HTIW COALITION

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HEALTH EFFECTS ON ANIMALS

Issues Related to Refractory Ceramic Fiber

- It is important when comparing the effects of different fibers to explore how these effects relate to dimension and durability, rather than simply to exposure concentrations. In this regard, when such data are available, attention should also be paid to the differences between exposure concentrations and lung tissue burden.
- The RCF samples, to which the animals were exposed, were significantly different both to the aerosols to which humans may be exposed and to the other, non-RCF MMVF samples tested at the Research and Consulting Company (RCC). These differences are important for risk assessment purposes and to any comparisons made among man-made mineral fibers (MMVFs).
- Contrary to early reports, pulmonary clearance was overwhelmed by the high RCF particulate levels and the maximum tolerated dose (MTD) was therefore exceeded in the RCC experiments with both rats and hamsters. In a continuation of these experiments, as in most modern inhalation studies, overload was monitored much more carefully before selecting test doses. (See, for example, Ref. 3.)
- Pulmonary overload by even innocuous particulate has been shown to produce inflammation, fibrosis and tumors in the rat, thus confounding the results of the RCC rat studies. (See Ref. 2.) In addition, particle exposures promote the production of mesothelioma when mixed with fibers. (See Ref. 2.)
- Most regulatory guidelines require effects occurring at pulmonary overload concentrations to be discounted, as these would only occur at very high doses that are not seen in humans.
- There is strong evidence that had the RCF samples been prepared by the same method used for the other "MMVF" samples neither overload nor tumors would have occurred. (See Ref. 1.)
- The quantity of fibers remaining in lung tissue depends upon the fibers' ability to persist and accumulate; these characteristics are determined by the fibers' biopersistence, which is heavily dependent on the chemical composition of the fiber. The biological activity of fibers, on the other hand, is largely determined by their size and shape. For man-made wools, this depends upon how long fibers in the wool are broken, which in turn depends upon how the fibers are manufactured. Therefore, it is only meaningful to measure the biological activity of a fiber in a laboratory setting if the samples tested are in a way that resembles the aerosols produced during normal handling and use.
- The chart below provides a summary of the animal tests in which RCF was involved.

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Summary of Animal Inhalation Tests Related to RCF

Fiber Type	Animals at Risk	Exposure duration (h/d; d/w; wks)	Concentration WHO f/cc (SD) mg/m^3 (SD)	Tumor Incidence (%)		Reference
				Lung	Mesothelial	
Syrian Hamster Experiments						
Air Control	58	6: 5; 104	0	2	0	Smith 1987
Kaolin	70	6; 5; 104	200	0	1	
Air control	119	6; 5; 104	0	0	0	McConnell 1995
Kaolin	112	6; 5; 104	256 (58) 29.2 (7.7)	0	38	
SPF Wistar Rats (AF/HAN) Experiment						
Unspecified	48	7; 5; 52	95	17	0	Davis 1984
Fischer Rat (344/N) Experiments						
Air Control	130	6; 5; 104	0	1.5	0	Mast 1995a
Kaolin	121	6; 5; 104	234 (35) 29.1 (5.2)	14.0	1.7	
Mock after service Kaolin	118	6; 5; 104	206 (48) 30.1 (7.8)	4.2	0.8	
High purity	121	6; 5; 104	213 (44) 29.2 (7.0)	14.0	1.7	
Zirconia containing	121	6; 5; 104	268 (45) 28.9 (4.5)	8.3	2.5	
Air control	132	6; 5; 104	0	0.8	0	Mast 1995b
Kaolin	126	6; 5; 104	162 (37) 16.5 (1.1)	1.6	0	
Kaolin	128	6; 5; 104	91 (34) 8.8 (0.7)	3.9	0.8	
Kaolin	125	6; 5; 104	36 (17) 3.0 (0.4)	1.6	0	

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