

ISSA

GENERAL GUIDE TO CHEMICAL CLEANING PRODUCT REGULATION

*International Sanitary Supply Association, Inc.
7373 N. Lincoln Avenue
Lincolnwood, Illinois 60646-1799 USA
800/225/4772 • Fax 847/982-1922
www.issa.com • E-Mail : info@issa.com*

Prepared by :
Daniel S. Wagner
Manager of Regulatory Compliance: ISSA
2000

Introduction

Chemical cleaning products may be subject to a variety of federal labeling, hazard communication and/or registration requirements promulgated by OSHA, EPA, FDA, CPSC, DOT, and other agencies. Your chemical cleaning products, whether intended for institutional, occupational, or consumer use, may be subject to the various provisions of one or more of these agencies.

Which regulations and requirements your products may be subject to depends largely on the manner in which the products are marketed. For example, products marketed as general purpose disinfectants (i.e.: those making a claim that they “ kill harmful bacteria”) must be registered with EPA as a pesticide and must meet the labeling requirements established by that particular agency. Further, if you market a product as an industrial general purpose cleaner, it would be subject to OSHA labeling and MSDS requirements as established by the Hazard Communication standard.

The purpose of this outline is to describe in brief the various regulatory requirements that may apply to the labeling, registration, and transportation of your chemical cleaning products. Divided by product category and market focus, this outline is intended for use as a general reference tool. The outline also attempts to provide readers with information regarding where more in-depth information on a particular subject matter can be found. Consequently, each section contains the specific Code of Federal Regulations (CFR) cite, as well as a brief listing of recommended resources, including internet sites. Please keep in mind that many of the specific documents and publications referenced to can be located at ISSA's website: <http://www.issa.com>. Furthermore, *all* referenced print documents are available from ISSA. Please call ISSA at 800/225-4772 for details.

Note: This outline does not address requirements that pertain to the regulation of facilities that manufacture or distribute chemical cleaners such as the Emergency Planning and Communication Right-to-Know Act (EPCRA). For information on facility specific regulations, please contact ISSA.

I Disinfectants/ Antimicrobials

A. General Purpose Disinfectants

1. **Generally:** The Environmental Protection Agency requires registration of all products that claim to “prevent, destroy, repel, or mitigate any pest,” including harmful microorganisms.
2. **Agency:** Environmental Protection Agency (EPA)
3. **Regulations:** Outlined in 40 CFR 152, the regulations relating to general purpose disinfectants require that all applicable products be registered with EPA prior to sale.

- a. *Products subject to EPA registration regulation:* In general, antimicrobial pesticides used on inanimate surfaces, such as disinfectants and sanitizers, are subject to the EPA pesticide regulations.
- b. *Registration:* All products must be registered if:
 - The person who distributes or sells claims, states or implies that the substance is intended for a pesticidal purpose (i.e. used to prevent, destroy, repel or mitigate harmful microorganisms).
 - The substance consists of one or more active ingredients and does not have a significant commercially viable use other than its use as a pesticide.
- c. *Labeling:* EPA registered pesticides must be labeled in accordance with 40 CFR 156. Please refer to the actual regulation to determine exactly what information is required on the label.
- d. *Adverse Effects Rule:* Section 6(a)(2) of the Federal Insecticide, Fungicide, Rodenticide Act requires that all incidents adversely affecting humans or other non-target organisms must be reported to EPA.

4. ***Additional Resources***

- a. *Internet:* Access to Federal pesticide regulations, laws and policies can be had at the EPA Office of Pesticide Program (OPP) home page: <http://www.epa.gov/pesticides/index.html>.
- b. *Internet:* <http://www.epa.gov/docs/PesticideApplication> provides comprehensive general information on applying for pesticide registration.; including the complete text of a reference manual designed to assist in the application process.
- c. *Internet:* All necessary pesticide registration forms are available at <http://www.epa.gov/opprd001/forms>. This includes: an application for registration; confidential statement of formula; data reference sheet; formulator's exemption statement; and certification with request to citation of data.
- d. *Print:* The "Label Review Manual" contains a detailed analysis of exactly what EPA wants on a pesticide product label. (Also available on-line at www.epa.gov/oppfead1/labeling/lrm).

5. **State Regulation:** Pesticides also must be registered in individual states and the appropriate fee must be paid. ISSA's "State Pesticide Registration Survey," contains a detailed listing of each state's registration requirements, fees and authorities and is an invaluable resource. This publication is available at www.issa.com or by contacting ISSA at 800/225-4772.

B. **Hospital Use Disinfectants**

Introduction: Disinfectants, sterilizers, etc., ordinarily regulated by EPA under the Federal Insecticide Fungicide, Rodenticide Act, which are used by health care facilities to clean medical devices are considered to be medical devices themselves. These products, therefore, are also subject to regulation by the Food and Drug Administration. Which agency has primary authority depends on whether the product is deemed a critical, semi-critical or non-critical device.

Critical and Semi-Critical Medical Devices

1. **Generally:** Liquid chemical cleaning agents properly used on critical or semi-critical medical devices are subject to the Food and Drug Administration's jurisdiction and regulations.
2. **Agency:** Food and Drug Administration (FDA)
3. **Regulations:** FDA, under the Federal Food, Drug and Cosmetic Act, codified at 21 CFR, requires that all chemical germicides used as sterilants and applied to critical or semi-critical medical devices must submit and have approved an FDA 510(k) premarket clearance.
 - a. **Critical and Semi-Critical Devices:** Critical devices are those which are introduced directly into the human body and which must be sterilized. Semi-critical devices are those which contact mucous membranes but do not penetrate the blood barrier and which should be sterilized.
 - b. **Premarket Review:** Prior to marketing and sale, all products used on critical and semi-critical devices must be approved by FDA. Every manufacturer must submit a premarket approval application and data relating to the product's efficacy and effectiveness.
 - c. **Labeling:** Products that fall under the jurisdiction of FDA should not contain EPA reference numbers (Registration/Establishment).

Non-Critical Medical Devices

1. **Generally:** EPA is primarily responsible for the premarket review of liquid

chemical germicides that are intended for use on non-critical medical devices.

2. **Agency:** Environmental Protection Agency (EPA)
3. **Regulations:** Disinfectants used at health care facilities to disinfect non-critical devices are termed general purpose disinfectants and must be registered with EPA pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act.
 - a. **Non-Critical Devices:** Defined as those devices that are used on medical equipment surfaces, including wheelchairs, and which should undergo intermediate or low level disinfection.
 - b. **Labeling:** In addition to being subject to the general labeling requirements of 40 CFR 156, the label of disinfectant products intended for use on non-critical devices must contain the warning “not to be used as a terminal sterilant or high level disinfectant.” Further, the label may not contain “mixed claims:” claims that suggest effectiveness as a general purpose disinfectant and as a cleaner of critical and semi-critical medical devices.
 - c. **Registration:** EPA will only approve those products that meet efficacy and performance standards.
4. **State Regulation:** Many states continue to regulate all antimicrobial and disinfectant cleaning products, whether intended for use on critical, semi-critical or non-critical medical devices, as pesticides.

C. **Food Contact Surface Sanitizers**

Generally

1. **FQPA:** The Food Quality Protection Act provides that EPA regulations shall govern sanitizers used on food contact surfaces.
2. **Agency:** Environmental Protection Agency (EPA)
3. **Regulations:** Food surface sanitizers must be registered with EPA and should be formulated in accordance with FDA standards, codified at 21 CFR 178.1010. If formulation differs from that which has been approved by FDA, the appropriate party must apply for a tolerance from EPA.
4. **Additional Resources**

- a. *Internet:* EPA's Pesticides and Food Home Page is located at <http://www.epa.gov/pesticides/food/> and includes an explanation of EPA's role in regulating food contact sanitizers and information on safe food practices.
- b. *Internet:* To better understand FDA regulations and how they apply, go to <http://vm.cfsan.fda.gov>, FDA's Center for Food Safety and Applied Nutrition website.

Meat and Poultry Establishments

1. ***Generally:*** Meat and poultry establishments must operate in a sanitary manner as regulated by the U.S. Department of Agriculture and the Food Safety & Inspection Service.
2. ***Agency:*** United States Department of Agriculture (USDA) and the USDA's Food Safety & Inspection Service (FSIS).
3. ***Regulations:*** FSIS has issued a final rule on Sanitation Requirements for Official Meat and Poultry Establishments, establishing Hazard Analysis and Critical Control Points (HACCP) Systems regulations. Under HACCP, all establishments must identify critical control points where contamination can occur and must institute controls to help reduce hazards. In regard to cleaning products, the regulations provide the following:
 - a. All cleaners and sanitizers used by meat/poultry facilities must be *safe and effective* under the conditions of use.
 - b. All food-contact surfaces are required to be cleaned and sanitized "*as frequently as necessary*" to prevent insanitary conditions and the adulteration of product.
 - c. ***Documentation:*** Meat and poultry processing plants must maintain documentation evidencing that cleaners, sanitizers and other non-food compounds are safe and effective for use in a food processing environment. This documentation may be in one of the following forms:
 - Proof that the product was previously approved by USDA and the formulation has not been altered;
 - Certification by a third party;
 - Letter of guaranty provided by a manufacturer/supplier.
4. ***Additional Resources***

- a. *Internet:* <http://www.fsis.usda.gov> is the site of FSIS and provides info on HACCP regulations, including implementation assistance.
- b. *Print:* Guidelines for Obtaining Authorization of Compounds to Be Used in Meat and Poultry Plants was issued by USDA under its old program but continues to provide valuable assistance in defining acceptable formulations.
- c. *Print:* Sanitation Performance Standards Compliance Guide is a publication specifically tailored to helping companies comply with the new final rule and HACCP Systems.

Note: The above two documents can be found at www.issa.com under the Legislative & Regulatory Reference Library.

- d. *Print:* Standard Operation Procedures for Sanitation are guidelines around which distributors and manufacturers should build their marketing programs for cleaners and sanitizers used in a food processing environment.

D. **Antibacterial Hand Sanitizers and Soaps**

- 1. **Generally:** Hand sanitizers are defined as “drugs” and, therefore, regulated by the Food & Drug Administration (FDA).
- 2. **Agency:** Food and Drug Administration (FDA)
- 3. **Regulations:** Codified at 21 CFR, FDA has established hand sanitizer regulations that include premarket approval, labeling and testing guidelines.
 - a. **“Drugs:”** Antimicrobial handsoaps and sanitizers are defined as drugs because they are intended and labeled for topical anti-microbial use to prevent disease in humans.
 - Must be registered as a drug establishment
 - Must be registered as a drug product
 - Must be manufactured in conformance with Good Manufacturing Practices regulation.
 - b. **Tentative Final Monograph (TFM):** Products and ingredients that existed in the marketplace on or before December 4, 1975 are subject to the OTC Drug Review and may be included in the “Topical Antimicrobial Drug Product Monograph.”

- Contains listing of drugs recognized by FDA as safe and effective and which can be legally marketed and sold.
 - Products must be intended for the same use as they were on or before December 4, 1975.
- c. *New Drug Application*: products and ingredients which did not exist prior to December 4, 1975 must be approved in accordance with the 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.
- d. *Skin protectants and barrier creams*: to successfully market and sell these products, one **must** submit a new drug application.

4. *Additional Resources*

- a. *Internet*: FDA maintains its website at <http://www.fda.gov>. This site has general information on regulation of human drugs and cosmetics and contains links to various guidance documents.
- b. *Internet*: Specific FDA new drug application testing guidelines can be found at <http://www.fda.gov/cder/guidance/index.htm>, along with a number of documents offering guidance in other areas.
- c. *Print*: Regulation of Antibacterial Handsoaps is a complimentary memo and is available by contacting ISSA or by going to the electronic Legislative & Regulatory Reference Library, located at www.issa.com.

II Consumer Cleaning Products (other than those registered with EPA)

- A. *Generally*: Assuring the safety of products used by consumers in the household environment, the Consumer Product Safety Commission regulates all chemical cleaning products that are properly defined as hazardous substances.

- B. **Agency:** The Consumer Product Safety Commission (CPSC)
- C. **Regulations:** 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.
1. **Products Subject to CPSC Regulations:** CPSC's labeling requirements apply to all products (1) containing any hazardous substance *and* (2) if such substance may cause substantial injury or illness. The products must also, under customary or reasonably foreseeable use, be brought into or around a house or home.
 2. **Exemptions for Specific Products:** A number of products are exempt from CPSC regulations, including: specific polishing/ cleaning products (*see* regulations); cleaning/ spot removing kits; and products containing Sodium Chloride or Ferrous Oxide.
 3. **Required Language on the Label:** Each regulated product **must** contain the following information on its label:
 - Name and place of the business of the manufacturer
 - Common or usual name of the hazardous component.
 - Signal word “DANGER” on extremely flammable, corrosive or highly toxic substances, or the word “WARNING.”
 - An affirmative statement of the principal hazard.
 - 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” if necessary.
 4. **Location of the Label:** All labels must be prominently located, preferable on the principal display panel.
 5. **Highly Toxic Products:** “Highly toxic” products must contain the word “poison” and the skull and crossbones, when appropriate.
 6. **Poison Prevention Packaging:** Under the Poison Prevention Packaging Act of 1970 (16 CFR 1700 et seq.), substances that present a significant hazard to children must be packaged in accordance with CPSC package effectiveness specifications.
 7. **Reporting:** CPSC requires manufacturers and distributors to notify CPSC immediately in two situations: (1) when it can reasonably be concluded that a product has a defect that presents a substantial risk, and (2) when a

product has been involved in two or more lawsuits in a two year period.

D. ***Additional Resources***

1. *Internet:* CPSC has set up an internet homepage at <http://www.cpsc.gov>. This site provides access to industry guidance documents and CPSC personnel contact information.
2. *Print:* Regulated Products Handbook: This document contains detailed information needed by manufacturers and distributors who are charged with violating CPSC statutes/regulations. Available by contacting CPSC at 301/504-0621 and requesting document #8001.
3. *Print:* Corrective Action Handbook: Serves as an excellent guide and reference tool for manufacturers and distributors concerning reporting requirements under CPSC. Available by contacting CPSC at 301/504-0621 and requesting document #8002.

III. **Institutional Cleaning and Maintenance Products** (other than those registered with EPA)

- A. ***Generally:*** Chemical cleaning products marketed to institutional and industrial users are subject to the Occupational Health and Safety Administration's Hazard Communication Standard.
- B. ***Agency:*** The Occupational Health and Safety Administration (OSHA)
- C. ***Regulations:*** Codified at 29 CFR 1910, OSHA's Hazard Communication Standard regulations apply to all "hazardous chemicals" and contain provisions relating to labeling, material safety data sheets and employee information and training.
 1. ***Hazard Determination:*** Generally, "hazardous chemical" means any chemical which presents a health or physical hazard. Health hazard indicates that there is statistical evidence that health effects may occur in exposed employees. Physical hazard suggests that the material is a combustible liquid, compressed gas, explosive, flammable, an organic peroxide, an oxidizer, unstable, or water reactive.
 2. ***Employers:*** "HCS applies to all employers who have employees who may be exposed to hazardous chemicals under normal operating conditions. For distributors and wholesalers the requirements are not as strict..
 3. ***Labeling:*** Chemical manufacturers, importers, distributors, and employers all have responsibilities relating to labeling.

- a. Suppliers of chemical products must ensure that all chemicals are labeled with the following information:
 - Identity of the hazardous chemical, although for end use products, the identity may be the brand or trade name.
 - Appropriate hazard warnings.
 - Name and address of the chemical manufacturer, importer, or other responsible party.
 - b. Employers must ensure that secondary containers are labeled properly unless the container is a portable “intended only for the use of the employee who performs the transfer.”
4. *Material Safety Data Sheets:* Intended to be the primary source of information in the workplace, MSDSs are required for every hazardous chemical product and must comply with the provisions set forth at 29 CFR 1910.1200.
 5. *Employee Information and Training:* The HazCom Standard provides a general framework for the training of employees. Training must occur before the employee is first exposed to a hazardous chemical and must include all information necessary for the employee to fully understand the risks associated with the chemicals with which they will be working.

D. *Additional Resources*

1. *Internet:* OSHA’s home page, located at <http://www.osha.gov>, contains comprehensive information on OSHA regulations, workshops, programs, services, and recent developments.
2. *Internet:* OSHA created the National Institute for Occupational Health and Safety (NIOSH) to conduct research and make recommendations for the prevention of work related illness and injury. Their internet site is located at: <http://www.cdc.gov/niosh/homepage.html>.
3. *Print:* The American National Standards Institute (ANSI) publishes two documents that can be used in the preparation of MSDSs and in the creation of product labels. These “Standards” provide invaluable guidance and are available by contacting ANSI at 212/642-4900.
4. *Print and Video:* “Right-to-Know Training for Employees” is a comprehensive program, addressing all essential elements of employee training, including an overview of right-to-know regulations, MSDSs, labeling, health and physical hazards in the workplace, and written hazard communication programs. Includes a 25 minute videotape, instructor’s

manual, reusable handbooks, a training log, and other necessary documentation. Please contact ISSA at 800/225/4772 for details and ordering.

IV **Transportation of Hazardous Materials**

- A. **Generally:** All products which meet the definition of “hazardous material” are subject to the Department of Transportation’s Hazmat regulations.
- B. **Agency:** The U.S. Department of Transportation (DOT)
- C. **Regulations:** Codified at 49 CFR 100-185, DOT has issued various regulations regarding: hazardous material classification; shipping papers; marking; labeling; placarding; packaging; and training of employees.
 - 1. **Hazardous Material Classification:** DOT recognizes nine classes of materials that they consider hazardous. The classifications of primary concern to the chemical cleaning products industry include: corrosives, flammables, combustibles, poisons, and oxidizers.
 - a. **Packing Groups:** Hazardous material is further classified based on its “packing group.” Packing Group I represents great danger, Group II medium danger, and Group III minor danger.
 - b. **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 DOT regulation. Further, materials shipped in limited quantities and materials of trade are also exempt from many of DOT’s regulations.
 - 2. **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.
 - 3. **Marking:** All packaging must be marked in accordance with the provisions of DOT regulations. Regulations differ for bulk and non-bulk packages.
 - 4. **Labeling:** All hazardous materials must be labeled as specified in the Hazardous Materials Table.
 - 5. **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.

6. *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.
7. *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).

D. ***Additional Resources***

1. *Internet:* U.S. DOT Hazardous Material Regulations are available at: <http://hazmat.dot.gov/hazhome.htm>. This site also includes various guidance documents and training information.
2. *Internet:* International information can be found at: <http://hazmat.dot.gov/nomslst.htm> (Mexico) and http://tc.gc.ca/tdggoods/general/main_e.htm (Canada).
3. *Print:* ISSA offers a variety of written manuals pertaining to DOT regulations, including the "Transportation of Hazardous Material Manual," and "DOT Hazmat Employee Training." ("DOT Hazmat Employee Training" includes a video).

V. **Volatile Organic Compound Regulation**

- A. ***Generally:*** The Environmental Protection Agency has issued regulations limiting the volatile organic compound concentration in various institutional and consumer cleaning products and architectural coatings.
- B. ***Agency:*** Environmental Protection Agency (EPA)
- C. ***Federal Regulations:*** EPA has attempted to address ozone depletion by regulating the VOC content of institutional and consumer cleaning products and architectural coatings. Companies that manufacture, import and/or distribute products covered in these categories must comply with record-keeping, reporting, and labeling obligations through regulations found at 40 CFR Parts 9 and 59.
 1. ***Consumer Products Rule:*** Twenty-four categories of institutional and household consumer cleaning products are subject to the rule and the volatile organic compound concentration is limited in accordance with the VOC content limits table (Table 1 to Subpart C of the Consumer Products Rule).

- a. *Record-Keeping*: The regulated entity must maintain all records of each product's formulation for three years.
 - If the distributor's name appears on the label, the distributor is responsible for record-keeping.
 - If the distributor's name does not appear on the label, the manufacturer or importer is responsible.
- b. *Reporting*: The only report required is a one-time initial notification report, which must contain the following information: company name; list of product categories; description of date-coding system; name, address and phone number of certifying company official; and name and location of the record-keeping agent.
- c. *Labeling*: Each product container must contain the day-month-year of manufacture or a date-code indicating such.

2. ***Architectural Coatings Rule***: Extremely similar to the Consumer Products Rule in that VOC limits are imposed, an initial notification report must be submitted and the container must include the date of manufacture; the Architectural Coatings Rule does contain some significant differences.

- a. *Exceedance Fees*: The listed VOC content limit may be exceeded if the manufacturer or importer chooses to pay an "exceedance fee."
- b. *Tonnage Exception*: Coatings are not subject to the Rule if sold or distributed in limited quantities. The total mass of VOC regulated products may not exceed 23 megagrams (25 tons). *Note, the total mass allowed under the exception will decrease to 18 megagrams (20 tons) in 2001.
- c. *Record-Keeping*: Records must only be maintained in cases where one is paying an exceedance fee or claiming a tonnage exception

D. ***State Regulation***: At one point, about a half-dozen states regulated the VOC content of cleaning products. The adoption of a National VOC standard, however, has made state regulation of VOCs a moot point because, for the most part, the pre-existing state regulations are consistent with the federal regulations.

One notable exception exists. The state of California continues to implement its own VOC regulations which are more stringent than those contained in the National VOC regulations. California VOC regulations, in general, cover more product categories, and, in many cases, impose stricter VOC limitations.

E. *Additional Resources*

1. *Internet:* Containing general VOC information, a compliance guide and the regulatory text of the Consumer Products Rule, <http://www.cisutk.edu/teleconf.html> is the number one website for information.
2. *Internet:* Information on the Architectural Coatings Rule and its application can be found at <http://www.epa.gov/ttnuatw1/183e/aim/aimfact/html>.
3. *Internet:* California's VOC regulations, as well as general VOC information can be accessed at the California Air Resources Board (CARB) internet site: <http://www.arbis.arb.ca.gov/consprod/consprod.htm>.