TLV Recommendation

The quantitative data available for PVC dusts, including epidemiological and toxicological studies, from which a TLV could be derived are extremely limited. Epidemiology studies, while providing suggestive evidence of pulmonary function changes, radiographical abnormalities, and subjective symptoms, generally do not provide adequate information regarding exposures to provide an adequate characterization of an exposure-response relationship. Two animal studies which serve as potential candidates for deriving a TLV include: (1) a study in rats, guinea pigs, and monkeys that identifies a chronic LOEL of 13 mg/m^3 for benign pneumoconiosis without change in pulmonary function (Groth et al. 1981); and (2) a study in rats that reports a concentration dependent increase in lung inflammation and hyperplasia following chronic exposure to 3.2-20 mg/m^3 (Takenaka et al. 1987). The strengths of the former study include its use of primates as one of the test species, thereby making the results potentially of greater relevance to human exposures. The primary weakness of this study, however, is that only a single test concentration of PVC dust was examined. The strengths of the latter study include the testing of three dust concentrations and the availability of kinetic information in a companion study (Muhle et al. 1990), which could be used to assess the importance of lung burden and clearance in toxicity [VI: WE HAVE ORDERED A FEW STUDIES CITED IN MUHLE ET AL., WHICH MIGHT CONTAIN ADDITIONAL TOXICITY DATA. WE EXPECT TO RECEIVE SHORTLY. IF ADDITIONAL TOXICITY DATA FOR THE TAKENAKA STUDY ARE AVAILABLE, IT COULD IMPACT TLV RECOMMENDATION]. The critical weaknesses of this study, however, include the lack of specific information regarding the incidence and/or severity of the lung effects observed at each concentration, and the difficulties encountered when attempting to extrapolate information from rats, whose respiratory tract and breathing patterns (obligate nose breathers) are fundamentally different from humans. In our opinion, neither of these studies are well suited for deriving a TLV.

A tentative TLV value could be derived from the results of Groth et al. (1981), however, confidence in the value would be considered low. The LOEL value of 13 mg/m^3, when divided by an uncertainty factor of 3 (3 for LOEL to NOAEL extrapolation; 1 for interspecies extrapolation), could be used to support a TLV of 4.3 mg/m^3. An uncertainty factor of 3 for LOEL to NOAEL extrapolation is justifiable since no decrease in pulmonary function was reported in the exposed animals (Groth et al. 1981). An uncertainty factor of 1 is considered to be appropriate for interspecies extrapolation since the architecture of the respiratory tract and breathing patterns (ability to mouth breathe) in monkeys is similar to that for humans. For this reason, depositional processes for PVC dusts are expected to be similar between the two species. However, differences may exist between non-human