ISSA'S GUIDE TO THE REGULATION OF ANTIBACTERIAL HAND SOAPS

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I. **Introduction**: Antibacterial hand soap regulation is designed to ensure that these products are safe and effective when applied to human skin.

A. "Drugs": Antibacterial hand soaps are drugs as defined by § 201(g) of the Federal Food, Drug & Cosmetic Act (FFDCA). They are categorized as drugs because they are intended and labeled for topical antimicrobial use to prevent disease in humans. Therefore, they are regulated by the Food & Drug Administration (FDA) as over-the-counter (OTC) drugs. In accordance with the provisions of the FFDCA.

Antibacterial products that fall under the jurisdiction of FDA include all hand soaps, dips, and alcohol based washes for use when water is not available, also known as instant hand sanitizers.

The fact that they are designated as such triggers certain responsibilities. They include:

1. Registering with FDA as a drug establishment pursuant to 21 CFR § 207.20.

a. Owners and operators of all drug establishments, including foreign establishments, *must* register by submitting Form FDA-2656. FDA will assign all registrants a permanent establishment number and a labeler code. Private label distributors are technically not required to *register*, but still must submit Form FDA-2656 to FDA in order to receive a labeler code.

b. Drug establishment registration is used to capture information for the Drug Registration and Listing System (DRLS) database.

c. Each drug establishment must renew its registration annually and within 30 days of receipt of Form FDA-2656e from FDA. Renewal forms are mailed by FDA according to an alphabetical schedule. (i.e.: Establishments whose names begin with A or B receive renewal forms in January, C, D and E, in February, etc.)

2. Listing the specific product as a drug pursuant to 21 CFR § 207.20.

a. Each establishment must also submit a drug listing for each drug product in commercial distribution, even if the product does not enter interstate commerce. Commercial distribution includes *any* distribution of a product other than for investigational purposes.

b. Drug listing is generally accomplished by submitting Form FDA-2657 to FDA. This form must be submitted at the same time as the initial establishment registration form (2656).

c. Private label distributors and foreign drug establishments must list all drug products. Private label distributors can list their products on their own or may rely on the manufacturer to do it for them.

   i. If a private label distributor will be listing its products on its own, he must provide a copy of Form FDA-2656 to the manufacturer to advise him that he will be responsible for listing with FDA. The distributor must then submit Form FDA-2657.

   ii. If the manufacturer will be listing the distributor's products on his behalf, the manufacturer must submit Form FDA-2658 and provide a copy to the distributor.

d. Drug listing information must be updated biannually, at the end of June and the end of December. Changes in formulation, labeling, packaging, or manufacturing are to be reported to FDA as soon as possible, however.

e. Sample completed forms (FDA-2656, 2657 and 2658) are available from FDA by calling 301-594-1086.

3. Complying with "Good Manufacturing Practices," (21 CFR § 211) the standards designed to ensure that safety and effectiveness is not sacrificed during the manufacturing process. This includes regulations regarding:

   a. Quality control
   b. Adequate buildings and facilities (lighting, ventilation, heating, sewage, sanitation)
   c. Appropriate design, cleaning and maintenance of equipment.
   d. Record keeping in the areas of production, distribution, quality control and customer complaints.
   e. Companies must also have an appropriate written procedure regarding their quality control.

4. Subjecting themselves to periodic inspection by FDA

B. Lawfully marketing and selling antibacterial hand soaps

Companies that wish to market and sell antibacterial hand soaps and sanitizers must comply with all specific regulations issued by FDA. Simply put, these products *must* be approved by FDA before they are marketed and sold. There are two ways to get a product approved.

1. * Way # 1: Product included in the OTC Drug Review and listed in the FDA Monograph.

2. * Way # 2: Completion and submission of a New Drug Application.

Both of these ways are discussed in greater detail below.

II. OTC Drug Review and Listing in the "Topical Antimicrobial Drug Product Monograph"

Introduction: The preferable way of obtaining FDA approval is through the OTC Drug Review and Monograph process. Products containing certain active ingredients will be able to avoid the extensive testing requirements of a new drug application, if FDA, after the OTC Drug Review, determines that they are generally safe and effective. The ingredients will then be listed in the future final monograph. The final monograph will contain a comprehensive list of acceptable ingredients, as well as testing and labeling requirements. FDA is currently conducting the Review and industry is awaiting the final monograph.

A. Introduction to the Monograph and OTC Drug Review Process

1. The OTC Drug Review and Monograph process was started because of FDA's concern with over-the-counter drug products that had been on the market for years prior to the passing of laws requiring proof of safety and effectiveness.

2. FDA is, therefore, establishing Monographs for each class of drug products.

3. The Drug Review and Monograph process is specifically handled by the Center of Drug Evaluation & Research's Division of Over-the-Counter Drug Products in the Office of Drug Evaluation. They are assisted by an advisory committee, the Nonprescription Drug Advisory Committee.

4. Monographs are "recipe books," listing acceptable ingredients, doses and formulations. They also include specific labeling requirements and testing provisions. Monographs can be updated as needed, with the addition of ingredients.

B. Monographs are issued in three stages:

1. Proposed
2. Tentative
3. Final

Note: While all three documents contain provisions that can offer significant guidance to industry, technically only the *final* monograph is legally enforceable. Therefore, prior to the final monograph's issuance, FDA will only initiate enforcement action in cases where there is an evident public safety concern.

C. The OTC Drug Review: After FDA publishes a proposed monograph, the Center for Drug Evaluation & Research begins analyzing the safety and effectiveness of products in the OTC Drug Review. Such a review is currently ongoing and the results of this review will form the basis for the ingredients listed as safe and effective in the final monograph.

D. Products eligible for the review: Only products having the same formulation, labeling and dosage as those that existed in the marketplace on or before December 4, 1975 are eligible for the Drug Review. All hand sanitizers included in the Review require a water rinse followed by drying except: "instant hand sanitizers" and certain USDA authorized hand dips used in the food processing industry.

FDA has divided all the active ingredients that are in the Review into three categories. These categories indicate whether the product can be lawfully marketed and sold while industry is waiting for the final monograph. Please review "Appendix A" for a full listing of the ingredients that are included in the Review. "Appendix A" also indicates the ingredient's designated category.

1. Category 1: Those ingredients that are listed in Category 1 have been determined to be safe and effective by FDA. Products containing these ingredients can be marketed and sold lawfully.

2. Category 2: Ingredients listed as Category 2 cannot be marketed and sold because FDA has determined that they are not safe and effective.

3. Category 3: Contains those ingredients for which FDA has declared there is insufficient evidence to determine whether they are safe and effective. FDA is not, however, presently objecting to the marketing and sale of products containing these active ingredients.

Note: FDA may still make a determination that these ingredients are not safe and

effective and choose *not* to include them in the final monograph.

Note: Triclosan is currently listed as a Category 3 ingredient. This is due to CDER's perceived lack of in vivo data to support existing in vitro data. Specifically, data is needed on the germicidal activity of the vehicle alone.

E. Antibacterial Hand soaps are part of the "Topical Antimicrobial Drug Product Monograph" under Subpart E: Heading: "Health Care Antiseptic Drug Products."

In June of 1994, FDA issued a tentative monograph that applies to all antibacterial hand soaps. The tentative monograph contains most of the provisions that can be expected to be included in the final monograph, whenever it is issued. When the final monograph is published, companies involved with hand soaps will have to comply with *all* provisions.

Generally the monograph defines a health care antiseptic drug product as an: "antiseptic containing drug product applied topically to the skin to help prevent infection of to help prevent cross-contamination."

These products are divided into three "product categories."

1. Antiseptic Hand Wash or Health Personnel Hand Wash

Most general antibacterial hand soaps will fall into this category. Specifically, any product falling under the definition: "antiseptic containing preparation designed for frequent use, reduces the number of transient microorganisms on intact skin to a baseline level after adequate washing, rinsing and drying; it is broad spectrum, fast acting and, if possible, persistent."

FDA has already determined that alcohol 60-95% in an aqueous solution and povidone iodine 5-10% are safe and effective when used for this purpose.

2. Patient Preoperative Skin Preparation

Defined by the tentative monograph as: "fast acting, broad spectrum and persistent antiseptic containing preparation that significantly reduces the number of microorganisms on skin."

FDA has determined that the following active ingredients are safe and effective and, therefore, acceptable:

a. Alcohol 60-95% in an aqueous solution
b. Iodine Tincture U.S.P.

c. Iodine Topical Solution U.S.P.
d. Isopropyl alcohol 70-91.3% by volume in an aqueous solution
e. Povidone iodine 5-10%

3. Surgical Hand Scrub Drug Product

Includes all products falling under the definition: "an antiseptic containing preparation that significantly reduces the number of microorganisms on intact skin and is broad spectrum, fast acting and persistent."

Currently, alcohol 60-95% in aqueous solution and povidone iodine 5-10% are considered safe and effective by FDA.

Labeling: The tentative monograph also contains labeling requirements. These labeling provisions are expected to be included in the final monograph and, therefore, must be complied with.

There are general labeling requirements that apply to all three product categories:

1. Every label must include a statement of identity. Each product should be identified as an antiseptic and/ or with the appropriate statement of identity for the specific category. The product label should also include the established name of the drug.

Note: Although antiseptic, antimicrobial and antibacterial essentially all mean the same thing, antiseptic is the preferred term and is required to be included on the label.

2. Every label must include appropriate indications and directions for use.

3. Every label must include applicable warnings

Examples of warnings: "For external use only"
"Do not use in eyes"
"Discontinue use if redness or irritation develops"
"Flammable, keep away from fire or flame"

Note: "Descriptive statements" are not regulated by the labeling provisions of the monograph. If the statement does not speak to the safety or effectiveness of the product it is not governed by the monograph. Examples of descriptive statements include: "Contains antibacterial ingredients," or "For purposes of promoting good hygiene."

"Antibacterial" and "Antimicrobial" should *not* be used as indications on the label.

4. The monograph also contains various labeling provisions that apply

specifically to a particular product category under certain circumstances

a. Labeling pertaining to the directions of use

i. Category 1: Products to be used with water. "Wet hands and forearms. Apply 5 mililiters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for (applicable time). Rinse and repeat."

ii. Category 1: Products to be used without water: "Place a palmful (5 grams) of product in one hand. Spread on both hands and rub into the skin until dry (1-2 min.). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist and rub into the skin until dry."

b. Labeling pertaining to indications

i. Category 1 products may note on the label: "For handwashing to decrease bacteria on the skin before contact with a person under medical care" or "Recommended for repeated use."

ii. Category 2 products may include on the label: "For preparation of the skin prior to surgery" and for those that include alcohol: "For preparation of the skin prior to injection."

iii. Category 3 product labels may note: "Significantly reduces the number of microorganisms on the hands/ forearms prior to surgery or patient care."

Testing: The final monograph will include a list of active ingredients that are presumed safe and effective when used for a specific purpose, but products containing a listed ingredient will still be required to undergo testing prior to being placed on the market. The testing provisions in the monograph are detailed and specific and include a clinical study requirement. Generally, the necessary testing is designed to test the safety and effectiveness of the product.

1. Product must undergo both in vitro and in vivo testing.

a. In vivo testing must be conducted on the final product.
b In vitro testing must be conducted on the antiseptic ingredient, the vehicle and the final product.

2. Testing must be conducted for both positive and negative organisms as well as yeast.

3. Testing must be conducted on how quickly the drug product achieves its antimicrobial effect.

F. Lawfully Marketing and Selling Antimicrobial Hand Soaps Under the FDA Drug Review and Monograph Process: Checklist

As mentioned, the FDA Drug Review and Monograph process is the preferable manner in which to have antimicrobial hand soaps approved by FDA. Furthermore, unless a product is approved by FDA, it cannot be lawfully marketed and sold.

The following checklist provides a quick analysis of whether a product can be legally marketed and sold through the monograph process:

1. *Is the active ingredient included in the FDA OTC Drug Review?*

   More specifically, did the "product" exist in the marketplace in the same formulation and dosage on or before December 4, 1975?

   If the answer is yes, the product is probably included in the Review and, therefore, is eligible for inclusion as an "approved" product in the final monograph. All products included in the review are listed along with their ingredient categories in Appendix A.

   Until the final monograph is issued, all ingredients listed as category I or III are considered "approved" by FDA. Please note that FDA, through the Drug Review, reserves the right to determine that a listed ingredient is *not* safe and effective and, therefore, is not approved as an antibacterial hand soap.

2. *Is the product labeled and intended for the same usage?*

   For the product to be approved, the active ingredient had to have existed in the marketplace prior to December 4, 1975, and had to also have been used for the exact same purpose. For example, if Triclosan was used as a general antibacterial hand soap before that date, it can be used as a general antibacterial hand soap now. It could not, however, be used as a patient preoperative skin preparation under these circumstances because its intended use differs.

3. *Is the product labeled in accordance with the provisions of the tentative monograph?*

4. *Has the final product formulation been tested for safety and effectiveness prior to marketing in conjunction with the monograph's testing*

requirements?

5. *Have all "drug" requirements, including registering as a drug establishment, listing as a drug product, and following Good Manufacturing Practices been complied with?*

***If the answer to each of the above questions is "yes," and antibacterial hand soap may presently be marketed and sold in conjunction with the FDA Drug Review and Monograph process.

III **New Drug Applications (NDA)**

Introduction: If a product is not eligible for the Drug Review and, therefore, cannot be listed in the monograph, a new drug application must be submitted in accordance with the provisions of the Federal Food, Drug & Cosmetic Act (Section 505). FDA will carefully review the new formulation and product to determine if it is safe and effective when used as intended. If ruled safe and effective, the new drug application will be approved and the product can be lawfully placed on the market.

1. Approved products are listed in the publication "Approved Drug Products With Therapeutic Equivalence Evaluations." This is also known as the "Orange Book" and is published annually with monthly supplements.

2. The Orange Book is available at the CDER/FDA web site, from the Superintendent of Documents/Government Printing Office, or the National Technical Information Service.

A. Application Process: A full application form must be signed and submitted pursuant to 21 CFR § 314. It will then be reviewed by the FDA Institutional Review Board in accordance with the following policies:

1. The Board will have 180 days to review the information submitted and reach a decision regarding approval or denial of the application.

2. Applications shall be denied in cases where the submitted data is insufficient to determine whether the product is safe and effective.

3. End of Review Meeting: At the conclusion of FDA's review of an application, applicants will have the opportunity to meet with the agency's reviewing official to discuss the denial of an application. Notice of the meeting should also be given to manufacturers and distributors of similar drug products.

B. The Application: Applicants must include a myriad of information in a new drug application. Essentially, FDA requires the submission of all information and data relevant to the safety and effectiveness of the new product.

An application for a new drug product will generally contain: (1) an application form; (2) an index; (3) a summary; (4) five or six technical sections; (5) case report tabulations of patient data; (6) case report forms; (7) drug samples; and (8) sample labeling.

1. Application form: Must include:

    a. The name and address of the applicant
    b. The name of the drug product, including its established, code, proprietary, and chemical names
    c. The dosage form and strength
    d. The route of administration
    e. The drug product's proposed indications for use.
    f. Various additional statements are required in accordance with Section 5 of the FFDCA.

2. Summary: An application is required to contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and information contained within, including an understanding of the quantitative aspects of the submitted data.

    The summary must also include the proposed text of the labeling and individual summaries of the other sections of the application, including all technical sections.

3. Technical sections: Each technical section is required to contain data and information in sufficient detail to permit the agency to make an informed decision about approving the application.

    a. Chemistry, manufacturing and controls section: Must describe the composition, manufacture and specification of the drug, including all physical and chemical characteristics of the drug.

    b. Nonclinical pharmacology and toxicology section: Describing, with the aid of tables and graphs, animal and in vitro studies.

    c. Human pharmacokinetics and bioavailability section

    d. Clinical data section: Must describe the clinical investigations.

    e. Statistical section: Including a statistical evaluation of the clinical data.

    f. Pediatric use section: Describing the investigations of the drug on pediatric populations.

***_Note_: Products *cannot* be marketed or sold pending the approval of a new drug application.

C. Labeling: Products approved pursuant to a new drug application must be labeled in accordance with the Federal Food, Drug & Cosmetic Act (21 CFR § 201). Generally, each statement proposed on the label must be justified by the submitted efficacy data. Specifically, the label must contain the following elements:

1. Principal Display Panel: The label must include a central information panel that includes a statement of identity (established name of the drug) and a declaration of net quantity.

2. The "outside container of wrapper" should include the following information (in the order listed):

   a. Drug Facts
   b. Active Ingredient (the established name and the quantity of each active ingredient per dosage unit)
   c. Purposes (principal intended action of the drug)
   d. Uses (Indications)
   e. Warnings

      I.e.: "For External Use Only"
      Allergic Reaction Warnings
      Flammability Warnings

   f. Directions For Use
   g. Other Information (as required by an applicable Monograph)
   h. Inactive Ingredient Identification
   i. "Questions?" or "Questions and Comments?" followed by a telephone number of a source to answer questions about the product.

3. The following information should also be included on the label:

   a. The name and business of the distributor, manufacturer or packer
   b. Dosage information and the route or method of administration
   c. Lot number: Capable of yielding the complete manufacturing history of the product

   d. The National Drug Code number is requested but not required

4. Format: The FDA requires that drug product labeling adhere to specific format requirements, including uppercase lettering, letter height, type size

and text bullet style. The format requirements can be found at 21 CFR § 201.66 (d).

D. Testing: Products approved by a new drug application must also undergo extensive testing. The required testing focuses on whether the product is safe and effective and includes both in vitro and animal studies. FDA has issued specific testing guidelines titled "Guidelines for the Format and Content of the Clinical and Statistical Sections of an Application." This document is available over the Internet at FDA's web site: http://www.fda.gov/cder/guidance/index.htm.

E. Skin Protectants and Barrier Creams

Recently, there has been a growth in the market for products that are placed on healthy human skin in order to protect it from harmful organisms, including hazardous chemicals, allergens, and pathogens. These products are preventive and attempt to act as a barrier. Like, antibacterial hand soaps, these products are drugs and must be approved by FDA before they are marketed or sold.

Skin protectants and barrier creams are regulated as new drugs by FDA and, therefore, a new drug application must be submitted and approved. This is the case even in situations where the active ingredient is included in the monograph, because the product's intended use differs from its intended use in the past. For example, if a *hand soap* containing Triclosan existed prior to December 4, 1975, it will be included in the Drug Review for purposes of acting as a *hand soap* only and future Triclosan *hand soaps* may be approved through the monograph. However, if the manufacturer thereafter produces a *skin protectant* with Triclosan, it must be approved pursuant to a new drug application and cannot rely on the inclusion in the Drug Review and possible listing in the monograph.

Recently, Bristol Myers Squibb was sent a warning letter by FDA with regards to the Keri Antibacterial Hand Lotion. FDA specifically noted that skin barrier products lie outside the scope of the tentative monograph and that there is no evidence that topical antimicrobials were used as skin protectants prior to the start of the Drug Review. FDA maintains that they are unaware of any data showing that these products are safe and effective when used as intended.

IV **Petitioning FDA for Inclusion in FDA Drug Review and Monograph**

Introduction: If a product is not eligible for inclusion in the FDA Drug Review and Monograph, because it did not exist on or before December 4, 1975, a company can petition FDA and request that it be added to the list. If it is added, it will be reviewed by CDER for safety and effectiveness and if it is determined to be safe and effective it will be listed in the future final monograph.

Once the final monograph is published and ingredients are listed, the only way to be added to the list is to submit a petition.

A. Petitioning FDA should be done in accordance with 21 CFR § 10.30: Citizen's Petitions.

B. The petition should include a statement of the action requested and a statement of grounds.

C. Petitioners should include all clinical data relating to the safety and effectiveness of the product. All chemical information should also be submitted.

D. Example: USDA authorized products that were introduced after December 4, 1975.

Many hand cleaners and sanitizers were previously approved by USDA and included in the USDA "List of Proprietary Substances and NonFood Compounds." This included most sanitizers used in conjunction with food handling and preparation. USDA, however, discontinued its approval program in late1998 and will no longer approve or list products.

Despite previous USDA authorization and listing, products that were introduced into the marketplace after December 4, 1975 will have to be approved by FDA through the submission of a new drug application. Manufacturers, however, can attempt to bypass the new drug application by petitioning FDA to have the specific product which was previously approved by USDA included in the Drug Review.

V. **FDA Enforcement**

A. Warning letter is sent by FDA: FDA concerned with company's response. Did they offer to relabel the product? Did they offer to voluntarily pull the product off the market?

B. Seizure of Product: Recall of product only requested where there is a hazard associated with the product.

C. Injunction or Prosecution

1. Civil: monetary penalties may be assessed after the warning letter is sent and seizure of the product has occurred. Usually limited to prescription drugs.

2. Criminal penalties: can be instituted in cases where FDA determines that a violation is fraudulant or fragrant. Notice will be given to the company who will have the opportunity to show cause as to why criminal prosecution is improper. Notice will *not* be given in case where there is a perceived threat of fleeing or destruction of property.

VI. **Detergent Substances, Other than Soap, Intended for Use in Cleansing the Body**

Introduction: Detergent substances intended for cleansing the human body and which are not "soap" are regulated as cosmetics by FDA. As such these products are subject to 21 CFR § 701 et.al..

A. Designation of Ingredients: The labels of cosmetic products must contain the name of each ingredient in descending order of predominance except that fragrance may be listed as "fragrance." (21 CFR § 701.3)

B. Principal Display Panel: The principal display panel must be large enough to accommodate all the mandatory label information with "clarity and conspicuousness," and without obscuring designs, vignette, or crowding. The area of the panel must conform to the requirements of 21 CFR § 701.10.

C. Statement of Identity: The principal display panel must bear, as one of its principal features, a statement of identity of the product consistent with 21 CFR § 701.11.

D. Name and Address of the Manufacturer, Packer or Distributor: The label of a cosmetic product shall contain the name and place of business of the manufacturer packer or distributor in accordance with the particulars set forth in 21 CFR § 701.12.

E. Declaration of the Net Quantity of Contents: The label of a cosmetic in package form shall bear a declaration of a net quantity of content. The content shall be expressed in terms of weight, measure, numerical count or a combination thereof. The declaration of the net quantity of contents must conform to 21 CFR § 701.13.

VII. **Soap**

A. Definition: In implementing the Federal Food, Drug & Cosmetic Act, FDA interprets the term "soap to apply to products that meet the following two conditions:

1. The bulk of the non-volatile material in the product consists of an alkali salt of fatty acids and the detergent properties of the product are due to the alakli-fatty acid compounds; and

2. The product is labeled, sold and represented only as soap.

B. Regulations: Soap is ***not*** regulated by the FDA. Soap may be subject to one of the following requirements:

1. CPSC Regulations: Soap intended for sale to general consumers may be

regulated as "hazardous" and may be subject to the Consumer Product Safety Commission's (CPSC) precautionary labeling requirements set forth at 16 CFR § 1500.

2. OSHA Hazcom: Soap intended for sale to institutional users may be regulated as "hazardous" and may be subject to the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard. The OSHA Standard is codified at 29 CFR § 1910.1200.

3. Soaps not falling into any of the above categories which are targeted to consumer markets will generally be subject to the labeling regulations under Section 4 of the Fair Packaging and Labeling Act. The regulations implementing these provisions can be found at 16 CFR § 500 et.al..

APPENDIX A

Topical Antimicrobial Ingredients: Summary of Health-Care Antiseptic Active Ingredients

Active Ingredient	**Category Listing for an Antiseptic Handwash**	**Can Product be Lawfully Marketed?**
Alcohol 60-95 percent	I	Yes
Benzalkonium	III	Yes
Benzethonium	III	Yes
Chlorhexidine gluconate	N/A	No
Chloroxylenol	III	Yes
Cloflucarban	III	Yes
Florosalan	II	No
Hexachlorophene	II	No
Hexylresorcinol	III	Yes
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate)	III	Yes

Iodine Active Ingredients	**Category Listing for an Antiseptic Handwash**	**Can Product be Lawfully Marketed?**
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)	III	Yes
Iodine Tincture U.S.P.	N/A	No
Iodine Topical Solution U.S.P.	N/A	No
Nonylphenoxypoly (ethyleneoxy) ethanoliodine	III	Yes
Poloxamer – iodine complex	III	Yes
Povidone iodine 5-10 percent	I	Yes
Undecoylium chloride iodine	III	Yes
Isopropyl alcohol 70-91.3 percent	III	Yes
Mercufenol chloride	N/A	No
Methylbenzethonium chloride	III	Yes
Phenol (less than 1.5 percent)	III	Yes
Phenol (greater than 1.5 percent)	II	No
Secondary amyltricresols	III	Yes
Sodium oxychlorosene	III	Yes
Tribromsalan	II	No
Triclocarban	III	Yes
Triclosan (not intended to be limited to use in bar soap)	III	Yes

Combinations	**Category Listing for an Antiseptic Handwash**	**Can Product be Lawfully Marketed?**
Calomel, oxyquinoline benzoate, triethanolamine, & phenol derivative	N/A	No
Mercufenol chloride and secondary amyltricresols in 50 percent alcohol	N/A	No
Triple Dye	N/A	No

N/A = Not applicable because not evaluated as an antiseptic handwash