MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

TO: Polyvinyl chloride (powder) file (CAS # 9002-86-2)

FROM: Gary Butterfield, Toxics Unit, Air Quality Division

SUBJECT: Initial Threshold Screening Level (ITSL) for Polyvinyl chloride (powder)

DATE: August 27, 1997

Polyvinyl chloride is also commonly known as PVC. There are no OELs and EPA has no RfD or RfC for PVC. There are OELs and EPA does have values for the vinyl chloride monomer, which is a known carcinogen. An on-line literature search of CAS and NLM articles (on April 24, 1997) was conducted to look for relevant toxicity studies that could be used to develop the screening level for PVC dust.

There are several epidemiology studies of effects from PVC exposure; however, in many of those studies the workers were also exposed to vinyl chloride monomer or to thermal decomposition products produced when PVC was heated during the product formation process. Studies where workers received exposure to vinyl chloride monomer (VCM) and thermal decomposition products in addition to PVC dust were not considered useful for development of the screening level for PVC dust, as it is considered that the only exposure relevant to development of the PVC dust ITSL is PVC dust exposure.

There are some animal studies and human occupational studies that identify a PVC dust pneumoconiosis as being the result of exposure to PVC dust.

Animal studies generally have found a weak biological reactivity to PVC dust. Histopathology of exposed rats finds aggregates of 'foamy' macrophage, PVC particles within macrophage, elevated levels of pulmonary surfactant and elevated lung acid RNAase activity (Richards et al 1981) .

Some epidemiology studies of workers exposed to PVC dust have found signs of pneumoconiosis (Ng et al 1991, Ernst et al 1988, Lee et al 1991, Mastrangelo et al 1981, Siracusa et al 1988, Soutar et al 1980). The worker's pulmonary function tests have generally found a slight increase in loss of pulmonary function, and an increase in number of radiological opacities. Ng et al (1991) studied workers exposed to PVC dust with negligible amount of exposure to VCM or PVC thermal degradation products. In this study, pulmonary function testing found low exposure (less than 10 mg/m^3-years) to PVC dust caused a 4% decrease in FEV1 and FVC, while high exposure (more than 10 mg/m^3-years) caused a 7% decrease. Only the high exposure was a statistically significant change ($P<0.01$) in pulmonary function. There also was a statistically increased ($P<0.05$) number of radiological opacities associated with the higher exposure. Thus , the low exposure can be identified as a no observable adverse effect level (NOAEL). This NOAEL is also supported by the Soutar et al (1980) study, which found PVC dust effects in a cohort exposed to 12.9 mg/m^3-years. The monitored exposures in the Ng et al study (0.2 to 1.5 mg/m^3) were lower than those levels monitored in many of the other studies, which also found decreases in pulmonary function tests following PVC dust exposure.

For example, Ernst et al (1988) was another of the studies that found a significant decrease in the ratio of FEV1 to PVC when the pulmonary function test results of PVC dust exposed workers were compared to non-exposed workers. Exposure of up to 21 mg/m^3 of PVC dust was found in this study. Mastrangelo et al (1981) report x-ray changes (small opacities) that occurred in workers exposed to PVC dust at 10 mg/m^3 or more. Soutar et al (1980) found monitored levels of 2.88 mg/m^3.

Significant changes in worker's pulmonary function occurred at the high exposure (>10 mg/m^3-year) from the Ng et al (1991) study, which can be identified as the LOAEL. The screening level can be calculated according to the methods used by EPA in calculating an RfC, EPA (1994). An uncertainty factor of 10 should be used to account for sensitive individuals within the population. The NOAEL(HEC) can be calculated from the occupational exposure (10 mg/m^3-year) by dividing by the life time number of years, 70, and adjusting the NOAEL for the amount of air consumed while working, 10 m^3, to full day inhalation rate of 20 m^3. These methods for adjusting an occupational exposure with units of mg/m^3-year were used by EPA in the calculation of silica exposure, EPA (1996). Thus, the ITSL can be calculated as follows:

NOAEL = 10 mg/m^3-year
NOAEL(HEC) = (10 mg/m^3-year) x (1/70) x (10/20) x (5/7) = 51 $\mu g/m^3$
RfC = ITSL = (51 $\mu g/m^3$) / (10) = 5 ug/m^3 with annual averaging.

Where an uncertainty factor of 10 is applied to the NOAEL(HEC) for sensitive individuals within the population. It is also considered most appropriate to use the annual averaging time (rather than 24 hours as is normally used for ITSL calculated on the RfC based method), because the original study from Ng et al used long-term cumulative exposures and the study's exposure dose was reported as mg/m^3-years.

It should be noted that this ITSL does not consider the impact on NAAQS for Particulate Matter (PM). PVC dust would be considered PM. The impact of any one facility's emissions should be considered on the surrounding areas ability to meet the NAAQS for PM.

References:

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