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December 21, 1973

Hearing Clerk
Food & Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Md. 20852

Subject: Asbestos particles in Food and Drugs, the subject of proposed rulemaking of the Food and Drug Administration, Federal Register, Vol. 38, No. 168, 9/28/73, (21 CFR Parts 121, 128 and 133)

Dear Sir:

As a major talc producer, this division is vitally concerned with this subject.

On September 7, 1972, we commented on the Federal Register publication of August 12, 1972 proposing regulation of asbestos-containing talcs for food additives. A copy of this letter is attached for your reference.

We have, since that time, carried out numerous programs designed to identify and quantify asbestos impurities occurring in talcs of various origins.

Methods tried include transmitting and scanning electron microscopy for fiber detection; electron and X-r diffraction; and X-ray fluorescence for mineral identification. We also carried out extensive work using the proposed optical polarizing microscopy method.

We found this method uncertain and misleading with identification of asbestos erring both positively and negatively. The reason for this is that some talcs have been observed with indices of refraction in excess of 1.5928 for $\eta\gamma$ while some fiber bundles have given refractive indices below 1.5928 for $\eta\alpha$ and higher than 1.5928 for $\eta\gamma$. Therefore, distinguishing amphibole asbestos from fibrous talc (or talc plates on edge) in the 1.59 liquid is subject to considerable difficulty.

As an alternative method for tremolite, we repeat our earlier suggestion that X-ray diffraction be the basic tool. We have refined this technique and are now able to state:

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Tremolite can be determined quantitatively in talc by X-ray diffraction and X-ray spectrometry. The tremolite peak at 8.38 a.u. can be semi-quantitatively determined by normal powder diffraction techniques in the presence of chlorite and talc using a scanning technique and $\text{Cu K}\alpha$ radiation with a monochromator. The results can be confirmed and made more quantitative by making X-ray spectrometer determination for calcium in the talc material before and after acid leaching to remove calcium compounds such as dolomite and calcite. Tremolite contains calcium oxide in the approximate level of 14%, and the CaO level can be determined easily to 0.015%, equivalent to 0.105% tremolite. The acid leaching at low temperature affects neither the talc nor tremolite.

Unfortunately quantitative chrysotile determination in talc is a more difficult problem which requires a combination of techniques. The scanning electron microscope technique permits ready identification of asbestos forms, particularly with tilting stage and in the high magnification range. The scanning electron microscope can show chrysotile fibers which are not present in sufficient quantity to show in normal powder diffraction techniques and optical microscopy.

Transmission electron microscopy of higher magnification can be of value for observing chrysotile fibers, and electron diffraction used in conjunction with the transmission microscope can permit single fiber determinations.

It is noted that Colgate Palmolive Company, Research and Development Department, Research Report 2675, August 15, 1973 states one worker has reported successful determination of chrysotile in talc by the X-ray diffraction technique for powder sample and step scanning technique, but United Sierra has not had an opportunity to attempt this procedure in detail with the step scanning procedure. It is reported to have success with a lower limit of detection of 0.2% chrysotile

We evaluate our own production talcs routinely via X-ray diffraction with or without step scanning depending on tremolite content.

If we are concerned with very small amounts of tremolite, the XRS after acid leaching described above is also used.

Since tremolite is the only asbestos impurity with which we contend, and only then in small amounts in certain California talcs, these measures suffice our normal needs.

Work on competitive talcs, which may or may not contain chrysotile is carried out via scanning electron microscope using electron diffraction for positive identification of individual fibers.

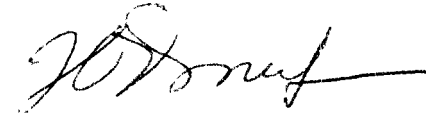
Recommendations

We recommend that the proposed identification method be rejected and that:

1. X-ray fluorescence after acid leaching be adopted as the official method for tremolite determination. Accuracy to 0.2% can be obtained.
2. A program involving government and industry to establish a more accurate, simpler method of chrysotile determination be instituted. This division would be pleased to participate in such a program.

Very truly yours,

UNITED SIERRA DIVISION
Cyprus Mines Corporation



H. T. MULRYAN
President

HTM:EE

September 7, 1972

Hearing Clerk
Department of Health, Education & Welfare
Room 6-88
5630 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

We refer to the Federal Register document of August 12, 1972 concerning proposed regulations for asbestos containing talcs as food additives. In this connection we should like to make the following comments:

Concerning the quoted article in "Science", the basis for its discussion is very weak and hypothetical as the subsequent letters from the readers of the magazine proved.

Moreover, the term "asbestos-form" is, in our opinion, arbitrary in that any fibrous material including such materials as cellulose, cotton, etc. could be considered "asbestos form". We believe that the various types of asbestos, that is, chrysotile, crocidolite, anthophyllite, tremolite, etc. should be spelled out as the contaminant. This has the double advantage of also providing a satisfactory means of analyzing for the asbestos impurity. We believe this matter has been brought to your attention in connection with cosmetic talcs. Our opinion, as well as that of many others, is that the X-ray diffraction method of detecting asbestos minerals mineralogically is the quickest and most accurate method. It can detect as little as 1% of these impurities and clearly distinguishes them from other minerals including talc, which may take the form of a fiber or rolled-up platelet.

The proposed regulation makes no reference to the size of the contaminating fibers. Literature clearly indicates that the range of 5 to 50 μ m in length is considered hazardous; smaller or larger particles not.

If the agency insists that a limit must be placed on asbestos content, we propose a maximum permissible asbestos mineral content of 1% of talc content by weight. Reliable detection by X-ray diffraction can be set at this level.

Very truly yours,

UNITED SIFREA DIVISION
Cyprus Mines Corporation

H. T. MULRYAN