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Johnson & Johnson
CONSUMER PRODUCTS WORLDWIDE
SKILLMAN, NJ 08558-9418

January 29, 1996

FAXED -30

Ian Phillipson
Head of Scientific Services
The Cosmetic Toiletry & Perfumery Association Limited
Josaron House 5/7 John Princes Street
London, W1M 9HD

Dear Ian,

RE: **Talc Working Party**

Please find attached a note to myself from Bill Ashton who is a long serving talc expert in J&J. I showed Bill a draft of the CTPA guide for his comment.

As you see, he has some concerns on the matter of tremolite. The issue is whether there should be any concern over non-fibrous tremolite.

I have a lot of respect for Bill's views on details such as this and would propose that you might sound out Fred Pooley on this matter.

If the final CTPA monograph is not yet issued to print, could you consider helping resolve this issue as soon as possible. You will see from the second paragraph of Bill Ahston's letter that there are long-standing and wider issues also.

I will phone you to discuss when you have had time to consider. Kind regards.

Yours sincerely,

John Hopkins

JH:jk
Attachment
TalcWP

EXHIBIT
16

Johnson & Johnson
CONSUMER PRODUCTS WORLDWIDE
SKILLMAN, NJ 08558-9418

CONFIDENTIAL

January 22, 1996

TO: J. HOPKINS

FROM: W. H. ASHTON

SUBJECT: COSMETIC TALC
CTPA 1995 REISSUE

Attached is page eleven of the current issue of A CTPA Guide, wherein Fred Pooley makes the suggestion that any batch of cosmetic talc which reads positive for the presence of amphiboles, should be rejected even if subsequent examination establishes whether or not the mineral is fibrous or non-fibrous. We need clarification on this since it is in conflict with all work here in the US based primarily on the mineral tremolite which is present in trace amounts in many high grade talcs.

The mineral tremolite is chemically a calcium magnesium silicate and occurs in two crystallographic habits: fibrous, which is called tremolite asbestos, and prismatic or non-fibrous, which is not asbestiform. Here in the US a controversy has been underway for the past 25 years. All agencies and health oriented groups have accepted the view that only the rare fibrous tremolite might be hazardous as opposed to the harmless prismatic form. This has been fought at many meetings of science groups and in the courts, mainly spearheaded by the R. T. Vanderbilt Co. who sells large tonnage of tremolitic talc to the ceramic industries here and abroad. I have spoken to John Kelse, Corporate Industrial Hygienist for Vanderbilt who is concerned about the CTPA position. It turns out that they have Fred Pooley on retainer for some of their European industrial talc problems and I would not be surprised that Kelse might call Pooley.

The details in the main body of the CTPA spec call for X-ray methodology, which can be capable of seeing as little as 0.1% of the tremolite or other amphibole in talc substrate.

Perhaps you know someone in the UK who could call Pooley and find out what he really means by the new look of equating fibrous to non-fibrous forms of the associate mineral in talcs of our grade.

W. H. Ashton

5.2 Fibrous Minerals: Amphiboles

The inhalation hazards of fibrous minerals have long been recognised (15, 16, 17). The CTPA view is that fibrous minerals should not be detectable in a cosmetic talc by 'state of the art' methods.

As the description of the mineralogical processes involved in the formation of talc may have shown, amphiboles are possible contaminants: these include tremolite, anthophyllite, actinolite, etc. Tremolite, the most common amphibole contaminant, occurs only rarely as the fibrous form, and the varieties of massive tremolite which under the microscope appear to contain fibres, commonly comprise mainly thick fibres or cleavage fragments which do not present the same hazard as asbestos. However, in order to eliminate any hazard to the consumer which might arise from the need to interpret fibre shape and dimensions, and to facilitate routine screening, the CTPA view is that if an amphibole is detected by X-ray diffraction, that batch of talc is unacceptable for cosmetic use, whether or not subsequent examination by optical or electron microscopy shows that the contaminant is not fibrous. In this respect the CTPA Specification is even more stringent than others which refer only to fibrous amphiboles.

Chrysotile is classed with the asbestos minerals but is not one of the amphiboles, which have a chain silicate structure; it is a sheet silicate, as are talc and chlorite. Chrysotile has been reported to occur in certain talc deposits, notably in New York State (18), but it has not been found in talc from sources used in the UK.

5.3 Silica/Quartz

Workers exposed to quartz dust over a period of years may develop silicosis, but the risk can be minimised if the daily exposure to respirable particles of quartz is not allowed to exceed a certain value. That value is determined by the average concentration of respirable quartz dust and is currently set at $0.4 mgm^{-3}$ (19).

A CTPA funded study showed that a consumer may be exposed to a concentration of respirable talc up to about 2 mg/cu.m during use of talc products (2), but this is only for a few minutes per day.

It can be shown that the 'safety factor' for the consumer is at least 500:1 compared with the permitted occupational exposure limits.

Thus the consumer is not exposed to any risk of silicosis from quartz in cosmetic talc.

5.4 Chlorite

To a mineralogist, 'chlorite' is not one mineral but a family, varying considerably in composition but all having a layered structure which gives some chlorites a 'slip' similar to talc. Chlorites are widely distributed and are often the consequence of the hydrothermal alteration of parent rocks related to those which give rise to talcs by similar processes, so they would be expected to be common contaminants of talc.