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DEPARTMENT OF MATERIALS CHEMISTRY

Non-Metallic Minerals Section

THE PHYSIOLOGICAL EFFECTS OF GYPSUM

Information Services
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for

The Gypsum Association
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Attention: Mr. Fred Rogers, Director
Administrative Services

PLAINTIFF'S EXHIBIT

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1. INTRODUCTION

The mining Enforcement Safety Administration (MESA) has recently proposed new regulations concerning occupational exposure to mineral fibers. These proposed regulations would essentially classify a wide range of mineral fibers, including gypsum, into the same category as asbestos.

At the request of the Gypsum Association, ORF has conducted a preliminary literature survey of any studies carried out to determine the physiological effects of gypsum.

The two studies described in this report are the only known reported studies in which fibrous gypsum was used. Other studies have been made using non-fibrous gypsum since most of the gypsum utilized by gypsum product manufacturers is of the non-fibrous type. These studies are not covered in this report, but they support the position that gypsum is soluble in the body.

2. SUMMARY

A survey of the literature showed that there are only two publications concerned with the injection of fibrous gypsum into animals. Both of these publications were by Friedrichs who reported the absence of tumors in one paper, while in the other, the presence of 5% tumors was reported. This level is considerably below the level of tumors produced by chrysotile, glass fibers, and nemolite.

In addition to published work, the opinion of several medical experts actively involved in animal studies was obtained. The general opinion was that because of the high solubility of gypsum, tumors would not be expected to be produced by this material. One particular study carried out by Birchall using fibrous calcium carbonate in the aragonite phase, showed that this material behaved as an inert dust. Birchall felt that gypsum would give a similar response.

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3. RESULTS OF SURVEY

3.1 Animal Studies

In 1972, an article by F. Pitt and K.-H. Friedrichs⁽¹⁾ (Medizinisches Institut für Lufthygiene und Silikoseforschung, Universität Düsseldorf, Düsseldorf, Federal Republic of Germany) appeared in Naturwissenschaften 59:318. Animals were injected with dusts of various materials, including some in the fibrous form. The animals were examined after 530 days' exposure, and in the case of gypsum, no tumors were found.

Dr. Friedrichs, at the IOEH Conference held in Montreal, October 29, 30, 1973,⁽²⁾ repeated these findings, as follows.

In the following experiments we used a series of fibers which were of different chemical composition. For example, chrysotile, glass, nemalite, fibrous gypsum and pectolite. And on the other hand, dusts which had similar chemical composition but no fibrous structure; for example, brucite, and talcum and biotite. After a time of 530 days, we only found tumors in rats which were injected with chrysotile, glass and nemalite.

However, a December 1974 article by F. Pott, F. Huth and K.-H. Friedrichs⁽³⁾ contained the following information.

Fibrous dusts (chrysotile, glass fibers, nemalite, palygorskite, and gypsum) and granular dusts (actinolite, biotite, hematite, pectolite, sanidine, and talcum) were injected intraperitoneally into rats. The fibrous dusts (other than gypsum) resulted in a high incidence of mesothelioma (30 - 67%). Gypsum produced only 5% and granular dusts none at all.

Dr. Mearl F. Stanton of the National Cancer Institute, Bethesda, Maryland, said that he has injected three different types of gypsum into the pleural cavity of rats, although none of the types was conspicuously

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fibrous. So far as he was able to recall, none of the types had any significant effect on the host tissue.

Dr. J. D. Birchall of Imperial Chemical Industries Limited, Mond Division, Cheshire, England, provided a similar opinion in a letter to the undersigned dated 2 September, 1976. Dr. Birchall said that he is unaware of any work on gypsum itself, but experiments have been done at ICI on a fibrous form of calcium carbonate in the aragonite phase. These were crystals in the size range of 1-2 μ diameter and 10-100 μ in length, with an average length of 30 μ . In in vitro tests using macrophages incubated with the dust, followed by examination for the proportion of dead cells, fibrous calcium carbonate behaved as an inert dust and in no way different from normal equidimensional calcium carbonate crystals. (In this particular test, high levels of cell death are normally associated with a fibrotic response in lung tissue.) Dr. Birchall felt that gypsum would give a similar response.

3.3 Literature Search

The following entries were found in Dangerous Properties of Industrial Materials by N. Irving Sax, Third Edition, 1968.⁽⁴⁾

Sulphate

Toxicity: Variable. In general the toxic qualities of substances containing the sulphate radical is that of the material (cation) with which the sulphate is combined.

Calcium Sulphate (pure anhydrous)

Toxic Hazard Rating: Unknown; a nutrient and/or dietary supplement food additive.

According to the definitions section of this publication, the designation "unknown" is given to substances which fall into one of the following categories:

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- (a) No toxicity information could be found in the literature and none was known to the authors.
- (b) Limited information based on animal experiments was available but in the opinion of the authors this information could not be applied to human exposures.
- (c) Published toxicity data were felt by the authors to be of questionable validity.

In reference to the use of substances as food additives, the book makes the following statement.

In the implementation of the food additives law the term "safe" means that there is reasonable certainty among qualified scientists that no harm will result from its use. It is not required to prove beyond any possible doubt that the additive is safe under all conceivable circumstances of use or misuse.

The Encyclopedia of Occupational Health and Safety⁽⁵⁾ contained the following entry under "Gypsum".

Workers employed in the processing of gypsum rock may be exposed to high atmospheric concentrations of gypsum dust (especially during crushing, grinding, etc.), furnace gases and smoke. In gypsum calcining, workers are exposed to high environmental temperatures, and there is also the hazard of burns. Crushing, grinding, conveying and packaging equipment presents a danger of machinery accidents.

Gypsum dust has an irritant action on the mucous membranes of the respiratory tract and eyes, and there have been reports of conjunctivitis, chronic rhinitis, laryngitis, pharyngitis, impaired sense of smell and taste, bleeding from the nose and reactions of

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the tracheal and bronchial membranes in exposed workers. Experimental animals exposed to gypsum dust developed pneumonia and interstitial pneumosclerosis, and blood and lymph circulation disorders occurred in the lungs.

Dust formation in gypsum processing should be controlled by mechanisation of dusty operations (crushing, loading, conveying, etc.), addition of up to 2% by volume of water to gypsum prior to crushing, use of pneumatic conveyors with covers and dust traps, enclosure of dust sources and provision of exhaust systems for kiln openings and for conveyor transfer points. Good housekeeping and maintenance are essential in preventing the accumulation of deposited dust, and it is advisable, in the workshops containing the calcining kilns, to face the walls and floors with smooth materials to facilitate cleaning. Hot piping, kiln walls, drier enclosures, etc. should be lagged to reduce the danger of burns and to limit heat radiation to the work environment.

Workers should wear close-fitting working clothes of dust-tight material and, where necessary, should be supplied with respiratory protective equipment and goggles. It is advisable for gypsum and gypsum-products workers to receive a pre-employment examination followed by periodic examinations each year.

3.4 Computer Search

A computer search was done employing the TOXLINE file (U.S. National Library of Medicine) as follows:

	<u>Key Words</u>	
	(gypsum	
or	(calcium sulphate	(1)
	(calcium sulfate	
	(physiolog;	
or	(toxic:	(2)
and	1, 2	

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Of the title citations, two were judged to have possible relevance. One of these was a Russian article without an English abstract, titled Standardization of Gypsum Mineral Dust and the second a German article (Einbrodt, H. J.: Threshold Values for Dust-like Air Pollutants and other Anti-pollution Measures) with an abstract containing the following relevant information.

A preliminary four-group classification is proposed; acutely toxic dusts (As, asbestos, Be, Ca, Hexavalent Cr compounds); dangerous dusts (Ba, I, Te, aluminum carbide, CaO, basalt); dusts dangerous for some persons (Mn, Mo, aluminum carbide, etc.) and generally inert dusts such as gypsum, iron oxide, dolomite, etc. Proposed limiting values for these categories ranged from 20-150 mg/m³.

A search was also made of the CANCERLINE file (MEDLINE data base) using identical key words and commands to the above. No relevant data were retrieved from this source.

3.5 Literature Search at the Institute of Occupational and Environmental Health

A literature search was carried out at the Institute of Occupational and Environmental Health in Montreal, Quebec, at the invitation of Dr. Premysl V. Pelnar. Four references were found, photocopies of which are attached.

3.6 Solubilities

(From the Handbook of Chemistry and Physics, 57th Edition; 1976-1977)

	<u>Solubilities in Grams per 100 cm³</u>	
	<u>Cold Water</u>	<u>Hot Water</u>
Gypsum (CaSO ₄ ·2H ₂ O)	0.241 (0°C)	0.222 (100°C)
Calcium Carbonate (CaCO ₃) (aragonite phase)	0.00153 (25°C)	0.00190 (75°C)

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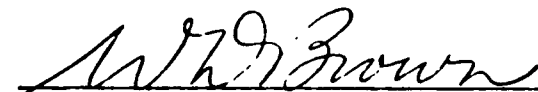
4. CONCLUSIONS

Only two papers have been published which describe specific studies of the injection of fibrous gypsum into animals. These two papers appear to be contradictory concerning whether tumors are formed or not. In the case where tumors were formed, the number of tumors was considerably smaller than the number observed for chrysotile asbestos, glass fiber and nemalite. In addition, the overwhelming opinion of several medical people widely recognized as expert in the field of animal studies is that tumors would not be expected to occur with fibrous or non-fibrous gypsum because of the high solubility of this material.

Other studies, not covered in this report, deal with the effect of non-fibrous gypsum and support the position that gypsum is soluble in the body. This is significant because most of the gypsum utilized by gypsum product manufacturers is of the non-fibrous type.

With one exception, all of the evidence and medical opinion suggests that the physiological effect of fibrous gypsum is similar to that for a non-fibrous gypsum dust.

WDB:pmt


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REFERENCES

1. Pott, F. and Friedrichs, K.-H.: Tumors in rats after intraperitoneal injection of fibrous dusts (German), Naturwissenschaften 59:318, 1972.
2. Reported in Fibres for biological experiments, edited by Dr. Premysl V. Pelnar; transcript of the Institute of Occupational and Environmental Health Conference, held in Montreal, Quebec, 29, 30 October, 1973.
3. Pott, F., Huth, F., and Friedrichs, K.-H.: Tumorigenic effect of fibrous dusts in experimental animals. Environmental health perspectives, Vol. 9, pp 313-315, 1974.
4. Sax, N. Irving: Dangerous properties of industrial materials, Third Edition, 1968; Pub. Reinhold Book Corporation.
5. Encyclopedia of occupational health and safety. Pub. International Labour Office, Geneva.

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APPENDIX

Information Sources

The following provided the names of researchers who had conducted investigations into the physiological effects of fibrous materials.

Dr. P. V. Pelnar
Institute of Occupational
and Environmental Health
Montreal, Quebec

The following replied that they were unaware of any work that had been done on the physiological effects of fibrous gypsum. They are listed in the order in which they were contacted.

Mr. A. A. Winer
Department of Energy, Mines
and Resources
Ottawa, Ontario
Chairman of the E-34 Naturally
Occurring Inorganic Fibres Task Force

Mr. Marcel Cossette
Director of the Quebec Asbestos
Mining Association Testing
Research Laboratory
University of Sherbrooke
Sherbrooke, Quebec

Dr. William Nicholson
Department of Community Medicine
Mount Sinai School of Medicine
New York, N.Y.

The following expressed opinions on the physiological effects of gypsum, without personally having done any work with the compound.

Dr. J. D. Birchall
Imperial Chemical Industries
Mond Division
Runcorn, Cheshire
England

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The following stated that they had done animal implants with gypsum.

Dr. Mearl F. Stanton
National Cancer Institute
Bethesda, Maryland

From the literature:

Dr. Karl-Heinz Friedrichs
Medizinisches Institut für Lufthygiene
und Silikoseforschung
Universität Düsseldorf
Düsseldorf
Federal Republic of Germany

The literature sources are contained in the Reference section.

energy

energy conservation programmes, coal & lignite processing, wind & solar power analyses, heat transfer analyses, heat recovery & storage systems, combustion optimization techniques, building systems monitoring, waste recovery & re-use, insulation design & evaluation, . . .

environment

data collection, odours & emissions, ambient air & work-room surveys, waste treatment, trace metals and organics, reverse osmosis, instrument design, wet oxidation, noise & vibration, industrial hygiene, process evaluation and development, sewage systems development and evaluation, . . .

materials

specification development, failure analyses, mechanical and chemical and thermal properties, particle characterization, organics, inorganics, metals, composites, specialty formulations, glass/ceramic/metal seals, biomaterials, adhesives and coatings, building materials, ceramic processing, flame retardants, textiles, metal powders & alloys, metallography, electron microscopy, thin films, thick films, organic synthesis, . . .

products & processes

mathematical & structural analyses, specialized machinery development, ultrasonic and fluid shear devices, electronic devices, microprocessor applications, industrial chemistry, microbiology, process development, systems analyses, paper formulations, clothing & footwear, quality control, pulp & paper processes, chemical surfactants, ceramic processing, separation techniques, technical and economic evaluations, . . .

resources

mineral processing pilot plant, mineral dressing, hydrometallurgy, pyrometallurgy, coal evaluation and processing, flow sheet development, pulp & paper raw materials evaluation & processes, wood evaluations & standards, waste bark & foliage utilization, asbestos applications & evaluations, glass & ceramic raw materials selection, . . .

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