



August 23, 2007

Dear Stakeholder,

Green Seal's GS-37, Environmental Standard for Industrial and Institutional Cleaners, is in the process of being updated. The primary is to bring the standard up to-date and to more adequately represent current technology and science and to advance the protection feasible for sensitive populations.

The revised criterion will aim to represent leadership levels in the product category. A separate claim verification program, with additional criteria, may prove to be needed for vulnerable populations if such requirements necessitate levels beyond the scope for leadership products.

The development of the revision has involved several preliminary steps to involve stakeholders. The first was a scoping phase, to get input on the areas to consider for the research and development of the standard. These comments were used by the Standard Development Team, with input from the Stakeholders Committee, and advice from additional experts to begin researching the revision. The scoping comments were carefully considered and represented the framework for the research. A summary of the scoping comments is available on the Green Seal web site. The progress of this research has been compiled into a Discussion Document.

Please find attached the Discussion Document for Stakeholder Review of GS-37 Revision Progress. This document represents the current status of each individual criterion under review or development. The discussion document contains topics included in the current GS-37 criteria and additional areas suggested from the scoping comments, along with a discussion of issues related to each topic and the potential language for the revision under consideration. Relevant references and definitions and potential impact on the certification cost or marketplace are also included, where known. However, many of the topics require feedback on market feasibility. This not only will aid in the development of the revisions to the standard to ensure its leadership level, but will also help determine if and what areas might need to be included in a separate claim verification program for vulnerable populations. For criteria still under development, the issues under consideration have been presented as a primer for discussion and comment.

The document for review by stakeholders and represents an important point for your involvement and input. Because this is not a formal proposal or a planned balloting cycle, the review period will by necessity be limited. To formally participate, please review the attached Discussion Document and submit your comments by **Thursday, September 14, 2007**. Comments must be submitted electronically in MS Word format using the comment form attached to this e-mail. Completed comment forms should be sent by e-mail to GS37@utk.edu. Only comments submitted electronically using this form by the established date will be considered.

Each of the comments, as submitted, will be shared with the Standard Development Team and the Registered Stakeholders to aid the development of the proposed revisions of the standard. A summary of comments will be compiled and made available on the Green Seal website. While written responses to each comment will not necessarily be made, each comment will be considered carefully and a commenter may be contacted about their comments by the Standard Development Team or the Stakeholders Committee.

Thanks in advance for your participation in this important process. Please contact Jack Geibig, jgeibig@utk.edu, if you have any questions or comments.



Discussion Document for Stakeholder Review of GS-37 Revision Progress

Green SealTM Environmental Standard
for
General Purpose, Bathroom, Glass, and Carpet Cleaners
Used for Industrial and Institutional Purposes

August 23, 2007

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Introduction

Green Seal's GS-37, Environmental Standard for Industrial and Institutional Cleaners, is in the process of being updated. This document represents the current status of each individual criterion under review or development. The discussion document contains topics included in the current GS-37 criteria and additional areas suggested from the scoping comments, along with a discussion of issues related to each topic and the potential language for the revision under consideration. Relevant references and definitions and potential impact on the certification cost or marketplace are also included, where known. While all items need careful review and comment, many of the topics require specific feedback, especially on market feasibility. This not only will aid in the development of the revisions to the standard to ensure its leadership level, but will also help determine if and what areas might need to be included in a separate claim verification program for vulnerable populations. For criteria still under development, the issues under consideration have been presented as a primer for discussion and comment.

Please review this Discussion Document and submit your comments by **Friday, September 14, 2007**. Comments must be submitted electronically using the comment form provided in MS Word format, and sent by e-mail to GS37@utk.edu.

Scope

Current Standard Language

This standard establishes environmental requirements for industrial and institutional general-purpose, bathroom, glass, and carpet cleaners. For purposes of this standard, general-purpose, bathroom, glass, and carpet cleaners are defined as those cleaners intended for routine cleaning of offices, institutions, warehouses, and industrial facilities. The standard does not focus on the use of cleaners in households, food preparation operations, or medical facilities.

Due to the large number of possible cleaning products, processes, soil types, and cleaning requirements, the compatibility of cleaners with surface materials is not specifically addressed in this standard. Product users should follow the manufacturers' instructions on compatibility.

Each criterion states whether it applies to the undiluted product or to the product as used.

Discussion of Issues

The scope will be modified to be consistent with the criteria within the standard once the language for individual criteria have been finalized. For example, the scope will need to be expanded to include schools.

Definitions

This section includes definitions included in the standard currently and potential new definitions.

Asthmagen. An asthmagen is defined by the Association of Occupational and Environmental Clinics as a chemical that has been *documented in peer reviewed literature* to have met at least one of two major criteria, or two of four minor criteria. With the Major criteria (1 of 2): 1. Specific inhalation challenge test positive; 2. Workplace challenge with physiologic response (spirometry or peak flow) shows reversible expiratory airflow obstruction. The minor criteria (2 of 4): 1. Non-specific airways hyperreactivity demonstrated in patients while employed. 2. Exposure related reversible wheeze heard. 3. Positive specific IgE in 2 or more patients. 4. Remission / recurrence with stop-resume work test.

Bathroom cleaners. This category includes products used to clean hard surfaces in a restroom or bathroom such as counters, walls, floors, fixtures, basins, tubs, and tile. It includes products that are required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), such as disinfectants and sanitizers, but does not include products specifically intended to clean toilet bowls.

Carcinogen. A chemical listed as a known, probable, or possible human carcinogen by the International Agency for Research on Cancer (IARC) (Groups 1, 2A, and 2B), the National Toxicology Program (NTP) (Groups 1 and 2), the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) (weight-of-evidence classifications A, B1, B2, and C), or the Occupational Safety and Health Administration (OSHA).

Carpet cleaners. This category includes products used for routine cleaning of carpets and rugs. This category may include, but is not limited to, products used in cleaning by means of extraction, shampooing, dry foam, bonnet or absorbent compound. It does not include products intended primarily for spot removal. This category does not include any products required to be registered under FIFRA, such as those making claims as sterilizers, disinfectants, or sanitizers

Concentrate. This is a product that must be diluted by at least eight parts by volume water (1:8 dilution ratio) prior to its intended use.

Dispensing-system concentrates. These are products that are designed to be used in dispensing systems that cannot be practically accessed by users.

General-purpose cleaners. This category includes products used for routine cleaning of hard surfaces including impervious flooring such as concrete or tile. It does not include cleaners intended primarily for the removal of rust, mineral deposits, or odors. It does not include products intended primarily to strip, polish, or wax floors, and it does not include cleaners intended primarily for cleaning toilet bowls, dishes, laundry, glass, carpets, upholstery, wood, or polished surfaces. This category does not include any products required to be registered

under FIFRA, such as those making claims as sterilizers, disinfectants, or sanitizers.

Glass cleaners. This category includes products used to clean windows, glass, and mirrored surfaces. This category does not include any products required to be registered under FIFRA, such as those making claims as sterilizers, disinfectants, or sanitizers.

Ingredient. Any constituent of a product that is intentionally added or known to be a reaction product, contaminant that comprises at least 0.01% by weight of the product.

Intentional Introduction: The act of deliberately utilizing a restricted material in the formation of a packaging or packaging component where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality.

Mutagen. A chemical that meets the criteria for category 1, chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans, under the Harmonized System for the Classification Of Chemicals Which Cause Mutations in Germ Cells (United Nations Economic Commission for Europe, *Globally Harmonized System of Classification and Labeling of Chemicals (GHS)*. First Edition 2003).

Optical brighteners. Fluorescent whitening agents added to enhance the appearance of colors and whiteness in materials by absorbing ultraviolet radiation and emitting blue radiation. .

Ozone-depleting compounds. Any compound with an ozone-depletion potential greater than 0.01 (CFC 11 = 1).

Postconsumer Material. Material that would otherwise be destined for solid waste disposal, having completed its intended end-use and product life cycle. Postconsumer material does not include materials and by-products generated from, and commonly reused within, an original manufacturing and fabrication process.

Product as used. This is the most concentrated form of the product that the manufacturer recommends for a product's intended use. For health and environmental criteria we look at the most concentrated form, but *not* for performance. With the addition of chamber testing, some standardization of dilution levels and applications may be needed (because products often have a range of dilutions for different applications, e.g., light soil, heavy-duty cleaning, daily mopping, etc.), For example, if a manufacturer recommends a product be diluted 1:64 or 2:64 for use as a general-purpose cleaner, the product shall meet the environmental and performance requirements at a dilution of 2:64

Primary packaging. This packaging is the material physically containing and coming into contact with the product, not including the cap or lid of a bottle.

Recyclable package. This 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.

Recycled. This is a product or material which has been diverted from disposal in a landfill and has been reused in the production of another product.

Refillable Package. This is a rigid plastic packaging container which is routinely returned to and refilled by the product manufacturer at least five times with the original product held by the package. For the purpose of this program, the product manufacturer or the product manufacturer's agent may refill a package.

Reproductive Toxin. A chemical listed as a reproductive toxin (including developmental toxins, and female and male reproductive toxins) by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, et. Seq.).

Respiratory Irritant. A respiratory irritant is defined by the Organisation for Economic Cooperation and Development as R37, “substances and preparations which cause serious irritation to the respiratory tract in humans, or result in positive results from appropriate animal tests.”

Reusable Package. This is a rigid plastic packaging container which is routinely reused by consumers at least five times to store the original product contained by the package.

Serious eye damage. Serious eye damage is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Skin Absorption. The ability of a chemical to be transmitted across the skin into the body with the potential to produce systemic health effects away from the site of application.

Skin corrosion. Skin corrosion is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions.

Undiluted product. This is the most concentrated form of the product produced by the manufacturer for transport outside its facility. Note: Some manufacturers make an ultra-concentrate, sell it to a private-label manufacturer who dilutes it further for sale.

Product-Specific Performance Requirements

Current Standard Language

Each product *as used* when diluted with water from the cold tap at no more than 50 ° F, shall clean common soils and surfaces in its category effectively, as measured by a standard test method. Carpet cleaners may be diluted with warm or hot water where required by the test method or performance considerations. Green Seal recommends the following test methods:

General-purpose cleaners. The product shall remove at least 80% of the particulate soil in the American Society for Testing and Materials (ASTM) D4488-95, A5.

Bathroom cleaners. The product shall remove at least 75% of the soil in ASTM D5343 as measured by ASTM D5343.

Carpet cleaners. Using a standard test method, the manufacturer must demonstrate that its product performs as well as a nationally recognized product in its category in both cleaning efficiency and resoiling resistance. Acceptable test methods/procedures to demonstrate performance include, but are not limited to, the following sources: the American Association of Textile Chemists and Colorists (AATCC), ASTM, the Institute of Inspection, Cleaning and Restoration Certification (IICRC), the International Organization for Standardization (ISO), WoolSafe, the Carpet and Rug Institute (CRI) or laboratory testing conducted as part of a bid evaluation by a government purchasing entity.

Glass cleaners. The product shall achieve at least a rating of three in each of the following Consumer Specialty Products Association (CSPA) DCC 09 categories: soil removal, smearing, and streaking.

Using standard test methods, a manufacturer can also demonstrate that its product performs as well as a nationally recognized product in its category or achieves the removal efficiency defined in this section.

Discussion of Issues

The performance of a cleaning product is an important metric particularly for environmental-based cleaners. Currently, products can be certified either by a successful demonstration of cleaning under one of a series of cleaning test methods, or alternatively can demonstrate comparable cleaning performance to any other product currently sold on the market.

The certification through comparable performance clause was added to provide a mechanism for assessing the performance of products whose intended use was not covered adequately by an existing performance standard. However, the exception has the potential for abuse, allowing a manufacturer to select a marginally performing product to justify acceptable performance of their product. It is desirable to remove this exception in favor of a broader menu of acceptable performance tests to level the playing field and to maintain a threshold of acceptable performance. Other performance standards are

currently being reviewed to cover the other identified uses and applications of products covered under this standard.

On a conference call held to discuss performance issues, there was much discussion about the 50 F temperature requirement for water during lab testing. Specifically, a change in language was proposed to eliminate the temperature requirement in favor of language specifying that “unheated” water be used in the testing. After consideration, it is proposed that the temperature requirement remain for the laboratory testing to provide a controlled temperature during testing and to promote uniformity and repeatability in test conditions. However, it is agreed that water used to dilute a cleaner during actual use (as opposed to testing) directly from the cold tap, not heated or chilled to a specific temperature. Language clarifying what is meant by “cold water” will be discussed under the labeling requirements appearing in that section.

Potential Revised Language:

Each product *as used* when diluted with water from the cold tap at no more than 50 °F, shall clean common soils and surfaces in its category effectively, as measured by a standard test method. Carpet cleaners may be diluted with warm or hot water where required by the test method or performance considerations. Green Seal recommends the following test methods:

Bathroom cleaners. The product shall remove at least 75% of the soil in ASTM D5343-06 as measured by ASTM D5343-06.

Carpet cleaners. Using a standard test method, the manufacturer must demonstrate that its product performs as well as a nationally recognized product in its category in both cleaning efficiency and resoiling resistance. Acceptable test methods/procedures to demonstrate performance include, but are not limited to, the following sources: the American Association of Textile Chemists and Colorists (AATCC), ASTM, the Institute of Inspection, Cleaning and Restoration Certification (IICRC), the International Organization for Standardization (ISO), WoolSafe, the Carpet and Rug Institute (CRI) or laboratory testing conducted as part of a bid evaluation by a government purchasing entity.

Glass cleaners. The product shall achieve at least a rating of three in each of the following Consumer Specialty Products Association (CSPA) DCC 09 categories: soil removal, smearing, and streaking.

General-purpose cleaners. The product shall remove at least 80% of the particulate soil in the American Society for Testing and Materials (ASTM) D4488-95, A5.

References

ASTM D5343-06: Standard Guide for Evaluating Cleaning Performance of Ceramic Tile Cleaners. 2006.

ASTM D4488-95: Standard Guide for Testing Cleaning Performance of Products Intended for Use on Resilient Flooring and Washable Walls. 1995

Consumer Specialty Products Association (CSPA) DCC-09: Glass Cleaners.
<http://www.cspa.org/>

Toxic Compounds

Current Standard Language

The *undiluted* product shall not be toxic to humans. Dispensing-system concentrates shall be tested as used. A product is considered toxic if any of the following criteria apply:

Oral lethal dose 50 (LD_{50}) $\leq 2,000$ mg/kg

Inhalation lethal concentration (LC_{50}) ≤ 20 mg/L*

* If the vapor-phase concentration of the product at room temperature is less than 20 mg/L, it should be tested at its saturation concentration. If it is not toxic at this concentration, it passes the inhalation criterion.

Toxicity shall be measured on the product as a whole. Alternatively, a mixture need not be tested if existing toxicity information demonstrates that each of the ingredients complies. Ingredients that are nonvolatile do not require inhalation toxicity testing (Appendix A). It is assumed that the toxicity of the individual component compounds are weighted and summed and that there are not synergistic effects (Appendix A).

The toxicity testing procedures should meet the requirements put forth by the Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals. These protocols include Acute Oral Toxicity Test (TG 401), Acute Inhalation Toxicity Test (TG 403), and Acute Dermal Toxicity Test (TG 402).

Discussion of Issues

The proposed revised toxicity criteria have been split into three sections according to the routes of exposure. The rationale for the proposed approach is described below.

Oral Toxicity

The current criteria of Oral $LD_{50} \leq 2,000$ mg/kg was established a few years ago. The criterion is under evaluation to determine if the threshold should be raised to increasingly protect human health and to account for the capability of current formulations in the marketplace. Current standards such as the Environmental Choice CCD-146 standard requires an Oral $LD_{50} \leq 4,000$ mg/kg for bathroom cleaners, an Oral $LD_{50} \leq 5,000$ mg/kg for products designed for sensitive populations, and an Oral $LD_{50} \leq 10,000$ mg/kg for glass cleaners. Other standards have followed this trend. The proposed new threshold

of 4,000 mg/kg or greater, while still under evaluation, would at a minimum bring the standard in line with other similar standards for oral toxicity measured using the OECD toxicity test for mammals (TG 420, 423, or 425).

Inhalation Toxicity

While the details of the testing approach are still being actively discussed and considered, the basics of the overall approach are becoming increasingly clear. In principle, the testing approach would follow certain principles regarding indoor air and testing.

Green Seal's standard (GS-37), along with other green cleaning standards, have attempted to minimize the impact of cleaning products on indoor air and the associated health risks to building occupants, including school age children.

Nonetheless, studies measuring VOCs in schools, home and workplaces often implicate cleaning products as potential sources of the chemicals detected in the air (Rumchev, *et. al.*, 2004; Shendell, *et. al.*, 2004; Franke, *et. al.*, 1997; Cole and Foarde, 1992). Some epidemiological studies have suggested an association between cleaning chemicals and respiratory ailments (Declos, *et. al.*, 2006; Medina-Ramon, *et. al.*, 2003). These studies continue to raise questions about the impact of cleaning products on indoor air quality and respiratory health.

The proposed approach is intended to address the airborne impact of cleaning products. Testing to determine exposures to chemicals is based on ASTM D 5116 – 06. *Standard Guide for Small Scale Environmental Chamber Determination of Volatile Organic Emissions from Indoor Materials / Products*. To every extent possible, testing methodologies should be developed for use in small chambers to limit costs.

The referenced exposure limits values (e.g. cRELS) may not include the full range of ingredient chemicals for the variety of formulations for this product category either for those currently GS-37 certified or on the market. To expand the list to include more ingredients, additionally relevant lists may be used in GS-37 if an adequate uncertainty factor is applied. One relevant list in particular is the list of RD 50 limits¹. There is an ASTM test method used to determine chemical RD 50 levels, ASTM E981 that could be required as part of the GS 37 criteria for formulations that have ingredients that have no maximum acceptable limit assigned to them by any other list.

Because of the unique nature of the chemicals used in cleaning products, it is important to measure impact of both short-term and long-term exposure to product application and compare exposures to generally accepted health risk assessment criteria. Measurement of total volatile organic compounds (TVOCs) is additionally measured, even though there

¹ <http://www.yvesalarie.com/rd50valuessince1993.htm>

may not be specific health risk criteria associated with some of these chemicals. There are many VOCs seen in products that do not have specific risk assessment levels (e.g., Chronic Reference Exposure Limits). Therefore, measuring TVOCs serves as a safety net for the myriad potential chemicals that might be emitted. For this reason, domestic (e.g., Carpet & Rug Institute's Green Label / Green Label Plus, GREENGUARD) and international (Canada's Environmental Choice, Germany's Blue Angel and AgBB) programs measuring emissions include various TVOC measures.

ASHRAE is the most widely accepted ventilation standards in the US and provides the appropriate basis to measure the impact of cleaning products on indoor air. While using the most recent ASHRAE guidelines is appropriate, some studies indicate that older buildings, including schools, may not comply with current ASHRAE guidelines for ventilation. As a consequence, it might be appropriate to include a safety factor in any model using ventilation to reflect the diverse age and condition of schools.

Due to the manner in which chemicals are released from cleaning products and the diverse methods of supplying and distributing product, products should be measured as applied per manufacturers' recommended use. For product categories, this should be standardized to limit variability.

Dermal Toxicity

The development of dermal toxicity criteria is still under consideration. However, the standard has acted to limit the risk to populations resulting from dermal exposure through the development of criteria for skin sensitization and skin irritation criteria, skin absorption criteria, and through the oral and inhalation toxicity criteria. These criteria are likely to adequately account for most of the expected exposures to cleaning chemicals making additional criteria for dermal toxicity redundant.

General Comments

The effects on the market and on certification cost have not been fully developed yet. The cost of small chamber testing is estimated at just over \$1,000/day making the cost of testing a product for this criteria more roughly \$2,000. If this cost is determined to be unfeasible, what are the best alternative recommendations to address these health and environmental issues?

Potential Revised Language:

Oral Toxicity

The *undiluted* product shall not be toxic to humans when ingested. A product is considered toxic if the following criterion applies:

Oral lethal dose 50 (LD_{50}) $\leq 4,000$ mg/kg

Toxicity shall be measured on the product as a whole. The toxicity testing procedures should meet the requirements put forth by the Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals Acute Oral Toxicity Test (TG 420, 423, or 425).

Alternatively, a mixture need not be tested if existing toxicity information demonstrates that each of the ingredients complies. It is assumed that the toxicity of the individual component compounds are weighted and summed and that there are not synergistic effects (Appendix A).

Inhalation Toxicity

The product *as used* shall not be toxic to humans when inhaled. When tested using the Small Chamber Emissions Test Method (Attachment B), a product is considered toxic if any of the following criteria are exceeded:

	Short-Term (Acute)	Long-Term (Chronic)
TVOC (mg/m ³) ¹	≤5.0	≤0.22
Formaldehyde (ppm) ²	≤0.040	≤0.013
Carcinogens ³	NA	Less Than the CA Prop 65 NSRL and the EPA IUR
Chronic Noncancer Toxins ⁴	NA	Less Than the ATSDR MRL, the CA CREL, and the EPA RfC
Acute Noncancer Toxins ⁵	Less Than the ATSDR MRL and the CA AREL	NA
Developmental/Reproductive Toxins ⁶	Less Than the CA Prop 65 MADL, the ATSDR MRL, and the CA AREL	NA
Other Individual VOCs	Less Than the ACGIH STEL/C (or Less Than 1/10 TLV if no STEL/C)	Less Than 1/100 ACGIH TLV and Less Than ½ CA CREL

NA = Not Applicable

¹Defined to be the total response of measured VOCs falling within the C₆ – C₁₆ range, with responses calibrated to a toluene surrogate.

²Short-term level based on the ATSDR Acute Duration Minimal Risk Level (MRL). Long-term level based on ½ CAL-EPA 1-hour Reference Exposure Level (REL).

³Compared to CA Prop 65 No Significant Risk Levels (NSRLs) and EPA Inhalation Unit Risk (IUR) (cancer potency factor). Excludes formaldehyde, which is covered by (2) above.

⁴Compared to the EPA Reference Concentration (RfC), CA CREL, and the ATSDR Intermediate or Chronic Duration MRL. Intermediate MRLs shall be used if a Chronic MRL is not available for that compound. Excludes Developmental and Reproductive endpoints (see Developmental/Reproductive Toxins).

⁵Compared to ATSDR Acute Duration MRL and CA Acute Reference Exposure Level (AREL). Excludes Developmental and Reproductive endpoints which are covered by Developmental/Reproductive Toxins in (6) below.

⁶Compared to CA Prop 65 Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity, CA ARELs, and ATSDR MRLs for chemicals with Developmental or Reproductive endpoints.

Small Chamber Emissions Test Method Summary

Testing to determine exposures to chemicals is based on ASTM D 5116 – 06 *Standard Guide for Small Scale Environmental Chamber Determination of Volatile Organic Emissions from Indoor Materials / Products*. In this test, indoor air exposures are generated using dynamic environmental chambers to test emissions from products. Indoor air is measured for acute and chronic exposure levels. The test is to be conducted for a minimum of 48 hours. Acute levels should be met between 1-4 hours; chronic levels must be met at 48 hours.

The product is to be prepared as directed from the manufacturer, and the test conducted as directed by the ASTM method and using sample prep guidelines still under development. To establish exposures, three samples points are to be taken, two of which should be at 24 and 48 hours after chamber application. Three data points are required to establish an emissions decay curve. The third sample should be taken short-term, sometime between 1-4 hours.

VOC emission factor results obtained from chamber emission tests are to be converted through modeling into estimated airborne concentrations that are relevant to potential indoor inhalation exposures of building occupants. The calculation is accomplished using the steady-state mass balance model described in Equation C1. Room VOC concentrations shall be calculated by the following general equation:

$$C_{voc_j}(t = X) = \frac{A_{source} E_{voc_j}(t = X)}{Q_{office}} \quad (\text{Eq. C1})$$

where,

$C_{voc_j}(t = X)$ is the calculated office concentration for VOC j, at time X hours in $\mu\text{g}/\text{m}^3$

$E_{voc_j}(t = X)$ is the workstation emission factor for VOC j at time X hours, ($\mu\text{g h}^{-1} \text{m}^{-2}$)

Q_{room} is the room ventilation rate, m^3/h

A_{source} is the source amount.

To estimate airborne concentrations, the model requires input for the amount of product used, the volume of the space and the outdoor air ventilation rate in the room. The two scenarios presented below have been proposed and are under

consideration. It is our desire to select a single model, if possible, to use regardless of which product type is tested. The most conservative model that is reasonably predictive of occupant exposures will most likely be selected.

School Classroom Scenario: Use a 24- ft wide by 40- ft long classroom with an 8.5-ft high ceiling. Use a ventilation rate of 0.9 h⁻¹. Assume that only 90% of the room volume of 231 m³ is ventilated at this rate due to occupancy of the space by cabinetry, furnishings and other room contents. The calculations result in floor and ceiling surface area of 89.2 m². A net wall area of 94.6 m² is calculated based on the total wall area minus the area of a door and two windows. Various surface areas are described. This model is the California High Performance Schools model.

Bathroom Scenario: Use a 14-ft long by 10- ft wide bathroom with an 8 ft high ceiling. A ventilation rate of 0.72 h⁻¹ has been recommended. Key parameters include a room volume of 32 m³, Floor area of 13.1 m² and a wall area of 38 m². Various glass, fixture, and counter surface areas are described. The bathroom is conservative because of its low room volume and high surface area. This model is the GreenGuard Children and Schools model.

Other key parameters/aspects still under consideration include:

- Method of Sample Application - Samples can be modeled as applied or in excess to maintain constant emissions
- Time of thresholds samples- Proposed values are acute (t = 2 hr) and chronic (t = 48 hr)
- Ventilation rate- the values for both models are still open to discussion. Should be tied to ASHRAE rates.
- Model Used for Product type- which model should be used for each product type. It is desirable to select a model that can apply to all of the product types if possible.

References

Agency for Toxic Substance Disease Registry (ATSDR) Minimum Risk Levels (MRLs)
<http://www.atsdr.cdc.gov/mrls/index.html>

ASTM D5116 Standard Guide for Small-Scale Environmental Chamber Determinations of Organic Emissions from Indoor Materials/Products. http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/D5116.htm?L+mystore+gfvy9063

ASTM E981: http://www.astm.org/cgi-bin/SoftCart.exe/DATABASE.CART/REDLINE_PAGES/E981.htm?E+mystore

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) Acute Reference Exposure Levels (aRELS)

http://www.oehha.ca.gov/air/acute_rels/allAcRELS.html

Cal/EPA OEHHA Non-Cancer Chronic Reference Exposure Levels (cRELS)

http://www.oehha.ca.gov/air/chronic_rels/AllChrels.html

http://www.oehha.ca.gov/air/chronic_rels/pdf/relsP32k.pdf

Cole and Foarde: Foarde, K, E Cole, D Van Osdell, D Bush, D Franke, and J Chung. 1992. *Characterization of Environmental Chambers for Evaluating Microbial Growth on Building Materials*. Indoor Air, No. 9. Atlanta: ASHRAE.

Franke, Deborah L., Eugene C. Cole, Keith E. Leese, Karin K. Foarde, Michael A. Berry (1997). Cleaning for Improved Indoor Air Quality: An Initial Assessment of Effectiveness Indoor Air. 7 (1), 41–54.

GreenGuard Environmental Institute (GEI), October 2006. GreenGuard Emissions Criteria applied to general cleaners, glass cleaners, toilet cleaners, floor cleaners, carpet cleaners, hard surface cleaners, institutional cleaning systems, maintenance systems, aerosol products. www.greenguard.org.

State of California PROP 65 NSRL carcinogens

<http://www.oehha.ca.gov/prop65/getNSRLs.html>

Medina-Ramon: (212) Medina-Ramon M, Zock JP, Kogevinas M et al. Asthma, Chronic Bronchitis, and Exposure to Irritant Agents in Occupational Domestic Cleaning: A Nested Case-Control Study. *Occup Environ Med*. 2005; 62:598-606.

Rumchev: K Rumchev, J Spickett, M Bulsara, M Phillips, and S Stick "Association of domestic exposure to volatile organic compounds with asthma in young children," *Thorax*, Sep 2004; 59: 746 - 751.

Shendell DG, Winer AM, Stock TH et al. 2004b. Air concentrations of VOCs in portable and traditional classrooms: results of a pilot study in Los Angeles County. *J Exp Anal and Environ Epidemiol*, 14 (1): 44 – 59.

Tichenor. Criteria for Evaluating Programs that Assess Materials/Products to Determine Impacts of Indoor Air Quality. http://www.epa.gov/iaq/pdfs/tichenor_report.pdf

U.S. Environmental Protection Agency (EPA) Reference Concentration (RfC)

<http://www.epa.gov/iris/search.htm>

Carcinogens and Reproductive Toxins

Current Standard Language

The *undiluted* product shall not contain any ingredients that are carcinogens or that are known to cause reproductive toxicity. Carcinogens are defined as those chemicals listed as known, probable, or possible human carcinogens by the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency, or the Occupational Health and Safety Administration. Chemicals known to cause reproductive toxicity are defined as those listed by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, *et seq.*).

Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered ingredients if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 Code of Federal Regulations (CFR) Part 141.

Discussion of Issues

It is recommended that products do not contain any potential, possible, probable, reasonably anticipated, or known human carcinogens. Green Seal references known lists for carcinogens with the priority for international and national lists to follow the guidance of ISO 14024. This includes IARC, NTP, EPA, and OSHA. With these lists available, state lists such as California Prop 65 are not referenced for carcinogens. Green Seal does not cite specific URL's since these lists are readily available and the internet locations often change. However, the definition of carcinogen will be clarified to identify which lists Green Seal's references.

To further harmonize with the specifications of the European Union ecological criteria for cleaners, mutagens will also be prohibited and defined according to the GHS criteria for germ cell mutagenicity. Category 1 criteria are consistent with the EU classification and labeling criteria for category 1 and 2 mutagenic substances (Langezaal, 2002), which are required to be labeled as follows: R46 May cause heritable genetic damage.

It is further recommended that chemicals known to cause reproductive toxicity be prohibited and include both male and female reproductive toxins and developmental toxins. California Proposition 65 is the most readily available and accepted source for these compounds and should be cited. The NTP research progress can be used for additional information, though a list is not maintained.

Potential Revised Language:

Prohibition of Carcinogens, Mutagens, and Reproductive Toxins. The *undiluted* product shall not contain any ingredients that are carcinogens, mutagens or

reproductive toxins. For the purposes of this standard, naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered ingredients if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 Code of Federal Regulations (CFR) Part 141.

References

Langezaal, I. 2002. The Classification and Labelling of Carcinogenic, Mutagenic, Reprotoxic, and Sensitising Substances. Ispra, October.

GHS

Prop 65

Skin and Eye Irritation

Current Standard Language

The undiluted product shall not be corrosive to the skin or eyes. Dispensing-system concentrates shall be tested as used. The undiluted cleaning product shall not be corrosive to the skin, as tested using the Human Skin Construct systems (Liebsch *et al.* 2000; Fentem *et al.* 1998). The undiluted cleaning product shall also not be corrosive to the eye as tested using the bovine opacity and permeability test (BCOP) (Sina *et al.* 1995) after a 10-minute exposure. Green Seal will also accept the results of other peer-reviewed or standard in vitro or in vivo test methods demonstrating that the product mixture is not corrosive.

Discussion of Issues

The existing GS-37 already recognizes that the product should not be corrosive to the skin or eyes. The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) includes definitions (see below) and classification criteria for skin corrosion and “serious eye damage” (UN 2005). These definitions are consistent with the definitions used by the US and the European Union for acute dermal irritation/corrosion (EPA 1998a, OECD 2002a) and for acute eye irritation/corrosion (EPA 1998b, OECD 2002b).

Since GS-37 was last reviewed, considerable progress has been made in the development and validation of *in vitro* test protocols for assessing these health end points. In the US, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) has validated four *in vitro* test protocols for evaluating skin corrosion (ICCVAM 2004) and another four test methods for serious eye damage (ICCVAM 2006). The four test methods for skin corrosion are Corrositex[®], EPISKIN[™], EpiDerm[™] (EPI-

200), and the rat skin transcutaneous electrical resistance (TER) assay, and for serious eye damage they are the Bovine Corneal Opacity and Permeability (BCOP) assay, the Hen's Egg Test - Chorioallantoic Membrane (HET-CAM) assay, the Isolated Chicken Eye (ICE) assay, and the Isolated Rabbit Eye (IRE) assay. The European Centre for the Validation of Alternative Methods (ECVAM) is currently conducting a validation study of *in vitro* methods for acute skin irritation. The ECVAM Scientific Advisory Committee recently reviewed the ICCVAM 2006 report on eye irritants and supported the use of BOCOP and ICE assays, but had some concern for the HET-CAM and IRE assays. However, the ECVAM Committee reiterated that positive outcomes from all four of these tests can be used as the basis for classifying and labeling substances as serious eye irritants and referred to the European Commission's Manual of Decisions (EC 2006) which states:

“Positive outcome from the following *in vitro* tests for eye irritation are acceptable:

- 1) isolated rabbit enucleated eye (REET, IRE) test,
- 2) isolated chicken eye (ICE) test,
- 3) bovine corneal opacity & permeability (BCOP) test,
- 4) hen's egg test - chorio-allantoic membrane (HET-CAM) test.

Although these tests are not yet validated (and therefore not included in Annex V) it has been agreed that available evidence is sufficient to conclude that the methods are able to detect severe eye irritants. Thus, where a positive result is obtained, a substance can be considered a severe eye irritant and R41 should be applied with no further testing justified, respecting animal welfare. Where a negative result is obtained, an *in vivo* test should subsequently be required, as the *in vitro* tests have not been shown to adequately discriminate between eye irritants and non-irritants. As with Annex V test methods, these *in vitro* tests should be conducted according to GLP where both the full test report (including basic data) and the study protocol should be made available.” (p. 157)

There currently is an exception for dispensing system concentrates (as defined in the standard). This is because such systems typically do not require product handling by the user. There is discussion and consideration for removing this exception. The concern is that when workers handle undiluted product they can accidentally contact the undiluted product. Do such systems guarantee that the worker does not have accidental exposure?

The cost of testing is not expected to increase. The new testing requirements are not substantially different from the current GS-37 standard as the test using Human Skin Construct systems and bovine opacity and permeability test (BCOP) are among the validated *in vitro* tests currently approved by the U.S. and EU.

Potential Revised Language:

The *undiluted* cleaning product shall not be corrosive to the skin or cause serious eye damage. Dispensing-system concentrates shall be tested *as used*. The product shall be tested for skin corrosion and eye damage following OECD 435. Green Seal prefers that an *in vitro* test(s) validated by the Interagency

Coordinating Committee on the Validation of Alternative Methods (ICCVAM) or the European Centre for the Validation of Alternative Methods (ECVAM) be used. Green Seal will also accept the results of other peer-reviewed or standard *in vitro* or *in vivo* test methods demonstrating that the product mixture is not corrosive.

References

European Commission (EC). 2006. Manual of Decisions for implementation of the 6th and 7th amendments to Directive 67/548/EEC on dangerous substances (Directives 79/831/EEC and 92/32/EEC) – non-confidential version.) Available: <http://ecb.jrc.it/> [accessed 13 Aug 2007].

Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). 2004. Recommended Performance Standards for In Vitro Test Methods for Skin Corrosion. NIH Publication No: 04-4510. Available: <http://iccvam.niehs.nih.gov/methods/dermal/epiderm/ps/ps044510.pdf> [accessed 13 Aug 2007].

Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). 2006. ICCVAM Test Method Evaluation Report: *In Vitro* Ocular Toxicity Test Methods for Identifying Severe Irritants and Corrosives. NIH Publication No: 07-4517. Available: http://iccvam.niehs.nih.gov/docs/ocutox_docs/OTeval/OTevalrpt.pdf [accessed 13 Aug 2007].

OECD. 2006. Guidelines for testing of chemicals. Guideline 435: *In Vitro* Membrane Barrier Test Method for Skin Corrosion. Available: <http://fiordiliji.sourceoecd.org/vl=13634729/cl=21/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s51/p1.idx> [accessed 13 Aug 2007].

OECD. 2002a. Guideline for testing of chemicals. Guideline 404: Acute Dermal Irritation/Corrosion. Available: <http://miranda.sourceoecd.org/vl=439522/cl=12/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s4/p1.idx> [accessed 13 Aug 2007].

OECD. 2002b. Guideline for testing of chemicals. Guideline 405: Acute Eye Irritation/Corrosion. Available: <http://oberon.sourceoecd.org/vl=5857828/cl=17/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s5/p1.idx> [accessed 13 Aug 2007].

United Nations (UN). 2005. Globally Harmonized System of Classification and Labeling of Chemicals (GHS) – Revision 1. ST/SG/AC.10/30/Rev.1. United Nations, New York and Geneva. Available: www.unece.org/trans/danger/publi/ghs/ghs_rev01/01amend_e.html [accessed 13 Aug 2007].

United States Environmental Protection Agency (EPA). 1998a. Health Effects Test Guidelines: OPPTS 870.2500 Acute Dermal Irritation. Available: www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-2500.pdf [accessed 13 Aug.2007].

United States Environmental Protection Agency (EPA). 1998b. Health Effects Test Guidelines: OPPTS 870.2400 Acute Eye Irritation. Available: www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-2400.pdf [accessed 13 Aug.2007].

Skin Sensitization

Current Standard Language

The undiluted product shall not be a skin sensitizer, as tested by the OECD Guidelines for Testing Chemicals, Section 406. Dispensing-system concentrates shall be tested as used. Green Seal shall also accept the results of other standard test methods, such as those described in Buehler (1994) or Magnusson and Kligman (1969), as proof that the product or its ingredients are not skin sensitizers.

Discussion of Issues

The existing GS-37 already recognizes that the product should not be a skin sensitizer. At this time, an *in vitro* test for identifying skin sensitizers is not readily available. However, both EPA and OECD recommend the local lymph node assay (LLNA) as the preferred method for assessing skin sensitization. Compared to the traditional guinea pig test, it demonstrates an equivalent prediction of human allergic contact dermatitis. It also provides a quantitative assessment of dose-response, and it reduces animal welfare concerns as it reduces animal distress and can reduce the number of animals required to provide good quantitative data (Basketter *et al.* 2007, EPA 2003, Gerberick *et al.* 2005, OECD 2002).

There currently is an exception for dispensing system concentrates (as defined in the standard). This is because such systems typically do not require product handling by the user. There is discussion and consideration for removing this exception. The concern is that when workers handle undiluted product they can accidentally contact the undiluted product. Do such systems guarantee that the worker does not have accidental exposure?

Potential Revised Language:

The *undiluted* product shall not be a skin sensitizer, as tested by the local lymph node assay (OECD Guideline 429) or following EPA test guidelines for skin sensitization (OPPTS 870.2600). Dispensing system concentrates shall be tested *as used*. Green Seal shall also accept the results of other standard test methods, such as the guinea pig maximization test (OECD Guideline 406) or the Buehler test (OECD 406), as proof that the product in its most concentrated form is not a skin sensitizer.

References

Basketter, DA, F Gerberick, I Kimber. 2007. The local lymph node assay and the assessment of relative potency: status of validation. *Contact Dermatitis* 57 (2), 70–75. www.blackwell-synergy.com/doi/abs/10.1111/j.1600-0536.2007.01141.x [accessed 7/30/2007].

EPA. 2003. Health Effects Test Guidelines: OPPTS 870.2600 - Skin Sensitization. www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/870-2600.pdf [accessed 7/30/2007].

Gerberick, GF, CA Ryan, PS Kern, H Schlatter, RL Dearman, I Kimber, GY Patlewicz, DA Basketter. 2005. Compilation of Historical Local Lymph Node Data for Evaluation of Skin Sensitization Alternative Methods. *Dermatitis* 16(4):157-200.

OECD. 2002. Guidelines for testing of chemicals. Guideline 429 – Skin sensitization: the local lymph node assay. <http://caliban.sourceoecd.org/vl=7270265/cl=15/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s6/p1.idx> [accessed 7/30/2007].

OECD. 1992. Guideline for testing of chemicals. Guideline 406: Skin Sensitisation. <http://caliban.sourceoecd.org/vl=7270265/cl=15/nw=1/rpsv/cgi-bin/fulltextew.pl?prpsv=/ij/oecdjournals/1607310x/v1n4/s6/p1.idx> [accessed 7/30/2007].

Combustibility

Current Standard Language

The undiluted product shall not be combustible. The product or 99% by volume of the product ingredients shall have a flashpoint above 150 °F, as tested using either the Cleveland Open Cup Tester (ASTM D92-97) or a closed-cup method International Standards Organization (ISO) 13736 or ISO 2719. Alternatively, the product shall not sustain a flame when tested using ASTM D 4206.

Discussion of Issues

Propose essentially keeping the standard as is, which is largely consistent with other Green Seal standards, Canadian standards, and others. Most of the proposed new language is suggested to make the combustibility language more specific and readily accessible.

Potential Revised Language:

The undiluted product shall not be combustible. The product or 99% by volume of the product ingredients shall have a flashpoint above 150 °F, as tested using either the Cleveland Open Cup Tester (ASTM D92-05a) or the following closed-cup methods authorized by the International Standards Organization: the Abel Closed-Cup method (ISO 13736) or the Pensky-Martens Closed-Cup method (ISO 2719). Alternatively, the product shall not sustain a flame when tested using ASTM D 4206.

References

ASTM Standard Test Method for Flash and Fire Points by Cleveland Open Cup Tester, ASTM Standard D92-05a

ASTM Standard Test Methods for Flash Point by Pensky-Martens Closed Tester, ASTM Standard D-93-79 or D-93-80.

"Flammable and Combustible Liquids Code" (1977 or 1981), available from the National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

Photochemical Smog, Tropospheric Ozone Production, and Indoor Air Quality

Current Standard Language

The product *as used* shall not contain substances that contribute significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality. The volatile organic content of the product as used shall not exceed the following:

- 0.1% by weight for dilutable carpet cleaners
- 1% by weight for general-purpose and bathroom cleaners
- 3% by weight for glass cleaners
- 3% by weight for ready-to-use carpet cleaners

The volatile organic content shall be determined by California Air Resources Board Method 310.

Discussion of Issues:

Volatile organic compounds (VOCs) are carbon-based chemicals characterized by boiling points ranging from about 50-260°C and include alcohols, aldehydes, straight chain and cyclic alkanes, aromatic hydrocarbons, halogenated hydrocarbons, terpenes, ketones, and esters. VOCs are common ingredients in cleaning products and minimization of chemical exposures during cleaning has been recognized as a key indoor air quality strategy (Franke, et. al., 1997).

Adverse health responses potentially caused by VOCs in non-industrial indoor environments fall into three categories, namely 1) irritant effect including the perception of unpleasant odors and mucous membrane irritation, 2) systematic effects such as fatigue and difficulty concentrating, and 3) toxic effects such as carcinogenicity (Girman, *Occupational Medicine: State of the Art Reviews*, 1989). Creating appropriate levels of VOC content is essential to minimizing the potential health effects of cleaning products.

Even amongst cleaning product types, there are variations and interpretations on identifying the appropriate levels of acceptable VOCs. Classifying products can have a significant impact on VOC criteria used for certification. This criterion seeks to standardize the VOC levels across the applicable range of all affected product types to ease confusion, complexity and to provide consumers with a basis for comparison.

The analysis allowing the summation of product constituents qualifying as a VOC was added as an alternative to the testing process, given the known inconsistency of the AQMD method 313. By totaling the concentrations of those compounds considered VOC's, the method accounts for the entire content of the formulation likely to volatilize. The alternative method will also act to reduce the overall cost of certification to this standard.

Potential Revised Language:

The product *as used* shall not contain substances that contribute significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality. The volatile organic content of the product as used shall not exceed 10 g/l of material as measured using AQMD Method 313-06. VOC emission testing shall be conducted on the product as a whole.

Alternatively, a mixture need not be tested if the sum of the total VOC content expressed in g/l in the existing formulation is less than 10 g/l of the product when used as directed. Product constituents greater than 0.1% must be considered in this evaluation. For the purposes of this evaluation, formulation constituents are considered VOC's if both of the following conditions are true²:

1. Constituent is an organic compound with between 6 and 16 carbons.
2. Constituent Boiling Point is between 50 °C - 260°C

² ISO 16000 - 6 (2004) / World Health Organization

References

California Air Resources Board-Determination of Volatile Organic Compounds (VOC) in Consumer Products and Reactive Organic Compounds in Aerosol Coating Products June 22, 2000.

Franke, Deborah L., Eugene C. Cole, Keith E. Leese, Karin K. Foarde, Michael A. Berry (1997) Cleaning for Improved Indoor Air Quality: An Initial Assessment of Effectiveness Indoor Air 7 (1), 41–54.

Girman JR, (1989), Volatile organic compounds and building bake-out, Occupational Medicine: State of the Art Reviews, Volume 4, No. 4, October-December, 1989, pp. 695-712.
http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&list_uids=2690381&dopt=Citation.

International Standards Organization ISO 16000-6: Determination of volatile organic compounds in indoor and test chamber air by active sampling on Tenax TA sorbent, thermal desorption and gas chromatography using MS/FID. 2004.

South Coast Air Quality Management District (SCAQMD) METHOD 313-91: Determination of Volatil Organic compounds (VOC) by gas Chromotography/Mass Spectrometry (GC/MS). June 1993. <http://www.aqmd.gov/tao/methods/lab/313-91.pdf>

Toxicity to Aquatic Life

Current Standard Language

The product *as used* shall not be toxic to aquatic life. A compound is considered not toxic to aquatic life if it meets one or more of the following criteria:

Acute LC₅₀ for algae, daphnia, or fish ≥ 100 mg/L

For purposes of demonstrating compliance with this requirement, aquatic toxicity testing is not required if sufficient aquatic toxicity data exist for each of the product's ingredients to demonstrate that the product mixture complies. Aquatic toxicity tests shall follow the appropriate protocols in ISO 7346.2 for fish and in 40 CFR 797, Subpart B for other aquatic organisms.

Discussion of Issues

The criterion applies to a product *as used* because that is the most likely form of the product expected to be disposed of down the drain, eventually being discharged to surface water.

The OECD test methods were added and the 40 CFR test was dropped because OECD methods are now available and international test methods (ISO and OECD) are preferred over national standard methods.

We are not proposing to change the 100 mg/L cutoff. It is supported by the OECD globally harmonized system -- OECD defines three hazard categories for acute aquatic toxicity (OECD, 2001):

Acute toxicity hazard category	Type of test	Criteria
Acute I	96 hr LC50 (for fish) and/or	≤ 1 mg/L
Acute II	48 hr EC50 (for crustacea), and/or	>1 to ≤ 10 mg/L
Acute III	72 or 96 hr ErC50 (for algae or other aquatic plants)	>10 to ≤ 100 mg/L

Based on the OECD criteria, a product with an acute aquatic toxicity above 100 mg/L would not be classified as an acute toxicity hazard.

Acute aquatic toxicity is maintained as a distinct criterion, rather than combining with biodegradability and possibly other environmental fate considerations, because compounds can cause toxic effects before they biodegrade. (An exception to the requirement for ready biodegradability is proposed based on acute and chronic aquatic toxicity in the proposed biodegradability criterion.)

A weighted average approach can be used, instead of whole-product testing, if sufficient ingredient information available to keep testing costs down and reduce the demand for animal testing.

Potential Revised Language:

The product *as used* shall not be toxic to aquatic life. A compound is considered not toxic to aquatic life if it meets one or more of the following criteria:

Acute LC₅₀ for algae, daphnia, or fish ≥ 100 mg/L

For purposes of demonstrating compliance with this requirement, aquatic toxicity testing is not required if sufficient aquatic toxicity data exist for each of the product's ingredients to demonstrate that the product mixture complies, using a weighted average approach. Aquatic toxicity tests shall follow the appropriate protocols in ISO 7346-2 for fish, OECD test guidance 203 for fish, OECD test guidance 201 for algae, and OECD test guidance 202 for daphnia.

References

International Standard ISO 7346-2, second edition, 1996-06-15. Water Quality – Determination of the acute lethal toxicity of substances to a freshwater fish [*Brachydanio rerio* Hamilton-Buchanan (Teleostei, Cyprinidae)] Part 2: semi-static method.

Organization for Economic Cooperation and Development (OECD), 2001. Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. ENV/JM/MONO(2001)6.

OECD Guidelines for the Testing of Chemicals, Freshwater Alga and Cyanobacteria, Growth Inhibition Test, OECD 201, Adopted 23 March 2006.

OECD Guidelines for the Testing of Chemicals, *Daphnia* sp., Acute Immobilisation Test, OECD 202, adopted 13 April 2004.

OECD Guidelines for the Testing of Chemicals, Fish, Acute Toxicity Test, OECD 203 for fish, adopted 17.07.92.

Aquatic Biodegradability

Current Standard Language

Each of the organic ingredients in the product as used shall exhibit ready biodegradability in accordance with the OECD definition except for a FIFRA-registered ingredient in a bathroom cleaner and the polymer portion of a carpet cleaner. However, all other ingredients in a FIFRA-registered bathroom cleaner or carpet cleaner must comply. Biodegradability shall be measured by one of the following methods: ISO 9439 carbon dioxide (CO₂) evolution test, ISO 10708 (two-phase closed-bottle test), ISO 10707 (closed bottle test), or ISO 7827 (dissolved organic carbon removal). Specifically, within a 28-day test, the ingredient shall meet one of the following criteria within 10 days of the time when biodegradation first reaches 10%:

Removal of dissolved organic carbon (DOC)	> 70%
Biological oxygen demand (BOD)	> 60%
% of BOD of theoretical oxygen demand (ThOD)	> 60%
% CO ₂ evolution of theoretical	> 60%

For organic ingredients that do not exhibit ready biodegradability in these tests, the manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating dissolved organic carbon (DOC) removal > 90%.

Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases or proving that the ingredient was tested in accordance with standard test procedures.

Discussion of Issues

The criterion applies to a product *as used* because that is the most likely form of the product expected to be disposed of down the drain, eventually being discharged to surface water.

The cited test methods cited in the criterion have been increased to include currently-available ISO test methods 9408 and 14593, and OECD test methods 301 A-F and OECD 310.

Biodegradability is maintained as a distinct criterion, rather than combining with toxicity to aquatic life, and possibly other environmental fate considerations, because compounds can cause toxic effects before they biodegrade. However, an exception to the requirement for ready biodegradability is proposed here for organic ingredients with low acute *and chronic* aquatic toxicity that exhibit inherent, ultimate biodegradability, defined by OECD [2003] as biodegradation rates above 70%, measured as BOD, DOC, or COD.

The ready biodegradation tests are intended for pure chemicals. Some types of cleaning product ingredients are mixtures of structurally similar chemicals, such as surfactant homologues composed of ethoxylated alcohols of varying carbon chain lengths. Because biodegradation of specific chain length compounds would occur sequentially, the 10-day window requirement is waived for those ingredient mixtures (based on OECD guidelines, OECD 2003).

The criterion applies to specific individual organic ingredients, e.g., as identified by a unique CAS number. If a product raw material is a blend of two or more organic ingredients, each of those organic ingredients must meet the biodegradability criterion.

Potential Revised Language:

Each of the individual organic ingredients in the product *as used* shall exhibit ready biodegradability in accordance with the OECD definition except for a FIFRA-registered ingredient in a bathroom cleaner and the polymer portion of a carpet cleaner. However, all other organic ingredients in a FIFRA-registered bathroom cleaner or carpet cleaner must comply. Biodegradability shall be measured by according to ISO methods 7827, 9439, 10707, 10708, 9408, 14593; OECD Methods 301A – F; or OECD 310.). Specifically, within a 28-day test, the ingredient shall meet one of the following criteria within 10 days of the time when biodegradation first reaches 10%:

- Removal of dissolved organic carbon (DOC) > 70%
- Biological oxygen demand (BOD) > 60%

- % of BOD of theoretical oxygen demand (ThOD) > 60%
- % CO₂ evolution of theoretical > 60%

Per OECD guidance (2003) the 10-day window requirement does not apply to mixtures of structurally related chemicals [does this need to be defined?].

For organic ingredients that do not exhibit ready biodegradability in these tests the manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating dissolved organic carbon (DOC) removal > 90%.

An exception may be made for an organic ingredient that does not exhibit ready biodegradability if it has low aquatic toxicity and exhibits biodegradation rates above 70% (measured as BOC, DOC, or COD), per ISO test methods 9887 or 9888; or OECD 302A, B, or C. For purposes of this standard, low aquatic toxicity is defined as follows: acute *and* chronic aquatic toxicity >100 mg/L [chronic test specifics to be determined].

Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases or proving that the ingredient was tested in accordance with standard test procedures.

References

International Standard ISO 7827:1994, Water quality -- Evaluation in an aqueous medium of the "ultimate" aerobic biodegradability of organic compounds -- Method by analysis of dissolved organic carbon (DOC).

International Standard ISO 9439:1999, Water Quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium – Carbon dioxide evolution test.

International Standard ISO 10707:1994, Water Quality – Evaluation in an aqueous medium of the “ultimate aerobic biodegradability of organic compounds – Method by analysis of biochemical oxygen demand (closed bottle test).

International Standard ISO 9408:1999, Water Quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium by determination of oxygen demand in a closed respirometer.

International Standard ISO 14593:1999; Water Quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium -- Method by analysis of inorganic carbon in sealed vessels (CO₂ headspace test).

International Standard ISO 9887:1992, Water Quality – Evaluation of the aerobic biodegradability of organic compounds in an aqueous medium -- Semi-continuous activated sludge method (SCAS).

International Standard ISO 9888:1999; Water Quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium -- Static test (Zahn-Wellens method).

Organization for Economic Cooperation and Development (OECD), 2001. Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. ENV/JM/MONO(2001)6.

OECD, 2003. Introduction to the OECD Guidelines for Testing of Chemicals Section 3, Part 1: Principles and strategies related to the testing of degradation of organic chemicals, July 2003.

OECD Guidelines for the Testing of Chemicals, OECD 301(A – F) Ready Biodegradability, Adopted 07/17/92.

OECD Guidelines for the Testing of Chemicals, OECD 310, Ready Biodegradability – CO₂ in sealed vessels (Headspace Test), Adopted 23 March 2006.

OECD Guidelines for the Testing of Chemicals, OECD 302A, Inherent Biodegradability: Modified SCAS Test, Adopted 12 May 1981.

OECD Guidelines for the Testing of Chemicals, OECD 302B, Zahn-Wellens/EMPA Test, Adopted 07/17/92.

OECD Guidelines for the Testing of Chemicals, OECD 302C, Inherent Biodegradability: Modified MITI Test (II), Adopted 12 May 1981.

OECD Guidelines for the Testing of Chemicals, OECD 303, Simulation Test – Aerobic Sewage Treatment: 303 A: Activated Sludge Units, Adopted 22 January 2001.

Eutrophication

Current Standard Language

The product *as used* shall not contain more than 0.5% by weight of total phosphorus.

(no change recommended)

Concentrates

Current Standard Language

The product must be a concentrate, except for FIFRA-registered bathroom cleaners and absorbent compound carpet cleaners.

(no change recommended)

Fragrances

Current Standard Language

Manufacturers shall identify any fragrances on their material safety data sheets (MSDSs). Any ingredient added to a product as a fragrance must follow the Code of Practice of the International Fragrance Association.

Discussion of Issues

Fragrance materials have commonly been added to cleaning products to provide a pleasant scent to the product. In some cases, cleaning product formulas have inherent off-odors associated with them and a fragrance must be added to make the product acceptable. However, there are uses of fragrances that should not be encouraged such as the use of fragrances for product identification since it is not as reliable as clear labels or color. A growing trend is the number of products without added fragrances. In 2006, over 50% of Green Seal's GS-37 certified products did not have added fragrances.

The evidence is growing that shows that many fragrance materials have undesirable health outcomes. In a report summarizing the literature, Bridges (2002) noted many health concerns including skin sensitization, skin irritation, respiratory sensitization, respiratory irritation, neurological, and systemic effects. For example, complexes such as essential oils may contain known carcinogens (Jansson and Loden 2001). Many of the cited health concerns were linked to air quality issues with fragrances including total VOC's, peroxides, other harmful products, and sub-micron particles. For example, the emission of fragrance materials has been shown to contain materials with documented irritant and neurotoxic properties (Anderson and Anderson 1998). In addition to these health concerns, many fragrance ingredients are persistent in the environment and aquatic biodegradability is slow.

The International Fragrance Association (IFRA) Code of Practice includes material standards that set use criteria. The criteria can include limits, directions for antioxidant use, and prohibition of materials. In 2006, the Code was amended to change the format of the material standards to follow a Quantitative Risk Assessment (QRA) format (which addresses certain health concerns) for eleven different categories of products based on potential exposure associated with the product's use (RIFM 2007). The Research Institute for Fragrance Materials (RIFM) was consulted in 2007 to understand these

amendments to the Code. QRA assessment is performed by RIFM, and considering toxic mechanisms including toxicokinetics, it includes dermal absorption, acute toxicity, subchronic toxicity, dermal irritation, mucous membrane irritation, skin sensitization, photoirritation, photoallergy, mutagenicity, developmental and reproductive toxicity, and carcinogenicity. However, the RIFM safety assessment and the QRA does not include assessment of respiratory sensitization or respiratory (sensory) irritation and endocrine disruption, among others (RIFM 2007, Bickers *et al.* 2003, Ford *et al.* 2000). Furthermore, the IFRA Code is currently limited to only those materials that have been evaluated by RIFM, and RIFM does not anticipate completing the evaluation of all fragrance ingredients until 2016. As a result, this Code may not limit the use all materials of concern.

It is recommended that the criterion for fragrances ensure that any fragrance (as with any ingredient) meet pertinent environmental and health criteria. Following the Code of Practice of the International Fragrance Association covers many of these considerations, but evaluation of the additional health criteria is important as well. Thus, disclosure of the functional fragrance components is required (as it is currently), and explicitly stated in the criterion so Green Seal can evaluate these ingredients. Fragrance components that meet the ingredient definition for the standard would continue to be evaluated against all the other criteria in the standard including prohibited ingredients (such as carcinogens and phthalates), emissions and aquatic biodegradability and toxicity. The remaining areas that should be considered when including fragrance components are respiratory sensitization, respiratory irritation, neurotoxicity, endocrine disruption, indoor air emissions, the formation of sub-micron particles in air and oxidation products that may be respiratory sensitizers/irritants, and limiting the use of ingredients (e.g. essential oils) whose composition is unknown or not well characterized. The indoor emissions tests should be able to include these important considerations.

There is consideration whether the current ingredient cut off of 0.01% of the product results in effective prohibition of the components of concern. A lower cut-off will need to allow for practical considerations such as the level that addresses concerns more than the current level without adding prohibitive amounts of time and complexity for additional evaluation, considering the availability of data and the cost of additional testing required for additional components. An alternative to increasing the amount of fragrance components evaluated may be to test the product for sensitization or sensitizers or other end-points of concern that practically can be tested. Finally, defining “no-added fragrance” and adding claim verification criteria may allow for easier identification of such products, though this also, do not necessarily prohibit the components of concern.

Some fragrance components have been recommended to be prohibited because they are known to have adverse health or environmental impacts but are not prohibited by the IFRA Code. These include phthalates for their endocrine disruption and nitro-musks and polycyclic musks for their persistence and bioaccumulation. Finally, since some individuals appear to be sensitive to fragrance materials and testing has been unable to identify the particular component responsible for that sensitivity, it is important that any

use of fragrance components be disclosed to the public. As a result, it is recommended that the MSDS identify when fragrance ingredients have been added to a product.

Potential Revised Language:

Fragrances added to the product must follow the Code of Practice of the International Fragrance Association. All fragrance ingredients must be disclosed to Green Seal and meet all other criteria of this standard. The material safety data sheet (MSDS) must identify that fragrance has been added.

Additional criteria to consider broadly for the Standard:

- Additional Other Prohibited Ingredients: Phthalates and Nitro-musks (Musk xylene, Musk ketone) and Polycyclic musks (HHCB, AHTN)
- New criterion prohibiting asthmagens, endocrine disruption, and neurotoxins
- New criterion prohibiting respiratory sensitizers and irritants
- New criterion on indoor air quality

References

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Bridges, B. 2002. Fragrance: Emerging Health and Environmental Concerns. *Flavour and Fragrance Journal*. 17: 361-371.

Ford, RA, B Domeyer, O Easterday, K Maier, and J Middleton. 2000. Criteria for Development of a Database for Safety Evaluation of Fragrance Ingredients. *Regul Tox Pharm* 31(2):166-181.

Jansson, T. and M. Loden. 2001 Strategy to Decrease the Risk of Adverse Effects of Fragrance Ingredients in Cosmetic Products. *Am J Contact Dermat*. Sep;12(3):166-9.

Research Institute for Fragrance Materials (RIFM). June 2007. IFRA RIFM QRA Information Booklet Version 2.2. Available at www.rifm.org/doc/IFRA%20RIFM%20QRA%20Information%20booklet%20FINAL%20REVISED%202007%2006%2007.pdf [Accessed August 3, 2007.].

Prohibited Ingredients

Current Standard Language

The product shall not contain the following ingredients:

- Optical brighteners
- Ozone-depleting compounds
- Heavy metals including arsenic, lead, cadmium, cobalt, chromium, mercury, nickel, or selenium
- Dibutyl phthalate
- Alkylphenol ethoxylates

Discussion of Issues

2-butoxyethanol is currently listed as a possible human carcinogen by the EPA (classification 3) and as a result would be prohibited. However, in anticipation that its inclusion on this list may change, we propose to include 2-butoxyethanol in the list of other prohibited ingredients. Other additions to the prohibited ingredient list were discussed in the fragrance section and include phthalates, nitromusks, and polycyclic musks.

This section is anticipated to be further modified once the Proposed Revised Standard is compiled. It is the intention of the SDT to, where possible, develop criteria that prohibit undesirable chemicals due to their particular attributes, rather than to simply list them on a prohibited materials list. As such, this list will be used as a last resort to prohibit chemicals known to be undesirable, but for some reason are difficult to draft criteria to affect them (e.g. a highly absorptive chemical known to be toxic to humans that is too costly to test for).

Potential Revised Language:

Candidates for addition to the current list include:

- 2-butoxyethanol
- Nitro musks and polycyclic musks

Candidates for modification to the current list include:

- Phthalates (as a broad class of chemicals versus only dibutyl phthalate)

Training

Current Standard Language

The product manufacturer, its distributor, or a third party shall offer training or training materials in the proper use of the product. These shall include step-by-step instructions for the proper dilution, use, disposal of the product, and the use of equipment.

Manufacturers shall have product labeling systems to assist non-English-speaking or illiterate personnel.

Discussion of Issues

The Standard Development Team feels that it is important to clarify the current standard language and requirements related to training to ensure that training materials reach end-users. Currently, product manufacturers typically provide such information when it is requested by vendors or purchasers. Since the last version of GS-37, Green Seal has developed GS-42, which provides standards for Cleaning Services. GS-42 includes more rigorous requirements for training cleaning service personnel. However, the inclusion of better requirements for training materials and information under GS-37 would go a long way in further protecting human health, as well as coordinating the requirements of the two standards.

It should be directly pointed out that GS-37 can encourage training, but cannot require it. That requirement falls under the auspices of GS-42 and the best practices required of the users of products and equipment. However, GS-37 can and should make it easier for the users to use the products and equipment as safely, effectively, and efficiently as possible. This can be done through GS-37 by making such materials as accessible as possible. Thus, a balance needs to be struck in requiring appropriate training materials, and making them available in a format that they are as effective as possible. It seems reasonable to have such materials similarly available as product MSDSs, and offered both in electronic and hard copy.

How much guidance should be required within GS-37 on the content of training material remains unresolved and requires additional discussion with stakeholders. During the comment period on the scoping document, several stakeholders suggested providing requirements and language for specific items in the training materials (ex., dilution, PPE use, compliance with hazards communications, etc.). What languages should be required? What items should be included?

Potential Revised Language:

The product manufacturer, its distributor, or a third party shall offer training or training materials in the proper use of the product. These shall include step-by-step instructions for the proper dilution, use, disposal of the product, and the use of equipment, as well as recommended personal protection equipment for each stage of the product or equipment's use. Training materials shall be provided in multiple languages and with graphic icons to assist in communicating the information to non-English-speaking or illiterate personnel.

Product manufacturers should make the appropriate product and/or equipment training information available electronically as well as in hard copy.

Further, the following are potential modifications to existing equipment definitions still under consideration for adoption:

From commenter; not for inclusion in master definitions yet--

“Disposal” should be clarified to state that the instructions shall include how to properly dispose of unused/excess/spilled product and how to properly dispose (e.g., recycle) of empty packaging.

“Equipment” should be clarified to state that the instructions shall include the use of equipment required for cleaning (e.g., autoscrubbers, mops, cleaning cloths, spray bottles, etc.) and personal protective equipment (PPE) required.

References

“GS-42: Green Seal Environmental Standard for Cleaning Services, First Edition, September 1, 2006,” Green Seal, Inc.

Animal Testing

Current Standard Language

This section applies to Sections 4.1, 4.3, and 4.7. Green Seal wants to discourage animal testing and will accept the results of past peer-reviewed or standard tests demonstrating compliance with a criterion. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, Green Seal may accept non-animal (in-vitro) test results, providing that the test methods are referenced in peer-reviewed literature and the manufacturer provides the reasons for selecting the particular test method.

Rationale

This section has been changed to be consistent with the animal testing language recently revised in GS-8 Standard for Household Cleaners.

Potential Revised Language:

Green Seal wants to discourage animal testing and will accept the results of past peer reviewed or standard tests demonstrating compliance with a criterion. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, non-animal (in-vitro) test results may be accepted, providing that the test methods are referenced in peer-reviewed literature and the manufacturer provides the reasons for selecting the particular test method.

Asthma Triggers and Respiratory Irritants

Current Standard Language

Asthma and respiratory irritants are not directly addressed in the current standard.

Discussion of Issues

Over 30 articles over the last several years have documented the increased incidence and prevalence of asthma among janitors and other cleaning workers in many countries. Henneberger (2005) comments that “Over the past 15 years, professional cleaners have emerged as one of the high risk groups for work related asthma in industrialized nations.”

Eliminating the ingredients that are recognized asthmagens will reduce the capacity of cleaning products to cause new-onset asthma. It will also protect bystanders who are exposed to cleaning product ingredients when they are in the vicinity during application and in the time after application, including children in schools and day care settings.

AOEC list of asthmagens has been evaluated in the past and found to have limitations when used for product evaluations. However, research progress may prove that this list can be used in such a way. What is the consensus on the AOEC list?

To limit the use of respiratory irritants, the OECD R37 classification may be considered. We are seeking comments on this subject?

Another means to reduce the risk from asthmagens and respiratory irritants is to identify specific chemicals of concern and include those in the prohibited ingredient list. If this approach was taken, what chemical should be included?

With either approach, what is the commercial feasibility of products that would meet such limitations?

Potential Revised Language: while these topics require significantly more research and discussion, below is a starting point for review.

Asthmagens

The *undiluted* product shall not contain asthmagens. A compound is considered an asthmagen if it appears on the Association of Occupational and Environmental Clinics (AOEC) list of Asthmagens.

Respiratory Irritants

The product, as used shall not contain respiratory irritants.

References

Henneberger PK 2005. How “clean” is the cleaning profession? *Occ Environ Med* 62:586-587.

Jaakkola JJ, Jaakkola MS. 2006 Professional cleaning and asthma. *Current Opinion in Allergy & Clinical Immunology*. 6(2):85-90.

Karjalainen A, Martikainen R, Karjalainen J et al. 2002. Excess incidence of asthma among Finnish cleaners employed in different industries *Eur Resp Journal* 19:90-95.

Medina-Ramon M, Zock JP, Kogevinas, et al. 2005. Asthma, chronic bronchitis, and exposure to irritant agents in occupational domestic cleaning: a nested case-control study. *Occ Environ Med* 62:598-606.

Nazaroff WW, Weschler CJ. 2004. Cleaning products and air fresheners: exposure to primary and secondary air pollutants. *Atmospheric Environment* 38:2841-2865.

Organisation for Economic Cooperation and Development. Environment Directorate, Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. 24-Mar-2003. OECD Series on Testing and Assessment. Number 40. Detailed review document on classification in OECD member countries of substances and mixtures which cause respiratory tract irritation and corrosion. ENV/JM/MONO(2003)2.

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Rosenman KD, Reilly MJ, Schill DP, Valiente D, Flattery J, Harrison, R, Reinisch F, Pechter E, Davis L, Tumpowsky CM, Filios M. 2003. Cleaning products and work-related asthma. *Journal of Occupational and Environmental Medicine*, Volume 45(5):556-563.

Weschler CJ, Wells JR, Poppendieck D, Hubbard H, Pearce TA. 2006. Workgroup report: Indoor chemistry and health. *Environmental Health Perspectives* 114(3):442-446.

Zock JP, Kogevinas M, Sunyer J, et al. 2002. Asthma characteristics in cleaning workers, workers in other risk jobs and office workers. *Eur Resp J* 20:679-685.

Endocrine Disruptors

Current Standard Language

Endocrine disruptors are not directly addressed in the current standard. However, alkylphenol ethoxylates (APEs) and dibutyl phthalate are prohibited ingredients, in part, because evidence indicates that they act as endocrine disruptors.

Rationale

Considerable evidence has linked the exposure of wildlife to various chemicals in the environment to effects on the endocrine and reproductive systems of vertebrates, i.e., fish, amphibians, reptiles, birds and mammals (NAS 1999, www.epa.gov/endo/pubs/edspoverview/whatare.htm, www.sph.emory.edu/PEHSU/html/exposures/endocrine.htm, http://ec.europa.eu/environment/endocrine/definitions/affect_en.htm [accessed July 30, 2007]). Chemicals that exhibit these effects are called endocrine disrupters.

About 10 years ago, EPA initiated an Endocrine Disrupter Screening Program (EDSP) to screen and test chemicals for potential endocrine effects (www.epa.gov/oscpmont/oscpendo/index.htm [accessed June 20, 2007]). EPA is currently developing and validating screening and testing assays for the Endocrine Disrupter Screening program. A variety of assays are being validated (www.epa.gov/oscpmont/oscpendo/pubs/assayvalidation/status.htm [accessed June 20, 2007]), but none have achieved regulatory acceptance by EPA.

The Organization for Economic and Cooperation and Development (OECD) has also been working for about 10 years to develop new or revise existing Test Guidelines to detect endocrine disrupters (www.oecd.org/document/62/0,2340,en_2649_34377_2348606_1_1_1_1,00.html [accessed June 20, 2007]). Although several test methods are in the final stages of acceptance by the OECD, none has been published as a validated, approved method. In October 2004, the European Commission accepted a staff working document on implementation of the Community Strategy for Endocrine Disrupters (European Commission 2004). Part of the strategy entailed a literature review of chemicals that identified those chemicals with evidence of endocrine disruption or potential endocrine disruption in humans or wildlife. Annex 3 of the document includes a listing of “substances with evidence (Category 1) or evidence of potential endocrine disruption (Category 2).”

Dicyclohexyl phthalate and diethyl phthalate were identified as substances with evidence of endocrine disruption (Category 1). NAS (1999) identified several chemicals that might be used in cleaning products to have the potential endocrine: alkylphenol ethoxylates, butyl benzyl phthalate (BBP), dibutyl phthalate (DBP). In 2000, the Canadian Depository Services Program reviewed literature to summarize information about endocrine disrupters and included a list of eight phthalates as “known and suspected hormone disruptors.” In 2004, the Australian CSIRO and Australian Water Association reviewed endocrine disrupting chemicals associated with recycled water, and the report included a list of “suspected/known endocrine disrupting chemicals” that also included the same list of eight phthalates. Because a variety of phthalates have evidence of being endocrine disrupters and because phthalates are not important functional ingredients in cleaning, they should be prohibited ingredients.

Further, prohibition of the broad group of phthalates is currently included in other Green Seal standards, GS-40 and GS-8.

Potential Revised Language: In the prohibited ingredient section, continue to prohibit alkylphenol ethoxylates (APEs) and prohibit all phthalates, not just dibutyl phthalate.

References

Commonwealth Scientific and Industrial Research Organisation (CSIRO). 2004. Endocrine Disrupting Chemicals (EDCs) and Pharmaceuticals and Personal Care Products (PPCPs) in Reclaimed Water in Australia. Available http://www.clw.csiro.au/awcrrp/stage1files/AWCRRP_1H_Final_27Apr2004.pdf [accessed 6 August 2007].

Depository Services Program. 2000. Endocrine Disruptors Update. Available <http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/BP/prb0001-e.htm> [accessed 6 August 2007].

European Commission. 2004. Commission Staff Working Document on Implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife. SEC(2004) 1372. Available http://ec.europa.eu/environment/endocrine/documents/sec_2004_1372_en.pdf [accessed 21 June 2007].

NAS. 1999. Hormonally Active Agents in the Environment. National Academy Press, Washington, DC. Available <http://www.nap.edu/books/0309064198/html> [accessed 21 June 2007].

Skin Absorption

Current Standard Language

There currently are no requirements in the existing GS-37 standard for skin absorption.

Discussion Issues

The potential for skin absorption can be estimated using lists of chemicals with skin absorption potential from credible scientific sources. For example the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values for

Chemical Substances (TLV) list substances that have high potential for skin absorption (skin notation) and systemic health effects. Another list is from the German Deutsche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list for chemicals with a high potential for skin absorption (H notation). As the definitions of skin notations differ from the two organizations, the most conservative listing should be utilized to identify chemicals with high skin absorption potential.

Many cleaning products are mixed and applied in such a way that skin contact with the liquid is common. Some ingredients in cleaning products have a high potential for skin absorption; some have a potential for systemic toxicity. As these products are all mixtures, the presence of some solvents such as isopropanol (rubbing alcohol) and acetone have very low systemic toxicity, however they may facilitate the absorption of other more toxic ingredients in the formulation, thus presenting a dermal absorption hazard for the commonly used cleaning product.

Skin absorption is a very complex process. The physical characteristics of the undiluted product such as the octanol-water partition coefficient (K_{ow}) and the permeation coefficient (K_p) have been suggested as a means to determine skin absorption potential. Indeed, a number of modeling programs have been developed using these physical constants to predict skin absorption. However, the absorption of a chemical through the skin is not that simple. Factors such as temperature, pH, area of the skin, the number of appendages (hair follicles) and the presence of other agents in a formulation such as emulsifiers and surfactants have a significant impact on skin absorption.

Although there are established standardized methods to test for skin absorption, as specified by the OECD testing protocols 428 or 429 dated April 2004 or by the OPPTS 870.7600 for Dermal Penetration Studies, as published in EPA 712-C-98-350, August 1999, these tests are done on individual chemicals and the results may not be applicable to mixtures of chemicals as found in products covered by this standard.

There have been a number of lists, specifically those developed by the City of San Francisco and Seattle in their performance criteria for procurement of cleaning products. However, some of these chemicals such as monoethanolamine (141-43-5) are skin sensitizers. Solvents such as 2-butoxyethanol (111-76-2) are rapidly absorbed through skin; their absorption is enhanced in the presence of water making the diluted product more hazardous. However, there is not sufficient peer-reviewed literature on the health consequences of low exposures as proposed in this standard. Therefore no lists of chemical are included in this standard.

There are a number of lists that identify substances with a potential for skin absorption. Among the most commonly known lists are the American Conference of Governmental Industrial Hygienists (ACGIH) TLV list and the list of MAKs from the German Deutsche Forschungsgemeinschaft (DFG) list. Although the precise definition of skin absorption differs in these and other lists, they can provide an approximation of the potential for skin absorption particularly if the chemical is on both lists. Use of lists may prove to be more appropriate than requiring testing.

The impact of agents that are absorbed through the skin on sensitive populations such as residents of nursing homes or children in day care centers is expected to be minimal as they normally do not come in contact with the cleaning agents.

Potential Revised Language:

When tested to the following standard, the product *as used* shall have a low potential to absorb through the skin. In addition, each individual ingredient that comprises 1.0% or more of the concentrated product by weight shall have a low potential to absorb through skin. A “low potential” for skin absorption shall mean that less than 1.0% of the concentrated product or individual ingredient test dose absorbs through the skin of the test subject.

References

www.sfenvironment.com/aboutus/innovative/epp/specs_janchem05.pdf

www.seattle.gov/environment/documents/janitorialspecs.pdf

ACGIH: Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. ACGIH 2007. (list, pp 10-65; definition, pp 71-72).

DFG: List of MAK and BAT Values, 2005..Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Report No. 41. Wiley-VCH, Weinheim, 2005. (List pp17-129; definition pp 172-173).

OECD Guidance Document for the Conduct of Skin Absorption Studies: Organization for Economic Cooperation and Development (OECD), Environmental Directorate, OECD Environmental Health and Safety Publications, Series on Testing and Assessment No. 28, Paris, (2004).

OECD 427 – OECD Guideline for testing of chemicals – Guideline 427: Skin absorption: *In vivo* method. Organization for Economic Cooperation and Development, Paris (adopted 13 April 2004).

OECD 428 - OECD Guideline for testing of chemicals – Guideline 428: Skin absorption: *In vitro* method. Organization for Economic Cooperation and Development, Paris (adopted 13 April 2004).

Traynor, MJ, Wilkinson, SC, FM Williams: The Influence of water mixtures on the dermal absorption of glycol ethers. Toxicology and Applied Pharmacology 218: 128-134 (2007).

Packaging

Current Standard Language

The primary package shall be recyclable. Alternatively, manufacturers may provide for returning and refilling of their packages. An exception may be made for lightweight flexible packaging (e.g., pouches or bags) that represents a significant reduction in material use when compared with rigid packaging.

Discussion Issues

The existing GS-37 standard does not fully incorporate all aspects of environmental packaging design, many of which have become readily accepted by the cleaning industry due to regulatory and market-based changes. Issues which need to be incorporated, many of which were commented upon by stakeholders in the scoping comment period including: clarifying requirements related to recyclable v. post-consumer recycled content, inclusion of CONEG's heavy metal restriction requirements, and potential materials restrictions.

The proposed language for discussion is consistent with requirements of California's Rigid Plastic Packaging Container Act. The California regulations provide a rigorous series of options for plastic packaging that is reusable, refillable, recyclable, and recycled. However, it provides flexibility in allowing industry to select from those environmental-preferred packaging options.

In addition, language has been developed to provide consistency with the Council of Northeastern Governments' (CONEG) Toxics in Packaging requirements. These model requirements are broadly accepted in the marketplace, and have been adopted by 19 states as well as providing a basis for parts of the European Union's packaging requirements (94/62/EC).

Two additional issues were raised by several stakeholders during the scoping comment period that remain unaddressed and need resolution: 1) a prohibition on certain materials with known, negative environmental and human health impacts, such as ABS and PVC; and 2) for products which will be used in schools, the inclusion of requirements for child-resistant packaging.

Regarding restricted or prohibited materials, a subsection was added to address phthalates, to bring the standard into conformance with other Green Seal standards. Further, the conformance of requirements of the California Rigid Plastic Packaging Container Act, will, by default, limit the use of ABS and PVC containers. However, we should discuss whether a more rigorous restriction is appropriate.

Regarding the inclusion of requirements for child-resistant packaging, we should discuss whether this is appropriate within the full GS-37 revision or as a verifiable claim for sensitive populations (including children).

Potential Revised Language:

Recyclable Primary Package. The primary package shall be a recyclable package. If the primary package is not a recyclable package must be a refillable package. An exception may be made for lightweight packaging (e.g., pouches or bags) that represents a significant reduction in material use when compared with rigid packaging.

Recovered Material Content. The primary packaging shall contain the state-of-the-art amount of recovered and post-consumer content. For rigid plastic packaging, this means at least 25 percent post-consumer content. Where a product's packaging is below these levels, the manufacturer must demonstrate that efforts have been made to use the maximum available post-consumer material in packaging.

Concentrated Product Packaging. Concentrated products are prohibited from being packaged in ready-to-use forms, including but not limited to spray-dispenser bottles.

Aerosol Cans. Aerosol cans shall be recyclable. Further, manufacturers of products packaged in aerosol cans must show that recycling programs are widely available where the product is sold. In addition, manufacturers of products packaged in aerosol cans must demonstrate why aerosol cans are the most suitable packaging for a given product considering environmental, health, and performance considerations.

Secondary Packaging. Secondary packaging shall only be used for concentrates. An exception may be made for packaging of multiple units when up to one of the units is a ready-to-use form, including but not limited to spray-dispenser bottles, and total packaging (primary plus secondary) is a reduction in packaging material use.

Ancillary Products. Products may contain disposable towelettes or other disposable wiping materials if they are made from 100% renewable materials including, but not limited to cellulosic materials, and meet the state-of-the-art amount of recovered material content.

Heavy Metal Restrictions. Heavy metals, including lead, mercury, cadmium, and hexavalent chromium, shall not be intentionally introduced. Further, the sum of the concentration levels of these metals present shall not exceed 100 parts per million by weight (0.01%); an exception is allowed for packages that would not exceed this maximum level but for the addition of recovered materials. Further, intentional introduction does not include the use of one of the metals as a processing aid or intermediate to impart certain chemical or physical changes during manufacturing, where the incidental retention of a residual of that metal in the final package or packaging component is not desired or deliberate, if the final

package or packaging component complies with the incidental concentration restrictions of 100 ppm.

Other Restrictions. Phthalates are prohibited from being intentionally introduced, an exception is allowed for packages that would not have added phthalates but for the addition of recovered material.

References

California Rigid Plastic Packaging Container Act, Title 14, California Code of Regulations, Section 17944.

“California’s Rigid Plastic Packaging Container Law,” California Integrated Waste Management Board,
<http://www.ciwmb.ca.gov/plastic/RPPC/>

“GS-8: Green Seal Environmental Standard for General-Purpose, Bathroom, Glass, and Carpet Cleaners Used for Household Purposes, Second Edition, July 2, 2007,” Green Seal, Inc.

Model Legislation, Toxics in Packaging Clearinghouse, Northeast Recycling Council, <http://www.toxicsinpackaging.org/model%2Blegislation.htm>.

Labeling Requirements

Current Standard Language

The manufacturer’s label shall state clearly and prominently that dilution with water from the cold tap is recommended and shall state the recommended level of dilution. Carpet cleaner labels shall specify the use of cold water for products that do not suffer significant performance degradation in cold water. The manufacturer shall also include detailed instructions for proper use and disposal and for the use of personal protective equipment.

Whenever the Green Seal certification mark appears on a package, the package shall contain a description of the basis for certification. The description shall be in a location, style, and typeface that are easily readable. Unless otherwise approved in writing by Green Seal, the description shall read as follows:

“This product meets Green Seal’s environmental standard for industrial and institutional cleaners based on its reduced human and aquatic toxicity and reduced smog production potential.”

For FIFRA-registered bathroom cleaners, replace “toxicity” with the word “impacts.”

Discussion Issues

The current language for this criterion was modified to read "...unheated water directly from the cold tap..." to be consistent with the proposed changes under Section 3.0 Product Performance. This language has been modified to specifically indicate that unheated water be specifically indicated on the label for product use. The purpose of this clause is to 1) insure that cleaners that are often used with solutions that are close to ambient temperatures still perform effectively, and 2) reduce the life-cycle impacts associated with the use of products that require water be heated to perform adequately. The modification will clarify the requirement to insure that cold, unheated water from the tap be used.

As the revision progresses, the Development Team may want to discuss whether to sub-numerate the section, to make it consistent with the recent revision of GS-8 and the new GS-42 standards

Potential Revised Language:

The manufacturer's label shall state clearly and prominently that dilution with unheated water directly from the cold tap is recommended and shall state the recommended level of dilution. Carpet cleaner labels shall specify the use of unheated water for products that do not suffer significant performance degradation in cold water. The manufacturer shall also include detailed instructions for proper use and disposal and for the use of personal protective equipment.

Whenever the Green Seal certification mark appears on a package, the package shall contain a description of the basis for certification. The description shall be in a location, style, and typeface that are easily readable. Unless otherwise approved in writing by Green Seal, the description shall read as follows:

"This product meets Green Seal's environmental standard for industrial and institutional cleaners based on its reduced human and aquatic toxicity and reduced smog production potential."

For FIFRA-registered bathroom cleaners, replace "toxicity" with the word "impacts."

References

"GS-8: Green Seal Environmental Standard for General-Purpose, Bathroom, Glass, and Carpet Cleaners Used for Household Purposes, Second Edition, July 2, 2007," Green Seal, Inc.

"GS-42: Green Seal Environmental Standard for Cleaning Services, First Edition, September 1, 2006," Green Seal, Inc.

Other Revisions to be Considered

In addition to the material presented previously in this document, there are a few issues that remain to be considered that were flagged as an outcome of the scoping process. These issues have yet to be taken up by the SDT as of the time this report was developed, but will ultimately be evaluated for inclusion in the draft revised standard. The issues include:

- Good management practices
- Biobased ingredients
- Aerosol reaction products
- Full disclosure of ingredients through adequate testing
- If and what a claim verification program should be included for vulnerable/sensitive individuals

All of these issues were commented on or discussed in the document entitled GS-37 Scoping document that can be found at http://www.green seal.org/certification/g s37_iicleanersstandard_dev.cfm. For more details about the issues above, please refer to the comments within the document. These issues