

# Precautionary Labeling for Consumer Products

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## 1. INTRODUCTION

Concerned with the safety of *consumer products* used in the household environment, the Consumer Product Safety Commission (CPSC) has issued various labeling regulations. The regulations are codified at 16 CFR 1500 et seq. and are authorized under two statutes: (1) the Federal Hazardous Substances Act; and (2) the Consumer Product Safety Act. CPSC's labeling requirements apply to products which are directly marketed to consumers and to products where it is reasonably foreseeable that they may end up in the hands of general consumers.

Manufacturers and private label distributors bear the primary responsibility for determining whether their products are subject to CPSC requirements and for ensuring that all applicable regulations are complied with. However, since distributors are potentially liable for distributing unlabeled or mislabeled products under the law, it is crucial that *every* distributor is familiar with CPSC's labeling provisions in order to verify that the each container is labeled as is required.

Essentially, CPSC's labeling requirements compel disclosure of all acute and chronic health hazards associated with the various chemicals used in household products, including cleaners and sanitizers.

\*\*\**Note*: This outline is intended to be used as a general compliance guide. However, because the CPSC regulations can be highly technical and because each label warning must be tailored to the specific product, it is crucial that your company conduct a careful and cautious review of the actual regulations in order to determine your responsibilities and obligations under the law.

## II CPSC LABELING REQUIREMENTS: APPLICABILITY

A. **The law distinguishes between “consumer products” that are used in and around the household and “workplace products”** which are usually used by employees in the course of employment. Determining under what category your product falls, is the crucial first step in understanding how your product is regulated.

1. Consumer Products: Consumer products are regulated by CPSC. A consumer product is defined as: “any article, or component part thereof, produced or distributed (1) for

sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (2) for personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.

2. Workplace Products: Products used in the workplace are subject to the OSHA Hazard Communication Standard.

## **B. OSHA Exemptions for CPSC Regulated Products**

1. Consumer Products Exempted from OSHA Labeling Requirements: Under 29 CFR ? 1910.1200(b)(5)(v) a product is not required to meet OSHA's labeling requirements, if:
  - a. The product is a consumer product or hazardous substance as defined by the Consumer Product Safety Act or Federal Hazardous Substances Act and;
  - b. it is subject to CPSC labeling requirements.
2. Consumer Products Exempted from All OSHA Regulations: Under 29 CFR 1910.1200 (b)(6)(ix), a product is exempt from all OSHA regulations, if:
  - a. The product is a consumer product or hazardous substance as defined by the Consumer Product Safety Act or Federal Hazardous Substances Act and;
  - b. The employer can show that the product is used in the workplace for the purpose intended; and
  - c. Use of the product results in a duration and frequency of exposure which is not greater than the exposure that could reasonably be experienced by consumers.
3. Manufacturers and distributors who believe that their products are exempt from OSHA should refer to OSHA's Directive CPL2-2.38D, Inspection Procedures for the Hazcom Standard, for helpful guidance.

## **C. Consumer Products: Hazardous Substances**

1. Products that satisfy both of the following two criteria are considered hazardous substances for purposes of the law and are subject to CPSC labeling requirements.
  - a. The product contains any hazardous substance or mixture of hazardous substances which are toxic, corrosive, an irritant, a strong sensitizer, flammable or combustible, or which generate pressure through decomposition, heat or other means; and
  - b. The substance or mixture may cause substantial personal injury or illness as the

result of any foreseeable handling or use in or around a household, including reasonably foreseeable ingestion by children.

\*\*\**Note*: “Hazardous substance” is further defined in §1500.3 of the regulations, attached.

2. The “If” Clause: Paragraph (1)(b) immediately above is known as the “if” clause and is the subject of most litigation concerning alleged labeling violations. Congress included this clause, requiring the possibility of substantial injury or illness, to limit the applicability of the law. For example, water technically qualifies as a “hazardous substance” because it falls under the definition of an irritant, but Congress certainly did not want the law to extend to an innocuous substance.
  - a. Interpretation: The “reasonably foreseeable handling or use” language of the “if” clause has been interpreted in a very broad manner.
    - i) Accidental handling: The “if” clause has been interpreted to include reasonably foreseeable accidental handling by consumers.
    - ii) Industrial use products: The clause includes products, such as polishes and cleaners, designed primarily for professional use, but which are available in retail stores. However, the clause does not include industrial supplies which are marketed solely for industrial use, but are brought home by a serviceperson.
    - iii) Container size: Container size represents one factor to consider in determining whether household use is reasonably foreseeable but is not conclusive.
3. Exempted Products: The following products are exempt from CPSC labeling requirements:
  - a. Pesticides regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA);
  - b. Food, drugs and cosmetics regulated by FDA.
4. Exemption Requests: Any person who believes that a particular hazardous substance intended or packaged in a form suitable for use in a household should be exempted from CPSC labeling requirements, because of the size of the package or because the substance only presents a minor hazard, may submit to CPSC a request for an exemption. (16 CFR §1500.82)
5. Limited Exemptions for Specific Products (16 CFR §1500.83)

- a. Polishing or cleaning products: Packages which (1) consist of solid particulate or fibrous composition; and (2) which contain toluene, xylene, or petroleum distillates in the concentrations of 10% or more may qualify for an exemption if the chemical is fully absorbed in the solid particulate or fibrous compound and a person will not be exposed, under normal conditions.
- b. Products containing sodium chloride: Products are exempt from CPSC labeling requirements as long as the label includes a conspicuous statement that the product contains salt.
- c. Products containing ferrous oxalate: Labels of products containing 10% or more of ferrous oxalate are exempt from the requirement that they contain the word “poison” as required by 1500.129(f).
- d. Packages of single-use spot removers containing dry cleaning solvent: Packages are exempt from the labeling requirements insofar as they apply to the “flammable” hazard, provided that:
  - i) The article is packed in a sealed foil envelope;
  - ii) The total amount of solvent per package does not exceed 4.5 ml;
  - iii) The article will ignite only when in contact with an open flame.
- e. Packages of single-use spot removers containing methyl alcohol: Packages are exempt if:
  - i) The total amount of solvent per package does not exceed 4.5 ml of which not more than 25% is methyl alcohol; and
  - ii) The liquid is completely held by an absorbent material and there is no free liquid material.
- f. Cleaning and spot removing kits: Kits intended for use in cleaning carpets, furniture and other household items are exempt from certain CPSC requirements in certain specific circumstances. Please review 16 CFR ? 1500.83(a)(25) for further understanding of this exemption.

### III CPSC LABELING REQUIREMENTS: LANGUAGE

Products that are subject to CPSC labeling requirements must contain specific precautionary language or the product will be considered a “misbranded hazardous substance” and will be in violation of the law.

**A. Required Language:** The product label must *conspicuously* state:

1. The name and place of business of the manufacturer, packer, distributor or seller;
2. The common or usual name of each hazardous component which substantially contributes to the product's hazardous nature. If the component does not have a common or usual name, the chemical name may be used;
3. The signal word "DANGER" on all substances which are extremely flammable or corrosive as defined in 1500.3.
4. The signal word "DANGER" and the word "poison" for all substances defined as highly toxic. Highly toxic includes substances which are acute and chronic toxins, carcinogens, neurotoxicological toxins, or reproductive toxins;
5. The signal word "WARNING" or "CAUTION" on all other hazardous substances;
6. An affirmative statement of the principal hazards, such as "Flammable," "Combustible," "Vapor Harmful," "Causes Burns," or "Absorbed Through Skin;"
7. Precautionary measures describing the action to be followed or avoided;
8. Instruction, where necessary, for first-aid treatment;
9. Instructions for the handling and storage of packages that require special care in handling and storage; and
10. The statement "Keep out of the reach of children" or its practical equivalent and, if the product is intended for use by children, directions for the protection of children from the hazard.

**B. Conspicuousness and Prominence of Required Language**

1. Under customary conditions of purchase, storage and use, the required language shall be visible, noticeable and in clear and legible English.
2. The required language must be "prominently located."
3. Factors affecting the prominence and conspicuousness
  - a. Location of the required information;
  - b. Type size; and

- c. The contrast of the printing against the background.
4. Effectiveness of the language may also be judged on the resulting effect when a package's contents are spilled on the label.

### **C. Self-Pressurized Containers: Required Language**

If the only hazard associated with a self-pressurized container is that the contents are under pressure, the product will satisfy all labeling requirements if labeled as follows:

1. “WARNING - CONTENTS UNDER PRESSURE”
  - a. The word “CAUTION” may be used in lieu of “WARNING.”
  - b. This statement must appear on the principal display panel in capital letters.
2. “Do not puncture or incinerate container. Do not expose to heat or store at a temperature above 120 degrees F. Keep out of the reach of children.”
  - a. This language may appear on a label panel other than the principal display panel, as long as the principal display panel contains the statement “Read carefully other cautions on the [description of the location of the other panel] panel.”

### **D. Products Requiring Special and Supplemental Labeling**

CPSC and the National Clearinghouse for Poison Control Centers have determined that certain substances present special hazards and, therefore, require supplemental precautionary labeling. Please consult 16 CFR 1500.14 for specific supplemental labeling requirements for products containing any of the following substances in the concentrations listed.

1. Diethylene glycol: 10% or more by weight.
2. Ethylene glycol: 10% or more by weight.
3. Benzene: 5% or more by weight.
4. Toluene, xylene, or petroleum distillates: 10% or more by weight.
5. Methyl alcohol: 4% or more by weight.
6. Turpentine: 10% or more by weight.

## IV CPSC LABELING REQUIREMENTS: FORMAT

### A. Prominent Label Placement

To satisfy the requirement that precautionary language must appear “prominently” on the product label, all language must be placed on the label as follows:

1. Horizontal Placement of Precautionary Language
  - a. All precautionary language must appear in lines that are generally parallel to the base on which the package rests, as it is designed to be displayed for sale; or
  - b. If the precautionary language is on a display panel other than the principal display panel, it must be parallel to all other language on the panel.
  - c. Exceptions to the Horizontal Requirement
    - i) The name and place of the manufacturer, packer, distributor or seller does not have to appear in horizontal placement.
    - ii) Collapsible tubes, cylindrical containers with a narrow diameter, or F-type containers where both the front and back of the container represent principal display panels, are exempt from the horizontal placement requirement.

2. Principal Display Panel Labeling

The principal display panel is the portion of the surface of the container which bears the labeling designated to be most prominently displayed.

- a. Precautionary language must appear on the principal display panel of the immediate container and, if appropriate, on any other container or wrapping. At a minimum, the following information must be on the panel:
  - i) Signal words (“DANGER,” “WARNING,” “CAUTION,” “poison”)
  - ii) Statement of the principal hazard
  - iii) When required, the language “Read carefully other cautions on the [description of the location of the other panel] panel.”
- b. Blocking: The signal words, statement of principal hazard and, if necessary,

instructions to refer to another panel must be blocked together within a square or rectangle area on the principal display panel. The above mentioned statements can be in any order.

- c. Borders: All precautionary statements on the principal display panel must be separated on all sides from other printed or graphic matter (except for net contents) by a border line or by a space no smaller than the minimum allowable height of type size.
- d. More than one principal display panel: Depending on the package design or configuration of the label, a package may have more than one principal display panel. In such cases, each display panel must contain:
  - i) Signal words
  - ii) Statement of the principal hazard
  - iii) When required, the language “Read carefully other cautions on the [description of the location of the other panel] panel.”
- e. Principal display panels on the cap or lid: If the intended principal display panel is removable and can be separated from the container (i.e. lids), the container must contain a second principal display panel.

### 3. Label Panels Other than the Principal Display Panel

Precautionary language that does not appear on the principal display panel, must appear on a second label panel. For example, the name of the manufacturer, packer, distributor or seller may appear on a second label display panel.

### 4. Outer Containers and Wrappings

Precautionary language on the immediate container must also appear on any outer container or wrapping, which is used in the retail display of the product, in the same manner as is required for the immediate container, *unless* the precautionary language is clearly legible through the outer container or wrapping.

### 5. “Highly Toxic” Products

- a. Labels for products defined as “highly toxic” (see 1500.3(c)(1)) must include:
  - i) The signal word “DANGER” in all capital letters;
  - ii) The word “poison” in lower case letters; and

- iii) The skull and crossbones symbol.
  - b. Placement: The word “poison” and the skull and crossbones are not required to be on the principal display panel *unless* **all** the precautionary language is include on the principal display panel.
- 6. Substances named in the Federal Caustic Poison Act
  - a. A product containing a substance listed in 21500.129 must include the word “POISON” instead of “DANGER” on the principal display panel.
  - b. “POISON” must appear in all capital letters and must appear with the statement of principal hazard.

**B. Conspicuousness: Type Size and Style**

In order to satisfy the requirement that precautionary language be conspicuous and legible, the following requirements must be adhered to:

1. Calculating the area of the principal display panel for determining proper type size

The area of the principal display panel must be calculated in order to determine the proper type size of the precautionary language. For purposes of this calculation, the principal display panel is considered to include the entire surface of the side that bears the labeling required to be most prominently displayed. However, flanges the tops and bottoms of cans; conical shoulder of cans; and shoulders, handles and necks of bottles and jars are not included. The area of the principal display panel is to be calculated as follows:

- a. Rectangular packages: Product height (h) multiplied by the width (w) of the side that represents the principal display panel:  $(h \times w = \text{area})$ .
- b. Cylindrical packages: Height (h) of the container multiplied by the circumference (c) multiplied by 40%:  $(h \times c \times .40 = \text{area})$ .
- c. Others: Area of the principal display panel is calculated as 40% of the total surface area (SA) of the container excluding any top and bottom flange (TB):  $(SA \times .40 - TB = \text{area})$ .

2. Type-Size Requirements

- a. Type size refers to the height of the actual printed image of each capital letter. Type-size of the precautionary language must be reasonably related to the type-size of other printing on the principal display panel and must meet minimum size

- requirements listed at 1500.121(c)(2)(Table 1).
- b. The size specifications listed at 1500.121(c)(2)(Table 1) apply to each element of precautionary language, including any instruction referring one to another label panel.
  - c. The size of precautionary language appearing on a display panel other than the principal display panel, is determined by the area of the panel on which it appears.
3. Type-Style Ratio: The height of the capital letter must not be more than three times the width of the letter.
  4. Capital letters: All signal words and the word “POISON” where appropriate must be in capital letters. Further, the statement of principal hazard must be in capital letters.
  5. Multiple Statements of Hazards: All statements of principal hazards must be the same size, style of type, color, and “degree of boldness.”
  6. Accompanying Literature Containing Directions For Use
    - a. Includes any placard, pamphlet, booklet, book sign, or other visual device that provides written directions for use and that is used in connection with the display, sale, demonstration or merchandising of a product.
    - b. Any accompanying literature that contains directions for use must contain the same precautionary language that is required on the label.
    - c. Must contain precautionary language which is:
      - i) Reasonably close to and within the same general area as the directions for use;
      - ii) Reasonably similar in type size in comparison to other printing;
      - iii) In the same conspicuous and legible type as the precautionary language on the product label.

**C. Collapsible Metal Tubes: Labeling Requirements**

Precautionary language must be located as close to the dispensing end as possible.

**D. Unpackaged Hazardous Substances: Labeling Requirements**

1. Label or Tag

- a. When practicable, unpackaged products containing hazardous substances must

be labeled so that all required precautionary language appears on the product itself.

- b. If impracticable, because of the size or nature of the product, the required language must be on a tag which is at least 5 square inches in area and which is securely affixed to the product so that it will remain attached.

2. Precautionary Language Type Size: To determine the proper type size of the precautionary language, the area of one side of the tag shall be considered to be the area of the principal display panel.

## **V POISON PREVENTION PACKAGING REQUIREMENTS**

Manufacturers and private label distributors must also be aware of the Poison Prevention Packaging Act of 1970 (PPPA), codified at 16 CFR 1700 *et seq.* Enforced by CPSC, the PPPA consists of an additional set of regulations intended to protect children from serious personal injury or illness which may result from their exposure to specified substances.

### **A. Responsible Parties**

The following persons are primarily responsible for ensuring that products subject to the PPPA are packaged in as required: (1) manufacturers; (2) packagers; and (3) private label distributors.

### **B. Poison Prevention Packaging Standards**

1. Substances Subject to the PPPA: CPSC has determined that the packaging for the following substances must be designed and constructed in accordance with the specific standards contained in the PPPA.
  - a. Furniture Polish: Nonemulsion type liquid furniture polishers containing 10% or more of mineral seal oil and/or other petroleum distillates and having a viscosity of less than 100 Saybolt universal seconds at 100F must be packaged in accordance with 1700.15 (a), (b) and (d).
  - b. Sodium and Potassium Hydroxide: Household substances in dry form containing 10% or more by weight of free or chemically unneutralized sodium or potassium hydroxide and substances in other than dry form containing 2% or more of the same chemicals must be packaged in accordance with 1700.15(a) and (b).
  - c. Methyl Alcohol (Methanol): Household substances in liquid form containing more than 4% by weight methanol, other than products packaged in pressurized spray containers, must be packaged in accordance with 1700.15(a) and (b).
  - d. Sulfuric Acid: Household substances containing 10% or more by weight of sulfuric acid must be packaged in accordance with 1700.15(a) and (b).

- e. Ethylene Glycol: Household substances in liquid form containing 10% or more by weight of ethylene glycol, except products exempt under 16 CFR 1500.83, must be packaged in accordance with 1700.15(a) and (b).
- f. Hydrocarbons: Nonemulsion-type liquid household chemical products, including many cleaning solvents, that contain 10 % or more low-viscosity hydrocarbons by weight, must be packaged in accordance with 1700.15 (a) and (b). Products packaged in pressurized spray containers are exempt.

## 2. General Packaging Requirements

- a. For purposes of the PPPA, packaging is defined as: the immediate container or wrapping in which a household substance is contained. This includes any outer container or wrapping used in the retail display. It does *not* include:
  - i) Shipping containers used solely for transportation of a hazardous substance in bulk to manufacturers or wholesale/ retail distributors;
  - ii) Shipping containers used by retailers to ship or deliver a product to a consumer *unless* the container represents the only container.
- b. Packaging must function according to specific CPSC packaging effectiveness specifications (listed at 1700.15(b)). Testing of the package must be conducted. (Testing procedure and protocol is found at 1700.20).
  - i) Must test a situation where the packaging itself comes into actual contact with the substance contained therein.

\*\*\**Note*: This situation can be tested simply by conducting a scientific evaluation to determine that the chemical and physical characteristics of the substance will not compromise the packaging.
  - ii) Should test the packaging while keeping in mind the number of times that package is customarily opened and closed throughout the use of the product.

\*\*\**Note*: This requirement can be satisfied through a technical evaluation of physical wear and stress factors and the force required to open the package.

## 3. Noncomplying Packaging

In some circumstances, it is permissible to package products subject to the PPPA

in other than PPPA compliant poison prevention packaging.

- a. Packaging for elderly and handicapped persons: In cases where PPPA packaging effectively prohibits elderly or handicapped persons from using the product contained therein, CPSC permits the product to be packaged in noncompliant packaging of a single size, provided that:
  - i) Compliant packaging of the same product is also available; and
  - ii) Noncompliant packaging is conspicuously labeled with the statement “This package is for households without children.”
- b. “This package is for households without children.”
  - i) Statement must appear on the principal display panel(s) of the immediate container;
  - ii) Statement must be placed within the borderline of a square or rectangle on the panel and must be in easily legible capital letters;
  - iii) Statement must appear in lines that are generally parallel to the base on which the product rests; and
  - iv) Statement must appear in the proper type size based on the area of the principal display panel.
- c. If the area on the panel is too small to accommodate the required phrase, the substitute statement “Package Not Child Resistant” may be used.

## VI VIOLATIONS

### A. Sanctions Under CPSC Statutes

Congress has provided for specific sanctions to be levied against any company that violates any CPSC regulation or provision. Generally, these sanctions include both civil and criminal fines, *up to a maximum of \$1.25 million and can include imprisonment for not more than one year*. Furthermore, companies can be prevented from continuing to violate CPSC law and products can be seized.

\*\*\***Note:** In addition to the sanctions mentioned above, companies are likely to be sued for civil monetary damages in a product liability lawsuit. Consequently, one violation can result in a significant monetary loss to the noncompliant company.

1. Letters of Advice (LOA): A letter of advice is issued by CPSC when the agency determines that there is a violation. It will state that a violation has occurred and will site

the specific statute or regulation that has not been complied with. The LOA will not contain specific details regarding penalties.

2. Regulated Products Handbook: The LOA will refer a company to the “Regulated Products Handbook,” a document which contains detailed information needed by companies charged with violating CPSC law, including the appropriate steps that must be taken to comply with CPSC requirements. It is available at no cost by contacting CPSC and requesting Document #8001.

3. Noteworthy Violations

In 1998, the owner and president of a Colorado distributor was sentenced to nearly two years in jail for violating CPSC laws. The owner had pled guilty to 15 counts of improperly shipping hazardous substances after it was discovered that a teenage girl died after drinking a highly corrosive substance that she mistook for water. The substance had been packaged in a reusable plastic one-gallon container that lacked the appropriate and necessary warnings.

## **B. Reporting Requirements**

1. When is reporting required? Section 15(b) of the Consumer Product Safety Act requires manufacturers and distributors to notify CPSC immediately in two situations with regard to unsafe products. Reporting is required when:

- a. It can be concluded that a product has a defect that:

- i) Creates a substantial risk of injury to the public; or
- ii) Creates an unreasonable risk of serious injury or death; or
- iii) Violates a consumer product safety standard (including precautionary labeling requirements and PPPA provisions).

\*\*\**Note*: The product need not actually cause an injury, etc. The substantial or unreasonable risk is sufficient to trigger reporting obligations.

- b. A product has been involved in three or more lawsuits in a two year period

\*\*\**Note*: Each lawsuit must have involved an alleged death or grievous bodily injury and must have resulted in a positive result for the plaintiff.

2. ISSA Recommendation: Every company involved in the manufacture or distribution of consumer products regulated by CPSC should develop a system of reviewing and

maintaining consumer complaints, product liability suits and customer comments.

3. Corrective Action Handbook

This document offers invaluable guidance to manufacturers and distributors by helping them better understand CPSC reporting requirements. It is also helpful in helping companies initiate and implement product safety corrective action plans, such as product recalls. The Corrective Action Handbook is available from CPSC at no cost. Request document # 8002.

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