§ 740.10 Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.

(a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

Warning—The safety of this product has not been determined.

(b) An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product if:

(1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information;
(2) The new information does not demonstrate a hazard to human health; and
(3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.

(c) Paragraph (b) of this section does not constitute an exemption to the adulteration provisions of the Act or to any other requirement in the Act or this chapter.

[40 FR 8917, Mar. 3, 1975]

§ 740.11 Cosmetics in self-pressurized containers.

(a) The label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

Warning—Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 °F. Keep out of reach of children.

(b)(1) In addition to the warning required by paragraph (a) of this section, the label of a cosmetic packaged in a self-pressurized container containing or manufactured with a chlorofluorocarbon propellant or other ozone-depleting substance designated by the Environmental Protection Agency (EPA) are set forth in 40 CFR part 82.

(2) The warning required by paragraph (b)(1) of this section is not required for the following products:

(i) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.
(ii) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.
(iii) Products of a net quantity of contents of less than 2 ozs. that are designed to release a measured amount of product with each valve actuation.
(iv) Products of a net quantity of contents of less than ½ oz.

(2) The warning required by paragraph (b)(2) of this section is not required for the following products:

(1) Products expelled in the form of a foam or cream, which contain less than 10 percent propellant in the container.
(2) Products in a container with a physical barrier that prevents escape of the propellant at the time of use.
(3) Products of a net quantity of contents of less than 2 ozs. that are designed to release a measured amount of product with each valve actuation.
(4) Products of a net quantity of contents of less than ½ oz.