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Personal Care Products Council
Committed to Safety, Quality & Innovation

Formerly CTFA

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Dear Sirs:

On behalf of the Unites States-based Personal Care Products Council ("the Council", formerly known as CTFA—the Cosmetic, Toiletry & Fragrance Association), I am pleased to submit comments regarding draft documents on talc released by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China and Standardization Administration of the People's Republic of China Talc Powder (GB15342-200X), Methods for Physical Test of Talc (GB/T15344-200X). and Sample Preparation of Non-powder Cosmetics in Asbestos Testing (Huimin, F. Et al.)

The Personal Care Products Council (the Council) has over 600 member companies, including manufacturers and distributors of finished products, as well as suppliers of ingredients, raw materials, packaging, and other services used in the production and marketing of finished cosmetics and personal care products worldwide. Our member companies consistently strive to uphold and surpass the most stringent regulatory and product integrity standards worldwide. Many of the Council's member-companies are actively engaged in providing Chinese consumers with safe, innovative, and quality cosmetic and personal care products. We appreciate the opportunity to contribute to your deliberations on this important matter.

Our comments pertain specifically to the reliance only on the use of X-Ray diffraction (XRD) methodology for determining asbestos in cosmetic talc. Talc has many uses in cosmetics and personal care products. These include use as absorbents, anticaking agents, bulking agents, opacifying agents, skin protectants and slip modifiers to improve the feel and performance of the

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product. "Cosmetic-grade" talc is produced so that it conforms to established industry specifications (attachment 1 - CTFA Specification and attachment 2 - CTFA Test Method J 4-1) as well as the United States Pharmacopeia (USP) (attachment 3), which describe the purity criteria and method of analysis. These specifications have been the standards followed by the industry for decades and are recognized by the U.S. Food and Drug Administration. Cosmetic-grade talc (attachment 1) shares the identical requirement to USP (attachment 2) that there be no detectable asbestos fibers when tested using the methods described in the CTFA Specification and the USP monograph (standard). Similar specifications have also been issued by the European Pharmacopeia (CP); British Pharmacopeia (BP); Japan, Korea, and other countries.

In considering the safety of cosmetic and personal care products that contain talc, the presence of asbestos is only a concern where there is a possibility of inhalation. Topical application (and even ingestion) of low levels of asbestos does not present a risk to human health. Any market surveillance program for talc and asbestos does not need to include products such as mascara, eyeliner, lipstick, lotions, soap or any other product where there is no inhalation exposure.

It is very important to emphasize that the absence of asbestos from cosmetic grade talc is first confirmed by X-ray diffraction (XRD) and, if indicated by the XRD test, optical microscopy to confirm the type of asbestos present in the raw material. Proper application of the XRD and optical microscopy methodology to ensure that the specification of "no detectible asbestiform fibers" is an effective and efficient way to control the purity of talc. We commend your efforts to develop an appropriate standard for talc and hope that the following comments will provide you with further insight into issues that may arise with regard to the proposed methodology in Methods for Physical Test of Talc (GB/T15344-200X).

1. X-ray diffraction, when used without follow-up microscopy, is insufficient to determine the presence of asbestos. The X-ray diffraction technique indicates the presence of amphibole and/or serpentine; however, both asbestos and non-asbestiform varieties of amphibole and serpentine appear similar by X-ray diffraction. Therefore, we propose the following changes to the standard (GB/T153444).

Section	Existing wording	Proposed wording
4.6.3.4	Compare the X-ray diffraction data of the test sample with those of the asbestos minerals (see Appendix B), and judge whether the test sample contains asbestos and what types of asbestos it contains.	Compare the X-ray diffraction data of the test sample with those of amphibole and serpentine (see Appendix B), and judge whether the test sample contains either amphibole or serpentine minerals.

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4.6.4	If the X-ray diffraction data of the test sample fit with the X-ray diffraction data of any asbestos mineral in Appendices B1~B6, judge and report that the test sample contains that type of asbestos mineral. Otherwise, judge and report that the test sample contains no asbestos minerals.	If the X-ray diffraction data of the test sample indicates the absence of amphibole and serpentine, report that the test sample does not contain asbestos at the level of detection for the X-ray diffraction technique. Otherwise, if X-ray diffraction data of the test sample fit the X-ray diffraction data in Appendices B1 – B6, report that the test sample may contain amphibole or serpentine minerals. If amphibole and/or serpentine is detected by X-ray diffraction, additional analysis by microscopy is necessary to determine if the amphibole or serpentine is asbestos. X-ray diffraction cannot distinguish amphibole-asbestos from non-asbestiform amphibole; nor can X-ray diffraction distinguish serpentine-asbestos (chrysotile) from non-asbestiform serpentine (antigorite, lizardite).

2. As recommended in Point #1, follow-up microscopy should be used to determine if asbestos is present when XRD detects amphibole or serpentine. Polarizing light microscopy (PLM) is appropriate for the particle size range of talc products used for cosmetics and personal care products.

We recommend that a PLM section be added to the GB/T15344-200X standard as follows:

A section on analysis of the talc product by polarizing light microscopy (PLM) should be included to determine if any amphibole or serpentine detected by X-ray diffraction is amphibole-asbestos or serpentine-asbestos (chrysotile).

a. The following refractive index liquids should be included in the section:

- 1.550 to check for chrysotile
- 1.605 to check for tremolite-asbestos, actinolite-asbestos, an anthophyllite-asbestos

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- Additional refractive index liquids between 1.630 and 1.700 can be used to check for riebeckite-asbestos (crocidolite) and grunerite-asbestos (amosite), however, these are less common contaminants of talc.

b. PLM parameters for analysis should include:

- Morphology
- Color and pleochroism
- Birefringence
- Extinction angle
- Sign of elongation
- Refractive index (i.e. dispersion staining color)

c. The morphology of asbestos is characterized by the following,

"The presence of asbestos is confirmed if the following criteria are met:

- Mean aspect ratio of 20:1 or greater for fibers longer than 5 um,
- Very thin fibrils, usually less than 0.5 um in width, and
- Two or more of the following:
  - Parallel fibers occurring in bundles
  - Fiber bundles displaying splayed ends
  - Fibers in the form of thin needles
  - Matted masses of individual fibers
  - Fibers showing curvature."[3]

The above morphology definition is referenced in USP[1]/EP, WHO[2], the new Korean Pharmacopeia method and many other bulk asbestos analysis procedures. Note that further discussion on polarizing light microscopy for the analysis of asbestos have been published by the U.S. EPA,[4] U.S. OSHA,[5] and the British HSE.[6]

3. The standard should include a procedure for assessing and reporting the performance of the method to allow comparison across laboratories.

We recommend adding clarification on quantification and detection procedures to the XRD section of the GB/T15344-200X standard:

Typical methodology for quantification of XRD results includes:

- Simple comparison to known standards
- Internal standard method (typically using fluorite as an internal standard)

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- Method of standard additions

A limited scan range (i.e. 10 – 13° and 24 - 26° 2θ) coupled with slower scan rate (i.e. 0.1° 2θ/minute, or lower) would improve the sensitivity of the test and help avoid interferences that can produce a false positive result. For example, chlorite, which is often present in talc products, has an XRD peak very close to the serpentine XRD peak. Consequently, chlorite can be misidentified as serpentine.

As we have previously noted to the China State Food and Drug Administration (SFDA) the regulatory approach with respect to talc should be designed to avoid false positive results that cause unnecessary alarm to consumers, undue burden on government resources, and disruption of the market for cosmetics and personal care products.

We believe that a combination of XRD and PLM techniques, as outlined above, will avoid false positive results. Although we agree that the overall strategy of screening by X-ray Diffraction (XRD) is an important first analysis as discussed above, XRD is a screening step that does not differentiate between asbestos and non-asbestos morphology. The toxicological literature shows that non-asbestos particles do not have the same disease potential as asbestos particles.[7]

As a final comment regarding "Sample Preparation of Non-powder Cosmetics in Asbestos Testing (Huimin, F. et al.), the Personal Care Products Council suggests that testing for asbestos in talc is most effectively applied to the raw material i.e., directly to the cosmetic-grade talc. In any event, testing for asbestos should not be applied only to finished products, This approach is in line with most global references which apply testing exclusively to control of the raw material. Since all available specifications for cosmetic-grade talc (USP, EP, etc.) are based on raw material specifications, it is both unnecessary and counter-productive to apply tests to the finished cosmetic product. Applying tests to the finished products can lead to false positive results based on interference of other organic or inorganic materials that may be contained in the product. Removal of organic material from non-powder cosmetics by ashing improves the ability to detect asbestos, but it does not remove all interference arising from other inorganic materials, such as chlorite, which has similar particle size and shape or other ingredients used to formulate the product. In addition, testing finished cosmetics products at designated Chinese laboratories places unnecessary burdens on the Chinese regulators, and can also result in significant delays, especially in the marketing of imported products.

In order to ensure the most effective approach, cosmetic manufacturers can make available for review by the Chinese authorities documentation that confirms the talc meets the appropriate "cosmetic-grade" specification. This documentation most often takes the form of a "certificate of analysis" or "COA" demonstrating that the talc that has been used in the product formulation has been tested according to the appropriate test methodology, and presenting the results of those

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tests. To help ensure that only raw material meeting the established specification is used, raw material suppliers and finished product manufacturers establish and follow a well designed quality control program. Product manufacturers typically follow good manufacturing practices in the control of the raw materials used in preparation of finished products (see ISO 22716:2007 Cosmetics -- Good Manufacturing Practices (GMP) -- Guidelines on Good Manufacturing Practices). Talc suppliers participate in this program through certificates of analysis or other systems established between the supplier and manufacturer (i.e., supplier audits).

By adopting this type of system, the regulatory authorities in China would be aligning its regulatory practices to those of most global markets, including the United States, Europe, Korea and Japan. It would also be a more efficient and practical way to assure that talc meets Chinese standards, and would avoid the delays and burden of Chinese laboratories' testing thousands of finished products containing talc. Finally, it would emphasize that manufacturers of finished cosmetic products have responsibility for assuring that their products meet the requirements.

The Council recognizes the challenges in assuring accuracy and reproducibility of the analytical methodologies discussed above and offers to work with you to establish procedures that will accomplish the goal of avoiding asbestos in talc. For example, analyses of test samples by differing laboratories using set protocols would greatly enhance an understanding of the strengths of methodologies under scrutiny.

The Council sincerely appreciates having the opportunity to provide comments on this important matter. We are confident that you share our view that the development and application of an appropriate test method for asbestos in talc is a highly complex task. We would be pleased to engage in additional dialogue with your experts, either in writing or in a meeting, to discuss in greater detail the points we have raised in this letter, and to respond to any questions you might have.

Sincerely,

Francine Lamoriello

Francine Lamoriello
Executive Vice-President
Global Strategies

References:

References:

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[1]USP 32-NF27 monograph.

[2]WHO, Compendium addendum 11/FNP 52 Add. 11/83 (2003); FAO JECFA Monographs 1, vol. 3/479.

[3]Wylie, A.G. (1990) "Discriminating Amphibole Cleavage Fragments from Asbestos: Rationale and Methodology". Proceedings of the VIIth International Pneumoconiosis Conference, Pittsburgh, p.1065-1069.

[4]Perkins, R.L. and B.W. Harvey, U.S. Environmental Protection Agency. Test Method for the Determination of Asbestos in Bulk Building Materials. EPA/600/R-93/116 (June. 1993).

[5]Polarized Light Microscopy of Asbestos. OSHA Method ID-191 (1992).

[6]Asbestos in bulk materials: Sampling and identification by polarised light microscopy MDHS 77 HSE Books 1994 ISBN 0 7176 0677 5.

[7]Mossman, B.T. (2008): Assessment of the pathogenic potential of asbestiform versus non-asbestiform particulates (cleavage fragments) in *in vitro* (cell or organ culture) models and bioassays. Regulatory Toxicology and Pharmacology 52 (2008) p.S200-S203.

Attachments:

(1) CTFA specification for "cosmetic-grade" talc.

(2) CTFA Test Method J 4-1.

(3) USP monograph for talc.

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