PLAINTIFF'S EXHIBIT FOS-211

Material	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift	
			Concentration	Maximum duration
[illegible]	10 p.p.m.	25 p.p.m.	50 p.p.m.	10 minutes.
[illegible]	5 mg./M³	5 mg./M³	25 mg./M³	30 minutes.
[illegible]	0.1 mg./M³	3 mg./M³		
[illegible]	0.2 mg./M³	0.6 mg./M³		
[illegible]	50 p.p.m.	50 p.p.m.	100 p.p.m.	30 minutes in any 4 hours.
[illegible]	10 p.p.m.	25 p.p.m.	50 p.p.m.	5 minutes in any 4 hours.
[illegible]	20 p.p.m.	30 p.p.m.	60 p.p.m.	8 minutes.
[illegible]	20 p.p.m.	50 p.p.m.	200 p.p.m.	4 minutes in any 4 hours.
[illegible]	3 p.p.m.	5 p.p.m.	10 p.p.m.	30 minutes.
[illegible]	do.			
[illegible]	2.6 mg./M³			
[illegible]	0.2 mg./M³			
[illegible]	100 p.p.m.	200 p.p.m.	300 p.p.m.	5 minutes in any 3 hours.
[illegible]	500 p.p.m.	1,000 p.p.m.	2,000 p.p.m.	5 minutes in any 3 hours.
[illegible]	0.05 mg./M³	0.05 mg./M³		
[illegible]	100 p.p.m.	200 p.p.m.	500 p.p.m.	6 minutes in any 4 hours.
Trichloroethylene (Z37.19-1967)	do.	do.	300 p.p.m.	5 minutes in any 2 hours.
Tetrachloroethylene (Z37.22-1967)	do.	do.	do.	5 minutes in any 3 hours.
[illegible]	200 p.p.m.	300 p.p.m.	500 p.p.m.	10 minutes.
[illegible]	20 p.p.m.	20 p.p.m.	50 p.p.m.	10 minutes once only if no other exposure occurs.
[illegible]		1 mg./10M³		
[illegible]		[illegible]		

Table G-3—Mineral Dusts

Substance	Mppcf	Mg/M³
Silica:		
Quartz (respirable)	250	10mg/M³ ÷ (%SiO₂ + 2)
Quartz (total dust)		30mg/M³ ÷ (%SiO₂ + 2)
Cristobalite: Use one-half the value calculated from the formulas for quartz.		
Tridymite: Use one-half the value calculated from the formulas for quartz.		
Amosite, asbestos, containing natural dust combinations	20	80mg/M³ ÷ (%SiO₂ + 2)
Silicates containing less than 1% crystalline silica:		
Mica	20	
Soapstone	20	
Talc (containing no asbestos)	20*	
Talc (containing asbestos), use asbestos limit		
Tremolite asbestos, containing	20	
Portland cement	50	
Graphite (natural)	15	
Coal dust (respirable fraction less than 5% SiO₂)		2.4mg/M³ ÷ (%SiO₂ + 2)
For more than 5% SiO₂		10mg/M³ ÷ (%SiO₂ + 2)
Inert or Nuisance Dust:		
Respirable fraction	15	5mg/M³
Total dust	50	15mg/M³

Key: Mppcf—Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.
Mg/M³—Milligrams per cubic meter.

* Measurements determined by the membrane filter method at 430X magnification (4-mm objective) counting all particles visible in the field.

* The percentage of crystalline silica in the formula is determined from air-dust samples, using the X-ray diffraction procedure, except where other methods have been shown to be applicable.

* As determined by the membrane filter method at 430X magnification.

* Where concentration and percent quartz for the application of these limits are to be determined from the full-shift sampling prescribed in the Walsh-Healey Public Contracts Act, use an 8-hour sample.

* Containing < 1% quartz; if > 1% quartz, use quartz limit.

Approximate diameter (unit of density sphere)	Percent passing selector
2	90
2.5	75
3.5	49
5.0	25
10	0

The measurements under this note refer to the use of an AEC instrument. If the respirable fraction of coal dust is determined with a MRE the figure corresponding to 2 mg./M³ in the table for coal dust is 5 mg./M³.

§ 1910.93a Asbestos.

(a) *Definitions.* For the purpose of this section, (1) "Asbestos" includes chrysotile, amosite, crocidolite, tremolite, anthophyllite, and actinolite.

(2) "Asbestos fibers" means asbestos fibers longer than 5 micrometers.

(b) *Permissible exposure to airborne concentrations of asbestos fibers*—(1) *Standard effective July 7, 1972.* The 8-hour time-weighted average airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed five fibers, longer than 5 micrometers, per cubic centimeter of air, as determined by the method prescribed in paragraph (e) of this section.

(2) *Standard effective July 1, 1976.* The 8-hour time-weighted average airborne concentrations of asbestos fibers to which any employee may be exposed shall not exceed two fibers, longer than 5 micrometers, per cubic centimeter of air, as determined by the method prescribed in paragraph (e) of this section.

(3) *Ceiling concentration.* No employee shall be exposed at any time to airborne concentrations of asbestos fibers in excess of 10 fibers, longer than 5 micrometers, per cubic centimeter of air, as determined by the method prescribed in paragraph (e) of this section.

other [illegible] *compliance*—(1) *Engineering methods.* (i) *Engineering controls.* Engineering controls, such as but not limited to, isolation enclosure, exhaust ventilation, and dust collection shall be used to meet the exposure limits prescribed in paragraph (b) of this section.

(ii) *Local exhaust ventilation.* (a) Local exhaust ventilation and dust collection systems shall be designed, constructed, installed, and maintained in accordance with the American National Standard Fundamentals Governing the Design and Operation of Local Exhaust Systems, ANSI Z9.2-1971, which is incorporated by reference herein.

(b) See § 1910.6 concerning the availability of ANSI Z9.2-1971, and the maintenance of a historic file in connection therewith. The address of the American National Standards Institute is given in § 1910.100.

(iii) *Particular tools.* All hand-operated and power-operated tools which may produce or release asbestos fibers in excess of the exposure limits prescribed in paragraph (b) of this section, such as, but not limited to, saws, scorers, abrasive wheels, and drills, shall be provided with local exhaust ventilation systems in accordance with subdivision (ii) of this subparagraph.

(2) *Work practices*—(i) *Wet methods.* Insofar as practicable, asbestos shall be handled, mixed, applied, removed, cut, scored, or otherwise worked in a wet state sufficient to prevent the emission of airborne fibers in excess of the exposure limits prescribed in paragraph (b) of this section, unless the usefulness of the product would be diminished thereby.

(ii) *Particular products and operations.* No asbestos cement, mortar, coating, grout, plaster, or similar material containing asbestos shall be removed from bags, cartons, or other containers in which they are shipped, without being either wetted, or enclosed, or ventilated so as to prevent effectively the release of airborne asbestos fibers in excess of the limits prescribed in paragraph (b) of this section.

(iii) *Spraying, demolition, or removal.* Employees engaged in the spraying of asbestos, the removal, or demolition of pipes, structures, or equipment covered or insulated with asbestos, and in the removal or demolition of asbestos insulation or coverings shall be provided with respiratory equipment in accordance with paragraph (d)(2)(iii) of this section and with special clothing in accordance with paragraph (d)(3) of this section.

(d) *Personal protective equipment*—(1) Compliance with the exposure limits prescribed by paragraph (b) of this section may not be achieved by the use of respirators or shift rotation of employees, except:

(i) During the time period necessary to install the engineering controls and to institute the work practices required by paragraph (e) of this section;

(ii) In work situations in which the methods prescribed in paragraph (e) of

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other by their refractive indices, other optical crystallographic properties, and morphology as determined with a polarizing microscope (Methods of the Association of Official Analytical Chemists, 11th Ed., 1970, Sections 36.541–36.543, p. 717–721).[1] Talc occurs mainly in the form of thin plates, which may appear fibrous when seen edgewise in microscopic view. Beta and gamma indices of talc vary from about 1.575 to 1.590, beta being very close to gamma. All of the principal refractive indices of chrysotile are less than 1.550. Chrysotile asbestos is therefore distinguishable from fibrous looking talc particles in a 1.574 refractive index liquid and the other five amphibole types of fibrous asbestos from talc in a 1.590 refractive index liquid. The table of optical crystallographic properties for talc and the asbestos minerals in subparagraph (3) shows refractive indices which are usually encountered in these minerals, but occasional samples may have indices which are somewhat higher or lower. For practical measurement of optical properties shown in the table, particles identified by this method should be at least 5 μm or longer.

(2) Weigh out 1 milligram of a representative portion of talc on each of two microscope slides. Mix the talc with a needle to spread evenly over the suitable area on one slide with a drop of 1.574 refractive index liquid, and then the other with 1.590 liquid, and place on each a square or rectangular cover glass sufficiently large so that the liquid will not run out from the edge (ca. 18 mm. square) and will provide a uniform particle distribution. Fibers counted by this method should meet the following criteria: (i) Length to width ratio of 3 or greater (ii) length of 5 μm or less. Count and record the number of asbestos fibers found in each 1 milligram as determined from a scan of both slides with a polarizing microscope at a magnification of approximately 400 X. In the 1.574 refractive index liquid, chrysotile fibers with indices less than 1.574 in both extinction positions may be present; in the 1.590 refractive index liquid, the other five amphibole types of asbestos fibers with indices exceeding 1.590 in both extinction positions may be present. Check the extinction and sign of elongation for tentative identification. For specific identification of asbestos fibers, make additional mounts in appropriate refractive index liquids, and refer to the optical crystallographic data in the table. A count of not more than 1000 amphibole types of asbestos fibers and not more than 100 chrysotile asbestos fibers per milligram-slide constitutes the maximum

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044

limit in talc. These limits [illegible] purity of talc at least 99.9 percent free of amphibole types of asbestos fibers and

(3) Optical crystallographic characteristics of asbestos minerals and talc:

Substance	Refractive Indices (n)			Extinction	Elongation
	n_α	n_β	n_γ		
Actinolite	1.614	1.630	1.641	Inclined	Positive.
	1.615–1.655	1.625–1.675	1.64–1.68		
	1.621		1.640		
Amosite	1.675		1.702		
Anthophyllite	1.611	1.623		Parallel	Positive.
	1.596		1.621		
	1.598–1.621	1.606–1.665	1.618–1.667		
	1.605		1.631		
	1.610	1.636	1.639		
	1.619–1.653	1.624–1.682	1.630–1.682		
	1.629	1.635	1.650		
	1.633	1.654	1.672		
Chrysotile	1.543	1.551	1.557	Parallel	Positive.
	1.548	1.552	1.556		
	1.539–1.549	1.550–1.564	1.557–1.567		
	1.53 –1.55		1.54 –1.56		
	1.542		1.555		
	1.532	1.543 (calc.)	1.553		
	1.546	1.550	1.557		
	1.546	1.547	1.551		
	1.548	1.554	1.560		
Cordierite		1.533		Parallel	Negative.
	1.530	1.535	1.539		
	1.537	1.540	1.543		
Talc	1.539–1.550		1.575–1.589	Parallel or 2° or 5°	Positive.
	1.545	1.589	1.589		
	1.550	1.589	1.589		
	1.550	1.589	1.589		
	1.580	nearly = α	1.575		
	1.541	1.582	1.588		
	1.544	1.602	1.602		
		1.591	1.591		
	1.543	1.588	1.589		
Tremolite	1.599	1.613	1.624	Inclined	Positive.
	1.599	1.613	1.625		
	1.599	1.613	1.625		
	1.599–1.614	1.613–1.626	1.625–1.637		
	1.601	1.616	1.627		
	1.602	1.618	1.628		
	1.602	1.618	1.628		
	1.602–1.620	1.613–1.649	1.624–1.660		
	1.601	1.617	1.628		
	1.604	1.617	1.630		
	1.601	1.622	1.626		
	1.599	1.623	1.638		
	1.613	1.621	1.634		

[1] $\frac{n_\alpha + n_\gamma}{2}$

3. In Part 133 by adding the following new paragraph (i) to § 133.6 to read as follows:

§ 133.6 Components.

• • • • •

(i) Talc is a naturally occurring hydrous magnesium silicate which may reasonably be expected to contain asbestos fibers which may be injurious to health. Current methodology cannot assure the absence of asbestos in talc. Accordingly, any drug, drug ingredient, or drug packaging material containing talc that fails to meet the specifications of paragraph (c) of § 121.2006 of this chapter as determined by the method set out in that paragraph shall be deemed to be adulterated in violation of section 501(a) of the Act.

4. By adding the following new paragraph (j) to § 133.8 to read as follows:

§ 133.8 Production and control procedures.

• • • • • •

(j) Use of asbestos-containing filters: Filters used in the manufacture of a parenteral drug or parenteral drug ingredient shall not release fibers into such products. No asbestos-containing or fiber-releasing filter may be used in the manufacture of a parenteral drug or parenteral drug ingredient unless it is not possible to manufacture that drug or drug ingredient without the use of such a filter. If use of such a filter is required, an additional non-asbestos-containing or non-fiber-releasing filter such as a membrane filter shall subsequently be used to reduce the content of any asbestos-form particles in the drug or drug ingredient. Evidence for reduction shall be based on the use of the methods described in "Criteria for a Recommended Standard—Occupational Exposure to Asbestos," Report of Review Committee, National Institute for Occupational Safety and Health, Publication No. HSM 72–10267 (1972).[2] Use of an asbestos-containing filter without subsequent use of an additional non-asbestos-containing membrane filter is permissible only upon submission of proof to the Food and Drug Administration that use of a non-asbestos-containing membrane

[2] Copies may be obtained from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402

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