From: "Angus Crane"
To: <coshita@oehha.ca.gov>
Date: 5/5/2009 9:28 AM
Subject: NAIMA COMMENTS - CIC Proposed Chemicals for Consideration and Consultation - March 2009 - Rock Wool
Attachments: NAIMAComments050509OEHHACICRockWool.pdf

Dear Ms. Oshita,

Please find attached the North American Insulation Manufacturers Association ("NAIMA") comments on the Prioritization of Chemicals for Carcinogen Identification Committee Review: Proposed Chemicals for Committee Consideration and Consultation, March 2009 - Rock Wool. NAIMA is the trade association representing all North American manufacturers of rock wool insulation products.

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

Sincerely,

Angus E. Crane

Angus E. Crane

Executive Vice President, General Counsel

North American Insulation Manufacturers Association

Visit NAIMA online at:

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BEFORE THE
REPRODUCTIVE AND CANCER HAZARD ASSESSMENT BRANCH
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
CARCINOGEN IDENTIFICATION COMMITTEE

In Re:

PRIORITIZATION OF CHEMICALS FOR CARCINOGEN IDENTIFICATION COMMITTEE REVIEW: PROPOSED CHEMICALS FOR COMMITTEE CONSIDERATION AND CONSULTATION, MARCH 2009 – ROCK WOOL.

COMMENTS OF THE
NORTH AMERICAN INSULATION
MANUFACTURERS ASSOCIATION ("NAIMA")

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May 5, 2009

COMMENTS OF THE NORTH AMERICAN INSULATION MANUFACTURERS ASSOCIATION ("NAIMA") PRIORITIZATION OF CHEMICALS FOR CARCINOGEN IDENITFICATION COMMITTEE REVIEW: PROPOSED CHEMICALS FOR COMMITTEE CONSIDERATION AND CONSULTATION MARCH 2009 ROCK WOOL

INTRODUCTION

The North American Insulation Manufacturers Association ("NAIMA") appreciates the opportunity to submit comments on the California Office of Environmental Health Hazard Assessment's ("OEHHA") "Prioritization of Chemicals for Carcinogen Identification Committee Review: Proposed Chemicals for Committee Consideration and Consultation March 2009" (hereinafter "Prioritization of Chemicals for CIC Review"). NAIMA is the trade association for North American manufacturers of fiber glass and rock and slag wool insulation products. NAIMA's mission is to encourage safe production and use of insulation products and to promote energy efficiency and environmental preservation through the use of fiber glass and rock and slag wool insulation products. There are no rock wool manufacturing plants operating in the State of California.

OEHHA has listed rock wool as one of the 38 chemicals proposed for review by the Carcinogen Identification Committee ("CIC") under Proposition 65. As OEHHA noted, the chemicals are not proposed for listing at this time, but OEHHA is seeking public comments on which of these chemicals should proceed to the next stage of the listing process. As discussed more fully below, NAIMA and its members strongly urge OEHHA to recognize that rock wool has been the subject of extensive and thorough reviews by authoritative bodies, most notably by the International Agency for Research on Cancer ("IARC"), which placed rock wool in Group 3, not classifiable as to their carcinogenicity to humans. IARC reached the conclusion that the epidemiological studies on rock wool provide no evidence of increased risks of lung cancer or mesothelioma from occupational exposure to rock wool. The National Toxicology Program ("NTP") has never listed rock wool in its Report on Carcinogens ("RoC"). Also demonstrated below, occupational exposure to rock wool fibers are consistently below 1 f/cc and non-occupational exposures are even lower. Exposures are documented through an extensive exposure database, published articles, and wide ranging consumer exposure studies. These data, some of which post-date IARC 2002, support OEHHA's exposure characterization of "limited/occupational."[1]

Given the scientific data available on rock wool and the current economic constraints experienced by the State of California, an additional evaluation of rock wool by OEHHA is not warranted, is not necessary, and would be a poor use of OEHHA's valuable but limited resources. As the following comments illustrate, scientific evidence demonstrates that rock wool has been thoroughly examined and needs no further evaluation by OEHHA.

[1] Prioritization of Chemicals for CIC Review, p. 6.

BACKGROUND

Rock wool insulations have been produced naturally for centuries. During volcanic eruption, when a strong wind passes over a stream of molten lava, the lava is blown into fine silky threads that look like wool. Manufacturers of rock wool insulation use essentially the same processes of nature to make rock wool. Rock wool insulation is composed principally of fibers manufactured from a combination of aluminosilicate rock (usually basalt), recycled blast furnace slag, and limestone or dolomite. Slag is a byproduct from steel production that would otherwise end up in landfills; the use of recycled content is just one of the many environmental benefits offered by rock wool insulation. The typical chemical composition ranges for rock wool is set forth in Table 1 of the IARC Monograph.[2] Of course, the most important environmental benefit of rock wool is its ability to make buildings more energy efficient. A more detailed discussion on the benefits of rock wool and how those benefits support and facilitate the realization of California's regulatory agenda is set forth below.

Rock wool offers an array of unique attributes. The fibrous composition of rock wool insulation provides a flexibility and versatility not found in most other insulations. Because of its versatility, rock wool insulation comes in a wide variety of forms, shapes, and sizes, including board, batt, loose-fill, spray applied, and pipe insulation for many common and specialized applications. Rock wool insulation is used in residential, commercial, and industrial applications. Because of the raw materials from which rock wool is produced, this insulation is naturally non-combustible and remains so for the life of the product without the addition of harsh and potentially hazardous chemical fire retardants. Rock wool insulation can resist temperatures in excess of 2,000° F. Given this high-melting temperature, rock wool insulation can be used in a wide variety of applications that call for these unique properties and is used as passive fire protection in many buildings.

OEHHA'S FURTHER STUDY OF ROCK WOOL IS NOT NEEDED GIVEN THE EXTENSIVE SCIENTIFIC DATABASE WHICH HAS BEEN EVALUATED BY IARC, ATSDR, AND OTHERS

OEHHA is not proposing the listing of rock wool, but is seeking comments on whether rock wool should proceed to the next stage of the listing process. Rock wool is being considered based on "an initial, abbreviated appraisal of the information identified through screening level literature searches."[3] NAIMA requests that OEHHA carefully consider the evaluations that have been conducted by such organizations and agencies as IARC, the U.S. National Academy of Sciences, the Agency for Toxic Substances and Disease Registry ("ATSDR"), and scientific bodies in the United Kingdom,[4] Canada,[5] the Netherlands,[6] Australia and New Zealand,[7] and

[2] International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Man-Made Vitreous Fibres*, Vol. 81 (Lyon, France: WHO/IARC, 2002), p. 46.
[3] Prioritization of Chemicals for CIC Review, p. 1.
[4] United Kingdom Department of Health, *1994 Annual Reports on the Committees on Toxicity, Mutagenicity, Carcinogenicity of the Chemicals in Food, Consumer Products and the Environment*, (1995).
[5] Government of Canada, *Mineral Fibres (Man-Made Vitreous Fibres)*, (1993).
[6] Netherlands Committee of the Health Councils, *Man Made Mineral Fibers*, (Sept. 8, 1995).
[7] Insulation Wools Research Advisory Board, Sydney, Australia (Oct. 1995).

others.[8] These were in-depth examinations which took months of preparation and were undertaken by world-wide experts for an extended period of deliberation and critical assessment of the scientific data available on rock wool insulation. These evaluations focused on the specific areas of interest identified by OEHHA. Below is a summary of the findings of these different scientific bodies in each scientific category identified by OEHHA. The two most recent evaluations were conducted by IARC and ATSDR. Because these evaluations are of the most recent date, are comprehensive and thorough, and are both authoritative, NAIMA relies heavily upon them.

IARC and ATSDR

Based on a significant increase in available scientific data, IARC convened a Working Group in October 2001 to reconsider the 1987 classification of man-made vitreous fibers, which includes rock wool.[9] The research conducted since 1987 included updated epidemiology studies, animal inhalation studies conducted at RCC in Geneva, Switzerland, and evidence on the role that biosolubility and fiber size decreases retention of fibers in the human body.

For the October 2001 Working Group, IARC appointed an expert panel of 19 scientists from the field of fiber science and epidemiology to review the updated scientific information. Over a ten-day period at IARC Headquarters, these experts reviewed and deliberated on the far-reaching body of scientific evidence. Appropriately, virtually all of the scientific data cited in OEHHA's reference list for rock wool are drawn from the IARC 2002 Monograph. The full IARC Monograph 81 is available on the IARC website at: http://monographs.iarc.fr/ENG/Monographs/vol81/mono81.pdf.

Therefore, IARC re-evaluated the 1988 IARC assessment of glass fibers and removed glass, rock and slag wool fibers from its list of Group 2B substances "possibly carcinogenic to humans." All fiber glass and rock and slag wools that are commonly used for thermal and acoustical insulation are now considered not classifiable as to carcinogenicity to humans (Group 3). IARC noted specifically:

> Epidemiologic studies published during the 15 years since the previous IARC Monographs review of these fibres in 1988 provide no evidence of increased risks of lung cancer or 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.[10]

IARC retained its Group 3 classification for continuous glass filaments and the Group 2B "possible carcinogen" classification for certain special purpose glass fibers.

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[8] International Programme on Chemical Safety, WHO, *Environmental Health Criteria 77, Man-Made Mineral Fibres*, (1988).

[9] International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Man-Made Mineral Fibres and Radon*, Vol. 43 (Lyon, France: WHO/IARC, 1988).

[10] www.iarc.fr/ENG/Press_Releases/archives/pr137a.html.

The IARC change is consistent with the conclusion reached by the U.S. National Academy of Sciences, which in 2000 found "no significant association between fiber exposure and lung cancer or nonmalignant respiratory disease in the MVF [man-made vitreous fiber] manufacturing environment."[11]

The most recent review on synthetic vitreous fibers was conducted by the Agency for Toxic Substances and Disease Registry ("ATSDR").[12] ATSDR is a federal public health agency of the U.S. Health and Human Services Department. In 2004, ATSDR completed a Toxicological Profile on Synthetic Vitreous Fibers. Toxicological profiles are prepared in accordance with guidelines developed by ATSDR and the Environmental Protection Agency ("EPA"). ATDSR's toxicological profiles are a collaborative effort with input from experts employed by various federal agencies.

In these comments, NAIMA, like OEHHA, relies primarily on the IARC review, which reviewed the published data and categorized rock (stone) wool as Group 3, "*not classifiable as to their carcinogenicity to humans*."[13] This overall conclusion was based on "*inadequate evidence*" from the human, epidemiological data and "*limited evidence*" from animal studies.[14] In addition, NAIMA cites and has provided where appropriate, post-IARC publications and other data concerning exposure.

Epidemiology

On human carcinogenicity data, these 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. . . .[15]

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

[11] NRC Subcommittee on Manufactured Vitreous Fibers. 2000. Review of the U.S. Navy's Exposure Standard for Manufactured Vitreous Fibers. National Academy of Sciences, National Research Council, Washington, D.C.: National Academy Press.

[12] *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.

[13] IARC (2002) at p. 339.

[14] IARC (2002) at p. 338 (all emphasis in original).

[15] IARC (2002) at pp. 329-30.

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.[16]

Specifically, IARC found the U.S. rock wool cohort showed no association with "duration of exposure or with time since first exposure."[17] 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 estimated cumulative exposure to respirable fibers, with or without adjustment for possible confounding by smoking or other occupational exposures.[18] IARC concluded that the "results from these studies provide no evidence of an increased risk for pleural mesotheliomas or any other tumours."[19] 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."[20]

In its Toxicological Profile for Synthetic Vitreous Fibers, 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."[21]
- "[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."[22]

These comprehensive epidemiological studies have already received exacting scrutiny from the world's foremost experts. Moreover, there have been no additional epidemiological studies since IARC's decision that would change IARC's findings. Therefore, OEHHA should direct its resources to agents less studied and evaluated, and those with higher exposure potential.

Animal Data

For rock wool, the 2001 IARC Working Group evaluated the available animal data concluding that "[t]here is limited evidence in experimental animals."[23] In the 1988 IARC analysis, most of

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[16] IARC (2002) at p. 338.
[17] IARC (2002) at p. 329.
[18] IARC (2002) at p. 329.
[19] IARC (2002) at p. 330.
[20] IARC (2002) at p. 330.
[21] ATSDR at p. 18.
[22] ATSDR at p. 31.

the available animal data were from non-physiological routes of administration, such as injection or implantation in the pleural or peritoneal cavities. In the ten-plus years preceding the 2002 Monograph, multiple studies via inhalation were conducted using high-quality protocols (e.g., nose-only exposures, lifetime duration, air controls, positive controls with crocidolite or Canadian chrysotile asbestos) for various fiber types.[24] For the largest inhalation study of rock wool, which had three exposure groups and air and crocidolite controls, IARC summarized the data as follows:

> In a well-designed, long-term inhalation study in which rats were exposed to rock (stone) wool, no significant increase in lung tumour incidence and no mesotheliomas were observed. Crocidolite asbestos was used as the positive control and led to high lung tumour incidence and one mesothelioma.[25]

IARC's finding of limited evidence in experiment animals is consistent with its reclassification of rock wool to Group 3: unclassifiable as to carcinogenicity in humans. Agents found to have limited or even sufficient evidence of carcinogenicity in experimental animals may be placed in Group 3 when there is strong evidence that mechanism of carcinogenicity in experiment animals does not operate in humans. This principle certainly applied to rock wool.

In contrast to the inhalation data, ATSDR characterized the injection and implantation studies as of limited value since the inhalation data was a more appropriate route of exposure:

> Although many animal studies administering various synthetic vitreous fibers by injection or implantation into the intrapleural or intraperitoneal cavities have reported the development of administration site nonneoplastic and neoplastic lesions, these results are of limited usefulness for predicting health hazards in humans exposed by inhalation. Studies that exposed animals by inhalation to well-measured levels of respirable fibers are considered more appropriate for assessing potential risk to human health.[26]

These extensive animal studies have already received exhaustive evaluation from the most respected scientific bodies. Moreover, there is no new animal data since IARC's decision that would alter IARC's findings. Therefore, OEHHA should focus its resources on agents less studied and with higher exposure potential.

Exposure

As OEHHA's prioritization table recognizes, exposures to rock wool insulation are low and mostly occupational. The MMVF industry for many years has recommended a 1 f/cc exposure limit based on irritation. Continuation of the 1 f/cc Permissible Exposure Level ("PEL") through the NAIMA Product Stewardship Program reaffirms the exposure limit recommended by various governmental and authoritative bodies over the years, including OSHA's proposed 1 f/cc PEL of

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[23] IARC (2002) at p. 338.
[24] IARC (2002) at Table 61 (rock and slag wool), pp. 205-07.
[25] IARC (2002) at p. 332.
[26] ATSDR at p. 85.

1992;[27] the State of California's Air Contaminant Advisory Committee's recommendation of a 1 f/cc PEL in 1997;[28] the American Conference of Government Industrial Hygienists' ("ACGIH") adoption of a 1 f/cc Threshold Limit Value ("TLV") in 1997;[29] and the Health and Safety Partnership Program's OSHA-endorsed recommendation of 1 f/cc from 1995-2007.[30]

As part of the OSHA-NAIMA Health and Safety Partnership Program,[31] NAIMA established and maintains an exposure database containing sample data about exposure levels categorized by product type and specific work task. NAIMA has analyzed exposure data involving typical exposure levels for many common tasks, which shows that the vast majority of these tasks currently can be completed without exceeding the exposure limit of 1 f/cc for an 8-hour time weighted average ("TWA"). Where workplace exposures may exceed this PEL or the 0.5 f/cc action level, respiratory protection is recommended. The type of respirator recommended is an N95 series dust respirator certified by the National Institute of Occupational Safety & Health ("NIOSH"). The NAIMA exposure database currently includes data collected from a variety of sources, including manufacturers, insulation installers, fabricators, academic institutions, and third-party organizations. As reported in two peer-reviewed articles, the extensive exposure database contains over 14,000 data points and shows that the vast majority of applications, installation, and manufacturing, are well below the voluntary 1 f/cc PEL.[32]

The NAIMA exposure database was relied upon by both IARC[33] and ATSDR.[34] The NAIMA database provides data on occupational exposure – manufacturing, fabrication, and installation. A separate article on exposures for insulation installers concluded that due to smaller exposure times (installers are not employed as long as manufacturing workers), both do-it-yourself and professional insulation installers had much lower lifetime exposures than workers employed in the manufacturing setting. Because epidemiological studies of manufacturing workers show no increase in respiratory cancer, there is even less risk for installers.[35]

Consumer exposures to installed MMVF insulation products present the lowest exposures, and as described below, are de minimus, being generally in the range of 10^{-4} f/cc even under the worst-case conditions. In 23 studies (see attached), MMVF exposures are evaluated in a wide variety

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[27] 57 Fed. Reg. at 26,002 (June 12, 1992).

[28] http://www.osha.gov/sltc/syntheticmineralfibers/table.html.

[29] ACGIH, 2001, Synthetic Vitreous Fibers, Supplement to documentation of the threshold limit values and biological exposure indices, American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio.

[30] ATSDR at pp. 11, 218 (Table 8-1).

[31] The OSHA-NAIMA Health and Safety Partnership Program contained many elements, including work practices, development of an exposure database, and the 1 f/cc permissible exposure level. For more details, see "NAIMA's Health and Safety Partnership Program," North American Insulation Manufacturers Association, Pub. No. NO30, December 2002.

[32] 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; Gary Marchant, et al., "Applications and Findings of an Occupational Exposure Database for Synthetic Vitreous Fibers," *Journal of Occupational and Environmental Hygiene*, 6: 143-150, March 2009.

[33] IARC (2002) at pp. 89, 92-94, 122.

[34] ATSDR at pp. 11, 193.

[35] L. Daniel Maxim, Walter Eastes, John G. Hadley, Charles M. Carter, Janis W. Reynolds, and Ron Niebo, "Fiber glass and rock/slag wool exposure of professional and do-it-yourself installers, *Regulatory Toxicology and Pharmacology*, 37 (2003) pp. 28-44.

of buildings, including homes, schools, office buildings, and commercial buildings. Although the studies vary in their methodologies and criteria, they consistently find very low levels of MMVFs, in many cases below the level of detection. Average exposures in the studies range from 10^{-3} to 10^{-5} f/cc, which is several orders of magnitude lower than the recommended occupational exposure limits of 1 f/cc. In most of the studies, the maximum exposure measurement is well below 10^{-3} f/cc.

While the attached list of studies on consumer MMVF exposures in buildings report very low exposure levels, actual consumer exposures are likely to be generally even lower than reported in these studies for the following reasons:

- Many of the studies report MMVF exposures under atypical worst-case conditions. For example, several studies measured MMVF exposures immediately after installation or disturbance of MMVF insulation products, which results in exposure measurements well above normal day-to-day exposure levels, yet the exposure levels reported in these studies are already at low levels.
- The analytical methods used in many of the studies include other types of fibers in addition to MMVFs, and therefore over-estimate actual MMVF exposures. For example, many of the studies using phase-contrast optical microscopy include all fibers in the exposure measurement, of which MMVFs represent only a fraction of the total fiber concentrations reported. Other studies include all fibers not positively identified as non-MMVFs. The inclusion of other fibers in the sample can substantially over-estimate actual MMVF exposures. Even given the inclusion of many other fibers, the exposures were still low.
- Several of the studies did not detect any MMVFs at the limit of detection in some or most of the measurements in the study. These exposure measurements were reported in the study at the limit of detection, but actual exposure levels were necessarily lower than the reported default levels.
- Some of the studies report combined exposure levels for both respirable and non-respirable fibers, whereas only respirable fibers present a potential health concern.

Due to these factors, actual consumer exposures to MMVFs from installed insulation products are likely to be significantly lower than the already low levels measured in the attached list of studies.

Other Relevant Data

<u>Deposition, Retention, and Clearance</u>

ATSDR documented that fibers are unlikely to be retained in the human body:

- "If you swallow synthetic vitreous fibers (by eating, drinking, or by swallowing fibers that have moved from nasal or lung airways to your larynx), nearly all of the fibers pass through your intestines within a few days . . ."[36]

[36] ATSDR at p. 4.

- "If you get synthetic vitreous fibers on your skin or in your eyes, very few of these fibers, if any, pass through into your body."[37]
- "Synthetic vitreous fibers dissolve more readily in the lung than asbestos fibers."[38]
- "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."[39]
- "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. This property is not expected with synthetic vitreous fibers and may contribute to the difference in potency between asbestos and synthetic vitreous fibers."[40]
- "What happens to synthetic vitreous fibers when they enter the environment? . . . synthetic vitreous fibers will be broken down if the water or soil is very acidic or very alkaline . . . Synthetic vitreous fibers are not likely to move through soil."[41]
- "Is there a medical test to determine whether I have been exposed to synthetic vitreous fibers? . . . Because synthetic vitreous fibers leave the body quickly, most nonspecific tests would not be useful."[42]

<u>Genotoxicity</u>

ATSDR reported "no evidence for genotoxic activity of several synthetic vitreous fibers was found" in bacterial mutation assays or chromatid exchange assays.[43] Given the limited degree to which synthetic vitreous fibers are absorbed into the body, there is no mechanistic basis to suspect that reproductive or toxicokinetic effects may be of concern from exposures to synthetic vitreous fibers.[44]

<u>Structure Activity Consideration</u>

OEHHA notes that two other types of synthetic vitreous fibers are Proposition 65 carcinogens – glass wool and ceramic fibers. It is important to understand why neither of these listings should serve as further justification for further study of rock wool. First, ceramic fibers were reviewed by the same IARC Working Group in 2001. IARC changed the classification of rock wool, but left ceramic fibers as a Category 2B. IARC recognized a difference between these two fiber types based on animal data, biosolubility, chemical composition, and application. Second, glass wool is on the Proposition 65 because of listings on IARC and the National Toxicology

[37] ATSDR at p. 4.
[38] ATSDR at p. 4.
[39] ATSDR at p. 17.
[40] ATSDR at p. 123.
[41] ATSDR at pp. 2-3.
[42] ATSDR at p. 10.
[43] ATSDR at p. 110.
[44] ATSDR at pp. 112, 153, 154, 158-159.

Program's ("NTP") Report on Carcinogens ("RoC") that predate the 2002 IARC review and the extensive new data on epidemiology, animal inhalation, and other factors which were key to the IARC reclassification. NTP is currently reevaluating its listing of glass wool. The ATSDR put the NTP listing in proper perspective: "In 2002, the International Agency for Research on Cancer (IARC) considered all of the evidence regarding the possible carcinogenicity of synthetic vitreous fibers. Much of the evidence was collected in the 1990s and was not available for earlier assessments made by the U.S. Department of Health and Human Services (DHHS) [NTP]."[45] Similarly, the Proposition 65 listing of glass wool does not reflect the findings of current science research.

ROCK WOOL'S ENVIRONMENTAL ATTRIBUTES HELP TO ACHIEVE CALIFORNIA'S GOALS OF ENERGY EFFICIENCY AND REDUCTION OF GREENHOUSE GASES

As indicated above, the most important environmental attribute of rock wool is as thermal insulation. Indeed, California recognizes that insulation saves energy and reduces pollution caused by the generation of electricity and other power sources. A thermally efficient building reduces the amount of energy required to maintain a comfortable indoor environment. A reduction in energy consumption conserves non-renewable fuel supplies and reduces air pollution and greenhouse gas emissions such as CO_2 and NOx.

That is why the State of California believes that increased energy efficiency in buildings through insulation will be a key tool in reducing greenhouse gas emissions in California. The California Air Resources Board ("CARB") recently released the "Climate Change Proposed Scoping Plan: A Framework for Change." In that Scoping Plan, CARB recognized that increasing the energy efficiency of existing buildings provides the "greatest potential for GHG reductions in the building sector."[46] That is why CARB granted energy efficiency as the highest priority for meeting California's energy needs and recognizes it as an effective means to reduced greenhouse gases.[47] CARB's positioning of energy efficiency as the first priority is consistent with the California Public Utilities Commission and the California Energy Commission's Energy Action Plan.[48] Directly relevant to benefits of rock wool insulation, CARB also committed to "provide incentives to better insulate and weatherize older homes,"[49] require retrofits for existing buildings, impose mandatory energy efficiency improvements for older homes, and recognize that cost effective measures help meet goals and objectives expeditiously without overburdening budgets.[50] Insulation is the most cost-effective energy efficiency tool available. Therefore, rock wool can and will be an important and effective tool in realizing California's goals for improved energy conservation and reduction of greenhouse gas emissions.

These reductions of greenhouse gas emissions through insulation have other far reaching benefits. According to a Harvard University School of Public Health study, the reduction in

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[45] ATSDR at p. 7.
[46] California Air Resources Board, "Climate Change Proposed Scoping Plan: A Framework For Change," App. C at C-146, October 2008.
[47] California Air Resources Board, "Climate Change Draft Scoping Plan, June 2008 Discussion Draft," p. 21.
[48] CARB Draft Scoping Plan at p. 21.
[49] CARB Draft Scoping Plan at p. 66.
[50] CARB Proposed Scoping Plan, App. C at C-146 and C-108.

emissions as a result of energy efficiency through the use of thermal insulation greatly improves public health and saves lives.[51]

CONCLUSION

Rock wool insulation products are among the most thoroughly researched insulation products on the market. As NAIMA's comments have demonstrated, the weight of the scientific evidence shows no association between exposure to rock wool fibers and respiratory disease or cancer in humans. Based on this extensive scientific database, IARC now places rock wool in Group 3, not classifiable as to carcinogenicity, and rock wool has never been listed in the NTP's Report on Carcinogens. In 2004, ATSDR reaffirmed IARC's findings. Moreover, there is no new epidemiological or animal data since IARC's decision that would alter IARC's findings. As to OEHHA's current screening list, a further analysis of rock wool is not justified due to prior review by IARC, a Proposition 65 Authoritative Body; by ATSDR; and others, as well as the scientific research, low exposures, and the extensive record of product stewardship. OEHHA's limited resources would also be more appropriately directed elsewhere.

Attachment

[51] Jonathan I. Levy, Yurika Nishioka and John D. Spengler, "The public health benefits of insulation retrofits in existing housing in the United States," *Environmental Health: A Global Access Science Source*, April 2003, pp.1-16; Yurika Nishioka, Jonathan I. Levy, Gregory A. Norris, Andrew Wilson, Patrick Hofstetter, and John D. Spengler, "Integrating Risk Assessment and Life Cycle Assessment: A Case Study of Insulation," *Risk Analysis*, Vol. 22, No. 5, 2002, pp. 1003-1017.

<u>**Study**</u>

1. Schneider T., Burdett G., Martinon L., Brochard P., Guillemin M., Teichert U. and Drager U. (1996). Ubiquitous fiber exposure in selected sampling sites in Europe. *Scand J. Work Environ Health* 22: 274-284.

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SUMMARY OF PUBLISHED MMVF CONSUMER EXPOSURE DATA

Reference	Sample Description	Sampling Methodology			N	Exposure Levels (f/cc)	
		Micro-scope	Fiber Definition[a]	Type of Fibers		Average[b]	Maximum[c]
Schneider et al. (1996) *(1)*	Personal samples from 5 school children, 5 retired persons, 5 office workers, and 5 taxi drivers	SEM	WHO	Non-asbestos, non-gypsum inorganic fibers	80	0.0060	0.0171 (95%)
Miller et al. (1995) *(2)*	Fiber levels 24 hours after installation of MMVF in 14 homes	SEM	NIOSH 7400B	MMVF	14	0.0060	0.0120
		PCOM	NIOSH 7400B	All fibers	14	0.0020	0.0070
Tiesler et al. (1993) *(3)*	Office buildings, schools, privates houses, and laboratories with visible, uncoated MMVF	SEM	WHO	"Product fibers"	134	0.0006	0.0057
Fischer (1993) *(4)*	7 offices, 1 school, and 1 dwelling with MMVF ceiling boards are in direct contact with indoor air, plus 6 buildings with health complaints	SEM	WHO	"Product fibers"	150	0.0003	0.0018 (95%)
Jacob et al. (1992) *(5)*	Work area the night after installation of glass wool batt or blown insulation	PCOM	NIOSH 7400B	Glass fibers	53	0.0001	0.0009
NIOSH (1991a) *(6)*	Office building with health complaints after work disturbance of fibrous glass insulation	PCOM	NIOSH 7400	Glass fibers	5	<0.0030 (LOD)	<0.0030 (LOD)
NIOSH (1991b) *(7)*	Public school with health complaints; fibrous glass lined ventilation system	PCOM	NIOSH 7400	All fibers	12	<0.0050 (LOD)	0.0050
Schneider (1990) *(8)*	105 rooms containing MMVF ceiling tiles in Danish nurseries, kindergartens/ schools, offices	PCOM	diam. < 3μm	MMVF	105	0.0001	0.0016
Jaffrey et al. (1990a) *(9)*	Living area of house, within one week after attic installation of MMVF insulation	TEM	diam.: < 3μm length: >5 μm, <100μm	MMVF	10	<0.0029	<0.0050
Jaffrey et al. (1990b) *(10)*	1st floor of house, immediately after "major disturbance" of attic insulation.	TEM	diam.: < 3μm length: >5 μm, <100μm	MMVF	11	<0.0010	<0.0020

Reference	Sample Description	Sampling Methodology			N	Exposure Levels (f/cc)	
		Micro-scope	Fiber Definition[a]	Type of Fibers		Average[b]	Maximum[c]
Gaudichet et al. (1989) *(11)*	Buildings with MMVF insulation or ventilation surface materials	PCOM	diam. < 3μm	MMVF	69	0.0001	0.0062
Jaffrey et al. (1989) *(12)*	1st floor of house, after "major disturbance" of attic MMVF insulation	TEM	diam.: < 3μm length: >5 μm, <100μm	MMVF	8	<0.0020	0.0030
	Living area of house, within one week after attic installation of MMVF insulation				11	0.0099	0.0600
Dodgson et al. (1987) *(13)*	Living areas of houses during installation or disturbance of MMVF attic insulation	SEM	WHO	All fibers	30	0.0045	0.0232
	Same houses; measurements before and after (24 hrs. or 7 days) installation or disturbance				40	<0.0002	<0.0052
Nielsen (1987) *(14)*	140 rooms with MMVF acoustical ceilings	PCOM	Danish NIOSH method (not described)	All MMVF fibers	140	0.0001[d]	0.0013
van der Wal et al. (1987) *(15)*	Living areas of houses one day after installation of blown in glass or mineral wool insulation.	PCOM	WHO	Mineral fibers	8	0.0039	0.0100
Marfels & Spurny (1987) *(16)*	"Representative results" from private houses older than 15 years in Germany	SEM	length >5μm	Non-asbestos mineral fibers	6	0.0023	0.0050
Rindel et al (1987) *(17)*	12 kindergartens in Denmark with MMVF ceiling boards	PCOM	WHO	MMVF	36	0.0001	0.0002
Schneider (1986) *(18)*	11 randomly selected schools with mechanical ventilation in Copenhagen[e]	PCOM	WHO	All fibers not positively identified as non-MMVF	11	0.0001	0.0002
Altree-Williams & Preston (1985) *(19)*	22 office and plant buildings	SEM	WHO	Non-asbestos mineral fibers	193	0.0019	0.0130

Reference	Sample Description	Sampling Methodology			N	Exposure Levels (f/cc)	
		Micro-scope	Fiber Definition[a]	Type of Fibers		Average[b]	Maximum[c]
Schneider (1984) *(20)*	Kindergartens and offices required to be measured by local inspectorate because of problems attributed to MMVF; ceilings consisting of hard MMVF boards or batts	PCOM	WHO	All fibers not positively identified as non-MMMF	7	0.0133[f]	0.0840
Esmen et al. (1980) *(21)*	Estimation of indoor fiber concentrations based on measurements of entrainment of MMMF from medium grade commercial air filters	PCOM	aspect ratio of 3 or greater	all fibers	42	0.0001 (after day 1)	0.0010 (day1)
Balzer (1976) *(22)*	Glass fiber concentrations in ventilation systems lined with fibrous glass	PCOM	Not defined	All glass fibers	37	0.0087	0.0020
Balzer et al. (1971) *(23)*	3 buildings on U. Cal (Berkeley) campus with air transmission systems lined with fibrous glass	PCOM	Not defined	All glass fibers	n.a.	0.0002	0.0006
	10 other buildings with air transmission systems lined with fibrous glass				n.a.	0.0036	0.0090

NOTES

a. Whenever possible, data for respirable fibers is presented. The NIOSH 7400B counting rules include fibers with a diameter <3 μm, a length ≥ 5 μm, and an aspect ratio greater than 5. The WHO criteria for respirable fibers are a diameter <3 μm, a length ≥ 5 μm, and an aspect ratio greater than 3.

b. Unless otherwise indicated, the average concentrations presented are the arithmetic means.

c. Studies that report 95% upper confidence limits rather than maximum exposures are indicated with a "95%" in parentheses.

d. This study reports average concentrations for 9 types of ceiling categories, but does not indicate the number of measurements in each category. The average value presented in the Table above represents the average of the 9 category averages, which assumes equal number of measurements in each category.

e. This study also reported another set of data for 5 schools and one office that were previously reported in the Schneider (1984) study described below.

f. The mean is 0.0015 f/cc when the outlier maximum measurement of 0.084 f/cc is excluded.