



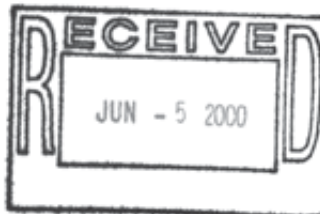
R. T. Vanderbilt Company, Inc.

INDUSTRIAL MINERALS AND CHEMICALS

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June 2, 2000

Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens
MD EC-14
P.O. Box 12233
Research Triangle Park, NC 27709



RE: 10th ROC NOMINATIONS – PUBLIC COMMENT
Talc (containing asbestiform fibers)

Dear Dr. Jameson:

R. T. Vanderbilt Company, Inc. ("Vanderbilt") and its wholly-owned subsidiary, Gouverneur Talc Company, are engaged in the mining, milling and marketing of industrial talc that is used primarily in the paint and ceramic industries. Vanderbilt appreciates the opportunity to comment on the captioned NTP nomination. We believe that the available evidence does not support the need for a separate entry for talc containing asbestos or asbestiform fibers. Such an entry would suggest to the public that this is a real and far reaching exposure potential, when in reality it is extremely rare (if it occurs at all). While talc containing asbestos or asbestiform fibers may be perceived as a substantial cancer threat, in reality, such a threat is not reasonably supported. Further, there is no need to consider the carcinogenicity of asbestos, since the latter is already listed. Vanderbilt's comments are divided into two main areas: Nomenclature and Justification. We have also appended several reference documents which are organized under general topic tabs as well.

NOMENCLATURE

The entry "talc containing asbestiform fibers" is misleading. If the entry means the mineral talc contaminated with "asbestos," it would be more clearly expressed as "talc containing asbestos". That change would also be consistent with the way most government agencies and mineral scientists describe this mineral category. For example, the Occupational Safety and Health Administration (OSHA) uses the phrase "talc containing asbestos" in its current Permissible Exposure Limits Tables (OSHA, ref. 1, tab 1). The American Conference of Governmental Industrial Hygienists (ACGIH) expresses the exposure in the same way in its Threshold Limits Values for Chemical Substances and Physical Agents (ACGIH, ref. 2, tab 1). The Environmental Protection Agency (EPA) also addresses the exposure as "asbestos" (ref. 3, tab 1).



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The NTP currently lists asbestos as a known human carcinogen. Accordingly, any material containing asbestos would reasonably be assumed to pose a carcinogenic risk, depending upon the amount of asbestos involved, the duration of exposure, the type of asbestos involved, the route of entry, etc. The origin of this entry is understood to be Supplement 7 (1987) to the International Agency for Research on Cancer (IARC) which characterizes the exposure as "talc containing asbestiform fibers". However, this IARC reference is neither up to date nor accurate. The studies noted in Supplement 7 have been superseded by a more advanced understanding of mineral nomenclature and biological issues concerning talc and asbestos.

The word "asbestos" is a commercial term applied to six specific minerals, but only when they exhibit an "asbestiform" crystal growth structure or "habit". The asbestiform crystal growth pattern is extremely rare in nature, and the six minerals are far more abundant in their nonasbestiform habit. When these six minerals do not exhibit asbestiform crystal growth they are not classed as asbestos. In their far more common nonasbestiform habit some of these minerals are called by other names even though chemically and structurally (internal structure) they are the same mineral. (See references 4 to 9, tab 2 and references 10 and 12, tab 3 for a more complete discussion.) The amphibole minerals tremolite, anthophyllite and actinolite are called by the same name, regardless of their crystal growth habit.

In addition to the six asbestos minerals, many minerals (including the mineral talc itself) can be found in nature in an asbestiform "habit" (Steel, et al, ref. 5, tab 2). Such occurrences, however, are rare. When growing in this habit, these minerals share the same basic external crystal growth structure as the six asbestos minerals, but differ in other respects (physio-chemical properties, harshness, durability, etc.). It is therefore misleading to use the term "asbestiform" as a synonym for asbestos. "Asbestiform" refers only to a crystal growth habit. Mineral scientists from academia, government and industry have taken great pains to describe these distinctions (see references 4 to 9, tab 2 and 10 and 11, tab 3), but confusion still exists.

As pointed out by Campbell, et al (U.S. Dept. of Interior, ref. 4, tab 2), "Precise definitions acceptable to mineral analysts, regulatory personnel, and medical scientists are essential because of the present lack of conformity in terminology concerned with measuring and controlling asbestiform particulates and their related health effects". The meaning of terms like "fiber", "asbestos" and "asbestiform" are unfortunately unclear to many health investigators. Such ambiguity can lead to misleading exposure characterization in health studies involving elongated particles.

One series of studies, prominently referenced in the NTP cited IARC supporting monograph, exemplifies error. These references involve early mortality studies conducted by Kleinfeld, et al (ref. 38, tab 5), and NIOSH (Brown, et al, ref. 36, tab 5) on upstate New York tremolitic talc miners and millers. The NIOSH study exclusively involves Vanderbilt talc miners and millers.

In these studies NIOSH incorrectly characterized nonasbestiform amphibole cleavage fragments as asbestos, as they had previously done in another study involving amphibole

minerals (Homestake Gold mining study – see ref. 24, tab 5 pages 38-39). Much of the concern involving asbestos in talc originated from this erroneous characterization by NIOSH. Over the years, however, this complex mineral mix has been studied by many highly regarded analysts who repeatedly confirmed the absence of asbestos in this talc (see references 10 to 14, tab 3 and ref. 17, tab 4).

The nonasbestiform amphibole controversy associated with these talc worker studies spanned several decades and was ultimately the center of a protracted OSHA rulemaking process. This rulemaking culminated in and an OSHA final rule in 1992 which stated decision in 1992 that substantial evidence is lacking to conclude that nonasbestiform tremolite, anthophyllite and actinolite present the same type or magnitude of health effects as asbestos (OSHA, ref. 8, tab 2). The complete OSHA record, which includes extensive mineral nomenclature discussion and health study reviews pertinent to this NTP review can be obtained under Docket H-033-d of the Occupational Safety and Health Administration; 200 Constitution Avenue N.W.; Room N2625; Washington, DC (OSHA, ref. 8, tab 2).

In its rulemaking, OSHA recognized the key mineral distinctions discussed above and specifically acknowledged that the mineral composition of Vanderbilt talc was in fact correctly stated on the company's Material Safety Data Sheet and that this talc did not contain asbestos (MSDS, ref. 15, tab 3). Prior to the final OSHA rulemaking, a more accurate understanding of the actual composition of this talc was recognized by OSHA's own laboratory (Crane letter, ref. 11, tab 3). This is the same talc incorrectly characterized in the IARC monograph as "asbestos-containing". We urge that the NTP not perpetuate this error.

If any particular nonasbestos mineral caused the same health effects as asbestos, it would certainly be important to regulate and control that mineral exposure just as asbestos is controlled. However, we should not confuse cause and effect associations and "mechanism" studies designed to predict risk by obscuring (rather than clarifying) the nature of the exposure. For this reason throughout the years, Vanderbilt and others have repeatedly appealed to health researchers to use proper mineral nomenclature when addressing of health effects. As discussed by Dr. Campbell (supra), it is critically important to call things what they are.

If the intent of the "talc containing asbestiform fibers" entry is to characterize and evaluate the carcinogenic risk of talc containing asbestos, the entry should specifically say "talc containing asbestos". Alternatively, the entry might be deleted altogether since asbestos is already listed as a known human carcinogen. The IARC references underlying the nomination suggest that actual "asbestos" exposure is being discussed (valid characterization or not).*

* If the intent is to address any mineral in the asbestiform habit, then risk information for asbestiform minerals other than asbestos would need to be addressed and be reasonably shown to have a carcinogenic effect (such as that shown for asbestos).

JUSTIFICATION

Should the NTP continue with the entry "talc containing asbestiform fibers" as a known human carcinogen, justification for that entry needs to be addressed. Presently, there is scant support for such an entry. A review of the 1987 IARC Supplement monograph in which this mineral combination was characterized as a known human carcinogen reflects the following supporting references and arguments.

- a. Asbestos was found in assorted, off-the-shelf cosmetic talcs in the 1970's (Rohl, et al), posing a risk to general consumers and supporting the perception that asbestos is a common contaminant in talc.
- a. Asbestos was reported by NIOSH in New York State industrial grade tremolitic talc, posing a risk to miners and millers as well as industrial users of this talc (ceramics, paint, etc.). See Brown, et al, ref. 36, tab 5.
- a. The asbestos NIOSH reported in New York talc (tremolite and anthophyllite specifically) was said to be the etiologic agent in the elevated lung cancer observed in these talc miners (Brown, et al, ref. 36, tab 5). Earlier studies of New York talc miners from the same region showed a similar lung cancer excess (Kleinfeld, ref. 38, tab 5).
- a. Four case reports of mesothelioma were said to be linked to upstate New York talc mining (Vianna, 1981).

Each of these references is addressed below.

- A. Asbestos was found in some cosmetic talcs and may therefore be a common contaminant in talc.

Reports of trace asbestos found in some off-the-shelf samples of cosmetic talc appeared in the 1970's through the work of Mt. Sinai researchers (Rohl, et al). At that time the principal researcher (Rohl) also found asbestos in New York State tremolitic talc (Vanderbilt talc) in support of the NIOSH work. These findings are incorrect (Langer, ref. 17, tab 4).

Given the lack of definitional specificity and the less rigorous analytical protocols that existed at the time (Langer, ref. 17, tab 4 and National Bureau of Standards, ref. 22, tab 6), the accuracy of these early reports of contamination is unclear. Petitions to require asbestos labeling on cosmetic talc were denied by the Consumer Product Safety Commission (CPSC) with the support of the Food and Drug Administration (FDA) due to concerns about the reliability of these reports (see CPSC, ref. 21, tab 4). Analytical deficiencies in these reports were detailed in the National Bureau of Standards' Special Publication 506 and supporting documentation (see also Krause, et al, ref. 23, tab 4).

According to mineral scientists, the notion that asbestos is commonly found in talc ore deposits is not correct. The occurrence of asbestos in talc ore bodies is in fact rare, and is essentially limited to serpentine asbestos (chrysotile). In addition, upgrades in federal and industry talc purity standards as well as quality control procedures make asbestos contamination in talc rare to nonexistent. The Zalenski, et al, paper entitled "Talc: Occurrence, Characterization, and Consumer Applications" discusses these considerations more fully (see Zalenski, et al, ref 18, tab 4), as does the National Bureau of Standards' Special Publication 506 referenced above. If this reported contamination is of critical concern to the NTP, it is strongly encouraged to obtain additional confirmation from knowledgeable mineral scientists.

B. Asbestos was reported in Vanderbilt talc and thus poses an asbestos risk to the miners and millers of this talc as well as downstream users of this talc.

The absence of asbestos in Vanderbilt talc is discussed above. If references 10 through 15, tab 3, and ref. 16, tab 4 do not adequately confirm the absence of asbestos in this talc, we urge the NTP to review complete analytical documents which were submitted to OSHA. (A listing of all the analytical reports available to us, and basic results from 1973 through 1990, are included at ref. 16, tab 3). Clarification that the minerals reported as asbestos by NIOSH (tremolite and anthophyllite) were in fact not asbestos is important since the mortality studies of upstate New York talc miners and millers are also relevant to the NTP evaluation.

The only truly fibrous or asbestiform particulate in Vanderbilt tremolitic talc (the sole producer of New York state talc since 1974) is a minor quantity of talc fiber, and to a lesser degree a very rare talc/amphibole mixed fiber. The genesis and composition of this rare mixed fiber remains undetermined after considerable study; but, it is known that these fibers are intergrown at the lattice level and can therefore not be separated. Although it has been asserted that talc fiber may be found in any talc if one looks long enough, these fibers are relatively easy to find in Vanderbilt talc. However, these fibers are still a very minor component. An analysis by weight percent of various grades showed the average highest grade % to be 0.00788 for combined talc fiber and mixed talc/amphibole fiber (Van Orden, ref. 20, tab 4). In accordance with OSHA's Hazard Communication Standard and/or Asbestos Standard, such a product would not be considered asbestos-containing even if talc fiber were regulated as asbestos (which it isn't). Some of the confusion linked to the perception that asbestos exists in talc comes from the observation of these rare fibers. Health investigations involving talc fiber will be discussed below (Wylie, Mossman at ref. 25, tab 5).

It must also be recognized that if the amphibole in Vanderbilt talc (especially tremolite) was asbestos, the health effects discussed in the next section would be dramatic, since upwards of 50% of the ore and product contains these minerals. Tremolite asbestos, for example, appears to be a rather potent carcinogen, as evidenced by limited exposures to it (below a 10% content) and the prevalence of carcinogenic response associated with the mining and milling of vermiculite (Libby, Montana, see ref. 24, tab 5, pages 18-19). Animal studies also clearly reflect the elevated carcinogenic potential of tremolite asbestos (see ref. 24, tab 5, pages 22-31).

- C. "Asbestos" reported in the NIOSH mortality study of Vanderbilt talc miners and millers is said to be responsible for the excess lung cancer observed in this cohort. A similar excess was observed earlier by Kleinfeld, et al, in miners from the same area. That is, exposure to this talc causes lung cancer.

In tab 5, we have included every health study known to us involving Vanderbilt talc. The references are preceded by a summary of these studies (Pictorial Exhibit, ref. 24, pages 42 to 47, tab 5). The animal and cellular studies include (in several cases) component concentrates (tremolite and talc fiber) tested against asbestos. Most of the studies involve epidemiological studies of our talc miners and millers. We believe that few other (if any) worker populations or mineral exposures have been studied as extensively.

Though rare, the presence of talc fiber noted in this talc may understandably be a source of concern (beyond the issue of what is and is not asbestos). In this regard, a careful review of Wylie, Mossman (ref. 25, tab 5) is helpful. In this cellular study, the authors conclude: "Our experiments also show that fibrous talc does not cause proliferation of HTE cells or cytotoxicity equivalent to asbestos in either cell type despite the fact that talc samples contain durable mineral fibers with dimensions similar to asbestos. These results are consistent with the findings of Stanton, et al (1981), who found no significant increases in pleural sarcomas in rats after implantation of materials containing fibrous talc." The authors also point out the consistency of these findings with another negative tumor animal study involving Vanderbilt talc and epidemiological studies involving Vanderbilt talc (discussed below). The cellular study involved a talc fiber concentrate that does not reflect of any real world exposure known to us.

Cohort mortality studies of upstate New York talc miners and millers are also critical because they directly address human exposure and response. While animal and cellular studies involving carcinogenicity may provide a more controlled evaluation (all are negative for Vanderbilt talc – see Stanton, ref. 34 and Smith, ref. 37, tab 5 & McConnell, ref. 39, tab 5), few worker populations have been as extensively studied as Vanderbilt talc miners and millers. Today, a two to threefold excess in lung cancer mortality persists in this cohort (to 1990 at least). However, more recent mortality studies of these talc miners and millers do not support a dust etiology (Delzell, ref. 26; Gamble, ref. 27; Lamm, ref. 30-31; Stille, ref. 32, in tab 5).

The causal association to tremolitic talc dust suggested by Kleinfeld (ref. 38, tab 5) and NIOSH (Brown, ref. 36, tab 5), is not supported in subsequent, larger, more discriminating studies (Delzell, ref. 26 and Gamble, ref. 27 in particular). Today, these miners and millers are no longer considered exposed to asbestos, and most now agree that the observed excess lung cancer is not linked to the workplace.

Earlier mortality studies (both pro and con for a dust causal link) suffer from many methodological shortcomings. These shortcomings include the small study population involved, the lack of dust exposure, smoking histories and proper internal controls (case - control evaluation), the lack of prior work histories and many unsupported notions which contradict

basic cause/effect principles (i.e., Hills criteria in determining causation). IARC had only these earlier studies to cite in its review.

While it has been said that virtually all epidemiological efforts have shortcomings, the most recent work by Delzell and Gamble strives to address earlier studies weaknesses. In both studies, the researchers conclude that the excess lung cancer observed is unlikely to be linked to dust exposure, principally because they demonstrated that smoking could account for the excess and no dose response relationship is demonstrated. In fact, the latter is inverse in relation to observed nonmalignant respiratory disease mortality. The frequently referenced NIOSH study merely recorded the excess lung cancer, incorrectly found "asbestos" where it did not exist and concluded that this "asbestos" was the logical cause of the excess. Although time from first exposure to death did support a causal link, other key causality considerations were not properly addressed (smoking history, exposure by either tenure or dust levels, consistency with other findings, etc.). References 40 through 47 and 49 to 51, tab 6 contain critiques which address several of the cohort studies (principally the Brown, et al, NIOSH study). These critiques (the Gamble critique in particular – ref. 40, tab 6) provide compelling criticism of the NIOSH work.

Reference 33, tab 5 reflects a mortality study of Vanderbilt talc users ("population at risk") underwritten by the National Paint and Coatings Association (NPCA) and published in 1981. This study finds no excess pulmonary cancer in over 16,000 paint workers from 32 plants in the United States. A cover sheet attached to this reference explains the very high use of Vanderbilt talc in the paint industry (which persists to this day).

At present, the predominant use of Vanderbilt talc is in paint manufacturing. Ceramic use has dramatically declined due to process upgrades in the ceramics industry allowing for the use of cheaper raw materials. There are no other Vanderbilt talc user health studies known to us. One pottery worker study referenced by the NTP in support of its review of pure talc (Thomas, et al) suggests excess lung cancer among workers exposed to pure talc (among other things), but not among a subpopulation of these pottery workers earlier exposed to tremolitic talc (origin of the talc unclear). This study gives no support to a link between tremolitic talc and cancer.

It can reasonably be assumed that few if any downstream users of tremolitic talc would experience dust exposures greater than those experienced by our own miners and millers. If cancer can not be demonstrated in Vanderbilt talc miners and millers, or in direct animal testing involving this talc, a significant cancer risk to downstream users is difficult to imagine.

While Vanderbilt talc should not be viewed as asbestos-containing or cancer causing, there is no question that overexposure to this tremolitic talc (or any mineral dust) can result in nonmalignant respiratory disease. We believe that exposure to all talc has been reasonably linked to the development of pleural plaques, and we have seen this in our own talc workers. There is no clear evidence, however, that pleural plaques promote the evolution of pleural tumors or even pulmonary impairment such as diminished pulmonary function (Boehlecke, ref. 52, tab 7).

Reference 52, tab 7 contains comments submitted to the OSHA docket (1990) concerning the regulation of nonasbestiform amphiboles by Brian Boehlecke, M.D. Dr. Boehlecke is a pulmonary consultant who has reviewed the pulmonary condition of Vanderbilt miners and millers over the last eighteen years. We agree with Dr. Boehlecke's observations regarding pleural plaques and parenchymal pneumoconiosis ("talcosis"). Dr. Boehlecke has reviewed numerous talc studies and offers some comparative comments regarding the prevalence and type of pulmonary abnormalities noted in tremolitic talc workers in contrast with non-tremolitic talc workers. A review of this reference is highly recommended. The current pulmonary status is consistent with those reported by Dr. Boehlecke in 1990.

An interesting study was conducted in the mid 1980's by Dr. Steven Lamm during a follow-up cohort study. In this study, Dr. Lamm compared rates for lung cancer deaths and pneumoconiosis for Vanderbilt talc workers (said to be exposed to asbestos by NIOSH) and Vermont talc workers (said not to be exposed to asbestos by NIOSH) with at least one year of exposure. Cohort comparisons of this sort can be problematic for many reasons, but these groups did share many similarities (the cohort size was approximately similar, the years of exposure were similar, overall dust levels were similar, quartz exposure (trace) was similar in both dusts, etc.). In this comparison, the lung cancer rate was essentially the same and the rate for nonmalignant respiratory disease was slightly higher in the Vermont cohort. This comparison can be further reviewed in reference 31, tab 5 in a preliminary report entitled "Absence of Lung Cancer Risk from Exposure to Tremolitic Talc", February 14, 1986, pages 21 through 23.

While nonmalignant respiratory disease and other abnormalities linked to talc are not the subject of this NTP evaluation, we have addressed them because of the mistaken assumption by some that such abnormalities are only linked to asbestos or are a precursor to pleural cancers (i.e., mesothelioma).

C. Cases of malignant pleural mesothelioma have been reported for individuals exposed to tremolitic talc mining and milling.

This IARC reference is problematic. In the most recent cohort follow-up (Delzell, 1995 – ref 26, tab 5), two mesothelioma cases were reported, but neither was considered linked to talc exposure. The first case was reported by NIOSH (Brown, et al, ref. 36, tab 5) and was also discounted because the latency was too short (diagnosed 15 years after first talc exposure). The second case died in 1986 and worked 6 months at the mine in the Engineering office as a surveyor in 1948. After this brief encounter in 1948, he then worked many years repairing home heating systems.

Four case studies are referenced in the IARC Supplement (Vianna, et al) but are not sufficiently detailed in the text to determine if the case referenced in the NIOSH study was included. The other cases, unknown to us, may have involved exposures in other area mines (no longer in operation), may have been linked to other asbestos exposures or may have been misdiagnosed. It appears that the 1981 paper studied the general population in selected New

York State counties, and was not specific to talc mining in the region. Interpretive problems associated with case study reports are well understood, and frequently render such reports anecdotal at best. In addition, given experience with actual asbestos exposure (especially asbestos amphibole exposure), adequate latency in the Vanderbilt cohort could have reflected cases which would show an association by the end of 1989 (vital status cut off of the latest study) - although a latency beyond 40 years would be preferable.

There is much controversy regarding the cause and ("mis") diagnosis of mesothelioma, and the NTP panel members are no doubt familiar with these issues. Tab 8 contains relevant papers which address these problems. Given the available data on mesothelioma in general and Vanderbilt talc specifically, one cannot reasonably conclude that a cancer association exists.

In summary, if a review of "talc containing asbestos" or "talc containing asbestiform fibers" is undertaken, we request that the NTP recognize the shortcomings of the 1987 IARC Supplement and evaluate the category based upon all available studies and documentation. Considerable confusion obviously exists in this area. The unfortunate link between talc and asbestos has been highly publicized and tends to be an emotional issue. Moreover, some groups (i.e., NIOSH) have taken strong positions (especially regarding Vanderbilt talc) and objectivity may be challenged. For these reasons we believe that it is of particular importance that the weight of all available evidence be carefully considered. The NTP has an opportunity to help correct past errors, misperceptions and unsupported findings. We hope it will take advantage of this opportunity.

Respectfully submitted,

R. T. VANDERBILT COMPANY, INC.


By: _____

John W. Kelse
Corporate Industrial Hygienist
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REFERENCES

TAB 1 - Talc Containing Asbestos References

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TAB 2 - Mineral Nomenclature References

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TAB 4 - Asbestos in Talc References

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TAB 5 - Health Studies

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26. Delzell, Elizabeth, et al. "A Follow-up Study of Mortality Patterns Among Gouverneur Talc Company Workers". March 20, 1995.

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TAB 7 - Tremolitic Talc and Nonmalignant Respiratory Disease

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TAB 8 - Mesothelioma References

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