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North American Insulation Manufacturers Association

eurima
European Insulation Manufacturers Association

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Mr. Flemming R. Cassee
Editor-in-Chief
Particle and Fibre Toxicology Journal
National Institute for Public Health
and the Environment
The Netherlands

RE: “Composition, Respirable Fraction and Dissolution Rate of 24 Stone Wool MMVF with their Binder”

Dear Editor:

The North American Insulation Manufacturers Association (“NAIMA”) and the European Insulation Manufacturers Association (“Eurima”) (hereinafter “we”) have read with great interest the article, “Composition, Respirable Fraction and Dissolution Rate of 24 Stone Wool MMVF with their Binder,” by Wendel Wohlleben, *et al*.,[1] and we respectfully submit that the authors’ work is insufficient to warrant any change of the hazard assessment of stone wool fibres. As readers of the Journal will be well aware, man-made vitreous fibres (“MMVF”) have been vigorously studied over the last 40-plus years as the MMVF industry seeks to ensure, and assure the authors, that MMVFs are safe to manufacture, use, and dispose of at the end of life.

The hypothesis of the Article is that, based on a comparative analysis of chemical composition and *in vitro* solubility measurements on selected stone wool samples with and without binder, conclusions can be uniquely drawn on their potential hazard to humans in the workplace.

With this letter, we hope to help the authors further understand the results of the Article in the context of the well-established scientific understanding of the behavior of MMVFs *in vitro* and *in vivo*. *In vivo* biopersistence remains the key point of understanding for MMVFs as today’s hazard classification decisions are based on *in vivo*, as opposed to *in vitro*, test results. We will establish some key background facts around these fibres and their hazard classification, and review the results of previous studies involving fibre with binder, including placing context around the role of binder in MMVF products. We will also address actual exposure to MMVFs in the workplace, which is an important element in risk assessment. Finally, the sensitivity of *in vitro* dissolution measurements and the specifics of the protocols used in the Article will be evaluated, which we believe may significantly explain the authors’ results. Based upon our review, we believe the authors will be well assured that MMVFs remain safe to manufacture, use, and dispose of at end of life.

[1] Wohlleben W., *et al*., “Composition, Respirable Fraction and Dissolution Rate of 24 Stone Wool MMVF with their Binder,” *Particle and Fibre Toxicology*, (2017) 14:29 (hereinafter “Article”).

INTRODUCTION

Background on Hazard Classification of Man-Made Vitreous Fibres

MMVFs, which include fibre glass (wool), rock (stone) wool, and slag wool fibres, have been subjected to extensive scientific and medical research and testing over the last 40-plus years. Results have consistently demonstrated that MMVFs are safe to manufacture, install, and use, when recommended work practices are followed. A good starting point within this robust scientific research was one of the largest cohort mortality epidemiology studies ever conducted (nearly one million person-years),[2] aligned with extensive *in vivo* test data. All these data were relied upon by an expert panel convened by the International Agency for Research on Cancer ("IARC," part of the World Health Organization) to review MMVFs in October 2001. Following review of all available data, IARC removed all fibre glass (wool) and rock (stone) and slag wools that are commonly used for thermal and acoustical insulation from the list of possible carcinogens.

The IARC decision is consistent with findings by Health Canada in 1993,[3] and the U.S. National Toxicology Program ("NTP"). In June 2011, NTP removed from its Report on Carcinogens ("RoC") all biosoluble glass wool used in home and building insulation and for non-insulation products.[4] Rock (stone) and slag wool were never listed by the NTP as a possible carcinogen. Also in 2011, California's OEHHA published a modification to its Proposition 65 listing to include only "Glass wool fibers (inhalable and biopersistent)."[5]

The critical role of biopersistence in the safe manufacture and use of MMVFs also forms the basis today of regulation in place in the EU which allows fibres to be exonerated from classification as suspected carcinogens. The basis for the rigorous protocols allowing this distinction in fibre classification are standardized *in vivo* biopersistence tests derived from robust research, identified and validated by the EU Joint Research Center ("JRC").

The *in vivo* test protocols are defined under Note Q of the EU CLP-Regulation (EC) No 1272/2008 for the exoneration of classification of mineral wool insulation fibres. The authors are aware of these protocols, noting that as of today:

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[2] 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.

[3] Government of Canada, *Priority Substances List Assessment Report – Mineral Fibres (Man-Made Vitreous Fibres)* (1993).

[4] National Institute of Environmental Health Sciences, National Toxicology Program, Fact Sheet, "The Report on Carcinogens," June 2011. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, *Report on Carcinogens, Twelfth Edition*, 2011.

[5] 46-Z California Regulatory Notice register, p. 1878 (November 18, 2011).

> Only the in vivo studies are relevant for current MMVF classification . . . in-vitro dissolution studies remain indicative and cannot replace nor predict in-vivo studies of MMVF.[6]

We believe that statement reasonably reflects the status quo today, where it is understood that the "clearance," or half-life, of these fibres *in vivo* is substantially more complex than can be approximated by today's *in vitro* test protocols, which the authors endeavored to follow.

Summary of the Findings of the Article

The authors of the Article suggested that:

> . . . occupational risks by handling, applying, disposing modern MMVF may be underestimated . . . as conventional regulatory classification . . . seems to be based entirely on MMVF after removal of the binder.[7]

The hypothesis underlying this conclusion is that MMVFs are somehow more durable and hence, pose a greater hazard when binder is included in products made with MMVF.

A First Response – Studies with Binder on Fibres

The extensive epidemiology data on MMVF manufacturing workers comprise the best and most conclusive information on the safety of 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.[8] It is important to note that within the epidemiology studies and in the context of the authors' hypothesis that binders meaningfully impact *in vivo* behavior, the *fibres to which the cohort was exposed would have contained binder if indeed there is any binder on respirable airborne fibers*.[9]

Several studies examining fibres that include typical binders have concluded that no impact on dissolution rate or induction of disease *in vivo* was attributable to the binder. The authors recognized this point in citing the Potter and Olang study,[10] but they should also consider the work of Mattson, Bauer, and Smith in this regard.[11,12,13]

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[6] Wohlleben at p. 15.
[7] Wohlleben at p. 1.
[8] Marsh at pp. 741-834.
[9] It is also important to note that installers of batt and roll products have lower cumulative exposures than manufacturing workers, hence the potential for any adverse effects is even smaller in installers. Maxim LD, *et al*., "Fiberglass and rock/slag exposure of professional and do-it-yourself installers," *Regulatory Toxicology and Pharmacology,* 2002; 37(1):28-44.
[10] Potter, RM. and Olang, N., "The effect of a new formaldehyde-free binder on the dissolution rate of glass wool fibre in a physiological saline solution," *Particle and Fibre Toxicology*, 2013 10:13.
[11] Mattson, SM., "Factors Affecting Fiber Dissolution – In-vitro Experiments," Proceedings of the XVII International Congress on Glass, Vol 3, pp. 368-373, Chinese Ceramic Society, Beijing (1995).

Thus, we see significant work in the literature that provides direct contrast to the key conclusion from the Article.

We will now explore several elements of the Article in context of the extant science to further understand why we believe it appropriate to reject the conclusion.

THE CRITICAL ROLE OF EPIDEMIOLOGY EVIDENCE

When IARC evaluated all the epidemiology data in its 2002 review, it concluded that the epidemiology data were inadequate to suggest any adverse effect.[14]

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 atmosphere, these studies provide powerful evidence that traditional rock (stone) and slag wool fibres among manufacturing workers were not associated with disease.

THE USE OF BINDER IN MMVF MANUFACTURE: COVERAGE AND DISTRIBUTION

The authors hypothesize that the presence of organic binders on the fibre's surface affected dissolution of the fibres and hence, the assessment of the fibre's hazard potential. Inherent in that hypothesis are: (1) an (incorrect) assumption that binder coats all fibre surfaces; and (2) an assumption that the binder does not, in other ways, affect other aspects of exposure, etc.

Most MMVF products come in the form of rigid batts or rolls. Since MMVFs are inorganic and chemically inert, that rigidity is achieved through the application of a binder, essentially a thermosetting polymer that holds the fibres together to form a continuous network. A typical process for manufacturing stone wool insulation involves spraying aqueous solutions of binder precursors (silane, resins, de-dusting oil, etc.) on fibres immediately after forming.[15,16] The combination of fibres, water, and binder precursors are then conveyed to the curing oven where the water is driven off and the binder is thermally set, forming the final rigid bonded product. In practice, the application and curing process is similar to that used with glass wool insulation.[17]

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[12]Bauer, J.F., "Interaction of glass fiber with physiological fluids: The role of surface," Proceedings of XVIII International Congress on Glass, San Francisco, American Ceramic Society, pp. 1-10 (1998).
[13] Smith, DM., *et al*., "Long-Term Health Effects in Hamsters and Rats Exposed Chronically to Man-Made Vitreous Fibres, " *Ann Ocup. Hyg*., Vol 31, No. 48, pp. 731-754 (1987).
[14] 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.
[15] Chapelle, L., "Characterization and modelling of the mechanical properties of mineral wool," PhD Thesis, Technical University of Denmark, May, 2016.
[16] Mullan, John J. and Prentice, William H., "Binder distribution method for producing mineral wool board," Publication Number: US3343933, Publication date: 09/26/1967, Kind: Utility Patent Grant.
[17] Tooley, FV., "Fiberglass," *Engineered Materials Handbook, Volume 4: Ceramics and Glasses*, Schneider, SJ, ed., ASM International, pp. 402-408 (1991).

This process results in rock (stone) wool products with typically 1% to 5% by weight binder, wherein the binder does not uniformly coat the fibre surface. The binder instead, by design, forms isolated droplets at the junctions of fibres in order to achieve the desired mechanical properties. This incomplete coverage is well understood in the MMVF industry, and is inconsistent with the authors' assumption of uniform coating.[1,18,19,20]

Binders do present a complication during in vivo testing. Binders may increase fibre diameter, which may impair the ability of the fibres to be airborne and respirable. This is true both in maintaining the fibres within the network of other fibres, and by increasing the aerodynamic diameter of the fibres themselves. This is recognized within the *in vivo* tests which have been developed and are approved for use in the EU classification scheme, per Nota Q. Within these *in vivo* test methods, the only way to generate respirable aerosols, *i.e*., aerosols containing fibres of small enough diameter to naturally reach lung alveoli, is to remove the binder.

IARC also addressed the important role of binders in the final product:

> The ability of fibres to become airborne depends strongly on the degree to which they are immobilized in the product by binder, other additives and facing, and on the way they are handled. Thus, the best way to evaluate fibre length in relation to health effects is to analyse the airborne dust generated during the manufacturing and handling of the MMVF product.[21]

EXPOSURE AND THEORETICAL RESPIRABILITY OF MILLED SAMPLES

A critical consideration in risk evaluation is the nature and the level of exposure. Extensive field research consistently shows low exposures in both manufacturing and installation scenarios. This is substantiated by an extensive exposure database.[22] In the absence of significant exposure in the workplace, the question of the impact of binder is essentially mooted. Guidelines establishing the means to ensure safe exposure levels are well established, and are readily accessible from MMVF manufacturers.

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[18] Hjelmgaard, Thomas, "Analytical binder for mineral wool products," Assignee: Rockwool International A/S, Publication Number: EP2947117, Publication date: 11/25/2015, Kind: Patent Application Publication.
[19] Hager, William G.; Chen, Liang; Hinze, Jay W., "Surfactant-containing insulation binder," Assignee: Owens Corning Fiberglas Technology, Inc., Publication Number: US7157524, Publication date: 01/02/2007, Kind: Utility Patent Grant (with pre-grant publication).
[20] Buska, A. and Maciulaitis, R., "The compressive strength properties of mineral wool slabs: Influence of structure anisotropy and methodical factors," *J Civil Eng and Management*, 13:2, pp. 97-106 (2007).
[21] IARC Monograph at p. 58.
[22] G.E. Marchant, *et al*., "A Synthetic Vitreous Fiber (SVF) Occupational Exposure Database: Implementing the SVF Health and Safety Partnership Program," *Applied Occupational and Environment Hygiene*, 17(4): 276-285, 2002. Marchant, Gary, *et al*., "Applications and Findings of an Occupational Exposure Database for Synthetic Vitreous Fibers," *Journal of Occupational and Environmental Hygiene*, 6:3, 143-150 (2009).

While the authors discussed at length their findings on respirable-sized fibres following ball-milling of the products, they failed to even acknowledge the existence of extensive published data on airborne fibre exposures in both manufacturing and indoor environments. Marchant, *et al.*,[23] shows clearly that exposures are consistently low. As the authors created samples using high energy ball-milling, it is not clear what relevance these data have to actual airborne fibre exposures, as the pulverizing action of a ball mill creates material unlike that generated during routine handling of batts and rolls.

SENSITIVITY OF CONDITIONS AND COMPOSITION OF FLUIDS IN DETERMINING *IN VITRO* DISSOLUTION RATES

The Article compares a measured *in vitro* dissolution rate (k_{Si}) data to previously published data for MMVF21 (traditional stone wool) and MMVF34 (higher alumina stone wool).[24] The authors' inferred expectation was that the measured k_{Si} of the tested fibres would be similar to MMVF34; instead, their values for k_{Si} were comparable to previously published values for MMVF21. The hypothesis offered in response was that the difference (authors' data vs. previously published) was due to the presence of binder on the authors' studied fibres.

Critically, the study lacked two (2) key controls:

- A control to allow evaluation of whether or not the binder removal treatments caused a change in the dissolution rate of the tested fibres.
- Near or exact matches to the MMVF21 or MMVF34 fibres (fibre identification per the RCC studies, not this Article) to evaluate whether their chosen measurement conditions alone significantly altered their data vs. that cited in the literature for MMVF21 and MMVF34.

Without these key controls, we do not believe it is appropriate to attribute any changes to the dissolution rate uniquely to the presence of binder on the fibre surface.

Considering how the authors' experimental *in vitro* methodology may have impacted the measured dissolution rate, we recall that Steenberg, *et al*.[25] and Guldberg, *et al*.[26] illustrated several pertinent factors that strongly influence k_{dis} values obtained during *in vitro* testing of

[23] G.E. Marchant, *et al*., "A Synthetic Vitreous Fiber (SVF) Occupational Exposure Database: Implementing the SVF Health and Safety Partnership Program," *Applied Occupational and Environment Hygiene*, 17(4): 276-285, 2002. Marchant, Gary, *et al*., "Applications and Findings of an Occupational Exposure Database for Synthetic Vitreous Fibers," *Journal of Occupational and Environmental Hygiene*, 6:3, 143-150 (2009).
[24] Note the use of MMVF21 and MMVF34 in this note parallel the designations of specific fibres in the RCC studies cited by the authors, and do not reference the authors' samples in this specific work.
[25] Steenberg, T., *et al*., "Dissolution Behavior of Biosoluble HT Stone Wool Fibres," *Glastech. Ber Glass Sci. Technol*, 74 No. 4, pp. 97-105 (2001).
[26] Guldberg, M., *et al*., "Measurement of In-Vitro Fibre Dissolution Rate at Acidic pH," *Ann. Occup. Hyg*., Vol 42 no. 4, pp. 223-243 (1998).

higher alumina stone wool fibres, similar to MMVF34. These factors align with those classically accepted to be critical to glass dissolution rate,[27,28] including:

- Solution pH
- Fluid composition, in particular citrate levels
- Specific flow rate (fibre surface area/fluid volume flow rate)
- Test temperature

In examining the authors' methods critically, we note that pH and temperature were well controlled and correspond well to published methods. However, the authors used Stefaniak's phagolysosomal simulant fluid ("PSF"), a citrate-free simulated lung fluid,[29] vs. the citrate containing modified Gamble's solutions used in the Guldberg study. Significant uncertainty in specific surface area measures was also noted, as well as variable flow rates during testing.

The known effects of these critical differences and variations in experimental conditions invite alternate hypotheses to explain the differences in k_{Si} vs. the authors' hypothesis that the presence of binder was responsible for changes vs. expectation. These results equally may be explained by exclusion of citrate from the test fluid (by using PSF vs. modified Gamble's solution) and variation in flow rate, etc. We believe that had appropriate controls been used, these critical differences would have become evident.

CONCLUSION

We do not agree with the authors' conclusion that fibre dissolution rate is decreased by binder nor do their existing data support such a conclusion. Absent appropriate controls, especially that lack of any assessment of binder removal methods on dissolution rates, coupled with the known sensitivity of dissolution rate to exact experimental conditions, we do not feel the conclusions are justified based on the data presented in the Article. Our position is also supported by the results of previous *in vitro* and *in vivo* studies involving binder-coated fibres, as noted in the review.

With respect to the hypothesis that these findings merit review of the hazard assessment of stone wools, we find it compelling that the well-conducted and extensive epidemiology research concluded that there is no adequate evidence of an adverse hazard (cancer or non-cancer) from exposure to stone wools, fibre glass (wool), and slag wool fibres. Of note, the cohort in these studies would have been exposed to products including binders. This conclusion is supported by IARC, the most authoritative international scientific body concerning cancer hazard classification. This fact, combined with documented low exposures, establishes that MMVF occupational risks are minimal and effectively managed by recommended work practices.

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[27] Paul, A., "Chemical Durability of Glass," *Chemistry of Glasses*, Chapman and Hall, London, pp. 108-147 (1982).
[28] Ahmed, A.A.; Abbas, A.F.; and Youssof, I. M., "Attack of Lead Crystal Glasses by Solutions of Some Organic Acids," *Glastech. Ber Glass Sci. Technol*, 68 C1, pp. 223-229 (1995).
[29] Stefaniak, A.B., *et al*., "Characterization of Phagolysosomal Stimulant Fluid for Study of Beryllium Aerosol Particle Dissolution," *Toxicology in Vitro*, 19, 99, 123-134 (2005).

Through this review, we have broadly discussed the science around the issue of hazard classification of MMVFs, and contrasted the findings of the 40-plus years of research in this field to the authors' findings. In conclusion, we respectfully submit that the authors' work is insufficient to warrant any change of the hazard assessment of stone wool fibres.

Respectfully,

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