

RULES AND REGULATIONS

To be a valid assay, the percent column recovery should be 100 ± 2 percent.

(8) *Identity*. Proceed as directed in § 141.521 of this chapter, using a 0.5 percent potassium bromide disc prepared as described in paragraph (b) (1) of that section.

(7) *Crystallinity*. Proceed as directed in § 141.504(a) of this chapter.

§ 150g.11 Minocycline hydrochloride capsules.

(a) *Requirements for certification*—

(1) *Standards of identity, strength, quality, and purity*. Minocycline hydrochloride capsules are composed of minocycline hydrochloride and one or more suitable and harmless lubricants and diluents enclosed in a gelatin capsule. Each capsule contains minocycline hydrochloride equivalent to 100 milligrams of minocycline. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of minocycline that it is represented to contain. Its moisture content is not more than 12 percent. The minocycline hydrochloride used conforms to the standards prescribed by § 150g.1(a) (1).

(2) *Labeling*. It shall be labeled in accordance with the requirements of § 148.3 of this chapter.

(3) *Requests for certification—samples*. In addition to complying with the requirements of § 146.2 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(a) The minocycline hydrochloride used in making the batch for potency, safety, moisture, pH, minocycline content, identity, and crystallinity.

(b) The batch for potency and moisture.

(ii) *Samples required*:

(a) The minocycline hydrochloride used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1)

Potency. Proceed as directed in § 141.111 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar with sufficient 0.1N hydrochloric acid to give a stock solution of convenient concentration containing not less than 150 micrograms of minocycline per milliliter (estimated). Blend for 3 to 5 minutes. Remove an aliquot and further dilute with 0.1M potassium phosphate buffer, pH 4.5 (solution 4), to the reference concentration of 0.100 microgram of minocycline per milliliter (estimated).

(2) *Moisture*. Proceed as directed in § 141.502 of this chapter.

Data supplied by the manufacturer concerning the subject antibiotic have been evaluated. Since the conditions pre-

requisite to providing for its certification have been complied with and since not delaying in so providing is in the public interest, notice and public procedure and delayed effective date are not prerequisites to this promulgation.

Effective date. This order shall be effective upon publication in the FEDERAL REGISTER (12-7-71).

(Sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 367)

Dated: November 21, 1971.

H. E. SIMMONS,
Director, Bureau of Drugs.

(FR Doc. 71-17773 Filed 12-6-71; 8:45 am)

Title 29—LABOR

Chapter XIII—Bureau of Labor Standards, Department of Labor.

PART 1518—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Standard for Exposure to Asbestos Dust.

Pursuant to section 4(b) (2) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1592, 29 U.S.C. 653) § 1518.55 of Title 29, Code of Federal Regulations, is hereby amended in the manner indicated below in order to prescribe a new standard limiting the exposure of workers to asbestos dust. The new standard limiting the exposure of employees to asbestos dust is that adopted under section 6(c) of the Williams-Steiger Occupational Safety and Health Act of 1970 and published in the FEDERAL REGISTER on this date. The standard is hereby determined to be more effective than that presently provided under § 1518.55 to the extent that it prescribes minimum levels of exposure to asbestos dust. Therefore, by operation of section 4(b) (2) of the Act the new standard issued under section 6(c) supersedes the construction safety standard relating to exposure to asbestos dust.

Section 1518.55 is hereby amended by adding a new paragraph (c) thereto. As amended § 1518.55 reads as follows:

§ 1518.55 Gases, vapors, fumes, dusts, and mists.

(c) Paragraphs (a) and (b) of this section do not apply to the exposure of employees to airborne asbestos dust. Whenever any employee is exposed to airborne asbestos dust, the requirements of § 1910.93a of this title shall apply.

Effective date. This amendment shall become effective upon publication in the FEDERAL REGISTER (12-7-71).

(Sec. 4(b) (2), 84 Stat. 1592, 29 U.S.C. 653; Secretary's Order No. 12-71; 39 F.R. 8764)

Signed at Washington, D.C., this 2d day of December 1971.

O. C. GUENTHER,
Assistant Secretary of Labor.

(FR Doc. 71-17825 Filed 12-6-71; 8:47 am)

Chapter XVII—Occupational Safety and Health Administration, Department of Labor.

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Emergency Standard for Exposure to Asbestos Dust.

Pursuant to section 6(c) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1596, 29 U.S.C. 655), Part 1910 of Title 29, Code of Federal Regulations (39 F.R. 10460; May 20, 1971) is hereby amended in the manner indicated below in order to provide an emergency standard dealing with the exposure of employees to asbestos dust.

In light of increasing information on the results of exposure of employees to airborne asbestos dust, including recent studies by the National Institute for Occupational Safety and Health and others, and recommendations by the American Conference of Governmental Industrial Hygienists (ACGIH), it is hereby determined that (1) exposure under the present standard for asbestos dust in Table O-3, § 1910.93, of 12 fibers per milliliter greater than 5 microns in length or 2 million particles per cubic foot of air, which is derived from an established Federal standard promulgated under the Walsh-Healey Public Contracts Act on May 20, 1969, constitutes a grave danger to employees exposed to this 8-hour time-weighted average concentration; and that (2) an emergency standard is necessary to protect employees from this excessive exposure. The National Institute for Occupational Safety and Health concurs that the proposed change in the asbestos dust standard recommended by the American Conference of Governmental Industrial Hygienists should be the substantial base for the emergency standard.

Action concerning the standard will be commenced under section 6(b) in the immediate future. Any notice of proposed rulemaking under section 6(b) will give notice of the emergency standard as a proposed rule and also of any appropriate subsidiary proposals which may be required under subparagraphs (5) and (7) of section 6(b) relating to the exposure of employees to toxic substances.

Part 1910 is amended as follows:

1. Table O-3 following § 1910.93 (39 F.R. 15103, Aug. 13, 1971) is hereby amended by deleting the following:

Asbestos—12 fibers per milliliter greater than 5 microns in length or..... 2 Mppcf.
Tremolite..... 5 Mppcf. 30mg./M³
5 SIO.

TABLE 2-1-MINERAL RESOURCES

Notes: Conversion factors—
mips/ft²CM = million particles per cubic meter
= particles per c.c.

* Millions of particles per cubic foot of air, based on
inert air, samples collected by light-dust samplers.

The percentage of crystalline silica in the formula
is the amount determined from air-borne samples, ex-
cept in those instances in which other analyses have been
shown to be more accurate.

† Determined by the membrane filter method at
430 $\times$ magnification.

‡ High concentrations and percentages for the appli-
cations are based on the material from the fraction
having a size vector with the following characteristics:

The measurements under this pole refer to the use of an AEC instrument. If the respirable fraction of coal dust is determined with a MRE the figure corresponding to that of 2.4 $\mu\text{g}/\text{lit}$ in the table for coal dust is 4.8 $\mu\text{g}/\text{lit}$.

8 1910 93a Asientos dust.

(b) Engineering methods, such as but not limited to, enclosure, vacuum sweeping and local exhaust ventilation, shall

(d) (1). When an employer has employees who are exposed to asbestos dust exceeding the limits prescribed in paragraph (a) of this section and the exposure results from the operations described in the remaining subparagraphs of this paragraph (d), the employer shall

G. C. GUENTHER,
Assistant Secretary of Labor.

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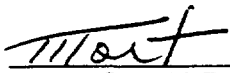
April 7, 2000

Robert E. Thaxton, Esq.
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Dear Bob:

Enclosed is a copy of the December, 1971 OSHA Asbestos Regulation. As you will see, there is not a monitoring recordkeeping requirement. So far, I have not found OSHA requiring monitoring recordkeeping until the 1975 regulation you showed me at BWI. This had a January, 1976 effective date. I'll keep looking.

Sincerely,


Morton Corn, Ph.D., CSP