cc: Talc Sec Exec Legal

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. (CTFA) is a national trade association representing the cosmetic industry. It includes more than two hundred active member companies which manufacture or distribute finished cosmetic products in the United States. In addition, CTFA includes more than two hundred Associate member companies from related industries, such as manufacturers of cosmetic raw materials and packaging materials. We estimate the CTFA members are responsible for more than 90% of the cosmetic products manufactured and distributed in the United States.

The CTFA Talc Subcommittee read with concern the first and second drafts of the Stanford Research Institute report to NIOSH entitled, "TALC". This Subcommittee, which is composed of industry scientists from various disciplines including mineralogy, offers the following comments which we hope will be helpful in the preparation of subsequent drafts:

I. CTFA STANDARD FOR COSMETIC GRADE TALC

The Stanford Research Institute, in developing this Talc Document, has opted not to provide recognition to the

PLAINTIFF'S EXHIBIT WCD-158

voluntary purity standard (Attachment 1) established in October, 1976 by the CTFA for Cosmetic Talcs. CTFA Cosmetic Grade Talcs, which specify a composition of 90% hydrated magnesium silicate and the absence of detectable asbestos, should not be grouped with industrial talcs of lower and less defined purity in the development of occupational hygiene standards.

Unlike that of very impure talc mixtures, the pathogenicity of high purity talcs (conforming to the CTFA Standard) has been extensively and carefully evaluated (References 1-10). It is stressed that these carefully defined studies must be distinguished from historic literature citations making loose generic reference to the term 'cosmetic talc' which only denote physical and tactile properties deemed appropriate for cosmetic use, but ~~carried~~ no universal meaning in terms of mineral composition or contaminants.

An extensive CTFA presentation has been made to the FDA/OTC Antiperspirant Drug Review Panel in July, 1975 in support of ~~the~~ CTFA Cosmetic Grade Talc as a safe and useful ingredient (Attachment 3). Similar positive reviews of data were conducted by the FDA/OTC Miscellaneous External Drug Review Panel in August, 1977 and the FDA/OTC Antimicrobial II Drug Review Panel in January, 1977. Other reviewers (Attachments 4,5,6,7,8) have also concluded that CTFA cosmetic talcs are not hazardous to its users.

There have been old reports in the literature of unsubstantiated findings of chrysotile asbestos in talcs. However, these mistakened detections of chrysotile were actually chlorite mineral, mis-identified in X-ray Diffraction through negligent confirmatory analyses. In your review of the CTFA Cosmetic Talc Standard, you will note the absence of a specification for chrysotile. This was supported and dictated by the absence of chrysotile, verified through a round robin study of 3,397 samples of cosmetic talcs from sources such as Montana, Vermont, Alabama, North Carolina and Italy. The results of this round robin study were submitted to the Food and Drug Administration in September, 1975 (Attachment 2).

II. BASIS FOR TLV AMENDMENT

There is no firm basis for projecting and amending the permissible occupational exposure limit. The available research data cited in the S.R.I. report suffer from a common deficiency of incomplete dust analysis and exposure measurements during the entire period of workers' exposure. The S.R.I. March 1979 report itself stated that the data available are insufficient to draw valid conclusions. For example:

new

- lines 5098, 5099 and 5100

  "More comprehensive epidemiologic studies concerning exposure to talc without asbestos minerals are needed with follow-up studies of populations and cohorts already reported on."

- lines 5141, 5142 and 5144

"Animal inhalation studies that evaluate the degrees of pathogenic effects on pulmonary tissue of pure talc, dolomite, chlorite, magnesite, non-fibrous tremolite, and the talc-related mineral pyrophyllite, alone and in combination, are needed."

- lines 4941, 4942 and 4943

"...the evidence presented in any one of these papers (17, 65, 68) is not conclusive for the purposes of setting a permissible exposure limit...

Various intimately-informed reviewers in the NIOSH Experts, Government Agency and External Panel have also commented on the inadequacies of the epidemiologic studies, for example:

Burgess, W.A. - External Reviewer A.I.H.A.

"....many of the early studies involved exposures to >10 mg/m^3 to a talc containing concentrations of free silica up to 18%."

"....It was not possible to obtain historical data for the previous decade. It is possible that a range of talcs were in use and the concentrations were higher than those noted during the environmental component of this study."

"The Selevan study does not present exposure data..."

Peters, J.M. - NIOSH Expert Reviewer

"....Rubino's study adds little useful information to standard setting."

"Selevan's study contains little reliable environmental information to match up with the health effects."

Thiessen, J.W. - Agency Reviewer, Dept. of the Army

"From an epidemiological perspective....none of the articles or studies cited establishes a direct causal relationship between non-asbestiform talc containing less than 1% quartz and a disease state."

"None of the evidence given demonstrates a reasonable model that shows the old standard as being too high."

"More toxicological data is needed concerning the health effects of relatively pure talc and talc with its associated minerals....as well as epidemiologic studies on occupationally exposed persons. Establishment of a new standard should be contingent on such studies."

Damstra, T. - Agency Reviewer, NIEHS

"Many of the studies cited did not adequately characterize talc by mineral composition, particle size, or purity...."

Markle, R.A. - Agency Reviewer, Bureau of Mines

"The exhaustive 87 page section on biological effects of exposure describes mainly studies done at concentrations much greater than the current TLV of approximately 3.0 milligrams per cubic meter or where the talc contained silica or asbestos."

CTFA agrees with S.R.I. that "the evidence presented by the literature references is not conclusive for the purpose of setting a permissible exposure." We also agree with S.R.I. that further epidemiological studies should be carried out, but urge that these should be designed toward projecting a recommended permissible exposure level which is based on determined exposures to talc that has been properly analyzed and shown to be in the category to be regulated. Until more valid data are generated, a lowering of the present TLV for CTFA Cosmetic Talc is wholly arbitrary and an unwarranted inflationary action.

III. LABELING AND POSTING

In the prevailing absence of direct occupational cause

and effect data, the proposed label and posting warnings which specifically single out Talc are unjustified and prejudicial. This type of warning language wrongly implies to the worker and the public that a high purity talc such as "CTFA Cosmetic Grade Talc" is very toxic.

The CTFA would endorse the recommendation for training and counseling under Section 5, page 9 as an effective documentable and controllable awareness tool in the handling of any general dust substance. However, we find the labeling and posting requirement to be a redundant, passive means of employee communication.

If NIOSH still considers warnings and postings to be necessary, then they should reflect the uncertainty of the data supporting this need. Therefore, it would be more appropriate to use language such as:

DUST

EXCESSIVE INHALATION MAY CAUSE

ADVERSE RESPIRATORY EFFECTS

IV. MEDICAL

In view of the known adverse effects of x-ray radiation, it is recommended that the medical surveillance requirements specify that a frontal view be done, followed by a side view only when necessary.

V. WORK PRACTICES

We recommend that NIOSH follow OSHA's recent standard setting precedence of stipulating performance type standards. It is preferable that examples of acceptable controls and work practices be provided as appendices and not as standards. In this manner OSHA would not inhibit innovative control techniques.

VI. ACTION LEVEL

The "action level" of the SRI document serves no purpose. We understand an "action level" ~~is~~ as that level above which medical, labeling and posting, personnel protective equipment, training, monitoring and record keeping take effect.

According to lines 52 to 58:

> "The "action level" is defined as a concentration in the air of the workplace at or above one-half the recommended environmental limit (see Section 1). Exposure to talc at LOWER concentrations requires adherence to the following sections 2, 3 (a and b), 4, 5, 6, 7 and 8 (a and c)."

The work LOWER implies that any measurable level down to zero activates the standard requirement as an "action level." We find this contrary to all existing OSHA standards and directives and indeed more stringent than any other standard, including the asbestos standards. This amounts to promulgating a zero standard.

The CTFA Talc Subcommittee hopes that the above comments will be helpful to you, and would be pleased to provide further assistance. In particular, the CTFA 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, CTFA Specification-The Cosmetic Toiletry and Fragrance Association Inc. (10/7/76 Revision).

✓2. Estrin, Dr. Norman, Letter to Dr. Robert Schaffner (FDA) September 23, 1975.

✓3. CTFA 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.

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II. Wehner, A.P., Wilkerson, C.L., Cannon, W.C., Buschbom, R.L., and Tanner, T.M.: Pulmonary Deposition, Translocation and Clearance of Inhaled Neutron-Activated Talc in Hamsters. Food and Cosmetics Toxicology 15:213-214, 1977.

III. Wehner, A.P., Tanner, T.M., Buschbom, R.L.: Absorption of Ingested Talc by Hamsters. Food and Cosmetics Toxicology 15:453-455, 1977.

IV. Wilkerson, C.L., Wehner, A.P., and Rancitelli: Leaching of Radionuclides from Neutron-Activated Talc in Serum and in Dilute Hydrochloric Acid. Food and Cosmetics Toxicology 15:589-593, 1977.

V. Teratologic Evaluation of FDA 71-43 (Talc), PB-221 804, Food and Drug Research Labs., Inc., January 1973.

VI. Mutagenic Evaluation of Compound FDA 71-43, Talc. PB-245 458, Litton Bionetics, Inc. 9 December 1974.

VII. Lord, G.H.: Biological Effects of Talc in the Experimental Animal. Food and Cosmetics Toxicology 16:51-57, 1978.

VIII. Phillips, J.C., Young, P.J., Hardy, K. and Gangolli, S.D.: Studies on the Absorption and Disposition of ^{3}H-Labelled Talc in the Rat, Mouse, Guinea-Pig and Rabbit. Food & Cosmetics Toxicology 16:161-163 1978.

IX. Luchtrath, H. and Schmidt, K.G., Beitr, Silikosforsch, 61,1, 1959.

X. MacNab, G. and Harington, J.S.: Nature London, 214,522, 1967.