Johns Manville Commentary on NTP Draft Background Document for Glass Wool Fibers: Special Purpose Fibers and Hazard Classification

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I appreciate the opportunity to provide comments on behalf of Johns Manville (JM) on some of the technical discussion in the above document. My purpose is to help the Expert Panel better understand the physical and chemical nature of glass fibers and, especially, the key differences between two glass fiber types (special purpose fibers and insulation wool fibers) that are relevant to cancer hazard classification, *i.e.*, whether certain glass fibers should be listed in the Report on Carcinogens (RoC).

Recent Developments in Glass Fiber Toxicology

Over the past twenty years, significant advances have been made in the science of glass fiber toxicology. These advances have led to a greater and more precise understanding by authoritative scientific bodies of the physical and chemical properties of fibers that are relevant to potential cancer hazard in animals. It is most important to note that the new science has shown that typical insulation glass wools, as represented, *e.g.*, by the batts and blankets of "fiber glass" found in home attics, do not appear to meet NTP criteria for listing. As discussed in the Background Document, there are, however, a very small group of older, more durable glass fibers known as special purpose fibers that were (and to a certain extent today still are) found in specialty applications where there is sufficient evidence of carcinogenic potential in animals to support listing them "reasonably anticipated" in the RoC.
Some distinctions between these fiber types have been given in the Background Document. My commentary will clarify the critical role of glass fiber durability in making the distinction between these fiber types with the objective of contributing to a more precise RoC listing of those less than 1% of all glass fibers that have carcinogenic potential in animals.

It is also important to note that IARC, NAS, ATSDR, and other scientific bodies have recognized distinctions between fibers that may have carcinogenic potential in animals and those that do not. The information provided to these bodies concerning fiber durability and the physical and chemical characteristics of durable fiber types was an important aid in helping them separate special purpose fibers as a distinct class of glass fibers with different (enhanced) potential for biological activity in animals.

As seen below, the term "special purpose fiber" was adopted by health effects researchers to categorize certain durable, flame attenuated glass microfibers that showed positive biological responses (including and especially tumors) in laboratory animals, evaluated mostly by IP injection. This term is still widely used today by those researchers, manufacturers and product stewardship professionals. Given the legacy and the importance of this RoC evaluation to manufacturers, workers and end users, we should achieve a clear understanding of these durable fiber types and how their properties may be related to their activity *in vivo.*

Special Purpose Fibers at Johns Manville

As noted in the Background Document, special purpose fiber formulations were developed to be durable, especially with respect to attack by aqueous fluids and water vapor (humidity). This was a necessary performance criterion for their specialized applications in high efficiency filter media, battery separators and the like. This, unfortunately, can also increase durability in lung fluids and other biological milieu, not surprising since these fluids are themselves greater than 98% water. However, during the time of their original development, this was not a consideration as correlation between biodurability of fibers and potential disease hazard was still years ahead. Insulation wools by comparison do not have such demanding requirements for aqueous durability and could be formulated to allow for greater rates of biodecomposition in lung fluids. In this sense, glass fiber development has benefited greatly from scientific advancements in the field of glass fiber toxicology over the past twenty years.

Over the years, JM has been the principal manufacturer of special purpose fibers designed for applications other than commodity thermal and acoustical insulations and JM is still today an industry leader. Other US manufacturers of special purpose fibers include Evanite, Lauscha and UPF (United Pacific Fiberglass). Certain foreign manufacturers (especially in China) also export special purpose fibers into the US.

Today, JM makes two principal fibers that qualify as special purpose fibers. The first is JM475, which is a high efficiency filtration fiber made by both the flame attenuation and a rotary type method. The second is JM253-FA, which is a battery separator fiber made by the flame attenuation method. Other manufacturers also make their own versions of JM475 and JM253. JM no longer makes either E-glass microfibers or JM753, two special purpose fibers tested in animals, especially in the early IP studies.

It is also important to note that JM is not developing any new durable special purpose fibers; to the contrary, newly-developed biosoluble fibers (*i.e.*, fibers whose biosolubility is in the range of, or greater than, MMVF 10 and MMVF 11) are beginning to replace JM special purpose fibers commercially for some applications. Yet the older, special purpose fibers are still widely accepted in the marketplace, having a long track record of proven performance. Good product stewardship efforts by JM, industrial hygiene monitoring, and improved PPE have also contributed to the continued acceptance of those special purpose fibers.

Special Purpose Fibers Are Clearly Identifiable

Several factors have been established as relevant in identifying special purpose fibers, especially those tested in health effects studies: fiber durability; use or application; customers; markets; average diameter; and, chemical composition. IARC stated in its 2002 Monograph at page 327 that, "Special-purpose glass fibres are limited-production, small-diameter fibre products that are typically used for purposes other than insulation as in filtration media and batteries." Method of manufacture is often cited as a distinguishing factor, and until recently was a meaningful distinction; however, method of manufacture is less useful today in distinguishing special purpose fibers.

Of all these factors, the key critical distinction between insulation glass wool fibers and special purpose fibers is fiber durability. In terms of physicochemical durability we can draw a clear map with no overlap between the two fiber types. As described below, durability is best measured experimentally and there are also statistical models that give a good estimate of fiber solubility.

The most reliable determination for fiber durability relative to its persistence *in vivo* is to determine the constant velocity or zero-order dissolution rate constant known as k_{dis}, measured in simulated lung fluids. The relevant derivations and background information for this are provided in reference 313 of the Background Document and in the references contained therein. k_{dis} values have been measured in *in vitro* acellular systems for a wide variety of glass fibers, including both insulation wools and special purpose fibers. Some of these are reported in Tables 5-1, G, H, and I in the Background Document for fibers evaluated in animal studies.

Reported k_{dis} values for special purpose fibers and insulation wools have also been provided in a number of publications (see, *e.g.*, Reference 130). Predictably, values for insulation glass wools are much higher than those for special purpose fibers; ranges found for insulation wools are about 100 to greater than 500 ng/cm^2 hr, while ranges for special purpose fibers are about 10 to 75 ng/cm^2 hr. Special purpose fibers are therefore more durable in biologically relevant media as well as in conventional aqueous solutions.

Scientific advances in glass fiber toxicology over the past twenty years have shown a good correlation between durability as measured *in vitro* (in simulated lung fluids) and biodurability determined *in vivo* (see, *e.g.*, references 130 and 185 in the Background Document). Furthermore, key correlations have been made between biodurability, biopersistence, and incidence of respiratory disease, especially cancer, in laboratory animals. The more durable (or biodurable) a fiber, the greater the chance for carcinogenicity.

Therefore, while the factors noted below are important, it is fiber durability that we believe provides the key critical difference in distinguishing glass wool insulation fibers from special purpose fibers for purposes of hazard determination.

It is important to consider, however, that only the most durable special purpose fibers were evaluated in the animal studies reported in the Background Document. These fibers (JM E glass microfiber, JM475 microfiber, and JM753 fiber) show dissolution rates in the range of only 10 to 30 ng/cm^2 hr. We understand similar fibers from Evanite, Lauscha, UPF and foreign manufacturers have similar dissolution rates and should also be considered special purpose fibers. Two of those fibers (JM E glass microfibers and JM753) have been discontinued and are no longer in JM production today. Those fibers were the subjects of many of the early investigations (1970's and '80's) and, in some cases, were intended to represent fiber types expected to have greatest toxicity.

Special purpose fibers are also distinguished from insulation glass wools in that special purpose fibers are sold exclusively to other companies who use them in the fabrication of OEM products. They are not available to the general public. Being highly engineered, they are also more expensive than insulation wools. Their intended end use (as indicated in the Background Document) is typically for specialized air and liquid filtration applications, battery separator media and some high end applications such as aerospace where their usage is multifunctional. Most special purpose fibers, as produced, would be too expensive and even unsuitable for typical thermal and acoustical insulation use.

Average fiber diameter is another property that is often used to discriminate special purpose fibers from insulation wools. Indeed, the technical requirements of most of the markets they serve demand that special purpose fibers be very fine, with geometric mean diameters of 0.5 μm or less. This means that their average diameters are roughly an order of magnitude smaller than the average diameters of typical insulation wool fibers. However, as noted in the Background Document, all glass fiber production necessarily results in some distribution of diameters. Because of this overlap in the

fiber diameter distributions, it can be difficult to make distinctions based on diameter alone.

Chemical composition is another characteristic that has been used to help delineate special purpose fibers from insulation wools. Distinctions based on chemical compositions of the glasses comprising the fibers were noted previously – a grouping of special purpose fiber and insulation glass wool compositions is given in Table 1 of IARC Monograph 81 (2002). As seen in that table, there are certainly differences in the ranges of concentrations of oxide components between these two fiber types, but also some overlap in ranges as well. The Background Document notes that special purpose fibers are highly engineered and typically contain higher concentrations of aluminum oxide and may also include components such as zinc, zirconium, and titanium oxides, all of which are designed to improve the durability (with respect to moisture resistance) of special purpose fibers relative to insulation wools, which are less demanding in this regard. However, none of these ingredients by themselves is responsible for making such a fiber a special purpose fiber or an insulation wool fiber.

Past and current special purpose fibers used in battery separator media contain limited amounts of aluminum oxide as that component is soluble in strong acids used as the electrolyte in several types of batteries. But in actuality, the individual oxide components (see Table 1-4 of the Background Document) are highly interactive and no simple compositional expression such as KNB, Z-score, or German KI index as discussed in Section 1.3 can suffice to determine whether a fiber is a special purpose fiber or an insulation glass wool fiber.

IARC Monograph 81 also provided a distinguishing characteristic of special purpose fibers based on manufacturing process. Here, special purpose fibers were reported to be produced by flame attenuation methods as compared to rotary methods, which is the dominant mechanism used for producing insulation glass wools. This is certainly true for the JM special purpose fibers evaluated in animal studies, all of which were made by flame attenuation. Today the picture is somewhat different. Some JM fibers serving the specialty applications and markets noted above are currently produced by

both flame attenuation and rotary processes, in about equal amounts. This represents simply advancement of technology as manufacturers have learned how to produce finer diameter fibers needed in special purpose fiber applications using more economical and energy efficient rotary methods. The very finest diameter products, however, still require flame attenuation. So manufacturing process is an important factor but alone cannot distinguish special purpose fibers from insulation wools or other fiber types.

Conclusion

Older, more durable special purpose fibers have been extensively tested and are an important part of the science of glass fiber toxicology over the past twenty years. This science points to fiber durability as the key critical factor in determining potential cancer hazard in animals. The older, durable special purpose fibers have shown some positive results in animal studies, although human data have been consistently insufficient. This understanding allowed scientific organizations such as IARC, ATSDR, and NAS to make more precise hazard classifications for glass fibers. From our current knowledge of both the physicochemical nature and properties of these fibers and of the animal science surrounding glass fibers, there is adequate support for NTP to follow the 2001 IARC action by: (1) removing insulation glass wools from the RoC; and, (2) retaining older, more durable special purpose fibers on the RoC as "reasonably anticipated."

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I am a materials scientist (not a toxicologist or health specialist) with over 30 years of experience in glass and mineral technology, a great deal of which involved development and characterization of fibers for commercial applications. My educational background includes a B. S. in Chemistry from Penn State University and M. S. and Ph. D. degrees from Lehigh University in Geological Sciences (specializing in geochemistry and mineralogy). My early professional years were spent with NASA at the Johnson Space Center in Houston and involved research on the formation of extraterrestrial minerals and naturally-formed glasses. The bulk of my professional experience, however, was obtained while at Johns Manville in Littleton, Colorado from where I retired in 2008 as Senior Scientist, R&D, following nearly 29 years of employment. During that time, I held a variety of technical and management positions, principally in glass and fiber technology. Experience that is perhaps most relevant to the issue before this Panel includes: (1) development of *in vitro* acellular systems for determination of fiber dissolution rates in simulated lung fluids and use of same to derive estimates of fiber biodurability *in vivo;* (2) evaluation of fibers recovered from lungs of laboratory test animals to determine mechanisms of fiber decomposition; and, (3) design, development and commercialization of new biosoluble fiber types to meet various market applications (with appr. 8 U. S. and foreign patents covering this technology). Public contributions include over 40 technical publications and 20 total patents (U. S. and foreign). I currently serve as a (part-time) consultant, primarily to the glass industry.