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Johnson & Johnson

New Brunswick, N. J.

April 15, 1969

Subject: ALTERNATE DOMESTIC TALC SOURCES

Project Code #101

Mr. W. H. Ashton:

Your inquiry of April 9th, 1969 addressed to Dr. G. Hildick-Smith has been referred to my attention for reply.

Over the years, I have reviewed the literature on the hazards relating to the inhalation of talc particles on several different occasions. In your memorandum, you indicate that Tremolite does have needle-type crystals and that our position has been that these could penetrate the skin and cause irritation. Actually, to the best of my knowledge, we have no factual information on this subject. It would seem logical that it could occur, although whether or not it would be of clinical significance would be conjectural.

We have been concerned to a much greater extent with regard to possible dangers relative to the inhalation of the talc with a spicule or needle-like crystalline structure as compared with the flat, platelet-type of crystalline structure. There are reports in the literature concerning talcosis which, as you know, is a form of pneumoconiosis attributed to the inhalation of talc. Reported studies have suggested that this does not occur in connection with the flat, platelet-type of talc, but does occur in connection with the spicule-type of crystalline structure characteristic of Tremolite. The reported instances have been extremely few but have, without exception, involved inhalations of high concentrations on an occupational basis of many years duration. Furthermore, we have occasionally received inquiries from various individuals, including General Johnson and several pediatricians, expressing concern over the possibility of the adverse effects on the lungs of babies or mothers who might inhale any substantial amounts of our talc formulations. In the past, we have replied to the effect that since our talc is essentially all of the platelet-type of crystalline structure, and is of a size which would not be likely to enter the pulmonary alveoli, we would not regard the usage of our powders as presenting any hazard. Obviously, if we do include Tremolite in more than unavoidable trace amounts, this sort of negation of such inquiries could no longer pertain.

Mr. W. H. Ashton April 15th, 1969

Upon various occasions we have discussed the possibility of carrying out studies on animals which might provide factual information with regard to whether or not variable exposures to talc suspended in the environmental atmosphere might be productive of fibrotic and/or inflammatory reactions in lungs. For a variety of reasons, these have never been carried out here.

Since pulmonary diseases, including inflammatory, fibroplastic, and neoplastic types, appear to be on the increase, it would seem to be prudent to limit any possible content of Tremolite in our powder formulations to an absolute minimum. To the best of my knowledge, we have never been faced with any litigation involving either skin or lung penetration by our talc formulations. Some years ago, we were faced with a more or less serious problem resulting from what we consider to have been an unjust accusation of danger due to the presence of a small amount of boric acid in our talc. This created such a furor that we were more or less compelled to remove boric acid from the formulation. It is conceivable that a similar situation might eventually arise if it became known that our talc formulations contained any significant amount of Tremolite. Since the usage of these products is so widespread, and the existence of pulmonary disease is increasing, it is not inconceivable that we could become involved in litigation in which pulmonary fibrosis or other changes might be rightfully or wrongfully attributed to inhalation of our powder formulations. It might be that someone in the Law Department should be consulted with regard to the defensibility of our position in the event that such a situation could ever arise.

It is my personal feeling that until we have at least substantial evidence, based on animal work, to the effect that the presence of Tremolite in our talc does not produce adverse effects, we should not extend its usage beyond an absolute minimum previously mentioned.

T. M. Thompson, M. D.

TMT:JAG

cc: Dr. R. A. Fuller
Dr. Gavin Hildick-Smith
Mr. W. J. Ryan
Dr. G. H. Lord
Dr. J. E. Willson
Dr. J. Bothwell

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