

2531. Adulteration of Creme-A-Tone. U. S. v. 52 Bottles, etc. (F. D. C. No. 24910. Sample Nos. 2252-K to 2254-K, incl.)

LIBEL FILED: June 30, 1948, Northern District of West Virginia.

ALLEGED SHIPMENT: On or about March 15 and May 20, 1948, by Oxford Products, Inc., from Cleveland, Ohio.

PRODUCT: 52 quart bottles and 63 pint bottles of *Creme-A-Tone* at Clarksburg, W. Va. Analysis of the product (both sizes) showed that it contained an average of 2.49 percent of aluminum oxide. Analysis of the product packaged in the pint size showed that the volume of tenth-normal acid required to neutralize one gram of the gel was not more than 8.84 cc.

LABEL, IN PART: "Creme-A-Tone Aluminum Hydroxide Gel."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Aluminum Hydroxide Gel," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the standard set forth in such compendium since the article, in each size, contained the equivalent of materially less than 3.6 percent aluminum oxide, whereas the compendium provides that aluminum hydroxide gel shall contain the equivalent of not less than 3.6 percent of aluminum oxide; and in the case of the article in the pint-size bottles, the volume of tenth-normal acid required to neutralize one gram of the article was less than 12.50 cc., whereas the compendium provides that the volume of tenth-normal acid required to neutralize one gram of aluminum hydroxide gel shall be not less than 12.50 cc.

DISPOSITION: September 18, 1948. Default decree of condemnation and destruction.

2532. Adulteration and misbranding of adhesive bandages. U. S. v. 480 Packages * * *. (F. D. C. No. 25260. Sample No. 28566-K.)

LIBEL FILED: August 13, 1948, District of Colorado.

ALLEGED SHIPMENT: On or about March 25, 1948, by the American White Cross Labs., Inc., from New York, N. Y.

PRODUCT: 480 packages each containing 36 *adhesive bandages* at Denver, Colo.

LABEL, IN PART: "White Cross Sterile Waterproof Adhesive Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the standard provides that adhesive absorbent gauze must be sterile and meet the requirements of the sterility tests for solids prescribed therein, whereas the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile" was false and misleading.

DISPOSITION: September 28, 1948. Consent decree of condemnation and destruction.

2533. Adulteration and misbranding of prophylactics. U. S. v. 1,681 Gross * * *. (F. D. C. No. 24952. Sample No. 34250-K.)

LIBEL FILED: June 18, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about December 21, 1947, and January 12, 1948, by the Duratex Corp., from Newark, N. J.

PRODUCT: 1,681 gross of *prophylactics* at San Francisco, Calif. Examination of samples showed that 4.8 percent were defective in that they contained holes.

LABEL, IN PART: "Duratex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactics * * * for your protection * * * each piece thoroughly tested" were false and misleading as applied to an article containing holes.

DISPOSITION: September 21, 1948. Default decree of condemnation and destruction.