JM
Johns Manville

A Berkshire Hathaway Company

JUL 16 2004

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VIA HAND DELIVERY AND E-MAIL

July 16, 2004

Dr. C.W. Jameson
National Toxicology Program
Report on Carcinogens
Building 4401, Room 3118
79 Alexander Drive
Research Triangle Park, NC 27709

RE: Comments on the NTP'S 21 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Twelfth Edition – 69 Fed. Reg. 28,940 (May 19, 2004)

Dear Dr. Jameson:

Johns Manville submits the enclosed comments on the National Toxicology Program's 21 Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Twelfth Edition – 69 Fed. Reg. 28,940 (May 19, 2004).

If you have any questions, please do not hesitate to call me.

Sincerely,
[Redacted]

Tim Carey
Manager, Product Stewardship

Enclosures

BEFORE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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THE NATIONAL TOXICOLOGY PROGRAM'S 21 SUBSTANCES, MIXTURES AND EXPOSURE CIRCUMSTANCES PROPOSED FOR LISTING IN THE REPORT ON CARCINOGENS, TWELFTH EDITION

69 Fed. Reg. 28,940 (MAY 19, 2004)

COMMENTS ON THE PROPOSED LISTING OF SPECIAL PURPOSE GLASS FIBERS

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SUBMITTED BY JOHNS MANVILLE

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July 16, 2004

COMMENTS OF JOHNS MANVILLE

Johns Manville (JM), a Berkshire Hathaway company, is a leading manufacturer and marketer of premium-quality building and specialty products. In business since 1858, the Denver-based company has sales in excess of $2 billion and holds leadership positions in all of the key markets that it serves. Johns Manville employs approximately 8,500 people and operates 43 manufacturing facilities in North America, Europe and China. Johns Manville's website can be found at www.jm.com.

Part of JM's business is devoted to the manufacture of special purpose glass fibers or SPFs. JM's SPF products are of the same types as described in both the North American Insulation Manufacturers Association (NAIMA) comments on the May 19, 2004 Federal Register notice and also in the NAIMA document of January 7, 2004, a copy of which is appended hereto.

JM submits these comments on SPF only; JM endorses the comments submitted by NAIMA on glass wool insulation fibers. JM does not oppose the listing of SPF on the 12th Report on Carcinogens; rather, JM desires only to re-emphasize that these fibers pose very little, if any risk and to ensure that all SPFs are listed in the RoC and not just the several examples cited in the recent IARC Monograph.[1]

SPF PRODUCTION

There are a number of companies worldwide that produce SPFs. In the United States these companies include, but may not be limited to, the following: Johns Manville (Ohio); Evanite Fibers (Oregon) at http://www.evanite.com ; Lauscha (South Carolina) at http://www.lfifiber.com/en/index.htm; Glass Fiber, Inc. (California); and United Pacific Fiberglass (Conglass) in California. In addition, SPF is being imported into the United States in increasing amounts from China and other sources in Asia.

SPFs differ significantly from typical fiber glass insulation wool in several important ways. First, the chemistry of most SPFs includes the addition of oxides such as ZnO, and BaO that improve the ability to fiberize the glass at submicron diameters. In contrast to the insulation wools, SPFs are more highly engineered and hence, significantly more expensive than glass wool insulation. Unlike typical insulation wools, SPFs make up only a very small percentage of the man-made vitreous fiber market, accounting for roughly one percent of the total annual production of synthetic vitreous fibers.

[1] IARC (2002) *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, Vol. 81, *Man-made Vitreous Fibres*, Lyon, IARC *Press*.

SPF is not typically sold or even available to the general public. Instead, SPFs are sold by the fiber manufacturer in final products to commercial users or alternatively to other manufacturers where they are made into final products. Principal uses of SPF include: battery separator media; high performance liquid and air filtration (under designations such as HEPA, ASHRAE, ULPA, EU 10–13, EN1822, EN779 and S3 filters); and, high performance insulation for specialized aerospace and appliance applications. The appendix to this document contains specific examples of some SPF applications. JM filtration applications are described in detail on JM's website at http://www.jm.com/engineered_products/filtration/52.htm

SPF TERMINOLOGY

There are a number of chemical compositions for SPFs. While many discussions of SPFs refer to 475 and E-Glass, these are but two examples from the many SPFs available today. Typically, each manufacturer uses its own SPF product chemistries and designations. Table 1 shows some examples of SPFs and typical chemistry ranges.

Table 1

Oxide	**Typical Ranges of Composition of Special Purpose Glass Fibers**							
Component (weight %)	UPF 363	JM475	JM-E	Evanite M	Evanite B	Lauscha A-glass	Lauscha B-glass	Lauscha C-glass
SiO_2	58 - 59	59.0-57.6	54.5-55.5	65.8-71.2	56.4-60.4	69.0-72.0	55.0-60.0	63.0-67.0
Al_2O_3	5	6.2-5.4	13.5-14.2	3.3-4.4	5.2-6.4	2.5-4.0	4.0-7.0	3.0-5.0
B_2O_3	7 - 8	12.1-10.5	5.5-8.0	4.2-5.3	10-12	<0.10	8.0-11.0	4.0-7.0
CaO	0 – 0.2	1.9-1.7	18.5-21.5	4.8-6.6	1.5-2.3	5.0-7.0	1.5-5.0	4..0-7.0
MgO	< 0.1	0.4-0.25	2.3-2.5	2.3-3.3	0.15-0.5	2.0-4.0	0.7-2.0	2.0-4.0
BaO		5.4-4.6	< 0.01	0-02	4.5-5.5	0	3.6-6.0	<0.1
ZnO		4.4-3.6	< 0.01	0-04	3.5-4.5	0.0-2.0	2.0-5.0	<0.1
ZrO2	4							
TiO2	8							
Na2O + K2O	16 - 18							
Na_2O		10.3-9.1	0.7-1.3	10.9-12.9	9.0-11.0	10.5-12.0	9.8-13.5	14.0-17.0
K_2O		3.6-3	0.06-0.08	1.6-2.0	2.6-3.4	4.5-6.0	2.5-4.0	0-2.0
F_2	< 2.0	0.9-0.55	< 0.01-0.3	0.5-1.0	0.3-0.7	0	<1.0	<1.0

SPF PHYSICAL CHARACTERISTICS

SPFs are also typically more durable than insulation wools - in some instances, by an order of magnitude both as measured *in vitro* by k_{dis} and by $T_{1/2}$ and $WT_{1/2}$ in well-designed animal inhalation studies. The biopersistence of SPFs is due in part to their chemistry but may also be due, in part, to the method of manufacture.

JM 475 microfiber is produced in many different diameters based on customer needs but the most commonly sold products have mean diameters between 0.65 μm and 2.7 μm. Historically E glass microfiber was most commonly produced with mean diameters between 0.5 μm and 0.65 μm.

Fiber lengths are difficult to determine in bulk fiber products. However, work to date has shown that, in general, fiber length relates directly to diameter. The finest fibers in a distribution may only be 0.3 to 0.4 mm long, while the length of the coarsest fibers may exceed 5 mm. Typical mean lengths for the most common products noted above (mean diameters of 0.65 μm and 2.7 μm) will be in the range of 1.0 to 1.5 mm. The Evanite filter grade SPF has average fiber diameters of 0.5 to 7 μm and average fiber lengths exceeding 4.5 mm.

FIBER CONCENTRATIONS IN THE WORKPLACE

The manufacturers of SPFs follow the Health and Safety Partnership Program (HSPP) for all US locations.[2] These programs establish a voluntary maximum concentration for fiber exposure of 1 WHO[3] fiber/cc. To date, monitoring data collected for fiber manufacturing and use operations (including SPF) have shown fiber exposures to be well below 1 WHO fiber/cc for the vast majority of the samples collected.[4] Respirators are required to protect employees in rare operations where fibers are above 1 fiber/cc. As explained in the NAIMA comments, fiber concentrations measured in manufacturing is typically higher than that encountered in a facility installing or using products manufactured from SPF.

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[2] NAIMA (North American Insulation Manufacturers Association). 1999. Letter to Adam Finkel, Director of Health Standards, Occupational Safety and Health Administration on voluntary health and safety partnership program for fiber glass, rock and slag wool fiber products from Kenneth D. Mentzer, Executive Vice President of the North American Insulation Manufacturers Association (NAIMA), May 18, 1999. http://208.186.168.18/~admin42/pages/benefits/hspp/NAIMA_ltr_to_OSHA.html .

[3] WHO Fibers: A fiber with diameter = 3 μm, length = 5 μm and length to diameter ration of 3:1.

[4] G.E. Marchant, M.A. Amen, C.H. Bullock, C.M. Carter, K.A. Johnson, J.W. Reynolds, F.R. Connelly, and A.E. Crane, "A Synthetic Vitreous Fiber (SVF) Occupational Exposure Database: Implementing the SVF Health and Safety Partnership Program," *Applied Occupational and Environmental Hygiene*, Volume 17(4): 276-285, 2002.

FIBER HAZARD

SPFs have been extensively tested in animal inhalation studies. SPF production workers were also included in the large-scale epidemiology study cited in the NAIMA comments.[5] The only difference in hazard between SPF and the insulation wools arises in the animal data. As described in detail in the IARC Monograph, the human data show no increased incidence of either respiratory system cancer or non-malignant respiratory disease.

Following the 2001 IARC review of all human data on all SVF, IARC stated in its press release announcing its updated report that:

> Epidemiologic studies published during the 15 years since the previous IARC Monographs review of these fibers in 1988 provide no evidence of increased risks of lung cancer or of mesothelioma (cancer of the lining of the body cavities) from occupational exposures during manufacture of these materials, and inadequate evidence overall of any cancer risk.[6]

In its 2001 reconsideration of SVF, IARC retained the Group 2B classification for SPF. IARC made clear, however, that this was based on the combination of insufficient evidence in humans and sufficient evidence in animals.

[5] *Journal of Occupational and Environmental Medicine*, September 2001

[6] See: www.iarc.fr/pageroot/PRELEASES/pr137a.html.

APPENDIX

EXAMPLES OF USES OF SPECIAL PURPOSE GLASS FIBERS:

- In hospitals, the operating theatre suites are equipped with ceiling ventilation and the air is constantly filtered by HEPA filters. High efficiency filtration of the air is essential to reduce the risks of airborne disease contamination.

- In the clean rooms of pharmaceutical laboratories, drug production is carried out in environments protected from any external contamination and any inter-contamination. This protection is assured by HEPA filters. Certain processes of sterilization for injectables are also protected by HEPA filters. To resist the elevated temperatures in the hospital sterilization equipment, only glass fiber filters can be used.

- In the ultra-clean rooms of micro-electronics (circuit boards, *etc.*), space, nano-technology industries, several barriers of HEPA filtration are crucial prevent contamination that causes irreversible product defects.

- In microbiological laboratories, HEPA filters are used to block release of bacteria and viruses both within and from the laboratories.

- In nuclear power plants HEPA filters are needed both to prevent contamination from outside air and to keep within the reactors area any fine particle radionuclides. In this application, only fine glass fiber filters can still remain effective at the high temperatures that could be encountered in a fire or other uncontrolled situation.

- For the general public, the quality of the interior air is a function of the quality of filtration of the filters, especially the capability of filters to remove sub-micron particulate matter.

NAIMA

NORTH AMERICAN INSULATION MANUFACTURERS ASSOCIATION

January 7, 2004

Q. What is the difference between 475 and E-glass formulation Special Purpose Fibers and other formulations of Special Purpose Fibers?

A. E-glass and 475 Special Purpose Fiber ("SPFs") formulations do not differ from other SPFs. 475 and E-glass are but prominent examples of SPFs that have been tested extensively in animal inhalation studies. Although other SPFs have not been as extensively tested as these two, all SPFs share certain chemical and physical similarities that are described in more detail below. The human evidence for the carcinogenicity of all SPFs is considered inadequate by IARC.

Q. How are Special Purpose Fibers distinguished from Insulation Glass Wool?

A. There are very specific distinctions between SPFs and insulation glass wool. As explained more fully below, these distinctions include chemical composition, durability, applications, health effects data, and classification by other expert entities.

There are differences in the chemical composition of Special Purpose Fibers and Glass Wool Insulations.

E-glass and 475 refer to defined compositions. The chemistry of most SPFs include the addition of oxides such as $Zr0_2$, ZnO, and BaO that improve both the ability to fiberize the glass at submicron diameters as well as the durability of the finished fiber at those diameters.

Special Purpose Fibers are more durable than Glass Wool Insulation.

SPFs are also typically more durable than insulation wools – in some instances, by an order of magnitude both as measured *in vitro* by k_{dis} and by $T_{1/2}$ and $WT_{1/2}$ in well-designed animal inhalation studies. The durability of SPFs is due in part to their chemistry but may also be due, in part, to the method of manufacture.

Special Purpose Glass Fibers are used only in specialized applications requiring unique performance properties not found in glass wool insulation.

In contrast to the insulation wools, SPFs are more highly engineered and hence, significantly more expensive than glass wool insulation. Unlike typical insulation wools, SPFs make up a very small percentage of the man-made vitreous fiber market. SPFs account for about one percent of the total annual production of synthetic vitreous fibers. SPFs are sold in final products by the fiber manufacturer to commercial users or alternatively to other manufacturers where they are made into final products.

A significant market for SPFs is in battery separator media. This SPF is composed of an acid-resistant borosilicate glass fiber with specified fiber diameters. The purpose of the media is to physically separate the positive and negative plates within the battery while allowing the sulfuric acid electrolyte to pass through the media creating an electrical charge and filtering impurities.

SPFs are also used for both air and liquid filtration. The key to creating a successful filtration media is the ability to consistently produce fibers to specific fiber diameters. Both the method of manufacture and the specific chemical formulations are designed to meet these performance requirements.

Fine filtration or high efficiency filtration media include those designed for removal of particulates less than 1 μm in diameter. These filtration media are normally comprised of SPFs with average diameters from 1 to 0.1 μm. A special category of high efficiency filter media includes HEPA glass filters which, primarily in the form of pleated "papers," are used as filter materials in high performance settings. HEPA glass filters are capable of removing 0.025 μm particles. These papers are comprised of some of the smallest SPFs known – some with mean diameters of 0.2 μm and below.

SPF media have also been used in the separation of particulates from liquids, typically as part of cylindrical filter "cartridges" where they are employed as separate concentric layers in a composite that also includes a structural core and various reinforcing or protective organic fabric layers.

The properties of SPFs allow manufacturers to use them to produce a thin blanket of insulation for use in high temperature appliances, where space restrictions are important and high thermal efficiency and fine fiber diameters are essential. The IARC press release stated that MMVFs remaining in Group 2B included "certain special purpose glass wools not used as insulating materials." This statement may have left an impression that SPFs used for insulation purposes were somehow characteristically different from the typical SPFs described herein. When SPFs are used for insulation purposes, these fibers exhibit the same unique characteristics as found in other applications of SPFs. Therefore, insulation wools used in industrial, commercial, and residential settings do not share the same performance and physical/chemical properties as the SPFs used for insulation in aircraft and spacecraft.

SPFs are used as insulation materials on both aircraft and spacecraft where they have been specially designed for high efficiency at low weight. In commercial aircraft, SPFs are employed principally as a quilted or non-quilted blanket applied to the outer frame, where it serves as the primary thermal insulation for the fuselage, and also as an acoustical barrier for engine and other external noise. These blankets are typically made of fibers with mean diameters from 1 to 1.5 μm.

<u>The available medical-scientific information supports different conclusions on the possible carcinogenicity of SPFs and glass wool insulation.</u>

The animal studies database for the insulation glass wools is composed of data from well-designed, chronic inhalation studies that found no increase in either lung or pleural tumors. The results of these studies led the IARC Working Group to consider the animal evidence for glass wool as "limited" even though some positive data from intraperitoneal injection studies were available. The Working Group also concluded that well-conducted inhalation studies with rock and slag wools led to a classification of the animal evidence as "limited," though positive results from intraperitoneal studies were available. In contrast, the SPF database contains some positive data from inhalation and intratracheal instillation studies, which led the Working Group to find the animal evidence "sufficient."

Importantly, there is no difference in the human database for glass wools and SPFs. Extensive studies of manufacturing workers covering over one million person years have not identified any association between fibers and human disease.

<u>Expert entities that have assessed the carcinogenicity of glass fibers have separated SPFs from glass wool insulation.</u>

In 2001, IARC (Vol. 81) separated glass wool insulations from SPFs in its classification scheme, thereby adopting the same separation scheme previously reported by the WHO/IPCS in their 1990 document on "Safety in the use of Mineral and Synthetic Fibres," the Canadian Government's assessment of fiber safety in their 1993 document titled "Priority Substances List Assessment Report: Mineral Fibres (Man-Made vitreous fibres)," and the ACGIH Documentation of TLV's (1994). In each of these cases, SPFs were separated from the glass wool insulation.