NAIMA
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EPIDEMIOLOGY EVIDENCE SHOWS NO ADVERSE EFFECT FROM MMVF

The extensive epidemiology data on MMVF manufacturing workers comprise the best and most conclusive information on the safety of mineral wool and other MMVFs and take precedence over any *in vitro* data. These data have not shown any evidence of chronic disease, malignant or nonmalignant, directly attributable to MMVF exposure.[1]

When the International Agency for Research on Cancer ("IARC") evaluated all the epidemiology data in its 2002 review, it concluded that the epidemiology data were inadequate to suggest any adverse effect.[2] On human carcinogenicity data, the IARC experts concluded that:

> Results from the most recent cohort and nested case-control studies of US workers exposed to glass wool and continuous glass filament and of European workers exposed to rock (stone) and slag wool have not provided consistent evidence of an association between exposure to fibres and risk for lung cancer or mesothelioma. . .[3]

These conclusions are based on an unusually robust body of data from many countries – a European cohort study, an American cohort study, a Canadian cohort study, a Swedish cohort study, cohort studies narrowly focused on certain population segments or single production facilities, and case-control studies in England, Europe, the United States, and others. In Europe, the epidemiological studies were conducted under the direction of P. Bofetta, IARC, Lyon, France, with the associated industrial hygiene being carried out by the Institute of Occupational Medicine ("IOM"), Edinburgh. The epidemiological research in the United States was undertaken at the University of Pittsburgh in the Department of Biostatistics and the Center for Environmental Epidemiology with Gary Marsh as Principal Investigator. The industrial hygiene program was also conducted at the same University in the Department of Industrial and Environmental Health Sciences. To this day, these two studies – Europe and the United States – separately are among the largest occupational cohort studies ever undertaken. Based on this evidence, the IARC experts concluded that "[t]here is inadequate evidence in humans for the carcinogenicity" of rock wool and of other MMVF fiber types.[4]

Specifically, IARC found the U.S. MMVF cohort showed no association with "duration of exposure or with time since first exposure."[5] Moreover, IARC found that standardized mortality ratios ("SMR") were no longer elevated when indirect adjustment for smoking was made. The nested case-controlled study for rock wool showed no association between respiratory cancer and esti-

[1] Marsh, Gary, *et al.*, "Historical Cohort Study of US Man-Made Vitreous Fiber Production Workers: I. 1992 Fiberglass Cohort Follow-up," *Journal of Occupational and Environmental Medicine*, September 2001, vol. 43, no. 9, pp. 741-834.
[2] International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Man-Made Vitreous Fibres*, Vol. 81, 2002, World Health Organization, pp. 133-179.
[3] IARC Monograph at pp. 329-30.
[4] IARC Monograph at p. 338.
[5] IARC Monograph at p. 329.

mated cumulative exposure to respirable fibers, with or without adjustment for possible confounding by smoking or other occupational exposures.[6] IARC concluded that the "results from these studies provide no evidence of an increased risk for pleural mesotheliomas or any other tumours."[7] The extensive European epidemiology studies included a case-control study with "detailed information on exposure to fibres, individual smoking habits and potential occupational confounders, no increased risk of lung cancer with increasing fibre exposure was reported."[8]

In its Toxicological Profile for Synthetic Vitreous Fibers, the Agency for Toxic Substances and Disease Registry ("ATSDR"), after extensive review, reached the same conclusion as did IARC on the epidemiological evidence:

- "Epidemiologic studies (cohort mortality and case-control studies) of causes of mortality among groups of workers involved in the manufacture of fibrous glass, rock wool, or slag wool provide no consistent evidence for increased risks of mortality from nonmalignant respiratory disease, lung cancer, or pleural mesothelioma. A number of reviews of these cohort mortality and case-control studies concur that the studies provide inadequate evidence for the carcinogenicity of synthetic vitreous fibers in humans."[9]
- "[C]ohort mortality studies of workers involved in the manufacture of . . . rock wool . . . fibers have not found consistently increased risk of mortality associated with nonmalignant or malignant respiratory disease."[10]

These comprehensive epidemiological studies have already received exacting scrutiny from the world's foremost experts.

Since the release of the 2002 IARC Monograph, numerous epidemiological studies have evaluated the association between MMVF exposure and respiratory system cancer, including cancers of the lung, bronchus, larynx, and trachea. Dr. Marsh, *et al.*, conducted a systematic review and meta-analysis of epidemiological literature evaluating the association between exposure to MMVF and respiratory system cancers in 2019. The authors of the review and meta-analysis concluded that the 2002 IARC Group 3 classification of insulation glass wool, rock wool, and slag wool remains valid.[11]

The epidemiology study results, relied upon by IARC, did not find evidence that MMVF exposures were associated with cancer in manufacturing workers. As high quality epidemiology studies of workers are always the most significant evidence of the effect or lack of effect of any exposure, these studies provide powerful evidence that MMVFs among manufacturing workers were not associated with disease.

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[6] IARC Monograph at p. 329.
[7] IARC Monograph at p. 330.
[8] IARC Monograph at p. 330.
[9] *Toxicological Profile for Synthetic Vitreous Fibers* (U.S. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry), September 2004, p. 18.
[10] ATSDR at p. 31.
[11] Egnot, N.S., *et al*., "Systematic review and meta-analysis of epidemiological literature evaluating the association between exposure to man-made vitreous fibers and respiratory tract cancers," 112 *Regulatory Toxicology and Pharmacology*, 104585 (2020).

EXTENSIVE EVIDENCE FROM ANIMAL STUDIES CONFIRMS NO CANCER HAZARD FROM INSULATION MMVF

Extensive evidence from many studies in multiple animal species confirms that the MMVF in insulation products, both in products from decades ago and in use today, do not present a cancer hazard by inhalation. The animal studies performed in the 1990s, including long term inhalation studies that last for the entire life of the test animals, are well summarized in several peer-reviewed journal articles.[12] In its 2002 Monograph, IARC relied heavily on these animal studies in removing insulation MMVF from its list of Group 2B possible carcinogens.[13]

THERE IS A DISTINCT DIFFERENCE BETWEEN ASBESTOS AND SYNTHETIC VITREOUS FIBERS

Fiber glass and mineral wool fibers are distinctly different from asbestos. The ATSDR provided a detailed discussion on the differences between fiber glass insulation fibers and asbestos in its Toxicological Profile for Synthetic Vitreous Fibers:

- "Synthetic vitreous fibers . . . differ from natural mineral fibers such as asbestos because they do not have a crystalline molecular structure."[14]
- "Synthetic vitreous fibers dissolve more readily in the lung than asbestos fibers."[15]
- "While naturally occurring mineral fibers such as asbestos are crystalline in structure, synthetic vitreous fibers are amorphous materials."[16]
- ". . . synthetic vitreous fibers can be distinguished from other fibers, like asbestos, based upon their morphology."[17]
- "Synthetic vitreous fibers differ from asbestos in two ways that may provide at least partial explanations for their lower toxicity. Because most synthetic vitreous fibers are not crystalline like asbestos, they do not split longitudinally to form thinner fibers. They also generally have markedly less biopersistence in biological tissues than asbestos fibers because they can undergo dissolution and transverse breakage (see Sections 3.4 and 3.5)."[18]
- "Synthetic vitreous fibers have amorphous molecular structures that do not have planes of cleavage such as those in the crystal structure of chrysotile asbestos. The longitudinal cleavage of asbestos fibers can form thinner fibers that may more readily move into the interstitium or the pleura cavity (Agency for Toxic Substances and Dis-

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[12] See, *e.g.*, Hesterberg TW, Hart GA. 2001. Synthetic vitreous fibers: a review of toxicology research and its impact on hazard classification. Crit Rev Toxicol 31(1): 1-53; Hesterberg, T.W., Miiller, W.C., McConnell, E.E., Chevalier, J., Hadley, J., Bernstein, D.M., Thevenaz, P. & Anderson, R. (1993) Chronic inhalation toxicity of size-separated glass fibers in Fischer 344 rats. Fundam. appl. Toxicol., 20, 464–476; Hesterberg, T.W., Miiller, W.C., Musselman, R.P., Kamstrup, O., Hamilton, R.D. & Thevenaz, P. (1996c) Biopersistence of man-made vitreous fibers and crocidolite asbestos in the rat lung following inhalation. Fundam. appl. Toxicol., 29, 267–279; Hesterberg, T.W., Chase, G., Axten, C., Miiller, W.C., Musselman, R.P., Kamstrup, O., Hadley, J., Morscheidt, C., Bernstein, D. & Thevenaz, P. (1998b) Biopersistence of synthetic vitreous fibers and amosite asbestos in the rat lung following inhalation. Toxicol. appl. Pharmacol., 151, 262-275.

[13] IARC Monograph at pp. 181-240.

[14] ATSDR at p. 1.

[15] ATSDR at p. 4.

[16] ATSDR at p. 163.

[17] ATSDR at p. 208.

[18] ATSDR at p. 17.

> ease Registry 2001). This property is not expected with synthetic vitreous fibers and may contribute to the difference in potency between asbestos and synthetic vitreous fibers. In addition, asbestos fibers, especially amphibole fibers, undergo very little, if any, dissolution in *in vitro* pH 7.4 tests (see Table 3-2). The relatively high persistence of long amphibole asbestos fibers in lungs is demonstrated by long clearance half-times of amphibole asbestos in rats (as shown in Table 3-2). Chrysotile asbestos, the least persistent asbestos type, is also expected to be more persistent in lungs than most synthetic vitreous fibers."[19]

Thus, MMVF and asbestos are chemically, morphologically, and toxicologically distinct. While they may have some superficial similarities, well-established science and hazard classification decisions from authoritative scientific bodies confirm that asbestos presents serious health hazards while insulation MMVF does not.

EXPOSURES ARE LOW

Based on review of various exposure studies, IARC concluded that concentrations of airborne fibers measured during the production of glass and slag and/or rock (stone) wool are generally low (below 1 fiber/cm^3). ATSDR concluded that "The airborne levels of synthetic vitreous fibers have been shown to be higher under occupational settings as compared to ambient air levels, and thus, occupational exposure is far greater than the exposure for the general population." Based on various exposure studies and the NAIMA database,[20] ATSDR concluded that exposures were consistently below 1 f/cc. Testing of indoor exposures also demonstrates that exposures are very low.[21] Exposure monitoring conducted near fiber glass manufacturing facilities showed low exposures, too.[22]

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[19] ATSDR at p. 123.

[20] Marchant GE, Amen MA, Bullock CH, et al. 2002. A synthetic vitreous fiber (SVF) occupational exposure database: Implementing the SVF health and safety partnership program. Appl Occup Environ Hyg 17:276-285. Marchant, Gary; Bullock, Christopher; Carter, Charles; Connelly, Robert; Crane, Angus; Fayerweather, William; Johnson, Kathleen; and Reynolds, Janis (2009) "Applications and Findings of an Occupational Exposure Database for Synthetic Vitreous Fibers," *Journal of Occupational and Environmental Hygiene*, 6:3, 143-150.

[21] C.M. Carter, *et al*., "Indoor Airborne Fiber Levels of MMVF in Residential and Commercial Buildings," *American Industrial Hygiene Association Journal*, 60:794-800 (1999).

[22] Switala, ED, Harlan, RC, Schlaudecker, DG, and Bender, JR, "Measurement of Respirable Glass and Total Fiber Concentrations in the Ambient Air around a Fiberglass Wool Manufacturing Facility and a Rural Area," *Regulatory Toxicology and Pharmacology*, 20, S76-S88 (1994).