

Hon. Mark Novitch
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20460

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Petition for labeling of warning
of the hazardous effects produced by
asbestos in cosmetic talc.

The purpose of this petition is to request a labeling of warning as well as a detailed list of components of the commercial cosmetic talcs. Because of its geological formation cosmetic talc may contain significant amounts of asbestos particles producing hazardous effects by its continuous use. Since it is a cosmetic article its production and commercialization is regulated by the Food, Drug and Cosmetic Act. I am a graduate student of Marine Environmental Sciences and I am deeply concerned by the toxic effects produced by the constant and periodic use of talc by the public, specially children.

Because commercial talc deposits consist of natural admixtures of mineral, a number of mineralogically different materials have been used as commercial talc. Asbestos is a generic term for a variety of natural minerals which have the ability to be separated in filaments (1). Since the mining of talc rock almost invariably includes the mining of asbestos as well, the asbestos contaminant is carried over into the consumer product and thus introduces the risk of asbestos disease (2).

Knowledge of diseases associated with the use of asbestos apparently dates back 2000 years and detailed medical reports with the classification of asbestos as a harmful substance began about 1900 (3). It has been widely proven that the inhalation of asbestos is the direct cause of hemolysis (4,5,6) and diseases such as asbestosis, bronchial cancer, pleural mesothelioma and peritoneal mesothelioma (3,4,5,7,8,9,10).

Asbestosis is a diffuse pulmonary fibrosis initiated by the inhalation of asbestos particles. The particles above 10 microns are filtered in the passage through the nose and trachea to the lungs, but the inhaled air reaching the respiratory bronchioles and alveoli contains the small-sized particles (1-5 microns) that would tend to

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deposit (3). Timbrell found that the fibres of 3 microns diameter are the thickness that are likely to be deposited in the alveolar regions (11), and the fibres with a smaller diameter (less than 3 microns) -especially those below 1 micron- are carcinogenic if introduced into the pleural or peritoneal cavity (9). Neither the "cleaning" (mucociliary escalator) nor the immunological system (macrophages) are able to expell or destroy these particles (3,4,12). Then fibroblasts in an irreversible process produce the collagen, which forms the characteristic fibrosis of the asbestosis (5); these can lead to respiratory disability (5) and death may result from pulmonary hypertension and cardiac failure (3).

About 50% of the asbestosis patients may develop carcinoma, such as mesothelioma, a diffusive cancer that rapidly spreads over the surface of the lungs, abdominal organs and heart (3).

The exposure to talc dust has been shown to produce lung scarring, termed talcosis, and asbestos bodies are observed in lung tissues of individuals who die of talcosis (14). The "fibrous" talc appear to be more pathogenic than "platy" talc, so this disease is due to asbestos rather than talc (14,15). Timbrell found that due to their fibrous shape, asbestos particles remain airborne longer and show less tendency to sediment than granular microparticles of equivalent weight (16); this physical factor will increase the asbestos exposure of a person in an environment where talc has been recently used.

The asbestos diseases are due to occupational and non-occupational exposures (8,17); only 40.8% of the mesotheliomas found in patients of London Hospital from 1917 to 1964 were due to occupational exposures (8). Every body is affected by this air pollution, as has been demonstrated in lung studies done in France (18) and New York City (19). Permissible occupational exposure limits exist in several countries, in the USA, the Occupational Safety and Health Administration (OSHA) proposed in 1975 a non-occupational exposure limit of 5 fibers/ml for a period of 15 minutes (9).

Several mineralogical analyses have been made on commercial talc, and all the samples contained asbestosform mineral impurities (5,20). Snider et al in 1972 found that in eighteen commercial talcum powders, the asbestos impurities varied in amounts from 4 to 46% meanwhile the labels listed no impurities (20). In 51 common talcs analysed at

Mount Sinai Hospital, the asbestos content ranged as high as 87% (5). The purity of any commercially available talc in the U.S. is related to both the nature of the original talc deposit and the extent to which the rock is upgraded to eliminate contaminant minerals. As the percentage of asbestos impurities is not related to price (20), this labeling will probably force the producers to control their talc composition to maintain their revenues.

There have been many lawsuits relating to the health aspects of asbestos, and the causes of action in product liability lawsuits generally involve the operative allegations:

- Failure to warn: thus the consumer was unaware of the danger.

- Failure to test: by the producers to test their products to properly ascertain its hazard, risk and dangers.

- Failure to remove: by the producers to stop selling, or remedy (make safe) the asbestos product (3). Warning of the health risks of exposure to asbestos has been recommended as a measure to be taken within the European Communities in 1977, and stated:

"Asbestos containing products should be clearly labelled" (9).

The Food, Drug and Cosmetic Act is clear about these facts:

"If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things)...the extent to which the labeling fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use prescribed in the labeling thereof or under the conditions of use as are customary or usual". (21 USCS § 321.n)

"A cosmetic shall be deemed to be misbranded- (b)If in package form unless it bears a label containing (2) an accurate statement of the quantity of the contents in term of weight, measure, or numerical count." (21 USCS § 362)

"A cosmetic shall be deemed to be adulterated- (a)If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual." (21 USCS § 361)

Taking into account the widespread use of cosmetic talc, which starts at birth (mostly used in the first years of life) and continues in a great number of people as a periodic exposure throughout their lifespan, I address this petition to request the obligatory establishment of labels of quality (asbestos particle size) quantity (proportion of impurities) of components as well as a label of warning of the hazardous effects produced by asbestos with the continuous use of cosmetic talc.

Respectfully submitted,



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References

1. Speil, S and J.P. Leineweber. 1969. Asbestos Minerals in Modern Technology. Environ. Res. 2:166-208.
2. Rohl, A.N. 1974. Asbestos in Talc. Environ. Hlth. Perspec. 9:129-132.
3. Peters, G.A and B.J. Peters. 1980. Sourcebook on Asbestos Diseases: medical, legal and engineering aspects. Garland Press, NY. 443p.
4. Harington, J.S., A.C. Allison and D.V. Badami. 1975. Mineral fibres: Chemical, Physicochemical and Biological Properties. Advan. Pharmacol. Chemother. 12:291-402.
5. Selikoff, I.J and D.H.K. Lee. 1978. Asbestos and Disease. Academic Press, NY. 549p.
6. Light, W.G and E.T. Wei. 1977. Surface Charge and Hemolytic Activity of Asbestos. Environ. Res. 13:135-145.
7. Sawyer, R.N. 1977. Asbestos Exposure in a Yale Building. Environ. Res. 13:146-169.
8. Committee on Biological Effects of Atmospheric Pollutants. 1971. Asbestos. The need for and feasibility of air pollution controls. National Academie of Sciences. 40p.
9. Report for the Commission of the European Communities. Public Health Risks of Exposure to Asbestos. 1977. Pergamon Press. 149p.
10. Preger, L., D.T. Arai., P. Kotin., H. Weill and J. Werchick. 1978. Asbestos-related Disease. Grune & Stratton Inc. 271p.
11. Timbrell, V. 1973. Physical factors as etiological mechanisms. In: Biological effects of Asbestos. Ed. P. Bogovski e.a. 295p.

12. Suzuki, Y. 1974. Interaction of Asbestos with Alveolar Cells. Environ. Hlth. Perspec. 9:241-252.
13. Langer, A.M. 1974. The subject of continuous vigilance. Environ. Hlth. Perspec. 9:53-56.
14. Rohl, A.N and A.M. Langer. 1974. Identification and quantification of Asbestos in Talc. Environ. Hlth. Perspec. 9:95-109.
15. Smither, W.J. 1974. Asbestos in the Work place and the Community. Environ. Hlth. Perspec. 9:327-329.
16. Timbrell, V. 1965. The inhalation of fibrous dusts. Ann. NY. Acad. Sci. 132,255.
17. Zolov, C., T. Bourilkov and L. Badadjov. 1967. Pleural Asbestosis in Agricultural Workers. Environ. Res. 1:287-292.
18. Fondimare, A and J. Desbordes. Asbestos Bodies and Fibres in Lung Tissues. Environ. Hlth. Perspec. 9:147-148.
19. Langer, A.M., Selikoff I.J and A. Sastre. 1971. Chrysolite asbestos in the lungs of persons in New York City. Arch. Environ. Health. 22:348.
20. Snider, D.W., D. Epfeiffer and J.J. Mancuso. 1972. Asbestosform impurities in commercial talcum powders. Compass. 49, #2:65-67.