

## Summary Report for the Break out Session on the Test methods for Analysis of Talc and Mineral fibers in Cosmetics.

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The objective of the breakout session was to establish concurrence on an analytical protocol for mineral fibers in cosmetics contain talc. The scope of this is quite extensive and several factors were considered to complete the objective.

Talc is found in numerous cosmetics like body and shower products, lotions, eyeshadow, lipstick, deodorants and face products. In consideration of the objective stated above the following topics were attributes were considered.

- We first considered the implication of the objective in counting mineral fibers (Generic) and asbestos (asbestiform)
- Cosmetics with talc are finely milled and this can cause concerns with fiber resolution using light microscopy.
- Milling of Talc that is comingled with amphibole minerals could create cleavage fragments that mimics the asbestiform habit and could be counted as asbestos.
- Cosmetics can also contain binders and wax that can interfere with analysis and would require additional preparation prior to analysis.
- The analysis for mineral fibers generally requires host of instrumentation and tests. A single analytical technique may limit characterization.
- There are insufficient mineral reference materials that can be used as standards for verification or calibration.
- Defining a mineral habit (asbestiform vs non asbestiform) is assigned macroscopically on a hand samples. Can it be microscopically inferred?
- Where is the path for exposure and how does it influence the preparation an analysis of the cosmetic. (i.e. Lips – ingestion, Powders – inhalation/ingestion)
- What results are needed for interpretation? What units? (Percent, structures/gram, fibers/cc, structures/cc)
- What is the purpose of the analytical method? Testing for exposure – cancer / non-cancer? Testing for Quality (manufacturing), testing for regulation? Testing for risk/litigation?

Due to time constraints only one breakout session was completed. The group consisted of a mix of geologists, laboratory analysts, toxicologist/medical researchers and government employees.

The group recognized and agreed that there was no one method or analytical protocol that could be used for the analysis of mineral fibers in cosmetics. Several analytical techniques would be required to overcome any inherent limitation as well as to continue to refine the results of other methods. There was no consensus on which order the techniques should be used, but X-ray Diffraction (XRD), Polarized Light Microscopy (PLM) and Electron Microscopy (Scanning Electron Microscopy or Transmission Electron Microscopy) are what the majority of the commercial testing laboratories have been employing.

As demonstrated in the morning session, XRD is useful in the determination of minerals that are present in the sample and “looks at” a larger portion of the sample than PLM or Electron microscopy does. Where XRD main disadvantages, besides its inability to discern fibrous morphology, are that the limit of detection is too high for public health/ regulations and might give false negatives. PLM can be used to determine quickly if the sample contains elongate mineral fibers, but lacks the resolution to detect smaller diameter fibers that are noted for their toxicity. Transmission Electron Microscopy is typically seen as the ‘gold standard’ for analysis because it can quickly determine morphology, crystal structure, and chemical composition of fibers. However, it looks at such a small portion of the sample, that a non-homogenous sample could lead to overestimation of the mineral fibers or false negatives.

Other techniques were discussed if specific aspects of the sample wanted to be investigated further. For instance, the role that iron state (Ferric vs. Ferrous) or surface chemistry may play in disease. It was also suggested that for further research, that perhaps ICP/MS or Auger Electron Spectroscopy be considered.

The group recognized the desire of toxicologists to restrict or diminish sample preparation steps that might alter the matrix and any fibrous components. Aggressive preparation techniques (high temperature furnace separation, fine milling, etc.) might remove ability to discern how the various cosmetic product’s various components work synergistically and contribute to exposure. Therefore, the preferred analytical method for exposure would disturb or separate the sample as little as possible.

The groups spent some time evaluating the analysis documentation and reporting criteria required, since that would have an impact on which course of analysis would be chosen. The testing methods main objective is to record data and with the lack of consensus among the stake holders as to which aspects of the sample or fibers cause disease (cancer or non-cancer); the group thought that it would be best to record as much information as possible at the time of the analysis and place no limits on size, mineralogy, habit, etc. This would ensure that the results could be gathered into several different focused concentrations fitting the exposure model / exposure factor desired. It would also preserve the data in such a way that it could be re-evaluated or reclassified as new information becomes available.