBIT
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In reviewing the CIFA Cosmetic Talc Standards, you will note the omission of a specification for chrysotile. The omission of such a specification was dictated by ^{the absence of chrysotile} in a study of 3,397 samples of cosmetic grade talcs from (such sources) as Montana, Vermont, Alabama, North Carolina, ^{and} ~~(and)~~ in addition ~~the following sources, such as Italy.~~ Results of this round robin study were submitted to the Food and Drug Administration in September, 1975 (Attachment 2). These findings are especially interesting in the light of several reported findings of chrysotile in talc samples ^{report in the Stanford}. The CIFA Talc Subcommittee has determined that the x-ray diffraction method used for detection of chrysotile in these studies will give a false positive indication when chlorite is present. Unfortunately, the researchers failed to perform the confirmatory analyses, which we believe would indicate that the material detected was chlorite ^(a harmless material) rather than chrysotile.

- II. The CIFA Talc Subcommittee suggests that any occupational hygiene standards which may be developed for industrial grade talcs exclude cosmetic grade talcs. The basis for this suggestion is the extensive review by the U.S. Food and Drug Administration of the safety of cosmetic talcs. ^{Over-the-Counter} The CIFA has made presentations to the FDA/ ^A Antiperspirant Drug Review Panel in July, 1975, the FDA/OTC Miscellaneous External Drug Review Panel in August, 1977, and the FDA/OTC Antimicrobial II Drug Review Panel in January, 1977 (Attachment 3). The Talc Subcommittee's conclusion is also supported by other reviewers (Attachments 4, 5, 6, 7 and 8), who have concluded that cosmetic grade talcs are not hazardous to its users.

- III. The Stanford Research Institute Draft contains numerous ambiguities and misuses of mineralogical terms. Correct terminology has been adequately described in submissions made to NIOSH by CIFA's member companies,

Johnson & Johnson, Inc. and R. T. Vanderbilt, Inc. (Attachments 9 and 10).

The CIFA Talc Subcommittee suggests the use of the mineralogical definitions established by the U.S. Bureau of Mines (Attachments 11 and 12).

IV. The research data ^{cited} in the SRI report does not provide well-founded support for the environmental limit of 0.1 mg/m^3 for talcs which do not contain asbestos and/or quartz. Several recent epidemiology studies by investigators such as Fine, Selivan and Nagman suffer from the deficiency of incomplete dust ^{analysis during} [exposure] measurements over the entire exposure period of the workers' exposure. These studies do not contain adequate analysis of the dust to discern its composition and contaminants over the study period. The CIFA Talc Subcommittee does not ^{believe it is} feel it possible for a reliable dose/response relationship to be established on the basis of these and other limited studies in the literature. The Talc Subcommittee does, however, generally agree with line 3058 in the SRI report which states "Toxicological information in the available literature on humans and animals exposed to talc does not adequately characterize talc according to its particle size, mineral composition and purity."

V. The Subcommittee, in addition, has prepared the following specific comments:

a. ^{way concede} ~~Since it is generally accepted that smoking greatly increases respiratory diseases,~~ we find no precedent for the establishment of an occupational standard to protect against its ^{that hypothetical} cumulative effect of smoking.

b. The designation of talcs "not found to contain asbestos or free silica" (line 786), without specifying some level of content, presents difficulties. The ^{"zero"} concept implied by this designation could lead to impractical regulation and unnecessary economic problems. The detection and quantification of asbestos and silica at "zero levels" is arbitrary and clearly beyond the state of the art.

Can we suggest a level? If not, they may come up w/ one we don't like

for [what?]

- c. The adoption of a 0.1 mg/m^3 recommended limit would be cause for great concern when one considers the gravimetric methods currently available. Application of the gravimetric method would lead to results in which the normal levels of background particulates in an industrial environment frequently approach or exceed the proposed limit. If such a limit were to be adopted, it would become necessary to develop skillful analytical techniques for separating the talc component from the background particulates, and then quantitating it. This requires ^{would require} the application of difficult and sophisticated techniques not commonly available.
- d. The CIFA Talc Subcommittee does not believe that the labeling and posting recommendations are applicable to cosmetic grade talcs. Voluntary specifications developed by the cosmetic industry, and the submissions to FDA by the cosmetic industry, amply demonstrate the safety of cosmetic grade talcs. Labeling and posting requirements, such as those recommended in the SKI draft, would threaten the image of a product considered ^{sound?} safe by FDA under normal consumer usage.

relevant to higher exposure?

The CIFA Talc Subcommittee hopes that the above comments will be helpful to you, and would be pleased to provide further assistance. In particular, the CIFA would appreciate receiving copies of future drafts so that we may provide additional comments and information.

Sincerely,

Norman F. Estrin, Ph.D.
Vice President - Science

ATTACHMENTS

1. Cosmetic Talc, CIFA Specification - The Cosmetic Toiletory and Fragrance Association Inc. (10/7/76 Revision).
2. Estrin, Dr. Norman, Letter to Dr. Robert Schaffner (FDA) September 23, 1975.
3. CIFA Presentation to FDA/Over-the-Counter Antiperspirant Drug Review Panel, July 9, 1975.
4. Hildick-Smith, G.Y., The Biology of Talc. British Journal of Industrial Medicine 33:217-229, 1976.
5. Hildick-Smith, G.Y., Talc - Recent Epidemiological Studies. In Proceedings of the 4th International Symposium on Inhaled Particles and Vapours. Inhaled Particles IV, Part 2: 655-665, Edinburgh, 1975.
6. Cosmetic Talc Powder: The Lancet, No. 8026, June 25, 1977.
7. Kennedy, Donald, Letter to S. M. Wolfe, B. Gordon. Public Citizen Health Research Group, January, 1979.
8. GSA "Draft Commercial Item Description A-A-42 Talcum Powder", January 16, 1979.
9. Johnson & Johnson to Mr. Anthony Romero, December 13, 1978.
10. R. T. Vanderbilt to Dr. J. M. Lane, November 3, 1978.
11. Ampian, S.G., Asbestos Minerals and Their Non-Asbestos Analogs. Review of Mineral Fibers, Electron Microscopy of Microfibers, Pennsylvania State University. August 23-25, 1976.
12. Campbell, W. J. et al, Selected Silicate Minerals and Their Asbestiform Varieties: Mineralogical Definitions and Identification-Characterization. U. S. Department of the Interior. Bureau of Mines, IC 8751, 1977.