



## EcoLogo™ Program Standard Development: Discussion Document Instant Hand Antiseptic Products



May 20, 2009

The EcoLogo™ Program is inviting stakeholders to participate in the development of a newly proposed environmental leadership standard for *Instant Hand Antiseptic Products*. The product category can also be described as waterless hand sanitizers or waterless hand antiseptics, or professional hygienic hand rubs. Disinfectant soaps, hand sanitizing products that require rinsing, patient preoperative skin preparations, or surgical hand scrubs are outside the scope of this standard.

In developing environmental leadership standards, the EcoLogo™ Program welcomes and actively encourages the participation of a wide variety of stakeholders familiar with the product category. This includes environmental NGOs and other not-for-profit organizations, academics and other scientific experts, manufacturers, industry associations, government representatives, and purchasing professionals.

The EcoLogo™ Program will accept comments by e-mail, fax, and phone. This first stakeholder consultation period, which is intended to serve as an open discussion regarding the scope and potential criteria statements, will be open for 30 days beginning May 20, 2009. Comments must be received by June 18, 2009.

Your time and input in helping us to establish the most stringent environmental standards are very much appreciated. We will send you a reminder as our closing date for comments approaches.

Sincerely,

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# 1 Introduction

The EcoLogo™ Program has conducted preliminary research to identify potential environmental impacts across the life cycle of the product category, and has prepared a discussion document for public consultation. Stakeholder contributions play a pivotal role in the EcoLogo™ standards development process. In developing environmental leadership standards, EcoLogo™ welcomes and actively encourages the participation of a wide variety of stakeholders familiar with the product category. This includes environmental NGOs and other not-for-profit organizations, academics and other scientific experts, manufacturers, industry associations, government representatives, and purchasing professionals.

EcoLogo™ standards are updated on a regular basis, and products are also re-audited regularly to ensure certified products continue to offer significant environmental benefits. The purpose of this discussion document is to provide broad information regarding the market for hand antiseptics in Canada and the United States, and to present details on how the EcoLogo™ Program intends to establish certification criteria for hand antiseptics. The goal of the EcoLogo™ Program is to establish certification criteria that will promote environmental leadership in the marketplace.

The purpose of this discussion document is to highlight the major research findings associated with the development of an environmental leadership standard for instant hand antiseptics, more particularly to help initiate a discussion with stakeholders as to refine both the potential scope and criteria statements that will ultimately define the standard. To help initiate and guide the discussion, the EcoLogo™ Program has provided an initial potential scope and potential criteria statements, as well as a series of questions for the attention of stakeholders.

The information gathered in this discussion document comes from internal research found on various government, manufacturer, and other institutional web sites, in addition to input and literature provided directly by current EcoLogo™ licensees and/or stakeholders.

# 2 Scope and Category Definition

The product category of ***Instant Hand Antiseptic Products*** can also be described as waterless hand sanitizers, waterless hand antiseptics, or professional hygienic hand rubs. For the purposes of this document, an instant hand sanitizer will mean an

*antiseptic containing preparation designed for frequent application, which is intended for use without a water rinse, which reduces the number of microorganisms on intact skin. Moreover, instant hand antiseptic products can be defined as an antiseptic containing drug product applied topically to the skin to help prevent infection, or to help prevent cross contamination (FDA, 1994).* Disinfectant soaps, hand sanitizing products that require rinsing, patient preoperative skin preparations, or surgical hand scrubs are outside the scope of this standard.

It is the intention of the EcoLogo™ Program to restrict the use of EcoLogo™ certified *instant hand antiseptic products* to settings where care is provided, across the continuum of health care and food service. This includes settings where emergency (including pre-hospital) care is provided, as well as in hospitals, complex continuing care facilities, rehabilitation facilities, long-term care homes, outpatient clinics, community health centers and clinics, physician offices, dental offices, offices of health professionals, Public Health and home health care. It also includes the Food Service Industry; all establishments, types of businesses, and services that prepare and serve food away from a patrons' home. This includes full-service, limited-service, non-commercial, and catering operations, but not customer restrooms.

As such, the EcoLogo™ Program proposes to restrict the use of *instant hand antiseptic products* to settings where there is a high workload and high demand for hand hygiene, and where regular hand cleaning with soap and water is not always sufficient. Additionally, Health Care and Food Service are sectors where intervention with an effective hand sanitizing program utilizing instant hand antiseptics, can reduce the spread of infection (PIDAC, 2008). By restricting the scope of the standard, the EcoLogo™ Program considers that *instant hand antiseptic products* are not necessary in the consumer market where access to regular hand cleansing products such as soap and water are readily available and sufficient.

It is the intention of the EcoLogo™ Program to only consider *instant hand antiseptic products* in the physical forms of gels and liquids. Aerosols, sprays, and wipes will therefore not be considered for certification. Although some spray products have been positioned as “greener” due to a relatively simple formulation and purported lower use levels, the actual amount needed to achieve antimicrobial efficacy is no less than with other forms. Sprays have the significant downside of enhancing the exposure of droplet inhalation to the user. Foam products generally do result in less product weight per use, but typically contain more supplemental formulation chemicals beyond the active ingredient. Most wipes employ a synthetic nonwoven substrate which adds unnecessary impacts to the environment.

*Instant hand antiseptic products* are also available in a wide range of packaging and delivery systems but there are three basic categories: fixed-mount with a refillable dispensing system; bottles; and aerosol cans. There are of two types of fixed mount systems; open, refillable (or “bulk”) dispensers, and sealed cartridge systems. Open, refillable systems are contraindicated in many healthcare infection control guidelines,

and are seldom used in healthcare due to issues of contamination. Sealed, refillable dispensing systems are typified by “bag-in-box” systems that employ a fixed-mount dispenser and cartridge refills. Plastic bottles, typically PET, are a common package for hand antiseptics in the consumer market, while small size wearable products are mostly used by hospital staff.

**Question 1: Do you believe that limiting the scope of the standard to Health Care and Food Service is reasonable? Why?**

## 3 Background

### 3.1 North American Market Situation

The non-consumer *instant hand antiseptic products* market can be segmented in various ways, but unlike consumer markets, there is relatively little standardized market data for these segments. However, basic segmentation can be approximated from existing information nonetheless.

By active ingredient, healthcare and food handling markets in the United States, Canada and Europe, are dominated by alcohol-based hand antiseptics, with a share estimated at 96-97%. Quat based antiseptics comprise most of the remaining products at 2-3%, and a few other active ingredients comprise less than 1% of the market. Regulatory, safety, and efficacy requirements dictate this segmentation.

Healthcare markets have a similar pattern with a large majority of ethanol based products. European markets, and to a lesser extent Canada, are somewhat more diverse from a formulation standpoint with some butanol-containing products, several high (>70%) alcohol formulas, and a number of mixed active systems. There is a clear long-term trend in all markets toward ethanol-based formulations due to the aesthetic acceptance by workers.

Detailed segmentation by packaging is difficult to determine. Wall-mounted, sealed cartridge dispensing systems are widespread but the ratio between this type of packaging and bottles varies widely. Aerosol cans are estimated to capture up to 10% of the U.S. healthcare market, but almost nonexistent in food handling. Canada is estimated to experience similar trends to the U.S. market. They could however, have a lower percentage in healthcare than in the United States.

## Laws and Regulations

### In Canada

The regulatory assessment and approval of hand antiseptics are divided between Health Canada's Therapeutic Products Directorate (TPD) and Natural Health Products Directorate (NHPD). The two directorates worked together with industry to harmonize the Antiseptic Skin Cleanser monograph which was published in December 2006. Under this monograph, antiseptic skin cleansers are classified as either natural health products (NHPs) or as a pharmaceutical drug. Alcohol-based instant hand antiseptics are classified as Natural Health Products and are regulated under the jurisdiction of the Natural Health Products Directorate. Antiseptic skin products based upon quaternary ammonium compounds (chloroxylenol, triclosan, triclocarban, and chlorhexidine gluconate) are classified as non-natural based drugs and are regulated under the TPD.

### In the United States

In most cases, regulatory requirements define the primary compositional, performance, marketing and even packaging parameters for *instant hand antiseptic products*. In the United States, *instant hand antiseptic products* fall under the purview of the U.S. Food and Drug Administration and are regulated as pharmaceutical drugs. Hand antiseptics almost exclusively fall under the Over-The-Counter (OTC) Monograph. The latest (U.S. FDA, 1994) OTC Tentative Final Monograph for Healthcare Antiseptics classifies only two active ingredients as Generally Recognized as Safe and Effective (GRASE) for hand antiseptics: alcohol and povidone iodine. Triclosan, triclocarban, benzalkonium chloride, benzethonium chloride, and parachlorometaxyleneol are all potential active ingredients for skin disinfectants, which lack either safety or efficacy data sufficient for GRASE classification as hand antiseptics. No natural products' active ingredients, such as thyme, are listed in the Monograph and thus are precluded from legal use in the United States, unless an approved New Drug Application (NDA) is obtained, of which none have been granted.

An additional regulatory consideration in the U.S. is that hand antiseptics used in foodservice situations must conform to State Food Codes, based upon the FDA Model Code. This means the products must meet FDA requirements for both drugs and indirect food contact.

It is important to emphasize that while the EPA categorizes antimicrobials into four categories: (1) Sterilizers, (2) Disinfectants, (3) Sanitizers, and (4) Antiseptics and Germicides, only the fourth category of antimicrobials relate to *instant hand antiseptic products*. Because antiseptics and germicides are used on living humans, they are considered drugs and are thus approved and regulated by the Food and Drug Administration (FDA). As such, *instant hand antiseptic products* do not sterilize,

disinfect, or sanitize hands according to the EPA definition of these terms (Petru, 2007). Rather, *instant hand antiseptic products*, as defined by the FDA, are an *antiseptic containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination* (U.S. FDA, 1994).

## 3.2 Activities of Other Standards or Eco-Labels

To our knowledge no standard or eco-label exists for this product category.

# 4 Environmental Considerations and Proposed Criteria Statements

In the following section we will propose specific criteria for *instant hand antiseptic products*. Following each proposed criteria statement is a background rationale explaining the motivation, scientific arguments, and other details required to understand the necessity of the proposed criteria statement.

## 4.1 Raw Materials

It is the intention of the EcoLogo™ Program that whenever possible, a product be formulated to substitute renewable for non-renewable resources, recycled materials for virgin resources, or use less intrusive exploration or extraction techniques. Currently, the EcoLogo™ Program has identified two potential areas for leadership within the resource extraction/raw material phase of the life cycle: Bio-Based Content, and Less Intrusive and Recyclable Materials.

### 4.1.1. Bio-Based Content

#### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*

- (a) *Contain at least 73% bio-based content.*

**Question 2: Do you believe that requiring bio-based content is appropriate, and that a threshold of 73% is reasonable? Why?**

**Rationale:**

Preliminary research has revealed that approximately 15% of surveyed brands (n=33) using alcohol as active ingredient were bio-based (n.b. bio-based products determined by label claims) (Table 1). However, the exact amount of the product that is bio-based is unknown since many manufacturers do not disclose this information.

Table 1: Research data showing various alcohol-based (% alcohol is reported in the Active Ingredient column) hand antiseptics and whether they are bio-based or not (biobased).

Manufacturer	Brand	Active Ingredient
1	Brand 1	Isopropyl Alcohol 63%
2	Brand 2	Isopropyl Alcohol 63%
3	Brand 3	Ethyl Alcohol 85%
4	Brand 4	Ethyl Alcohol 72%
5	Brand 5	Ethyl Alcohol 71%
6	Brand 6	Ethyl Alcohol 70% (biobased)
7	Brand 7	Ethyl Alcohol 70%
8	Brand 8	Ethyl Alcohol 70%
9	Brand 9	Ethyl Alcohol 65%
10	Brand 10	Ethyl Alcohol 64%
11	Brand 11	Ethyl Alcohol 62% (biobased)
12	Brand 12	Ethyl Alcohol 62% (biobased)
13	Brand 13	Ethyl Alcohol 62% (biobased)
14	Brand 14	Ethyl Alcohol 62%
15	Brand 15	Ethyl Alcohol 62%
16	Brand 16	Ethyl Alcohol 62%
17	Brand 17	Ethyl Alcohol 62%
18	Brand 18	Ethyl Alcohol 62%
19	Brand 19	Ethyl Alcohol 62%
20	Brand 20	Ethyl Alcohol 62%
21	Brand 21	Ethyl Alcohol 62%
22	Brand 22	Ethyl Alcohol 62%
23	Brand 23	Ethyl Alcohol 62%
24	Brand 24	Ethyl Alcohol 62%
25	Brand 25	Ethyl Alcohol 61%
26	Brand 26	Ethyl Alcohol 60% (biobased)
27	Brand 27	Ethyl Alcohol
28	Brand 28	Ethyl Alcohol
29	Brand 29	Ethyl Alcohol
30	Brand 30	Ethyl Alcohol
31	Brand 31	Ethyl Alcohol
32	Brand 32	Ethyl Alcohol
33	Brand 33	Ethyl Alcohol

The EcoLogo™ Program is also aware that other alcohol-free *instant hand antiseptic products* found in the marketplace claim to be bio-based. Our preliminary research shows the total content of bio-based material in hand cleaners/hand sanitizers ranges anywhere from 21 to 95 percent as defined by ASTM D 6866-04 (Figure 1).

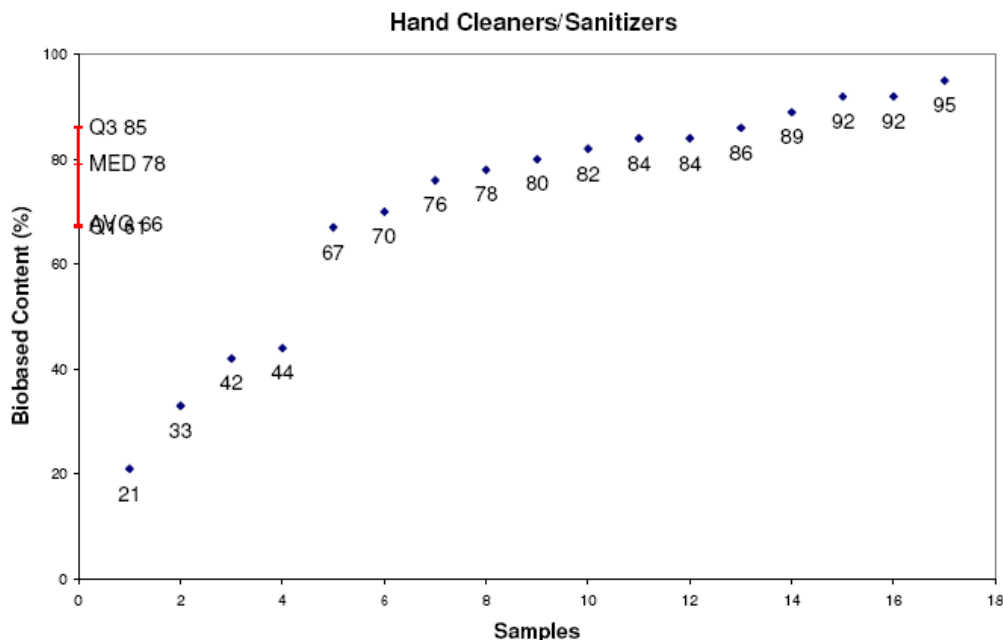


Figure 1: Bio-based content (%) for 17 samples of Hand Cleaners/Sanitizers according to the USDA - BioPreferred<sup>SM</sup> Program (Proposed Item for Biobased Designation. 2006-2007. Federal Biobased Products Preferred Procurement Program (FB4P). USDA - BioPreferred<sup>SM</sup> Program).

## U.S. Bio-based Legislation and Definition

The Farm Security and Rural Investment Act of 2002 (Public Law 107-17), better known as the 2002 U.S. Farm Bill, was signed by President Bush on May 13th, 2002. Section 9002 directs the USDA to create a Designated Bio-based Products List (DBPL) and provide purchasing recommendations to federal agencies. The law requires federal agencies to give procurement preference to USDA-designated bio-based products. It is now mandatory to purchase these products and federal agencies are required to develop affirmative procurement programs to purchase these products.

The term 'bio-based product' as defined by the Farm Security and Rural Investment Act of 2002, means a *product determined by the U.S. Secretary of Agriculture to be a commercial or industrial product, that is composed in whole or in significant part, of biological products or renewable domestic agricultural materials (including plant, animal, and marine materials) or forestry materials.* Bio-based products are produced from renewable natural resources and are generally more environmentally sensitive than petroleum-based products.

The EcoLogo<sup>TM</sup> Program has identified that the current market is capable of offering bio-based *instant hand antiseptic products*, for both alcohol-based and alcohol-free formulations. Until a comprehensive data base can be assembled for hand antiseptics, the EcoLogo<sup>TM</sup> Program proposes to use the *Minimum Bio-based Content* specified by

the BioPreferred<sup>SM</sup> program of the USDA for Hand Cleaners and Sanitizers - Hand Sanitizers (USDA - BioPreferred<sup>SM</sup> Program).

#### 4.1.2. *Less Intrusive and Recyclable Materials*

##### Proposed Criteria Statement

EcoLogo<sup>TM</sup> proposes to include in the *Product Specific Requirements* the following statement:

*For small size wearable products;*

*To be authorized to carry the EcoLogo<sup>TM</sup>, instant hand antiseptic products' refill cartridges must:*

- (b) Not be manufactured with PVC*
- (c) Be made of recyclable materials*

*To be authorized to carry the EcoLogo<sup>TM</sup>, instant hand antiseptic products' holsters must:*

- (d) Contain at least X % post-consumer recycled content.*

*For bag-in-box products;*

*To be authorized to carry the EcoLogo<sup>TM</sup>, instant hand antiseptic products' pouches or bags must:*

- (e) Not be manufactured with PVC*
- (f) Be made of recyclable materials*

*To be authorized to carry the EcoLogo<sup>TM</sup>, instant hand antiseptic products' rigid outer display box must:*

- (g) Contain at least X % post-consumer recycled content*

**Question 3: Do you agree that the EcoLogo<sup>TM</sup> Program should only certify "small size wearable" and "bag-in-box" products? Why?**

**Question 4: For "small size wearable" products, what do you believe the percentage of post-consumer recycled content should be? Why?**

**Question 5: For "bag-in-box" products, what do you believe the percentage of post-consumer recycled content should be? Why?**

## Rationale:

### Post-Consumer Recycled Content & Recyclable Materials

*Instant hand antiseptic products* are considered an OTC drug regulated by the United States Food and Drug Administration (FDA). In the instance of OTC products, the FDA prohibits the use of post-consumer recycled materials in primary packaging. The FDA Guidance for Industry Document, *Container Closure Systems for Packaging Human Drugs and Biologics* states: "Post-consumer recycled plastic should not be used in the manufacture of a primary packaging component. If used for a secondary or associated component, then the safety and compatibility of the material for its intended use should be addressed appropriately" (U.S. FDA, 1999). There are no FDA constraints regarding the use of recyclable materials such as PET or HDPE, in primary packaging. Secondary packaging is necessary for structural integrity or when primary packaging is not conducive to distribution. There are no restrictions on the use of recyclable materials or materials containing post-consumer content in secondary packaging. However, the strength and durability of secondary packaging should be considered when using post-consumer recycled materials.

### Small size wearable products

Larger volume dispensing systems allow for more use from a single package, thereby reducing waste. However, it is important to recognize the value of point-of-care products in compliance markets such as Health Care and Food Service. Small size wearable products are necessary for convenience in patient, food and customer contact. Wearable products typically come with holster, refill cartridges and accessories such as a lanyard and carabiner to help attach the product. The EcoLogo™ Program shall only consider packaging criteria for the holder and refill cartridges.

### Bag-in-Box Packaging

Traditional bag-in-box (BIB) products include an outer display box around a flexible pouch. Historically, standards have allowed for BIB products as long as the instructions guided the user to separate the display box from the pouch prior to loading the dispenser. Separating the components before use increased the likelihood the display box would be recycled.

### Bottles

Plastic bottles, typically PET, are a common package for *instant hand antiseptic products* in the consumer market. The EcoLogo™ Program considers small size wearable products and bag-in-box dispensing systems to be sufficient for both Health Care and Food Service; therefore small sizes bottles will not be accepted.

## PVC

Polyvinyl chloride (PVC) has been scrutinized for Health and Safety issues during production and disposal, and reputable organizations such as the U.S. Green Building Council have recognized its' potential to impact human health. Alternative materials are available, and in agreement with numerous organizations such as the Center for Health, Environment and Justice (CHEJ), the use of PVC in packaging will be prohibited.

## 4.2 Prohibited and Restricted Substances

### 4.2.1. Active Ingredients

#### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*

- (h) *have active antimicrobial ingredients that are listed in the FDA Tentative Topical Antimicrobial Drug Products for OTC Human use; Tentative Final Monograph for Healthcare Antiseptic Drug Products (Federal Register, Vol. 59, No. 116, Friday, June 17, 1994) that have been placed in Category I: GRASE (generally recognized as safe and effective).*

**Question 6: Do you agree that the EcoLogo™ Program should only certify products that have active ingredients in the GRASE Category-1? Why?**

#### Rationale

On September 13, 1974, the FDA published an advance notice of proposed rulemaking in the Federal Register (FR) to establish a monograph for over-the-counter (OTC) topical antimicrobial drug products. The notice incorporated the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial Drug Products (Antimicrobial I Panel). This panel was responsible for evaluating data on the active ingredients in this drug class. The panel prepared a report to the Commissioner of the FDA classifying OTC drug products into three categories: 1) Category I: generally regarded as safe and effective (GRASE) for the claimed therapeutic indication; 2) Category II: not GRASE or having unacceptable indications; and 3) Category III: insufficient data available to permit final classification. On June 17, 1994, the FDA published a notice of proposed rulemaking in the form of an amended Tentative Final Monograph that would establish conditions under which OTC topical healthcare antiseptics are GRASE and not misbranded.

OTC drugs are defined as GRASE for their intended use provided they are not misbranded, nor marketed using false or misleading statements. A manufacturer desiring to market a monographed (therapeutic classes of ingredients that are GRASE) drug need not seek clearance from the FDA prior to marketing. In this case, marketing is not exclusive and all data and information supporting GRASE status are publicly available. Monographs mainly address active ingredients in the product, and in most cases, final formulations are not subject to monograph specifications. Manufacturers are free to include any inactive ingredients that serve a pharmaceutical purpose, provided those ingredients are considered safe, and do not interfere with product effectiveness or required final product testing. In some instances even though the product may contain GRASE ingredients, the final formulation may need to meet a monograph testing procedure. An example would be the antiseptic drug products that are for healthcare personnel hand wash, surgical hand scrub, and patient preoperative skin preparation. These are required to meet in vivo and in vitro efficacy testing requirements to ensure that their formulated products are effective as an antiseptic. Inactive ingredients and emollients, when included in the products, may inhibit the antiseptic action, therefore testing must be performed to show effectiveness. Because the drugs in the monograph system are GRASE, there has been no requirement to report adverse events.

#### 4.2.2. Inactive Ingredients

##### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*

- (i) *Have components that are exempt from the requirements of being listed in the U.S. federal food additive regulations as specified in 21 CFR 170.39 threshold of regulation for substances used in food-contact articles OR;*

*Comply with and be listed in:*

- *21 CFR 178 - Indirect Food Additives: Adjuvants: Production Aids, and Sanitizers as regulated for use as a food additive with conditions of safe use, OR,*
- *21 CFR 182 Substances Generally Recognized as Safe, 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with food.*

To be authorized to carry the EcoLogo™, instant hand antiseptic products must:

- (j) Not be formulated or manufactured with phosphates, endocrine disruptors, and heavy metals.

To be authorized to carry the EcoLogo™, instant hand antiseptic products must:

- (k) Not be formulated with fragrances.

**Question 7: Do you agree with the product specific requirements for inactive ingredients? Why?**

**Rationale:**

Because the EcoLogo Program™ proposed to include Food Service, all ingredients, including emollients and perfumes that are constituents of *instant hand antiseptic products* used must comply with Title 21, the portion of the Code of Federal Regulations that governs food and drugs within the United States for the Food and Drug Administration.

Typical alcohol-based *instant hand antiseptic* formulations are relatively simple products, consisting mostly of water, alcohol, and low levels of other ingredients to improve aesthetics and skin compatibility. Similarly, non-alcohol formulations consist primarily of water and low levels of other ingredients. *Instant hand antiseptic products* generally do not contain chemicals of high environmental concern such as phosphates, endocrine disruptors, and heavy metals, however the EcoLogo™ Program intends to add requirements to assure users that they are free of any of these types of chemicals.

Many products are fragranced to counterbalance the odor of the active ingredients. However, the EcoLogo Program™ is aware that several “greener” *instant hand antiseptic products* claim to be fragrance-free. Because it is the intent of the EcoLogo Program™ to reduce the environmental footprint of products, and because fragrances are not absolutely necessary, and because some public places such as hospitals are adopting “fragrance-free” policies (<http://www.nontoxic.com/nontoxic/fragrancefree.html>), fragrances will not be allowed.

### 4.3 Health Hazards

The following are examples of the typical types of impacts often included in EcoLogo™ standards:

- Human toxicity
- Skin and eye irritation
- Respiratory sensitization

## Proposed Criteria Statement

EcoLogo™ **does not propose** to establish additional criteria regarding health hazards.

### Rationale:

The EcoLogo™ Program assumes the major health hazards have been covered in the Prohibited and Restricted Substances.

## 4.4 Environmental Hazards

The following are examples of typical types of impacts often included in EcoLogo™ standards:

- Biodegradability/compostability
- Aquatic toxicity (acute/chronic)
- Atmospheric pollution

### 4.4.1. Biodegradability

#### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*

- (I) *not be not be formulated or manufactured with classes of active ingredients that are not readily biodegradable*

**Question 8: Do you agree that *instant hand antiseptic products should be readily biodegradable? Why?***

### Rationale

The EcoLogo™ Program is currently uncertain if requiring active ingredients to be readily biodegradable is technically feasible and/or realistic. The main reason being that ***instant hand antiseptic products*** are designed to kill bacteria, even those involved in the biodegradation process. We also believe that inactive ingredients should not pose a threat to the environment because they must be listed in the federal food additive regulations, and therefore be biodegradable.

#### 4.4.2. VOC

##### Proposed Criteria Statement

EcoLogo™ **does not propose** to establish additional criteria regarding volatile organic compounds.

##### Rationale

Recently, the California Air Resources Board (CARB) committed to develop a measure for VOCs to be implemented by 2008 and 2010, that would achieve additional VOC emission reductions from consumer products from the already regulated categories and VOC level standards. In the July 19, 2006 VOC Consumer Products Regulatory Amendments, CARB proposed a new regulatory category: Personal Sanitizers with a proposed VOC limit of 1%.

This CARB proposal to limit the VOC content to 1% would eliminate the use of alcohol in no rinse antiseptic hand washes. However, based on strong testimony and evidence, the California Air Resources Board removed instant hand sanitizers from the proposed amendments to the VOC Consumer Products Regulations. By eliminating the use of alcohol as a drug active, CARB would force companies to turn to alternative actives which have not been found by the FDA to be generally safe and effective. This would place companies at a significantly high enforcement risk as well as severely limit public access to these important public health products. CARB also recognized that the effect of this proposal would have a significant impact on public health, and place the California public and its' workforce including healthcare workers, emergency first-aid responders, disaster relief workers, hospitality workers, and food handlers at a significant disadvantage. They would become more vulnerable to the transmission of germs which can lead to infection and disease, as well as limit their preparedness to address emerging pandemics.

The EcoLogo™ Program is not proposing to regulate VOCs since the requirement would preclude the certification of? alcohol-based *instant hand antiseptic products* which have been strongly recommended as a safe and effective product from most respected public health organizations and agencies worldwide as a key point in hand hygiene compliance to protect public health.

#### 4.5 Energy and Water

The following are examples of typical types of impacts often included in EcoLogo™ standards:

- Renewable energy/RECs/carbon offsets
- Energy reduction/conservation/Energy Star
- Water reduction/conservation

Preliminary research has failed to find relevant data to validate whether Energy and Water conservation are critical aspects of leadership in manufacturing *instant hand antiseptic products*. In other words, it is unclear if the manufacturers of *instant hand antiseptic products* are currently buying RECs and/or carbon offsets, or using technology to reduce energy and water consumption. Without data, the EcoLogo™ Program does not intend to propose such requirements in the standard.

**Question 9: Do you believe that in order to distinguish environmental leadership, the EcoLogo™ Program should establish strict requirements for energy and/or water consumption at the manufacturing site of the product? Why and what criteria statements do you think would be reasonable to establish?**

## 4.6 Performance and Safety Requirements

### 4.6.1. Performance

#### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*

- (m) Meet the Human Dermatology, Efficacy, and Compatibility performance tests outlined in Table 2.

**Question 10: Do you believe the EcoLogo™ Program should establish strict requirements regarding product performance or that manufacturers should be responsible for meeting industry standards and government regulations? If you believe that EcoLogo™ should establish requirements, do you think the proposed performance tests in Table 2 are sufficient and adequate?**

#### Rationale:

*Instant hand antiseptic products* are very effective antimicrobial products. They are required to be rapidly biocidal and broad spectrum in activity, yet safe when used very frequently (up to dozens of times a day). This requirement for frequent usage makes product aesthetics unusually important because they can directly influence use patterns. An unattractive product will have reduced usage which is contrary to the intended infection control purpose of the products. Thus, key technical performance considerations are antimicrobial efficacy, skin safety and aesthetics; somewhat contradictory objectives that make the fine points of formulation very important.

Since hand antiseptics are drug products, the antimicrobial performance requirements are specified by regulations. In the United States, hand antiseptics are required to demonstrate broad spectrum *in-vitro* activity and meet *in-vivo* antimicrobial performance criteria as specified in the FDA Tentative Monograph. The *in-vivo* performance test is a modification of ASTM E1174, and requires that products reduce transient contamination by 99% (2 log<sub>10</sub>) after one product application, and by 99.9% (3 log<sub>10</sub>) after ten contamination/wash cycles. A number of comments from leading infection control practitioners have been submitted to the FDA docket strongly questioning the logic of the tenth wash requirement. Further, it is current practice in the industry to test products by the actual ASTM method because of multiple, problematic issues with the FDA method, which can lead to an underestimation of product efficacy. This issue was addressed, but not resolved, at an FDA Nonprescription Drug Advisory Committee meeting in March 2005. The eventual Final Monograph(s) for Skin Antiseptics will likely incorporate E1174 as the required *in-vivo* test method, although the exact performance criteria (log reduction) are unclear. Also, the FDA has announced their intent to publish a notice of proposed rule making (NPRM) for testing methods. In view of this situation, it would be premature to establish the current *in-vivo* TFM test method and performance criteria as a basic requirement for a hand antiseptic. A more realistic approach might be a threshold performance of 2 log reduction after one application using ASTM E1174.

In Canada, antiseptic skin cleanser products are required to pass antimicrobial testing which is determined based on the product claims to be made. Compendial products (products which conform to the Monograph for Antiseptic Skin Cleansers) must be attested to meet the minimum requirements of the Compendium of Monographs. Products with composition or claims outside of the Monograph are considered Non-Compendial, and must conform to the *in-vitro* and *in-vivo* requirements of the Draft Guidelines for Antiseptic Hand and Skin Disinfectants, which are closely aligned with European Norms.

Additional performance requirements for hand antiseptics may be set by markets and users. In healthcare settings, hand antiseptics are generally required to show compatibility with latex and chlorhexidine gluconate. Standard tests are available for this determination.

Below is a table of commonly conducted testing, and the acceptance criteria for superior product performance.

Table 2: Human Dermatology, Efficacy, and Compatibility tests for instant hand antiseptic products.

Type of testing	Test Name	Reference	Purpose	Proposed acceptance criteria
Human Dermatology	21 day cumulative irritancy with challenge	Phillips et al. (Toxic and Applied Pharmacology 21:369-382)	Evaluation of skin irritation potential in humans.	Mild and low potential for sensitization

Human dermatology	Repeat Insult Patch Testing (RIPT)	Shelanski and Shelanski. (Toilet Goods Association 19:46-49, 1953.)	Determination of the dermal irritation and sensitization potential of the product.	Low potential for sensitization
Efficacy	Time kill or EN 1040 Bactericidal activity and EN 1275 Fungicidal and Yeasticidal	ASTM E2315 EN 1040 EN 1275	Evaluate the antimicrobial effectiveness of the product in vitro.	At least a 3 log kill versus the TFM specified organisms
Efficacy	Hygienic Handrub	EN 1500	Evaluate the antimicrobial effectiveness of the product in vivo.	Statistically equivalent or superior performance when compared to 2-propanol
Efficacy	Healthcare Personnel Handwash	ASTM E1174	Evaluate the antimicrobial effectiveness of the product in vivo.	2 log reduction in bacteria from baseline at Wash 1, 3 log reduction in bacteria from baseline at Wash 10
Compatibility	Glove compatibility: latex, vinyl, nitrile	ASTM D5151-99 following immersion in product	Confirm product will not affect the integrity of gloves	Meets FDA criteria for medical exam gloves
Compatibility	Chlorhexidine gluconate	Industry standard: modified surgical scrub test method	Assess the compatibility of the test article with a known Chlorhexidine Gluconate (CHG)	No impact to CHG activity

## 4.7 Labelling Requirements and Conditions for EcoLogo™ Use

### 4.7.1. Product Information on Label

#### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, Instant hand antiseptic products must:*

- (n) *Comply with the U.S. Food and Drugs Act as well as the Canadian Food and Drug Regulations and Natural Health Products Regulations, whenever applicable.*

#### Rationale:

In the United States, regulatory requirements define the primary compositional, performance, marketing, and even packaging parameters for hand antiseptics. In the United States, *Instant hand antiseptic products* fall under the purview of the U.S. Food and Drug Administration and are regulated as drugs. Hand antiseptics almost exclusively fall under the Over-The-Counter Monograph. An additional regulatory consideration in the United States is that *Instant hand antiseptic products* used in foodservice situations must conform to State Food Codes, based upon the FDA Model Code. This means the products must meet FDA requirements for both drugs and indirect food contact.

In Canada, *instant hand antiseptic products* are also regulated as drugs and are subject to the Food and Drugs Act and Regulations. Hand antiseptics are classified as either *non-pharmaceutical drug products* or *natural health products*, depending upon the active ingredient. Both drugs and natural health products must meet established criteria for efficacy and safety, and are required to undergo premarket review and approval by Health Canada prior to going to market.

Sufficient information necessary to support the labelled claim of an antiseptic product for human use should be made available to Health Canada.

This information should include (PWGSC, 2008):

- Evidence of positive supportive results of *in vivo* and *in vitro* testing conducted in accordance with acceptable test methods, and for *in vivo* studies, under the conditions of use prescribed on the label and;
- Evidence regarding the safety of the drug when there is no evidence available that the topically-applied medicinal ingredients are not systemically absorbed to a significant degree.

Finally, as per the Canadian *Food and Drugs Act*, any substance that is used for the “mitigation or prevention of disease” is a drug. Section 9(1) of the *Act* also specifies that a drug must not be labelled “...in a manner that is false, misleading or deceptive or is likely to create an erroneous impression...”

#### 4.7.2. Environmental Claims Labelling

##### Proposed Criteria Statement

EcoLogo™ proposes to include in the *Product Specific Requirements* the following statement:

*To be authorized to carry the EcoLogo™, instant hand antiseptic products must:*

- (o) *Meet all FTC and CSA regulations relating to environmental claims made on labels.*

##### Rationale

This requirement is to assure that EcoLogo™ products avoid greenwashing claims.

## 5 References

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U.S. Food and Drug Administration, 2005, 21 CFR 170.39 - Threshold of regulation for substances used in food-contact articles. Code of Federal Regulations - Title 21: Food and Drugs (December 2005): <http://cfr.vlex.com/vid/170-39-threshold-used-contact-articles-19707678>

USDA - BioPreferred<sup>SM</sup> Program (web site): <http://www.biopreferred.gov/Default.aspx>

## 6 Interpretation

**"Bag in box"** means a flexible bag held inside a rigid outside container (box) that is not removed prior to use of the bag;

**"Endocrine disruptor"** means an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations. Candidate endocrine disruptors are listed in Appendix 1 of *Towards the Establishment of a Priority List of Substances for Further Evaluation of Their Role in Endocrine Disruption* prepared for the European Union.

**"Fragrance Free"** means that there have been no fragrances added to the product, and no masking agent has been added in order to hide the scents from the other ingredients in the product.

**"GRASE"** is a term used to describe nonprescription drug products that are generally recognized as safe and effective.

**"Primary packaging"** means the material physically coming into contact with and containing the product.

**“Recyclable package”** means the package can be diverted from the waste stream through available processes and programs, and can be collected, processed, and returned to use in the form of raw materials or products.

**“Readily biodegradable”** means that an organic substance will be degraded into smaller molecular components by way of microbial metabolism. A substance can be defined as “ready biodegradable” if more than 60% or 70% biodegradability (depending on test method) is achieved within the 10- or 14-day window in any of the six test methods described in Organization for Economic Co-operation and Development (OECD) Guidelines for Testing of Chemicals, 301A-301F.

**“Secondary packaging”** means any packaging material other than primary packaging, including wrappers, boxes, and blister packs, but excluding shipping containers.

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ASTM E 1174-06 Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations.

European Standard DIN EN 1040 (March 2006) Test Objective: To determine basic bactericidal activity of test product

European Standard DIN EN 1275 (March 2006) Test Objective: To determine yeasticidal activity of test product.

EN 1275 Chemical disinfectants and antiseptics. Basic fungicidal activity. Test method and requirements (phase 1)

EN 1500 Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2)

Phillips et al (Toxic and Applied Pharmacology 21:369- 382) summarizes the method utilized for this evaluation. 21 Day Cumulative Irritancy Assay with Delayed Challenge

## 7 Additional Questions

Question 11: EcoLogo™ standards are established so that the top 20-30 percent of products or services within a specific category can achieve certification. Do you believe there is enough separation in the product category of *instant hand antiseptic products* to rationalize the existence of an environmental leadership standard such as EcoLogo™? Why?

Question 12: Do you believe this Discussion Document has addressed the main important aspects that are necessary to establishing an environmental leadership standard for *instant hand antiseptic products*?

\* Please feel free to comment on any aspects that were not addressed by the specific questions.