



EcoLogo™

Environmental Standard - Certification Criteria Document

Draft: CCD-170

Instant Hand Antiseptic Products

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First published

next scheduled review

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Certification Criteria Document 170 is proposed for use of the EcoLogo™ in association with Instant Hand Antiseptic Products.

This final draft incorporates the latest modifications to the standard following feedback from a public comment period that occurred from September 18th to October 26th, 2009 and subsequent follow-up research. Stakeholder comments, EcoLogo responses and course of action can be found in the EcoLogo Comment Report at <http://www.terrachoice-certified.com/en/criteria/revision/>

It is important to mention that while every effort has been made to acknowledge and act upon all comments provided by stakeholders, the Program must uphold its premier mandate; balance all stakeholder views while establishing an environmental leadership standard, which is roughly defined as the top 20 percent of products/services available in the market at the time of the development or revision of a standard with the lowest environmental impacts across all stages of the life cycle.

This proposed standard is meant to be the last draft before making the standard final. The EcoLogo Program is making the draft standard available for a 15 day comment period in order to give stakeholders a chance to provide final comments. Upon receipt of the comments the EcoLogo Program will determine if any modifications are needed, and will thereafter make the standard available for product certification. The final standard will be available at no cost on the EcoLogo website.

Final comments on all of the proposed criteria are welcome, and due by February 2, 2010.

Please forward all comments directly to:

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** The deadline for public comment on this final draft standard is Tuesday, February 2nd, 2010 **

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Introduction

The EcoLogo™ Program is designed to support a continuing effort to improve and/or maintain environmental quality by reducing energy and materials consumption and by minimizing the impacts of pollution generated by the production, use and disposal of goods and services.

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 antiseptic product refers to an antiseptic containing preparation designed for frequent application without a water rinse and which reduces the number of microorganisms on intact skin. Moreover, instant hand antiseptic products can be further defined as antiseptic containing drug products applied topically to skin to prevent infection, or to help prevent cross contamination. Disinfectant soaps, hand sanitizing products that require rinsing, patient preoperative skin preparations, surgical hand scrubs, and aerosols or wipes are beyond 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 the “away from home market” which encompasses healthcare and food service facilities, in addition to all other instances away from a personal residence. More specifically, 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 and dental offices, in addition to health professionals, public health and home health care offices. With regard to the application in the food service industry, instant hand antiseptic products designed for use in establishments, businesses, and services that prepare and serve food away from a patrons’ home will be eligible for certification. Products designed for use in schools, offices, daycare services, and all other locations besides the consumer home market are also eligible.

Based on a review of currently available life cycle information, the product category requirements will produce an environmental benefit through a substitution for less intrusive raw materials, a reduction of environmental hazards, and an increase of product recyclability. Life cycle review is an ongoing process. As information and technology change, the product category requirements will be reviewed and possibly amended.

Notice

Any reference to a standard means to the latest edition of that standard.

The EcoLogo Program reserves the right to accept equivalent test data for the test methods specified in this document.

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Interpretation

1. In this standard:

“asthmagens” means substances designated as asthma causing agents by the Association of Occupational and Environmental Clinics;

“away from home market” means 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. Schools, offices, daycare services, and all other locations besides the consumer home market will be accepted;

“bisphenol A” is an organic compound with two phenol functional groups such as, inter alia, 2,2-(4,4'-dihydroxydiphenyl)propane, 4,4'-isopropylidenediphenol, or 2,2'-bis(4-hydroxyphenyl)propane;

“biobased” means commercial or industrial goods (other than food or feed) composed in whole or in significant part of biological products, forestry materials, or renewable domestic agricultural materials, including plant, animal, or marine materials;

“EN 1500” means the standard called “Chemical disinfectants and antiseptics—hygienic handrub—test method and requirements (phase2/step2): 1997”;

“EN 13727” means the standard called “Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 1): 2003”;

“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;

“post-consumer” means material that has served its end-use at the consumer level, has been discarded by the consumer, and unless diverted, would enter the waste stream;

“primary packaging” means the material physically coming into contact with and containing the product; also includes those materials which ensure product integrity, safety, regulatory compliance (on-package labels, e.g.) and prevent illicit tampering;

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"PVC" means polyvinyl chloride, an industrial plastic derived from the polymerization of vinyl chloride, also known as chloroethene (CH₂CHCl);

"**quaternary ammonium compound**" or "quat" means an active ingredient used in disinfectants, that chemically is an organic nitrogen compound in which a central nitrogen atom is joined to four organic cations and one anionic acid radical. Such compounds include, inter alia, alkyl dimethyl benzyl ammonium chloride and didecyldimethylammonium chloride, benzalkonium chloride, benzethonium chloride, methylbenzethonium chloride;

"**recyclable material**" means material that 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**" for a component, is determined using any of the six test methods described in OECD Guidelines for Testing of Chemicals, 301A-301F; for a whole formulation, is determined using one of the methods described in OECD Guidelines for the Testing of Chemicals, provided that all measurements and calculations are based on the carbon content of the mixture and its degradation, i.e. dissolved organic carbon (DOC) removal (301A or 301E), CO₂ evolution (301-B) or oxygen consumption in the presence of an inhibitor of nitrogen metabolism (301C, 301D or 301F);

"**sealed refill products**" are products used in a sealed cartridge system. The sealed refill cartridges are individual pouches or bottles with their own dispensing pump that are sealed at manufacture. The sealed refill products are inserted into a dispensing unit — either wall-mounted or counter-mounted — and replaced when empty. Open refill systems, also referred to as bulk refill, are not accepted in the standard since they can lead to product contamination. "Bag-in-a-box" systems are also excluded from the standard since they necessitate an excessive corrugated packaging to encapsulate the cartridge;

"**secondary packaging**" means any packaging material other than primary packaging, including wrappers, boxes, and blister packs, but excluding shipping packaging;

"**shipping packaging**" means any packaging material, such as corrugated containers, required to ensure product integrity during shipping, but excluding the pallet and pallet load wrapping.

Category Definition

2. This category includes only instant hand antiseptic products designed for the "away from home market".



General Requirements

3. To be authorized to carry the EcoLogo, instant hand antiseptic products must:
 - a) meet or exceed all applicable governmental and industrial safety and performance standards; and
 - b) be manufactured and transported in such a manner that all steps of the process, including the disposal of waste products arising therefrom, will meet the requirements of all applicable governmental acts, bylaws and regulations.

Product Specific Requirements

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

Raw Materials

- a) be formulated or manufactured such that at least 73% of the total weight of the carbon in the product formula be biobased as demonstrated by ASTM D6866-08, OR demonstrate compliance with the USDA BioPreferred Program;
- b) for bottle products:
 - i. be sold in bottles of at least 8oz (236ml) in size,
 - ii. not be formulated or manufactured with PVC or Bisphenol A,
 - iii. the primary packaging be made of recyclable materials,
 - iv. not be packaged in secondary packaging, and
 - v. contain at least 20 % post-consumer recycled content in the shipping packaging;
- c) for sealed refill products:
 - i. not be formulated or manufactured with PVC, or Bisphenol A,
 - ii. the primary packaging be made of recyclable materials,
 - iii. not be packaged in secondary packaging,
 - iv. contain at least 20 % post-consumer recycled content in the shipping packaging, and
- d) not be sold in aerosol formats, sprays, or wipes;

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Prohibited and Restricted Substances

- e) not be formulated or manufactured with:
 - i. quaternary ammonium compounds
 - ii. chlorhexidine and chlorhexidine gluconate,
 - iii. chloroxylenol,
 - iv. flurosalan,
 - v. hexachlorophene,
 - vi. phenol,
 - vii. tribromosalan,
 - viii. triclocarban, or
 - ix. triclosan;
- f) not be formulated or manufactured with known asthmagens, endocrine disruptors or heavy metals;
- g) not be formulated or manufactured with fragrances or dyes;
- h) not be formulated or manufactured with fluorinated octanoic acid-based surfactants;
- i) products containing 5% or more alcohol must contain an ingredient (denaturant) to deter ingestion; the denaturant used shall be an appropriate denaturant listed with U.S or Canadian regulations, or have safety/toxicology data available to substantiate its safe use.

Environmental Hazards

- j) be manufactured or formulated such that all organic ingredients must be readily biodegradable OR the whole formulation be readily biodegradable;

Performance and Safety Requirements

- k) demonstrate a 2 log reduction in viable counts within 30 sec. according to EN 1500 *in-vivo* test against a single indicator organism, E. coli (K 12 NCTC 10538); **and**
- l) demonstrate a 2 log reduction in viable counts within 30 sec. according to EN 13727 *in-vitro* test on *Serratia marcescens* (ATCC 14756), *Escherichia coli* (K 12 NCTC 10538), *Staphylococcus aureus* (ATCC 6538), *Staphylococcus Epidermidis* (ATCC 14990).

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Labelling Requirements

- m) meet the labelling requirements of the U.S. Food and Drugs Act OR Health Canada OR the Canadian Food Inspection Agency;

Verification

- 5. To verify a claim that a product meets the criteria listed in the document, the EcoLogo Program will require access, as is its normal practice, to relevant quality control and production records and the right of access to production facilities on an announced basis.
- 6. Compliance with section 3(b) shall be attested to by a signed statement of the Chief Executive Officer or the equivalent officer of the manufacturer. The EcoLogo Program shall be advised in writing immediately by the licensee of any non-compliance which may occur during the term of the license. On the occurrence of any non-compliance, the license may be suspended or terminated as stipulated in the license agreement.

Conditions for EcoLogo Use

- 7. The EcoLogo mark may appear on wholesale or retail packaging, or on the product itself, provided that the product meets the requirements in this guideline.
- 8. A criteria statement must appear with the EcoLogo whenever it is used in association with instant hand antiseptic products. The intent of this statement is to provide clarification as to why the product was certified and to indicate constraints to which the certification is limited. This is to ensure no ambiguity over, or misrepresentation of, the reason(s) for certification.

The suggested criteria statement wording for this product type is "Certified Instant Hand Antiseptic CCD-170." The licensee may propose other wording for the criteria statement, but any such proposed wording must be approved by the EcoLogo Program.

- 9. All licensees and authorized users must comply with the U.S. Federal Trade Commission's *Guides for the Use of Environmental Marketing Claims*, the Canadian Competition Bureau's *Environmental Claims: A Guide for Industry and Advertisers*, and the EcoLogo Program's *Guide to Proper Use of the EcoLogo™* regarding the format and usage of the EcoLogo.

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10. Any accompanying advertising must conform with the relevant requirements stipulated in this guideline, the license agreement, the U.S. Federal Trade Commission's *Guides for the Use of Environmental Marketing Claims*, the Canadian Competition Bureau's *Environmental Claims: A Guide for Industry and Advertisers*, and the EcoLogo Program's *Guide to Proper Use of the EcoLogo™* regarding the format and usage of the EcoLogo™.

For additional copies of this standard, or for more information about the EcoLogo Program, please contact:

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