

following statement is placed on the product, its packaging, or supplemental printed material intended to be read by the patient: "This product contains [insert name of substance], a substance which harms the environment by depleting ozone in the upper atmosphere." In any case, the warning statement must be clearly legible and conspicuous at the time of the purchase.

(d) *Products not viewed by the purchaser at the time of purchase.* Where the purchaser of a product cannot view a product, its packaging or alternative labeling such that the warning statement is clearly legible and conspicuous at the time of purchase, as specified under paragraphs (a), (b), or (c) of this section, the warning statement may be placed in the following manner:

(1) Where promotional printed material is prepared for display or distribution, the warning statement may be placed on such promotional printed material such that it is clearly legible and conspicuous at the time of purchase; or

(2) The warning statement may be placed on the product, on its outer packaging, or on alternative labeling, consistent with paragraphs (a), (b), or (c) of this section, such that the warning statement is clearly legible and conspicuous at the time of product delivery, if the product may be returned by the purchaser at or after the time of delivery or if the purchase is not complete until the time of delivery (e.g., products delivered C.O.D.).

§ 82.110 Form of label bearing warning statement.

(a) *Conspicuousness and contrast.* The warning statement shall appear in conspicuous and legible type by typography, layout, and color with other printed matter on the label. The warning statement shall appear in sharp contrast to any background upon which it appears. Examples of combinations of colors which may not satisfy the proposed requirement for sharp contrast are: black letters on a dark blue or dark green background, dark red letters on a light red background, light red letters on a reflective silver background, and white letters on a light gray or tan background.

(b) *Name of substance.* The name of the class I or class II substance to be inserted into the warning statement shall be the standard chemical name of the substance as listed in 40 CFR part 82, appendix A to subpart A, except that:

(1) The acronym "CFC" may be substituted for "chlorofluorocarbon."

(2) The acronym "HCFC" may be substituted for "hydrochlorofluorocarbon."

(3) The term "1,1,1-trichloroethane" may be substituted for "methyl chloroform."

(c) *Combined statement for multiple class I substances.* If a container containing or a product contains or is manufactured with, more than one class I or class II substance, the warning statement may include the names of all of the substances in a single warning statement, provided that the combined statement clearly distinguishes which substances the container or product contains and which were used in the manufacturing process.

(d) *Format.* (1) The warning statement shall be blocked within a square or rectangular area, with or without a border. (2) The warning statement shall appear in lines that are parallel to the surrounding text on the product's PDP, display panel, supplemental printed material or promotional printed material.

(e) *Type style.* The ratio of the height of a capital letter to its width shall be such that the height of the letter is no more than 3 times its width; the signal word "WARNING" shall appear in all capital letters.

(f) *Type size.* The warning statement shall appear at least as large as the type sizes prescribed by this paragraph. The type size refers to the height of the capital letters. A larger type size materially enhances the legibility of the statement and is desirable.

(1) *Display panel or outer packaging.* Minimum type size requirements for the warning statement are given in Table 1 to this paragraph and are based upon the area of the display panel of the product or container. Where the statement is on outer packaging, as well as the display panel area, the statement shall appear in the same

minimum type size as on the display panel.

TABLE 1 TO § 82.110(F)(1)

	Area of display panel (sq. in.)					
	0-2	>2-5	>5-10	>10-15	>15-30	>30
Type size (in.) ¹						
Signal word	3/64	1/16	3/32	7/64	1/8	5/32
Statement	3/64	3/64	1/16	3/32	3/32	7/64

> Means greater than.
¹ Minimum height of printed image of letters.

(2) *Alternative placement.* The minimum type size for the warning statement on any alternative placement which meets the requirements of § 82.108(c) is 3/32 inches for the signal word and 1/16 of an inch for the statement.

(3) *Promotional printed material.* The minimum type size for the warning statement on promotional printed material is 3/32 inches for the signal word and 1/16 of an inch for the statement, or the type size of any surrounding text, whichever is larger.

§ 82.112 Removal of label bearing warning statement.

(a) *Prohibition on removal.* Except as described in paragraph (b) or (c) of this section, any warning statement that accompanies a product or container introduced into interstate commerce, as required by this subpart, must remain with the product or container and any product incorporating such product or container, up to and including the point of sale to the ultimate consumer.

(b) *Incorporation of warning statement by subsequent manufacturers.* A manufacturer of a product that incorporates a product that is accompanied by a label bearing the warning statement may remove such label from the incorporated product if the information on such label is incorporated into a warning statement accompanying the manufacturer's product, or if, pursuant to paragraph (c) of this section, the manufacturer of the product is not required to pass through the information contained on or incorporated in the product's label.

(c) *Manufacturers that incorporate products manufactured with controlled substances.* A manufacturer that incorporates into its own product a compo-

nent product that was purchased from another manufacturer, was manufactured with a process that uses a controlled substance(s), but does not contain such substance(s), may remove such label from the incorporated product and need not apply a warning statement to its own product, if the manufacturer does not use a controlled substance in its own manufacturing process. A manufacturer that uses controlled substances in its own manufacturing process, and is otherwise subject to the regulations of this subpart, must label pursuant to § 82.106, but need not include information regrading the incorporated product on the required label.

(d) *Manufacturers, distributors, wholesalers, retailers that sell spare parts manufactured with controlled substances solely for repair.* Manufacturers, distributors, wholesalers, and retailers that purchase spare parts manufactured with a class I substance from another manufacturer or supplier, and sell such spare parts for the sole purpose of repair, are not required to pass through an applicable warning label if such products are removed from the original packaging provided by the manufacturer from whom the products are purchased. Manufacturers of the spare parts manufactured with controlled substances must still label their products; furthermore, manufacturers, importers, and distributors of such products must pass through the labeling information as long as products remain assembled and packaged in the manner assembled and packaged by the original manufacturer. This exemption shall not apply if a spare part is later used for manufacture and/or for purposes other than repair.