Environmental Certification Services

Biodegradable Certification Standard

Version 4.0 November 03, 2011

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AMENDMENT HISTORY		
Date	**Issue**	**Brief Summary of Amendments**
1/14/05	01	Development Draft Released
03/18/08	02	Updated Draft Released
10/21/11	03	Updated Draft Released

PREFACE

This Environmental Certification Program was developed by Scientific Certification Systems (SCS) as part of its ongoing efforts to evaluate the environmental performance of products and services using established and/or advanced scientific principles, practices, materials, and standards. As such, the requirements and information herein are subject to change.

Concerns about the health of the earth's rivers, lakes, and oceans has generated enormous interest in cleaning products which biodegrade in water. However, the claim *biodegradable* has been used to mean different things by different companies, leading to consumer confusion.

To help overcome this confusion, and ensure that products making the biodegradable claim meet consumer expectations, Scientific Certification Systems (SCS) has developed a special certification standard for liquid soaps, detergents, degreasers, and cleansers.

This standard is designed to verify that products degrade efficiently under worst-case circumstances and that chemicals are not entering the environment at such a rate that they reach harmful concentrations before degradation can occur.

In conducting an evaluation, SCS conducts a thorough literature search for each ingredient in the product's formulation to determine the rate at which a product's ingredients break down into carbon dioxide, minerals, and water under aerobic conditions. However, laboratory test results may be requested for some products. SCS also reviews scientific literature, chemical manufacturers' data, and independent laboratory test results to determine whether the product has low toxicity to aquatic life and whether it can result in eutrophication (stimulation of algae growth) as additional requirements for this certification. SCS does not certify products that contain phosphates because of potential contribution to eutrophication of rivers, ponds, and other receiving waters.

This certification is in conformance with ISO Type I (14024) and Type II (14021) environmental labeling and declaration requirements.

This certification is to be used to engender confidence in the various stakeholders (manufacturers, suppliers, regulators, and consumers) that products labeled with the SCS mark consistently meet all requirements established in this standard.

Environmental Services Certification Program
Biodegradable Certification Standard

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1.0 Purpose, Structure, and Intended Uses

1.1. Purpose

This Biodegradable Certification Standard (hereafter referred to as the Standard) describes the requirements for third-party substantiation of biodegradability claims asserted by companies regarding liquid cleaning products.

This Standard allows a company:

(1) To demonstrate that the product or products assessed by SCS meet the technical requirements for a biodegradable liquid cleaner;
(2) To make claims about its product that conform to the Federal Trade Commission (FTC) Guides for the Use of Environmental Claims, and
(3) To make a self-declared environmental claim under section 7.3 of ISO 14021:1999.

1.2. Structure of the Standard

This Standard provides:

(1) Requirements for determining whether a product is biodegradable, displays aquatic toxicity, and contributes to eutrophication;
(2) Guidelines for vendors of ingredients to this product; and
(3) Marketing requirements that are applicable to all certified products.

Requirements for biodegradability certification include: a detailed ingredient review; product testing when appropriate; a documented quality control system; and compliance of a certified product with internationally accepted biodegradability criteria.

1.3. Intended Users

Intended users of this Standard are manufacturers of liquid cleaning or related products seeking third-party certification of conformance to the requirements of this Standard, as well as individuals, businesses, organizations, agencies, or consumers interested in conducting business with companies whose products meet the requirements of this Standard. This Standard also provides guidelines for vendors of ingredients to these products.

1.4. Voluntary Standard

This Standard is voluntary. It is not intended to replace any legal or regulatory requirements that may be applicable to user operations.

2.0 Scope, Goals and Limitations

2.1. Scope

This Standard applies to any liquid material belonging to a product category generally used with the intention to clean. This includes cleaners, degreasers, detergents, and soaps.

The term “shall” is used throughout the Standard to indicate mandatory requirements. The term “should” is used throughout the Standard to indicate preferred requirements.

2.2. Goals

2.2.1. The major goals of this Standard are:

(1) To provide a uniform standard by which to assess liquid products for biodegradability for manufacturers making Type II environmental claims (self-declared environmental claims as defined by ISO 14021:1999); and
(2) To promote confidence in the marketplace that SCS certified facilities or programs consistently meet the requirements of this Standard [and its normative references].

2.3. Limitations

2.3.1. This Standard does not purport to address all of the safety, health, comfort (e.g. odor) and performance concerns, if any, associated with its use. It is the responsibility of the user of this Standard to establish appropriate safety, health, and other performance conditions — and to determine the applicability of federal, state, or local environmental and other regulatory requirements. Users shall note that compliance with the requirements of this Standard is no guarantee of regulatory compliance.

2.3.2. The basic biodegradability requirement in this Standard considers the rate at which products break down. However, it does not consider the way the product is used. No assumption of actual biodegradability of certified products should be made for all potential uses of a product.

2.3.3. This Standard does not address environmental attributes of the packaging of the product being reviewed.

2.3.4. The Standard does not address any environmental benefits, compromises, or tradeoffs that may be associated with all life-cycle phases of the product.

3.0 Terminology

Specific terms and definitions are provided below.

Accredited Laboratory. Any laboratory that carries a certification recognized through the International Laboratory Accreditation Cooperation (ILAC). ILAC promotes laboratories that "demonstrate competence, impartiality, and capability". This type of certification is based on criteria established through ISO/IEC 17025, used for evaluating laboratories throughout the world.

ASTM International. Originally known as the American Society for Testing and Materials, ASTM International is one of the largest voluntary standards development organizations in the world.

Biodegradation. The breakdown of a substance by biological activity, especially by microorganisms, into smaller compounds. The microbial organisms transform the contaminants through metabolic or enzymatic processes. Biodegradation processes vary greatly, but the final product of *aerobic* degradation usually is carbon dioxide, water and minerals (salts). Other gases (e.g., N_2 or H_2S) may also result.

CAS number. Generated by the American Chemical Society, which indexes and compiles abstracts of worldwide chemical literature, the Chemical Abstracts Service Number is a number that uniquely identifies a chemical compound, element, mixture, or alloy.

Certification Assessment. An independent evaluation of a product claim using specific predetermined criteria and procedures with assurance of data reliability.

Certified Product. A finished product authorized to apply the SCS Certification Mark, as evidence that the product complies with the relevant certification program. *Note that certified products are listed on the Certified Products list issued by SCS. This list can be found on the SCS web site at http://www.scscertified.com/products.*

Chain of Custody. The path that a product takes from its point of production to the end consumer, consisting of records of each entity that takes legal and/or physical possession along this pathway.

Claim. Oral, written, implied, or symbolic representation, statement, or advertising or other form of communication presented to the public or buyers of products that asserts a verified attribute of a product.

Cleaner. A formulated product designed to assist in removing undesirable matter—often from, but not limited to, a surface.

Ingredient. Any component or additive of a product intentionally added or not, including any impurities. Synonymous with component, constituent, or additive.

EC_{50}. The Median Effective Concentration required of a compound to induce a response halfway between the baseline and maximum after some specified exposure time.

Eutrophication. The process by which an increase in chemical nutrients (compounds containing nitrogen or phosphorous) promotes a proliferation of plant life (especially algae) in a lake, pond, or stream. This plant life reduces the dissolved oxygen content and can cause the extinction of other organisms.

IC_{50}. The Median Inhibition Concentration is a concentration at which biochemical and biological functions are inhibited by 50%.

Literature Review. A literature review is the process of surveying current documents and publications on a particular topic or subject of interest, and is undertaken for determining a variety of characteristics for each ingredient in a product, or the product itself. Manufacturer statements, MSDS, peer-reviewed scholarly publications, lab reports, and government databases are primary sources of information for this review.

Manufacturer. An organization or individual responsible for the production of the product undergoing certification assessment. In some cases this may be a contractor that actually produces the product for the company undergoing the certification process.

MSDS. Material Safety Data Sheet. This is a form containing data regarding the properties of a particular substance, and may provide information on a variety of topics, including physical data; chemical properties; hazard information; health effects; toxicity; ecological information; first aid; stability and reactivity; handling, storage, and disposal of chemicals; first aid; protective equipment; spills and leak procedures; and may provide information on biodegradability.

DfE. The U.S. EPA's Design for the Environment program which aims to help consumers, businesses, and institutional buyers identify cleaning and other products that perform well, are cost-effective, and are safer for the environment.

OECD. The Organization for Economic Co-operation and Development is an international economic organization of 30 countries based in Paris. It defines itself “as a forum of countries committed to democracy and the market economy, providing a setting to compare policy experiences, seek answers to common problems, identify good practices, and co-ordinate domestic and international policies.”

OPPT. EPA’s Office of Pollution Prevention and Toxics manages program under the Toxic Substances Control Act (TSCA) and the Pollution Prevention Act (PPA).

Products of Concern. Byproducts of degradation with high acute aquatic toxicity ($L/E/IC_{50} \leq 10ppm$) and a slow rate of biodegradation (greater than 28 days).

Quality Assurance Plan. A plan that sets out documented procedures that are established, implemented, and periodically audited to assure that production, handling, management, certification, and other quality practices of the Manufacturer ensure consistent compliance with the requirements of this Standard.

Ready Biodegradability. A classification of biodegradability made by the OECD describing the degradation of an organic substance under aerobic conditions to carbon dioxide (CO_2), water (H_2O), and minerals by aerobic bacteria as determined by the measured change of Dissolved Organic Carbon (DOC), Biological Oxygen Demand (BOD), or CO_2 evolution over time in one of six different test methods, 301A-301F. A passing substance has to reach either a 60% BOD or theoretical CO_2 evolution, or 70% decrease in DOC, depending on test method, all of which use a 10 day window within a maximum 28-day test period for a successful determination. For this Standard, SCS accepts these specified tests or equivalent methodologies, for example ASTM 1720 E, and OECD 310.

Records. Any information in written, visual, or electronic form that documents the activities undertaken by, and/or use of components in assessed products by, manufacturers to demonstrate conformance with this Standard.

Salts. Ionic compounds composed of both positively charged ions (cations) and negative ions (anions) so that the product is electrically neutral.

Specified Testing Procedures. Recognized testing protocols for biodegradability that can be expected to be followed by any accredited laboratory personnel. The acceptable test methods for Ready Biodegradability by this Standard include the following:

- OECD Test Guideline 301A: DOC Die-Away
- OECD Test Guideline 301B: CO_2 Evolution
- OECD Test Guideline 301C: Modified MITI (I)
- OECD Test Guideline 301D: Closed Bottle
- OECD Test Guideline 301E: Modified OECD Screen
- OECD Test Guideline 301F: Manometric Respirometery
- OECD Test Guideline 310: CO2 in sealed vessels (Headspace Test)
- ASTM 1720 E

Alternate test methods for Ready Biodegradability include the following:
OPPTS 835.3110 – Ready Biodegradability
OPPTS 835.3140 – Ready Biodegradability – CO2 in Sealed Vessels (Headspace Test); an alternate to Test Guideline 301B-CO2 Evolution

Standard. When capitalized, refers to this Standard (Biodegradable Certification Standard).

Supplier. Organization that supplies a material, product, or service to the manufacturer. Synonymous with vendor.

Surfactants. Also know as surface active agents, are organic compounds that contain both water soluble and non water soluble groups (oil soluble) and used primarily in the cleaning products to reduce the surface tension of a liquid.

Third Party. A person or body that is recognized as being independent of the parties involved, as concerns the issue in question.

Toxicity. The ability of a substance to cause poisonous effects resulting in severe biological harm or death after exposure to, or contamination with, that substance. The following definitions are related to the issue of toxicity:

Acute Toxicity. An adverse effect produced from a single or short-term exposure (up to 96 hours). Exposure can take any one or more routes (e.g., oral, dermal). Acute toxicity is measured using statistical procedures (e.g. point estimate techniques or a t-test). The LD_{50} of a substance (the lethal dose at which 50 percent of test animals succumb to the toxicity of the chemicals) or LC_{50} can be typically used as a measure of acute toxicity.

Aquatic Toxicity. The adverse effects of marine life that result from being exposed to a toxic substance.

Ecotoxicity. The potential for biological, chemical, or physical stressors to affect fish, wildlife, plants and other wild organisms.

LC_{50}. The Median Lethal Concentration, which is the published concentration of a substance required to kill half the members of a sample population of aquatic organisms. This measure is generally used as a general indicator of a substance's acute toxicity when exposure to a chemical is through inhalation.

LD_{50}. The Median Lethal Dose, which is the estimated dose of a substance required to kill half the members of a sample population. LD_{50} figures are frequently used as a general indicator of a substance's acute toxicity when exposure to a chemical is through oral or dermal means, or by injection.

Ultimate Biodegradability. Similar to Ready Biodegradability, except that the biodegradation to water, CO_2 and minerals does not have to happen within the 10 day window specified for Ready Biodegradability, but still must adhere to the limits of biodegradability within the 28-day testing window. All products certified by SCS for Biodegradability must meet Ready Biodegradability requirements.

4.0 Referenced Documents

4.1. Normative References

The following normative documents contain provisions that, through reference in this text, constitute provisions of this Standard.

1. ISO 14021:1999, “Environmental labels and declarations – Self-declared environmental claims (Type II environmental labeling)” (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=23146)

2. ISO 14024:1999, “Environmental labels and declarations – Type I environmental labeling – Principles and procedures” (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=23145)

3. ISO 14020:2000, “Environmental labels and declarations – General principle.” (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=34425)

4.2. Additional References

1. Federal Trade Commission (FTC) Guides for the Use of Environmental Marketing Claims (http://www.ftc.gov/bcp/grnrule/guides980427.htm)

2. ISO 9001:2008, “Quality management systems – Requirements” (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=46486)

3. ISO 14001:2004, “Environmental management systems – Requirements with guidance for use” (http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=31807)

4. DfE’s Standard and Criteria for Safer Chemical Ingredients (http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm)

5.0 Requirements for Manufacturers

This section describes general conformance requirements for manufacturers.

5.1. General Conditions

5.1.1. Traceability

The manufacturer shall employ auditable traceability practices to ensure that all ingredients of products sold or distributed as conforming to this Standard can be tracked through the manufacturing process of said products.

5.2. Technical Requirements

5.2.1. Product Formulation

The manufacturer shall make available to SCS the complete detailed description of product formulation—which includes the common name, brand name, and/or chemical name of each ingredient in the product formulation, including the CAS number for each ingredient when available.

5.2.2. Literature Review

The manufacturer shall submit documentation for each ingredient in the product being assessed that definitively indicates that each ingredient demonstrates Ready Biodegradability as outlined in OECD methods 301A-F, ASTM 1720 E, OECD method 310, or equivalent. The primary sources of data shall be from MSDS, laboratory reports, government databases, and peer reviewed literary scientific articles.

5.2.3. Further Requirements for Achieving Biodegradability Certification

The applicant shall demonstrate, to a high degree of certainty based on current knowledge established through submittal of documentation or the Literature Review (5.2.2), that the product components or their degradation products do not contribute to:

5.2.3.1 Eutrophication

No product ingredient shall have been found to contribute to the eutrophication of receiving waters. No product that contains phosphates shall be certified.

5.2.3.2 Toxicity to Aquatic Life

No product ingredients[1] shall show aquatic toxicity. A product ingredient is considered not toxic to aquatic life if it meets the criteria of acute LC_{50} for algae, daphnia, or fish equal to or greater than 100 mg/L.

Appropriate methods to determine aquatic toxicity include ISO 7346.2 for fish and 40 CFR 797 Subpart B for other aquatic organisms, OECD test guidance

[1] see 5.2.3.2.1 for exception

203 for fish, OECD test guidance 201 for algae, and OECD test guidance 202 for daphnia.

5.2.3.2.1. Aquatic Toxicity of Surfactants

Surfactant components may demonstrate an aquatic toxicity <100 mg/L in exceptional circumstances

a) The manufacturer can reasonably demonstrate that no suitable substitute exists for the surfactant used.

b) The surfactant component represents no greater than 1% of the dry weight of the finished product mixture.

c) The aquatic toxicity of the surfactants component meets the following criteria modified from the EPA's design for the Environment (DfE) Program:

Table 1. Toxicity Values and Rates of Degradation for Surfactants

Acute Aquatic Toxicity ($L/E/IC_{50}$ Value)	Rate of Biodegradation	Acceptable Component?
≤1 ppm	n/a	No
>1 ppm and ≤10 ppm	Ready Biodegradability without Products of Concern	Yes
>10 ppm	Ready Biodegradability	Yes

Products of concern are byproducts of degradation with high acute aquatic toxicity ($L/E/IC_{50}$ ≤ 10ppm) and a slow rate of biodegradation (greater than 28 days). Products of concern shall be determined and tested by an approved lab in order to meet compliance with this requirement.

5.2.4. Testing

If Ready Biodegradability or aquatic toxicity cannot be easily determined from the information submitted by the manufacturer or client, it is at the discretion of the auditor to require that the full product under assessment be tested for Ready Biodegradability or aquatic toxicity by an accredited laboratory, using appropriate test methods as listed in sections 5.2.2 and 5.2.3.1., respectively.

5.2.5. On-site Audit Requirements

If document review is deemed insufficient to certify the product then a site audit may be recommended based on the auditor's discretion.

5.3. Requirements for Management

5.3.1. Quality Assurance Plan

The manufacturer shall have a Quality Assurance Plan containing the following components:

a) Quality Policy
b) Listing of current suppliers and material supplied

c) Product identification and traceability program. The manufacturer shall have a documented procedure to ensure that a finished SCS certified product is traceable to:
    i. Relevant batch information, including production dates and lot sizes and;
    ii. Batch inspection or test reports on those processes and materials which may affect compliance of the product with this program.

   The extent to which the manufacturer can demonstrate traceability must be clearly documented.
d) Control program for nonconforming product. The manufacturer shall establish and maintain documented procedures to ensure that any product that does not conform to the requirements of this Standard is prevented from unauthorized labeling with the SCS certification mark or otherwise sold as certified product. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.
e) Corrective and Preventative Action. The manufacturer shall establish and maintain documented procedures for implementing corrective and preventive action including:
    i. The effective handling of customer complaints and reports of product nonconformities;
    ii. Investigation of the cause of nonconformities relating to product, process and quality system, and recording the results of the investigation;
    iii. Determination of the corrective action needed to eliminate the cause of nonconformities; and,
    iv. Application of controls to ensure that corrective action is taken and that it is effective.

5.3.2. Record Keeping

The manufacturer or facility operator shall establish and maintain record-keeping procedures to provide evidence of conformity with this Standard's requirements. The user shall keep, at a minimum, records of all suppliers providing ingredients, and of all purchased materials used in production of the product(s) under review. The manufacturer or operator shall ensure that records are retained for a minimum of five years and are auditable.

5.3.3. Staff

The program or facility operator shall establish set responsibilities for personnel who conduct operations affecting the implementation of this Standard's requirements, including training procedures for manufacturing and record keeping.

6.0 Certification and Continued Conformance

6.1. Certification of Achievement

Once a product qualifies for certification based on conformance with this Standard, an SCS Biodegradable certificate of achievement is issued. Certificates are valid for one year, provided that the manufacturer maintains conformance with the requirements. By issuing a certificate of achievement, SCS demonstrates that it is satisfied that the manufacturer is capable of consistently producing a product complying with the requirements of this Standard. The manufacturer, by applying the SCS Certification Mark to a product, warrants that the product meets all relevant requirements of this Standard.

6.2. Continued Conformance

An annual renewal audit to demonstrate continued conformance with this Standard is required if the manufacturer or certificate holder wishes to continue making a certified claim.

7.0 Marketing Requirements

7.1. Geographic Requirements

All uses of the SCS Certification Certificate or references to the certification in advertising and marketing shall be conducted in conformance with U.S. Federal Trade Commission guidelines, or other national guidelines if outside of the U.S. Allowing the SCS Certification Mark to remain on non-conforming products offered for sale could invite prosecution under U.S. Trademark statues or attract other penalty provisions in other U.S. or State law.

7.2. SCS Requirements

The manufacturer shall comply with the requirements of the *SCS Certification, Validation and Verification Program Labeling and Language Guidelines* at all times.[21]

8.0 Complaints, Appeals and Disputes

All complaints, appeals and disputes are handled in accordance with the *SCS Complaint, Appeals and Disputes Procedure*.[32]

[2] Provided as a supplement to the SCS Assessment Services Agreement. This document is also available on the SCS website at: www.scscertified.com and upon request.
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