The Cosmetic, Toiletry and Fragrance Association, Inc.

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NOTED

JAN 10 1974

G. W. SANDLAND

Mr. George Sandland
Bristol-Myers Company
225 Long Avenue
Hillside, New Jersey

At a meeting on January 4th with Heinz Eiermann, George --

-- he stressed again the need for Industry supplying data on concentrations of Talc in the breathing area. He stated that the figure was of critical importance to both Industry and FDA in arriving at a suitable figure for regulatory purposes. He presented the following calculations which I am reproducing here for your study:

> The FDA proposal states that 1,000 fibers are equivalent to 0.1%; 100 fibers are equivalent to 0.01%. OSHA limits are 5 fibers per milliliter per 8 hour day and 10 fibers per milliliter, per 15 minutes, per 5 hour day. Five fibers per milliliter is equivalent to 5,000 fibers per liter which is equivalent to 0.5% or 0.005 milligrams.
>
> If one gram of Talc is suspended in 1 liter of air, it is equivalent to 0.005 milligrams per thousand milligrams or 0.0005% Asbestos in Talc.

What FDA urgently needs is a figure of how many grams or milligrams of Talc are suspended in one liter of air in, for example, a baby's breathing area so that a calculation such as the one above can be made and an Asbestos in Talc limit published.

I urge you tc discuss these calculations with your Subcommittee and to collect any necessary data.

Best personal regards.

Cordially,

Norman F. Estrin, Ph.D.
Vice President - Science

NFE:jj
January 8th, 1974

PLAINTIFF'S EXHIBIT
WCD-205

Colgate-Palmolive

November 16, 1973

TO: Mr. P. A. Minger

FROM: T. Wolf

Talc Dust Inhalation from Powdering of Babies

I recommend that estimate of respiration of dusting talc by babies best be carried out by an in vitro study with an Anderson Mini-sampler for air-borne dust, which classifies particles by their aerodynamic properties. The resulting "respirable" and "non respirable" fractions will be quantitated by atomic absorption measurement of magnesium. If this work were contracted to an outside laboratory, the findings would be more impartial than results obtained at Colgate.

The FDA needs information on the amount of talc a baby breathes while being powdered[1]. The parameters involved are:

- Amount breathed, that is, the amount of talc reaching the mouth and nose at a baby's respiration rate.
- Percent respirable, that is, the proportion retained by the lungs.
- Amount of talc used and how applied.
- Geometry of surface powdered and distance to the mouth.
- Absorption of powder by moist skin; assume initially that this is not significant.

To make the experimental determination, we need to consider:

1. HOW WE WILL DEFINE THE RESPIRABLE FRACTION.

Brown et al[2] state the nose filters out almost all particles larger than 5 micrometers (μm), that filtering efficiency falls with decreasing size and reaches zero at 1 μm. Below 1 - ½ μm, the lung no longer retains all particles breathed. The figures refer to spheres of unit density.

(1) See letter, C. W. Sandland to Members of Subcommittee on Asbestos in Talc, (C. H. Costello). Asbestos in Talc, Sept. 14, 1973.

(2) Brown, J. H., Cooke, K. M., Ney, F. C, and Hatch, T. F., "Influence of Particle Size upon the Retention of Particulate Matter in the Human Lung", J. Am. Public Health Assoc., 40 450-458 (1950).

Talc consists of platelets of density 2.8 gm/ml. The value found for "size" depends on particle shape, density and method of measurement. Only if the method of measurement depends on the same properties by which the nose discriminates against particles and by which the lung retains them are the results valid for non-spherical particles. The method of measurement should depend on aerodynamic properties(3).

2. SHOULD WE SUBDIVIDE THE RESPIRABLE FRACTION?

The 5 µm cut-off represents where some particles enter the lung, while not till 1 µm do all enter the lung. Also the 5 µm cut-off could possibly be changed by future research.

3. SHOULD WE COLLECT THE NON-RESPIRABLE FRACTION?

The baby may breathe through the mouth also.

4. SAMPLING FLOW

A baby's breath intake is so low that a large number of experiments may be required to obtain a measurable amount of talc. Higher flow will result in distortion of the dust cloud.

5. TYPE OF SAMPLER

We considerably reduce work by sizing into fractions during sampling. Sizing should be on the basis of the particle's aerodynamic properties.

6. HOW TO SIMULATE POURING AND WHERE TO PLACE SAMPLER

The procedure must be reproducible, yet must simulate powdering. A baby-sized doll would accurately position the sampler next to the nostrils, and create an area for applying the powder.

7. PRODUCTS USED

CASHMERE BOUQUET is suggested. Comparison of particle size distribution should enable estimation of results for other talcs.

8. MEASUREMENT OF AMOUNT COLLECTED

Talc, $Mg_3 Si_4 O_{10} (OH)_2$, contains 18% magnesium, which is reasonably specific for talc. We require 70 nanograms Mg/sample for detectability by Atomic Absorption.

9. NUMBER OF EXPERIMENTS

How many powderings are needed to accumulate a measurable amount of talc has to be determined by experiment. We need to run enough experiments to be statistically meaningful.

(3) Anderson, A.A., "A Sampler for Respiratory Health Hazard Assessment", American Industrial Hygiene Association Journal 27 160-165 (1966).

10. SCHEDULING PLACE AND TIME

A draft-and-dust-free room should be used. While it would be possible to run these tests at the Research Centre, we ought to consider whether more believable results would be obtained by contracting this study to Battelle Institute or some other independent laboratory.

It is impossible to estimate whether the work will require a few weeks or several months. It will depend on how the questions posed above are answered and how many powderings are needed to give a detectable amount of talc.

A large number of air samplers are available, based on many types of measurement. Those based on aerodynamic size that appear best suited are the Hexhlet and Anderson collectors.

HEXHLET (a,b) This collector consists of a soxhlet thimble, or a filter, through which air is drawn at 50 litres/minute, preceded by an array of horizontal shelves. All material of 5 μm (unit density, spherical, falling in air), and larger, deposits on the shelves.

Thus only respirable talc is collected on the filter. While it is possible to recover the larger diameter talc also, it is hard to do so accurately unless a substantial amount is deposited.

No information is possible on particle sizes within the respirable fraction. The filter would be ashed before analysis by atomic absorption.

ANDERSON, MODEL 21-000 (c,d,e) Air is drawn through a series of 8 plates, four inches in diameter, each having 400 holes. Flow rate is 28 litres/min. The first three plates collect particles too large to pass through the nose (> 29 μm, 9-30 μm, 5-11 μm), four collect the portion retained and partially retained (3-6 μm, 2-3 μm, 1-2 μ, 0.3-1μm) and one collects that not retained (0.1-0.3 μm). We would have to wash the talc from each plate, perhaps with a volatile washing liquid (since talc is not soluble). We could combine fractions.

(a) C. F. Casella & Co. Ltd., Regent House, Britannia Walk, London, W1, England.

(b) Higgins, R. I. and Dewell, P., "The Measurement of Airborne Dust Concentration in Iron Foundries using the Hexhlet Dust Sampler", BCIRA Journal 8 425-43 (1960).

(c) 2000 Inc., 5899 South State Street, Salt Lake City, Utah 84107

(d) Manufacturer's Literature

(e) Anderson, A. A., "A Sampler for Respiratory Health Hazard Assessment". American Industrial Hygiene Association Journal 27 160-165 (1966).

ANDERSON, MINI-SAMPLER (c, d) This is a smaller version using the same principles as the 21-000. There are five stages: 1 not reaching lung (> 5.5 μm), 3 respired (5.5-3.5 μm, 3.5-? μm, ?-0.3 μm) and 1 not retained (< 0.3 μm). The flow rate is 1.4 litres/min., the plate size 1 inch and the overall dimensions 1" x 1 1/8" diameter.

The Anderson Mini-sampler offers important advantages. The flow rate is about double the rate breathed by a sleeping, newborn baby (f), while the others sample at 20 times (Anderson 21-000) and 36 times (hexhlet) the Mini-sampler rate. It subdivides the respirable fraction into three, which could be pooled, but could also yield added information without unreasonable extra work. Also it separately collects the fractions filtered out by the nose and that only partially retained by the lung. Its small size would enable exact placement corresponding to a baby's nostrils, and make washing the talc from collection plates convenient. Its small size and low price ($115 in 1971) make it feasible to monitor each powdering experiment with, say, 3 samplers, thereby speeding up the work.

The question of whether a flow rate as low as 1.4 litres/minute is high enough to accumulate sufficient talc to measure will have to be determined by experiment. However, it does seem reasonable, since the sampler will be only 1-1½ feet from the powder source, the talc typically contains 25% material under 5 μm (sedimentation analysis, after breaking up agglomerates which might be present), and the detection limit for atomic absorption should be about 0.4 mg of talc.

(c) 2000 Inc., 5899 South State Street, Salt Lake City, Utah 84107

(d) Manufacturer's Literature

(f) Spector W.S (Ed) "Handbook of Biological Data", Philadelphia, 1956, page 267. Tidal volume for Newborn, asleep, 10-27 mls (mean 17); Respiration frequency, 24-116 min^{-1} (mean 43).

TW:cs

cc: C. H. Costello
W. J. King
J. P. Simko, Jr.
D. McCrae
Information Center