

Our Law Department advises us that the attached exchange of letters with the Food and Drug Administration means that FDA is in agreement with us that the use of asbestos fiber as a component of paper and paperboard used in contact with food is safe and is in compliance with the Food and Drug Act and that no specific regulation under the Food Additives Amendment is necessary. Our letter to FDA is dated October 31, 1963. Their reply is dated December 6, 1963. The correspondence is between Mr. Scriba of our Law Department and Mr. Cassidy of F.D.A.

A03149

UNION CARBIDE CORPORATION

270 PARK AVENUE

NEW YORK, N. Y. 10017

LAW DEPARTMENT

October 31, 1963

Food and Drug Administration
Washington 25, D.C.

Re: Asbestos Fiber

Gentlemen:

(1) This is to inquire whether you are in agreement with us that the use of asbestos fiber as an integral component of paper and paperboard does not result, and may not reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of the food when the paper or paperboard is employed in contact with food.

(2) If not, whether you are in agreement with us that this use of asbestos fiber is generally recognized as safe among experts qualified by scientific training and experience to evaluate its safety.

(3) If not, we ask you to file this letter as a petition for a regulation under Section 409 of the Federal Food, Drug and Cosmetic Act stating that this use of asbestos fiber is safe. We propose to sell asbestos fiber for this use. Responsible paper manufacturers tell us that it improves the quality of paper and paperboard for certain food contact use. We base this petition on the generally known physical characteristics of asbestos fiber. While we write in terms of "asbestos fiber" without limitation in view of your presumed interest in a broad regulation, our company's direct present interest lies in chrysotile asbestos (a magnesium silicate). We attach a table entitled "Solubility and Dissociation Data for Chrysotile in Water" from The Journal of Physical Chemistry, Vol. LX (1956) page 1220, and our summary of "Properties of Chrysotile Asbestos Fiber". We respectfully propose the following regulation:

¶121. Asbestos Fiber.

Asbestos fiber may be safely used as a component of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

Very truly yours,
UNION CARBIDE CORPORATION

By _____
George T. Scriba

GTS:R
enc.

A03-150

DISTRIBUTION

W. T. Cohen

J. A. Riddle

K. A. Wood

L. F. Crow

G. C. Brice

D. S. Kamens

K. West

G. Vessels

DATE: ~~March~~ 22, 1966

A. A. Andrade

File JAR

RECEIVED

MAR 28 1966

C.C. - MNG. & METALS DIV.
CALIF.MEMORANDUM

TO: Messrs. T. Dougherty
 R. A. Miller
 R. W. Stobaeus
 B. K. Barton
 T. R. van Fleet
 N. J. Setter
 R. T. Larkin

CC: L. S. O'Rourke
 T. J. Hall
 H. F. Reichard/R. G. Woolery
 J. A. Riddle ✓
 J. Derbecker
 P. R. Cheston
 T. F. Frangos

SUBJECT: Asbestos - Toxicology

Gentlemen:

Early in March the "New York Times" and the "Herald Tribune", reporting the establishment of a new environmental health laboratory at Mt. Sinai Hospital (New York City), revived some publicity (copy attached) in regard to Asbestos dust as a health hazard. We understand that a few newspapers in other cities picked it up.

"Out of context" reporting leads to erroneous conclusions, and this is no exception. Nevertheless, we should reckon that such a commentary will recur, and all of us should use the tool we now have at our disposal to make certain our customers are acquainted with the facts:

1. You have copies of Dr. Dernehl's "Asbestos Toxicology Report." Additional copies are enclosed. Use these, and call particular attention to Dr. Dernehl's statements in regard to "Threshold Limit Value" for asbestos. Control of asbestos dust exposure is necessary, as is control of exposure to any of a variety of dusty operations.

2. Union Carbide pellets offer a clear-cut means of handling asbestos under exceptionally low dust conditions.

3. No work yet conducted or published presents, nor professes to present, incontrovertible proof of a relationship between cancer and asbestos. Some publications have referred to the association of deleterious organic compounds, among them jute oils from jute sacking material, and 3,4 benzo(a) pyrene. We do not use jute bags. Further, we are

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analyzing random samples of our product, and expect shortly to prove the absence of any polycyclic aromatics.

Your pelleted asbestos affords customers the best means of avoiding dust hazards. Make this clear.

Very truly yours,



A.E. Pufahl/dh

Enclosures

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Asbestos Dust Called a Hazard To at Least One-Fourth of U.S.

By JANE E. BRODY

Asbestos dust, which has already been connected with the development of fatal cancer in one-half of asbestos workers, may be a potential health hazard for one-quarter of the population or more, it was reported yesterday.

This preliminary finding was described by Dr. Irving J. Selikoff in announcing the establishment of an environmental health laboratory at Mount Sinai Hospital. The laboratory will further investigate the dangers to man of asbestos and other environmental contaminants.

Dr. Selikoff said the link between cancer and asbestos had led him to suspect that other mineral dusts that contaminate both urban and rural air might create medical hazards for the public.

The new laboratory will be headed by Dr. Selikoff who, with Dr. Jacob Churg, found that asbestos workers eventually showed to seven times the normal death rate from lung cancer and three times the normal death rate from cancer of the stomach, colon and rectum.

Other Workers Affected

Dr. Selikoff noted that the dangers of exposure to asbestos dust were not limited to those who work directly with this ubiquitous insulator and filler material. The dangers, he said, extend to workers in "contiguous trades," such as other con-

struction workers and their families.

According to the findings of three recent limited studies, the dangers might extend to the general population. The studies, which involved autopsies on 1,100 persons in three cities, showed that 25 per cent of the people had asbestos lodged in their lungs.

Dr. Selikoff explained that the studies had used a "crude technique" that disclosed only those asbestos fibers that had become coated by an iron-rich material while lodged in the lungs. A more refined technique now shows that many persons harbor noncoated asbestos fibers as well, he said.

New Study Started

Dr. Selikoff and his colleagues at the new laboratory have started a three-year study in which they will:

1. Examine, with the deceased's family's approval, the lung tissue of the from 3,000 to 4,000 persons expected to die in the next two years at Mount Sinai, Elmhurst Hospital and Veterans Hospital in the Bronx. The doctors will look for uncoated as well as coated asbestos fibers in the tissues.

2. Look for correlations between the causes of death and the presence of asbestos fibers in lung tissue.

3. Determine the occupational history of the deceased and their relatives and other pertinent background information.

Asbestos is a fibrous mineral highly valued for its noncorrosive and long-wearing properties. In addition to its common use as a fireproof material, Dr. Selikoff said, asbestos makes up about 50 per cent of asphalt tile and is used in dental cement, brake linings, plastics, beer filters, gas masks and paper. Until last year, some schools used asbestos dust instead of sand for children to play in.

Study Links Asbestos To Cancer

By Earl Ubell

Science Editor

Scientists have known for a long time that asbestos was bad for your lungs. Now a study of New York City workers, both roofers and insulation blowers, reveals that exposure to the mineral sends lung-cancer death rates skyrocketing.

The figures—gathered by doctors at Mount Sinai Hospital—show that such workers have eight times the lung-cancer death rate as would be expected in a non-exposed population.

More suprisingly, the studies reveal that such workers run four times the risk of getting cancer in other parts of the body, with cancer of the colon particularly singled out. For all other diseases, the insulation workers have the same death rate as the rest of the population.

These findings were emphasized yesterday by Dr. Irving J. Selikoff, head of Mt. Sinai's Division of Environmental Medicine, on the occasion of the establishment of an environmental health laboratory in the hospital. The laboratory has received grants totaling \$324,000 from the United States Public Health Service and the New York City Health Research Council.

Dr. Selikoff also pointed out that cigarette smoking seems to heighten the effects of the asbestos. Among 130 men exposed to asbestos 20 years or more who were non-smokers, he found one lung-cancer death among 310 smokers, 21 such deaths.

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UNION CARBIDE CORPORATION

270 PARK AVENUE, NEW YORK, N. Y. 10017

ASBESTOS TOXICOLOGY REPORT

It has been known for many years that some persons working in asbestos production were prone to develop a disabling lung disease. In time, this condition became known as asbestosis and was related to exposure to high concentrations of asbestos dust. With further experience, it was found that men could work with asbestos without development of lung disease if dust concentrations were kept below a certain level. It is now generally accepted that a man can work a 40-hour week for a lifetime without developing asbestosis if the asbestos dust particle count is kept at or below 5 million particles per cubic foot of air. This dust concentration of 5 million particles per cubic foot of air is the Threshold Limit Value for asbestos, and no cases of asbestosis are known to have occurred when exposures have been maintained at or below this level, despite large-scale utilization (now approaching one million tons per year in the U.S.A.). This concentration of dust is generally not visible in the average work area unless a beam of light causing a Tyndall effect is present. Usually the dust concentration must be from 8-10 million particles per cubic foot before its presence is visible in average lighting conditions.

Several years ago, it was reported that there was an increase in the incidence of cancerous tumors, especially of the lung, associated with asbestosis. Recently there have been reports of some cancers occurring in individuals exposed to asbestos dust, but who have not developed clinical asbestosis. It is believed by most authorities that these cases have been associated with exposures significantly exceeding the Threshold Limit Value. A major manufacturer of asbestos products who also mines asbestos has not been able to show an increase in cancerous growths in men working where dust concentrations were maintained at the Threshold Limit Value.

Control of asbestos dust exposure is therefore necessary. The control methods are the standard ones applicable to a variety of dusty operations. They include closed flow systems, wet processes where possible, and adequate exhaust ventilation where openings in the system are necessary. Pelletizing is sometimes used to improve the handling characteristics of otherwise dusty materials. Where satisfactory containment to stay within the Threshold Limit Value is impractical or impossible, efficient and reliable respirators are available for the protection of the employee. A program of environmental monitoring is highly desirable to determine that Threshold Limit Values are not being exceeded. In paper manufacturing, it would be desirable to know the dust concentrations where the asbestos is dumped from bags into the pulp slurry. Concentrations should also be determined where dusting occurs in finishing products. While initial dust determinations should be made at frequent intervals, once the level has been established as satisfactory, the frequency may be extended to occasional tests to assure continuation of a satisfactory condition.

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Pre-employment and periodic physical examinations of workers are desirable. These should include chest X-rays to insure that the worker has no chest condition prior to work with asbestos and to determine that no lung changes are resulting from work with asbestos.

It is believed that the addition of asbestos at the proposed levels during the manufacture of paper products would be harmless to the consumer. Total dusting would have to be well in excess of any levels acceptable to the consumer for the asbestos concentration to approach the Threshold Limit Value.

In conclusion, while asbestos dust in excess of the Threshold Limit Value is potentially harmful, as are many other dusts encountered in industry, it is as readily controlled as other such dusts and it can be used safely with appropriate precautions.

Carl U. Dernehl, M. D.
Director of Toxicology

K. S. Lane, M. D.
Assistant Director of Toxicology

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