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Kenny Lloyd

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SUBJECT: Status Report* 8EHQ-0383-0473

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Revision Needed

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Chemical Selection and Profiles Team/CHIB

TO: Frank D. Kover, Chief
Chemical Hazard Identification Branch/AD

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Submission Description

W. R. Grace & Co. (Grace) provided preliminary results of an ongoing company epidemiology study of past/present workers at the Grace vermiculite mining and milling operation in Libby, Montana. According to the submitter, the Libby vermiculite deposit has been long known to be contaminated with tremolite, an asbestiform material. W. R. Grace & Co. also reported that in addition to its own epidemiology study, the "National Institute for Occupational Safety and Health (NIOSH), acting at the request of the Mine Safety and Health Administration (MSHA), began a study in March 1982 of the effects of tremolite exposure upon present and past employees at Libby." The submitter stated that the NIOSH study is a "cooperative effort" and stated further that Grace has made its data available to NIOSH. The submitting company also reported that it has "developed estimates of historical individual worker exposure levels" and has recently started to compile other employee data with these estimates of individual worker exposure levels. In addition, W. R. Grace & Co. reported that NIOSH is now in the process of developing its own exposure estimates so that NIOSH and the company will be able to use the other's estimates for cross-comparison purposes, an activity which Grace hopes will "provide a more precise final product."

In its submission, W. R. Grace & Co. reported that the Libby vermiculite mining and milling facility, which has been in operation since the 1930's, was purchased by Grace in 1963 and currently employs 170 people. The submitting company stated that although "dust exposure levels" at Libby were "very high" prior to 1963, "conditions gradually improved" following the company's acquisition of the operation. The submitter also reported that a 1971 study (conducted by the U. S. Bureau of Mines) showed fiber exposures at Libby ranging from 13 to 71 fibers/cubic centimeter (cc) of air. W. R. Grace & Co. stated, however, that following "time-consuming research" in overcoming unique technical design problems, "a new wet milling facility was placed into operation [in 1974] followed by further major process and operational

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*NOTE: This status report is the result of a preliminary staff evaluation of information submitted to EPA. Statements made herein are not to be regarded as expressing final Agency policy or intent with respect to this particular chemical. Any review of the status report should take into consideration the fact that it may be based on

improvements in the mine, mill and other areas which improved working conditions significantly." The submitting company also reported that since 1974/1975, fiber "exposures have been dramatically lowered and at present average less than 0.2 fibers/cc (0.01-0.9 fibers/cc range)."

With regard to the preliminary results of its own ongoing study, W. R. Grace & Co. reported that the company's "information indicates that of 109 known deaths of former Libby employees, the cause of death for 16 was listed in death certificates or insurance claim forms as lung cancer, and for two others the cause was listed as mesothelioma." The company stated that it did not have "sufficient medical information or sufficient occupational and personal history data in these cases to make a judgment as to the cause of these illnesses." The submitting company also reported that based upon "individual exposure estimates, it appears that certain [Grace] employees whose work history predates the new mill and who have a cumulative exposure of less than 100 fiber years show signs of asbestos-related disease" and that "all of these employees had exposure levels of more than 2.0 fibers per cc for varying periods of time prior to the new mill."

W. R. Grace & Co. pointed out "several methodological problems which have prevented [the company] from making any preliminary judgments" based on the reported preliminary information. First, the company pointed out that the information pertains to conditions which "do not exist in today's workplace environment" and that "all of the employees who show signs of asbestos-related disease were employed prior to 1976 when fiber levels were significantly higher than they are today." The company noted that in contrast, its "preliminary data [show that] none of the current employees hired since 1975 have asbestos-related disease." Second, the company pointed out that "there are those who question the validity of using cumulative exposures (averaging periods of significantly high exposure with later low exposure periods) and the fiber year concept as a proper basis for evaluating the effects of asbestiform material exposure." Finally, the company pointed out that "the Libby employee population has a history of both a large number of smokers (about 75%) and relatively heavy individual smoking histories (most employees smoked a pack or more per day)."

W. R. Grace & Co. stated the company believes that the submitted preliminary information "corroborates written scientific opinion on the effects of exposure to asbestiform material and that it is within the realm of expectation for a mining and milling population having exposures at the levels which prevailed at Libby in the past." In addition, the submitting company stated that "in some respects, the data are similar to what has been reported in studies of talc mining and milling operations in which the talc contained tremolite and other forms of asbestos." Finally, Grace stated that "despite the uncertainty as to the meaning of the data," the company had submitted the subject preliminary findings pursuant to Section 8(e) for the following reasons: "(1) the

expressed interest of EPA, NIOSH, OSHA and MSHA in determining whether the various asbestiform materials induce different medical effects, and (2) ongoing agency investigations as to whether current asbestos exposure standards are adequate."

Submission Evaluation

It is agreed that the reported serious health effects (i.e., 16 lung cancers/109 deaths and 2 mesotheliomas/109 deaths) are corroborative of written scientific opinion on the effects of exposure to asbestiform materials and that the effects are, as the submitter stated, "within the realm of expectation for a mining and milling population having exposures at the levels which prevailed...in the past."

In the submitter's study cohort, the proportion of men having smoked was estimated to be 75%, a figure that is consistent with other estimates of the proportion of males who have smoked in the past.(1) For lung cancer, the estimated probability of death due to lung cancer in males in the U.S. from age 35 until age 74 is .062 or 6.2%.(2) Because this was a working population, it is assumed that the deaths due to lung cancer did not occur before age 35 and the population was followed to at least age 74. The observed proportion of deaths due to lung cancer was 16/109 or .147 (14.7%). Therefore, the calculated relative risk would be approximately 2.4, which is statistically significant at $p < 0.01$ and is consonant with the known synergistic effects of asbestos in smokers.

For mesothelioma, there is no established background incidence for this disease. However, the rate estimates for asbestos-related mesothelioma in North America in the mid-1970's were $8.0/10^6$ for males and about $2.5/10^6$ for females.(3) If the incidence of mesothelioma observed in the deceased Libby employees (i.e., 2 mesotheliomas/109 deaths) is projected to a population of 10^6, the rate would be equivalent to 18,349 cases of mesothelioma. This finding is quite significant even though the exposure levels between the two groups (i.e., the North American males/females versus the studied Libby population) are not comparable. In addition, the finding is not necessarily surprising in light of the 13-71 fibers/cc found by the U.S. Bureau of Mines during the 1971 survey of the Libby facility. In addition, W. R. Grace & Co. stated in the submission that exposure levels at the Libby operation were even higher prior to 1970.

It would be of interest to know the actual past/present exposure levels for the current Libby employees who reportedly show signs of asbestos-related disease(s), the number of current employees affected, and the nature of the asbestos-related disease(s) that are occurring. In addition, it should be noted that the submitter's finding that none of the current employees hired since 1975 show signs of asbestos-related disease is not surprising because inadequate time has passed for the potential asbestos-related diseases to be significantly expressed.

The submitter's final comment that W. R. Grace & Co. has "no reason to believe there is any risk associated with the current uses of Libby vermiculite-containing products" remains to be determined and is dependent upon the potential exposure of users to asbestos from the Libby vermiculite-containing products and the inherent risk such uses impose.

Current Production and Use

Vermiculite is a naturally occurring hydrated magnesium-iron-aluminum silicate (CAS No. 1318-00-9) that when heated (2000°F) can expand (exfoliate) from 6-20 times its original size. The known major vermiculite deposits are located in South Africa, Wyoming, Colorado, Montana, North Carolina, and South Carolina. Vermiculite uses include: insulating and packing materials; filler for paints, plastics, and rubber; removal of strontium-90 from milk and phosphates from wastewater; animal feed and fertilizer additive; insecticide carrier; plant bedding; and general absorbant.

Tremolite (CAS No. 14567-73-8) is a variety of asbestos which is used particularly in paints, ceramics, and acid-resisting applications.

Comments/Recommendations

W. R. Grace & Co. reported that its medical surveillance program at the Libby facility includes annual chest X-rays (since 1964), annual pulmonary function tests (since 1974), and health status questionnaires (since 1978). The company stated that the results of these tests are made available to individual Libby employees and/or their personal physicians. In addition, the company reported that "based upon the recognition that smoking and asbestos exposure can increase the incidence of disease, Grace, in 1978, banned smoking at all Company facilities in Libby." W. R. Grace & Co. also reported that it has initiated a program designed to "help employees stop smoking, and the smoking population has been reduced to 25% of the staff." In addition, the company stated that "all new hires are required to be nonsmokers." W. R. Grace & Co. reported that because of the difficulties in interpreting the submitted information, the company plans to retain Drs. J. C. McDonald and A. D. McDonald (McGill University, Montreal, Canada) to "undertake a thorough analysis of the Libby data" in order to allow Grace "to reach a scientifically sound conclusion based upon [the company's] historical data." W. R. Grace & Co. also reported that the company does plan to continue to cooperate with NIOSH and has sent a copy of the company's 8(e) notice to NIOSH.

The National Toxicology Program (NTP) recently completed a lifetime carcinogenesis bioassay of blocky (nonfibrous) tremolite administered at a 1% concentration in the pelleted diet of male and female Fischer 344 rats (starting with the dams of the test animals). According to the DRAFT NTP Technical Report, "Under the conditions of this bioassay, nonfibrous tremolite was not

toxic and did not cause a carcinogenic response when ingested at a level of 1% in the diet of male and female Fischer 344 rats for their lifetime."

a) The Chemical Hazard Identification Branch (CHIB/AD/EPA) will request W. R. Grace & Co. to report the actual past and present exposure levels for the Libby employees who are reportedly experiencing asbestos-related disease(s), the number of employees affected by such disease(s), and the nature of those asbestos-related disease(s). The company will also be requested to submit, when available, a complete copy of the results (including methodologies and data) of the Libby data analysis which is to be performed by Dr. A. D. McDonald and Dr. J. C. McDonald at McGill University in Montreal, Canada.

b) The Chemical Hazard Identification Branch will provide copies of this status report to NIOSH, OSHA, CPSC, MSHA, OW/EPA, OSWER/EPA, OANR/EPA, ORD/EPA, and the "Asbestos Team" (CCD/OTS/EPA). Copies of this status report will also be transmitted to the Industry Assistance Office (IAO/OTS/EPA) for appropriate distribution.

References

1 Preventive Medicine. 1980. Vol. 9, pp. 747-759.

2 SEER Report, NCI Monograph 57, June 1981.

3 McDonald JC and McDonald AD. Mesothelioma as an index of asbestos impact. In: Peto R, Schneiderman M (ed), Banbury Report 9, Quantification of Occupational Cancer, Cold Spring Harbor Laboratory, 1981, pg. 73-82.

NOTE:

In a supplemental submission dated June 7, 1983 (8EHQ-0683-0473 Supplement), R. T. Vanderbilt Company, Inc. reported that the asbestiform (i.e., fibrous) variety of tremolite is correctly termed "tremolite asbestos" (CAS No. 77536-68-6), whereas the non-fibrous (i.e., non-asbestiform) variety is correctly termed "tremolite" (CAS No. 14567-73-8).