# Guide to the Regulation of Chemical Cleaning Products

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**November 24, 2015**

## I Introduction

The labeling, hazard communication and other aspects of chemical cleaners are governed in the United States by a variety of federal agencies and regulations including but not limited to the following:

- Occupational Safety and Health Administration
- Environmental Protection Agency
- Food and Drug Administration
- Consumer Product Safety Commission
- Department of Transportation

The specific federal agency and regulations that are applicable to a chemical cleaner is largely a function of how the product is marketed (i.e., to household consumers versus employers or institutional facilities), and where it is in the stream of commerce (i.e., products in the course of being transported). For example, products marketed to commercial or institutional facilities for use by employees as part of their job are typically regulated by the OSHA Hazard Communication Standard as revised by GHS (HazCom 2012). On the other hand, disinfectants that make a "kill" claim (i.e., kills harmful germs) are considered "pesticides" and are governed by EPA.

The purpose of this document is to provide an overview of the major federal agencies that regulate chemical cleaners and to define for you the specific product categories that fall within each respective agency.

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## II Occupational Safety and Health Administration (OSHA)

**A. Scope of Products Covered.** The OSHA Hazard Communication Standard as revised by GHS (HazCom 2012) governs the labeling and hazard communication requirements for the vast majority of hazardous chemical cleaning products marketed to institutional and commercial facilities for use by employees with exceptions noted below. Examples of product categories covered by HazCom 2012 include, but are not limited to, the following chemical cleaning and maintenance product categories:

- General purpose cleaners
- Glass cleaners
- Bathroom cleaners
- Carpet cleaners
- Metal polishes
- Floor maintenance products

**B. Exemptions.** OSHA HazCom 2012 exempts certain categories of products from the labeling requirements of this regulation if they are governed by and subject to the labeling requirements of other federal agencies including but not limited to the following:

- Disinfectants, sanitizers and other pesticides registered with EPA and labeled consistent with the Agency's regulations.
- Hand sanitizers that are regulated by FDA as over-the-counter drugs, and labeled pursuant to those regulations.
- Consumer products that are subject to and labeled consistent with the CPSC regulations.

**C. Labeling Elements.** HazCom 2012 has significantly revised the labeling requirements of the OSHA Hazard Communication Standard. Products subject to HazCom 2012 must have a label that contains the following elements:

- Product identifier (brand or trade name; must be same as product identifier on SDS)
- Signal word
- Hazard statement
- Pictogram(s)
- Precautionary statement
- Name, address and telephone number of manufacturer or other responsible party

**D. Safety Data Sheets.** HazCom 2012 sets forth a mandatory 16-section format for Safety Data Sheets (SDSs) that must be presented in the order set forth below.

- Sec. 1: Identification
    - Product identifier used on label
    - Recommended use of the chemical
    - Name, address and telephone number of manufacturer, importer or other responsible party
    - Emergency phone number
- Sec. 2: Hazard Identification
    - Hazard class, and category (i.e., flammable liquid, category 4)
    - Label elements:
    - Signal word (i.e., Warning)
    - Hazard statement (i.e., combustible liquid)
    - Pictograms (none for flammable liquid, cat. 4)
    - Precautionary statement
    - The above elements must be consistent with the label
- Sec. 3: Composition/information on ingredients
- Sec. 4: First-aid measures
- Sec. 5: Firefighting measures
- Sec. 6: Accidental release measures
- Sec. 7: Handling and storage
    - Precautions for safe handling and storage
- Sec. 8: Exposure controls
    - OSHA PELs, TLVs
    - Appropriate engineering controls (i.e., ventilation)
    - Personal protective equipment

- Sec. 9: Physical and chemical properties
- Sec. 10: Stability and reactivity
- Sec. 11: Toxicological information
- Sec. 12: Ecological information
- Sec. 13: Disposal considerations
- Sec. 14: Transportation information
- Sec. 15: Regulatory information
- Sec. 16: Date of preparation, last revision

**Note:** Sections 12-15 must be on the SDS, but OSHA will not enforce the content of those sections because it is outside the scope of their authority.

**E. Additional Information.** Please refer to the following additional resources available online:
- ISSA Safety and Health Portal: www.issa.com/shp
- OSHA: www.osha.gov/dsg/hazcom/index.html

## III Disinfectants and Sanitizers Used on Inanimate Surfaces

In general, disinfectants and sanitizers intended for use on inanimate surfaces are typically regulated by either U.S. EPA or the FDA depending on the nature of their intended use as outlined below.

**A. General Purpose Disinfectants and Sanitizers for Inanimate Surfaces.** Disinfectants and sanitizers intended for use on inanimate surfaces are generally regulated by the U.S. EPA as pesticide products.

**1. Pesticidal Claims.** In general, a product is considered to be a pesticide product if, among other things, the person who distributes or sells it claims, states, or implies that the product prevents, destroys, repels or mitigates a pest. Therefore, once a product label (or other statement made in connection with the sale or distribution of the product) includes any claim of pest mitigation, under 40 CFR § 152.15, the product is one that is intended for a pesticidal purpose and becomes subject to the EPA regulations issued pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), including product registration and labeling.

The following are examples of claims made in relation to cleaning products that EPA considers to be pesticidal in nature thereby triggering the requirement to register the product under FIFRA:
- Kills germs and harmful microorganisms
- Disinfects, sanitizes or sterilizes
- Cleans away, washes away or removes any pest covered by 40 CFR §152.5.
- Cleans away, washes away or removes biofilm or scum (unqualified).
- Cleans away, washes away or removes allergens (unqualified).
- Cleans away or removes allergens associated with a pest (e.g., dust mite allergens, cockroach allergens).

- Removes pests by suffocating or drowning.
- Cleans or removes pest habitats or breeding sites.
- Cleans, precipitates or removes contaminants, nutrients or matter that provide food or habitat for pests.
- Cleans, reduces or removes scum or sludge where pests breed, feed or live.
- Out-competes or displaces a pest for nutrition or habitat.
- Cleans or removes the habitat where biofilm, germs, allergens or microorganisms can hide, thrive or grow.
- Prevents, blocks, removes, neutralizes or controls bacteria or other pests that cause odors.

**2. Registration.** Pesticide products (including disinfectants and sanitizers and other antimicrobial pesticides intended for inanimate surfaces) must first be registered with EPA as a legal prerequisite to their lawful sale and manufacture.

For more information on the registration of disinfectants, sanitizers and other antimicrobial pesticides, please visit: http://www2.epa.gov/pesticide-registration/antimicrobial-pesticide-registration

For general information on pesticide registration: http://www2.epa.gov/pesticide-registration

**3. Contents of the Label**. The contents of a pesticide product label must show clearly and prominently the following information:

- The name, brand, or trademark under which the product is sold as prescribed in 40 CFR 156.10 (b);
- The name and address of the producer, registrant, or person for whom produced as prescribed in 40 CFR 156.10 (c);
- The net contents as prescribed in 40 CFR 156.10(d);
- The product registration number as prescribed in 40 CFR 156.10 (e);
- The producing establishment number as prescribed in 40 CFR 156.10 (f);
- An ingredient statement as prescribed in 40 CFR 156.10 (g);
- Hazard and precautionary statements as prescribed in 40 CFR Part 156 Subpart D for human and domestic animal hazards and Subpart E of this part for environmental hazards;
- The directions for use as prescribed in 40 CFR 156.10 (i); and
- The use classification(s) as prescribed in 40 CFR 156.10 (j).

**4. Label Review Manual.** EPA addresses in great detail the labeling requirements associated with pesticide products including disinfectants and sanitizers in a publication titled Label Review Manual, which is available online at: http://www2.epa.gov/pesticide-registration/label-review-manual.

**5. State Regulation.** General purpose disinfectants and sanitizers (and other pesticide products) also must be registered in each and every state in which the product will be

marketed. For most states, all this involves is an application and fee paid to the appropriate authority. For other states, like California, additional data and information may need to be submitted in support of that state registration.

For a listing of state pesticide registration agencies and fees, please refer to the ISSA State Pesticide Registration Survey posted at: http://www.issa.com/data/moxiestorage/regulatory_education/pest_surv_2015.pdf

**B. Liquid Chemical Sterilants.** Liquid chemical sterilants intended for use on "critical" or "semi-critical" medical devices are regulated by the U.S. Food and Drug Administration (FDA) if they meet all of the following criteria.

**1. Composition.** The product must be in liquid form as sold or distributed. Pressurized gases or products in dry or semi-solid form are not excluded from regulation under FIFRA. Ethylene oxide products are not liquid products and are therefore not excluded by this provision.

**2. Claims.** The product must bear a sterilant claim, or a sterilant plus subordinate level disinfection claim.

**3. Use Sites.** The product must be intended and labeled only for use on critical or semi-critical devices. A "critical device" is any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body. A semi-critical device is any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

- Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are jointly regulated by EPA and FDA, and must be registered by EPA.
- Liquid chemical sterilants that bear claims solely for use on sites that are not medical devices, such as veterinary equipment, are not excluded and are regulated solely by EPA.
- Liquid chemical sterilants intended to treat aseptic food packaging systems are also not excluded from FIFRA; these products are subject to registration by EPA as pesticides as well as approval by FDA as food additives.

Liquid chemical sterilants intended for use on "critical" or "semi-critical" medical devices are regulated by FDA pursuant to the Federal Food, Drug and Cosmetic Act, as medical devices. As such, manufacturers must first apply for and receive an FDA 510 (k) premarket clearance prior to the marketing and sale of these products.

The liquid chemical sterilants that fall under the jurisdiction of FDA should not contain EPA reference numbers (i.e, Registration or Establishment Number).

**C. Liquid Chemical Germicides Intended for Use on Non-Critical Medical Devices.** Liquid chemical germicides that bear claims solely for use on non-critical medical devices are primarily

regulated by EPA and must be registered with the Agency. In general, these products are regulated the same as general purpose disinfectants with exceptions noted below.

**1. Non-Critical Medical Devices.** Non-critical medical devices are those that come in contact with intact human skin but not mucous membranes, and include items like bedpans, blood pressure cuffs, crutches, and stethoscopes.

**2. Labeling.** In addition to being subject to the general labeling requirements applicable to general purpose disinfectants (see above), the label of these products must include the following disclaimer as per the Memorandum of Understanding Between the U.S. FDA and the U.S. EPA (MOU 225-93-4005):

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

**D. Food Contact Surface Sanitizers.** Antimicrobial solutions that are intended to be applied to counter tops, table tops, food processing equipment, cutlery, dishware or cookware to sanitize such objects after they have been washed are subject to regulation (registration and labeling) by EPA pursuant to the Antimicrobial Regulation Technical Corrections Act (ARTCA).

**E. Antimicrobial Products Used Solely on Processed Foods.** Antimicrobial products, such as sanitizers, used in or on processed food or in water that comes into contact with the food in the preparing, packing or holding of food for commercial purposes are legally not considered pesticides, and therefore are subject to FDA jurisdiction as a food additive.

The following activities constitute "food processing". Therefore, any food subjected to these activities becomes a "processed food" within the meaning of 40 CFR 152.5 (definition of a pest): canning, freezing, cooking, pasteurization, or homogenization, irradiation, milling, grinding, chopping, skinning, cutting or peeling. Processing also includes carcasses postslaughter which includes skinning, eviscerating and quartering. These post-slaughter activities result in "processed food" within the meaning of 40 CFR 152.5. In addition, seafood that is harvested is processed food. Activities done post-harvest to seafood include handling, storing, preparing, heating, eviscerating, shucking or holding.

Antimicrobial solutions used in these processes against microbes in or on the processed food are not pesticides under FIFRA and are regulated solely by the FDA under the Federal Food, Drug and Cosmetic Act.

**F. Antimicrobial Products Used Solely on Non-Processed Food (i.e., Post-Harvest Activities).** Sanitizers and other antimicrobial solutions that are intended to be used in or on

foods that are subject to post-harvest activities that do not constitute food processing are legally considered pesticides, and therefore subject to EPA jurisdiction (registration and labeling).

The following post-harvest activities do not constitute food processing within the meaning of 40 CFR 152.5: washing, coloring, waxing, hydro-cooling, refrigeration, shelling of nuts, ginning of cotton, and the removal of leaves, stems and husks. These processes do not meet the definition of "processed food" and are not subject to the exclusions of 40 CFR 152.5. Therefore, pesticides used during these processes are FIFRA pesticides and are regulated by EPA under FIFRA.

## IV Antibacterial Hand Sanitizers

Hand sanitizers are regulated as "over-the-counter" (OTC) drugs because they are intended and labeled for topical antimicrobial use to prevent disease in humans. As such, they are regulated by the U.S. Food and Drug Administration (FDA) in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (FFDCA).

The FDA regulations regarding hand sanitizers address premarket approval, labeling and testing guidelines that are described in more detail below.

**A. General Requirements.** Because hand sanitizers are regulated as OTC drugs, certain general requirements are triggered as set forth below.

1. Manufacturer must register their facility with FDA as a drug establishment pursuant to 21 CFR 207.20.

2. Manufacturer and private label distributors must list the specific product as a drug with FDA pursuant to 21 CFR 207.20.

3. Comply with Good Manufacturing Practices (21 CFR 211).

4. Subject to periodic FDA inspection.

**B. Premarket Approval.** As OTC drugs, hand sanitizers must first be approved by FDA before they are marketed and sold. There are two ways by which such products can receive FDA premarket approval.

**1. Compliance with the FDA Tentative Final Monograph for Healthcare Antiseptic Drug Products.** By far the easiest route to obtain FDA premarket approval is to comply with the FDA Tentative Final Monograph for Healthcare Antiseptic Products (TFM). To comply using this method, the hand sanitizer must have the same formulation, labeling and dosage as those that existed in the marketplace on or before December 4, 1975. The product must also contain active ingredients that are listed by FDA in the TFM as safe and effective; and the product must be intended for the same use.

The TFM also sets forth labeling requirements for hand sanitizers that addresses the following:

- Statement of product identity
- Directions for use
- Applicable warnings
- Product category specific labeling requirements

**2. New Drug Application. P**roducts and ingredients which did not exist prior to December 4, 1975 must be approved in accordance with the New Drug Application provisions of the Federal Food, Drug & Cosmetic Act.

- FDA will review the formulation and determine if it is safe and effective.
- Approved products are listed in the publication $Approved Drug Products With Therapeutic Equivalence Evaluations
- Applications must contain all information relating to the safety and effectiveness of the product, including: physical and chemical characteristics and clinical data
- Labeling: Subject to general labeling requirements for drugs at 21 CFR 207.201
- Testing: includes both in vitro and animal studies

For a more detailed discussion of the regulation of hand sanitizers, please refer to the ISSA Guide to the Regulation of Antibacterial Hand Soaps.

## V Consumer Cleaning Products (other than those registered with EPA)

Pursuant to the Federal Hazardous Substances Act, the Consumer Product Safety Commission (CPSC) regulates the labeling of consumer products that are considered hazardous. Consumer products are those products that are: 1) Intended to be sold to consumers for household use; or 2) Marketed in such a way that it is reasonably foreseeable that the product will fall into the hands of a household consumer.

**A. Exemptions.** The following product categories are exempt from the CPSC labeling requirements and regulations:

1. Pesticides regulated by EPA under FIFRA; and

2. Food, drugs and cosmetics regulated by FDA

**B. Labeling Requirements.** The CPSC has issued strict precautionary labeling requirements compelling disclosure of acute and chronic health effects of chemicals used in consumer products. These regulations can be found at 16 CFR 1500 et seq.

CPSC s labeling requirements apply to all products that contain a hazardous substance that may cause substantial injury or illness. Each regulated product must contain the following information on its label:

- Appropriate signal word
- An affirmative statement of the principal hazard
- Name and place of the business of the manufacturer
- Common or usual name of the hazardous component
- Precautionary measures describing the action to be avoided

- Instruction for first aid treatment, where appropriate
- Instructions for handling and storage
- The statement "keep out of the reach of children"

**C. Placement of Label Content**. The precautionary language and other label content required by CPSC is subject to very specific placement requirements set forth in the regulation that addresses

- Placement of precautionary language must be on principal display panel
- Blocking of content
- Borders
- Outer containers and wrappers
- Special warning requirements for Highly Toxic products and for products containing substances listed in 16 CFR 1500.129
- Font size and style
- Accompanying literature that contains directions for use must contain precautionary language

**D. Poison Prevention Packaging Requirements.** Pursuant to the Poison Prevention Packaging Act (PPPA), codified at 16 CFR § 1700 et. seq., manufacturers, private label distributors and packagers must ensure that the following products and substances must be in child resistant packaging consistent with the PPPA and its regulations:

**1. 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).

**2. 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 16 CFR 1700.15(a) and (b).

**3. 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 16 CFR 1700.15(a) and (b).

**4. Sulfuric Acid:** Household substances containing 10% or more by weight of sulfuric acid must be packaged in accordance with 16 CFR 1700.15(a) and (b).

**5. 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 16 CFR 1700.15(a) and (b).

**6. 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 16 CFR 1700.15 (a) and (b). Products packaged in pressurized spray containers are exempt.

## VI Regulation of Volatile Organic Compounds in Consumer and Institutional Cleaners

A patchwork of federal and state regulations governs the volatile organic compound (VOC) content of consumer and institutional products including a wide variety of chemical cleaners.

On the federal level, the U.S. EPA has issued regulations that limit the VOC content in 24 product categories. On the other hand, close to twenty state governments also have issued regulations that limit the VOC content of consumer and institutional products. By contrast, the state regulations cover significantly more product categories, and the VOC limits are stricter than their federal counterpart in most cases.

In general, the EPA VOC regulations are operative only in those states that do not have their own VOC limitations.

The following is an overview of the key components of state and federal VOC regulations.

**A. Scope of Products Covered.** State and federal VOC regulations only cover those product categories that are listed within the regulations. U.S. EPA addresses only 24 product categories, while the state regulations cover a much greater number and types of products. Numerous types of chemical cleaning products are listed in the state and federal regulations.

**B. VOC Limitations.** For each listed product category, the state and federal regulations set forth a limitation on the VOC content for that product category expressed as percent by weight. For concentrated products that are intended to be diluted with water prior to use, the VOC limit generally applies to the product only after the minimum recommended dilution has taken place (i.e., the use dilution recommended on the label which has the maximum amount of product).

**C. Labeling.** Each container of a regulated product category must set forth the date of manufacture or a code indicating such date.

**D. Additional Information.** For a side by side comparison of all state and federal VOC limitations, please refer to www.issa.com/vocsum.

## VII Products Used in Meat and Poultry Plants and Other Food Processing Facilities

Cleaning products and compounds used in meat and poultry establishments are governed by the Food Safety Inspection Service (FSIS) that is part of the U.S. Department of Agriculture (USDA). In general all other food processing establishments are under the jurisdiction of the U.S. Food and Drug Administration.

**A. Meat and Poultry Establishments.** Each meat and poultry establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

**1. Sanitation.** Under the FSIS regulations, meat and poultry establishments have a legal obligation to clean and sanitize food-contact as well as non-food contact surfaces as frequently as possible to prevent the creation of "insanitary conditions and the adulteration of product."

**2. Documentation.** Cleaning compounds, sanitizers, and other chemicals used by a meat and poultry establishment must be "safe and effective" under the conditions of use. Meat and poultry plants must maintain documentation substantiating the safety of a chemical's use in a food processing environment, and must be make this information available to FSIS inspection program employees for review upon request.

This documentation is typically provided by the vendor of the cleaning compound and may be in one of the following forms:

- Certification by a third party (such as NSF International); or
- Letter of guaranty provided by the manufacturer or supplier.

**B. Other Food Processing Environments.** In general, the U.S. Food and Drug Administration has jurisdiction over those establishments that process foods other than meat and poultry. FDA has established similar requirements for cleaning compounds and sanitizers used in those establishments.

## VIII Transportation of Hazardous Materials

In general, the U.S. Department of Transportation (DOT) regulates chemical cleaning products during transport that meet the Department's definition of "hazardous material". The following obligations are established by DOT in its regulations and apply to those companies that ship and/or transport products that are considered hazardous materials, including distributors and manufacturers of chemical cleaning products.

**A. Hazardous Material Classification.** Manufacturers of chemical cleaners must determine if their products meet the definition of a DOT hazardous material based on the nine classes of hazardous materials set forth in the DOT regulations. The classifications of primary concern to the chemical cleaning products industry include: corrosives (Class 8), flammables (Class 3), combustibles, poisons (Division 6.1), and oxidizers (Division 5.1).

**1. Packing Groups.** Hazardous material is further classified based on its "packing group" in most cases Packing Group I represents great danger, Group II medium danger, and Group III minor danger.

**2. Exceptions.** DOT notes certain exceptions to the general hazardous material classification scheme. Specifically, those products distributed in a form suitable for sale through retail agencies or instrumentalities are considered Consumer Commodities and are exempt from most of DOT's hazardous materials transportation regulations. In

addition, materials shipped or transported as a Limited Quantity" and "materials of trade" are also exempt from many of DOT's regulations.

**B. Shipping Papers**. Proper documentation must accompany every shipment of DOT regulated hazardous material. These shipping papers must contain a description of the material and an emergency response telephone number.

**C. Marking.** All packaging must be marked in accordance with the provisions of DOT regulations. Regulations differ for bulk and non-bulk packages.

**D. Labeling.** All hazardous materials must be labeled as specified in the Hazardous Materials Table.

**E. Placarding.** Appropriate placards must be displayed on the side of each motor vehicle that is transporting the hazardous material, including a common carrier. These placards are numerically and color-coded.

**F. Packaging.** DOT requires performance oriented packaging for all regulated hazardous materials. Prior to use, packages must undergo stringent testing. Further, packaging must contain the proper identification code.

**G. Training**. All employees performing any function regulated by DOT must be trained to increase awareness and safety considerations. This training must consist of: general hazardous material training; function specific training; safety training; and driver training (if applicable).