RESPONSE TO COMMENTS ON PROPOSED ENVIRONMENTAL STANDARD FOR HANDCLEANERS / HAND SOAPS CCD-104 / GS-41

Note: Supporting information presented in the background document will not be revised or re-issued; however, the comments on those sections have been taken into account in revising the standard itself.

Scope

1. The definition of institutional hand cleaners and hand soaps should be modified to specifically exclude healthcare and public/institutional food handling settings. These are situations where the use of antimicrobial products is, in many cases, mandated by infection control standards and practices, as well as government regulation. Both settings also have cross-over between consumers and workers in the restrooms. Unless Green certification standards are developed for antimicrobial hand wash products, these settings should be identified as being outside the scope of the current standard.

2. We noticed that exclusions have not been set for health care facilities and alcohol hand sanitizers, which perpetuate safety and health concerns for some of our major customers. Please specify how these will be treated?

3. The guideline defines an institutional hand cleaner as "products advertised for normal use in public buildings including restaurants, offices, stores and other public buildings". This definition ignores the fact that products used in health care, other food handling settings and day care settings are also institutional products. If the goal of this standard is to exclude products for those particular use patterns, it should indicate that in the introduction as well as in the definition. This is becoming increasingly important as more government entities adopt environmentally preferable procurement practices citing the observance of Green Seal standards.

4. Were hospital and healthcare markets purposefully excluded from the scope of this standard? The question is raised with respect to the ban of antimicrobials. 75% of hand soap sales are into the healthcare market and while non-antimicrobial soap may remove bacteria from the hands, the bacteria go into the sink or onto the counter and remains active for spreading around the facility. In healthcare in particular, it is important to have 99.9% efficiency in killing the bacteria on the hands because this stops the potential spread of the bacteria. The same could be said in food service preparation where restaurant workers often use the restaurant restroom as the means for washing their hands before food handling.

5. Is it the intent to have both Hand Cleaners and Institutional products under the same guidelines? They are distinctly two different types of products and have very different characteristics. It is our feeling if this is the intent, serious consideration needs to be made to keep two distinct categories – Hand Cleaners, to refer to industrial, heavy-duty type products for removal of difficult soils such as grease, oil, inks, resin, etc. and Institutional Skin Cleansers, referring to products for light soil removal, such as body fats, and generally found in public washrooms of restaurants, retail, schools and other public buildings, and showering areas.

Response: The type of products covered by this standard could be clearer. Alcohol hand sanitizers are not designed to remove organic and inorganic soils and would not be considered "industrial heavy duty hand cleaners" or "institutional hand cleaners." The scope of the standard will be revised to read as follows:

Hand cleaners are designed to remove both organic and inorganic soil from skin. Industrial products are found in garages, print shops, and other industrial settings. Institutional products are found in public washrooms of restaurants, retail, schools and other public buildings. The standard does not focus on the use of hand cleaners in households, food preparation operations, or medical facilities.

The format of the standard will be revised to make the different requirements for industrial versus institutional products clearer.

6. How will changes impact registered products…how many other standards are to be harmonized?

   Response: Existing certified products will have to re-assessed against the updated criteria and prove compliance to continue using the logo.

   Harmonization of ecolabelling standards is an objective of the Global Ecolabelling Network of which ECP and Green Seal are members. We will see how this goes and then evaluate what if any other criteria could be jointly developed.

Product Performance

7. "Hand soaps" for institutional use comprise a range of products with wide variation in soil removal, or cleaning performance. In general though, all soaps are capable of some degree of cleansing and relative differences ultimately may be due more to the underlying cost of the formulae than any other parameter. There is no generally accepted "control" for cleaning performance across the spectrum of institutional hand soaps. A manufacturer should provide evidence of good faith testing of a soap product to insure at least a threshold of acceptable performance.

   <u>Proposed change:</u>
   3.a. Product shall meet such performance standards as advertised by the supplier or generally accepted by the user. Manufacturers would be required to submit documentation of such performance, whether by internal or external testing.

8. The Health Care Personnel Hand Wash (HCPHW) ASTM method E-1174 for antimicrobial soaps should be the basis for judging efficacy against bacteria.

9. [Commentor] supports the option of utilizing internal test results that are done according to a "fixed repeatable procedure against a standard control."

10. Possible performance standards: ASTM E1174 - Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel or Consumer Handwash Formulations, ASTM E1183 -

Standard Test Method for Assessment of an Antibacterial Handwash Product by Multiple Basin Wash Technique

11. Would appreciate further information…Please define efficacy

Response: ECP and GS want products bearing the EcoLogo and Green Seal logo to perform as users/ purchasers expect and therefore the proposed standards require a proof of performance.

Several commenters identified ASTM test methods for antimicrobial soaps (ASTM E 1174 and E 1183). These tests provide useful standards for volume of product, temperature of water and duration of cleansing but the endpoint of the test is reduction in bacteria that have been artificially applied. Adopting ASTM E 1174 or 1183 is inappropriate without significant changes to the test method.

Based on comments received and testing procedures submitted, the performance criterion has been modified and the final standard language reads:

4. (a) using a fixed, repeatable procedure, demonstrate efficacy against a nationally recognized conventional product showing equivalent or better performance. The testing protocol should include, at a minimum: cleaning ability, lathering/rinsing, and skin condition after use. A standard soil shall be used and conclusions should be derived from at least six separate samples. All results, a summary of conclusions and a description of how any panelists are chosen shall be submitted

Skin Sensitization

12. The proposed standard recommends using OECD guidelines or other standard methods such as Buehler (1994) or Magnusson & Kligman (1969). Other methods should also be recommended, including Shelanski HA, Shelanski MV. (1953) Proceeding of Scientific Section Toilet Goods Association 204:107-110.

Response: The criterion in the proposed standard states that other standard test methods for skin sensitization may also be accepted as proof that the product or its ingredients are not skin sensitizers.

13. [Commentor] agrees that products shall not contain known skin sensitizers; however, we request that a clarification to 3b be provided specifically concerning the component level-
"if a product contains a known skin sensitizer at or above a concentration of 0.1%, then the product as a whole shall be considered a skin sensitizer, except where explicit data demonstrate that it is not a skin sensitizer, **this may include evidence that the product may be a skin sensitizer but not at levels less than (X), including levels greater than 0.1%."**

Response: The criterion in the proposed standard states, "If a product contains a known skin sensitizer at or above a concentration of 0.1%, then the product as a whole shall be considered a skin sensitizer, except where explicit data demonstrate that it is not a skin sensitizer."

The "it" referenced is the product, that is, the product shall not be considered a sensitizer under the following scenarios:

- if data shows that the whole-product when tested is not a sensitizer,
- if data shows that each of the raw materials is non-sensitizing, or
- if data shows that any known sensitizers are non-sensitizing when used at or below a certain level in the product (which includes levels of 0.1% and above).

The language in the final standard has been revised to more clearly reflect the requirements, which are consistent with the skin sensitization labeling requirements of the Globally Harmonized System for Classification and Labeling of Chemicals (GHS), published by the United Nations in 2003.

4. (b) not be a skin sensitizer as tested by OECD Guidelines for Testing Chemicals, Section 406, Buehler (1994), or Magnusson and Kligman (1969) or other peer-reviewed or standard test methods. The product shall not be considered a sensitizer under the following scenarios:

- *if test data shows that the whole-product is not a skin sensitizer,*
- *if test data shows that each ingredient present at or above a concentration of 0.1% is not a skin sensitizer, or*
- *if test data shows that any known skin sensitizers are non-sensitizing when present at 0.1% or greater in the product*

Skin Irritation

14. The document recommends using OECD guidelines. The method in the OECD guidelines is not used widely for personal care or cosmetic products. Other methods that should be included are:
• Lanman et al., 1968. The role of human patch testing in a product development program. Joint Conference on Cosmetic Sciences, The Toilet Goods Association, Washington DC, April 21-23
• Frosh & Kligman, 1990. The soap chamber test: a new method for assessing irritancy of soaps. Journal of American Academy of Dermatology. 95:543-547
• Robinson et al., 1998. Application of a 4-h human patch test method for comparative and investigative assessment of skin irritation. Contact Dermatitis 38:194-202

Response: Consistent with ISO 14020 and 14024, Green Seal and Environmental Choice prefer test methods developed by international and national organizations over those developed by local agencies or academia. It is acceptable for applicants to demonstrate evidence for low sink irritation with different tests results, but the burden for proving the test provides equivalent results to OECD 404 rests with the applicant.

15. [Commentor] would also request similar clarification to 3c, specifically "if a product contains a skin irritant at or above a concentration of 5%, then the product as a whole shall be considered a skin irritant, except where explicit data demonstrate that it is not a skin irritant, **this may include evidence that a component is a skin irritant, but not at levels less than (X), including levels greater than 5%."**

Response: Similar to Response 13 above, the "it" referenced is the product, that is, the product shall not be considered a skin irritant under the following scenarios:

- if data shows that the whole-product when tested is non-irritating to skin,
- if data shows that each of the raw materials is non-irritating, or

- if data shows that any known skin irritants are non-irritating when used at or below a certain level in the product (which includes levels of 5% and above).

The language in the final standard has been revised to more clearly reflect the requirements, which are consistent with the skin irritation labeling requirements of the Globally Harmonized System for Classification and Labeling of Chemicals (GHS), published by the United Nations in 2003.

4. (c) not be a skin irritant as tested by OECD Guidelines for Testing Chemicals, Section 404 or other peer-reviewed or standard test methods. The product shall not be considered a skin irritant under the following scenarios:

- *if test data shows that the whole-product is not a skin irritant,*
- *if test data shows that each ingredient present at or above a concentration of 5% is not a skin irritant, or*
- *if test data shows that any known skin irritants are non irritating when present at 5% or greater in the product*

16. Many surfactants are irritants and to have a product that is a degreaser or institutional/industrial soap is likely going to have more than 5% in it. Products used in extreme soil environments, such as garages, also have harsher chemicals (ie. petroleum distillates), which can also be skin irritants. Handsoaps are intended to have brief contact with skin, diluted with water during washing, and then rinsed off thoroughly. Since direct contact with the concentrated soap is minimal, the products should be tested at the appropriate use dilution. The industry standard for irritation testing on humans is typically 2-5% based on a variety of factors, including the inherent irritating properties of the products. If tested at full strength it will be difficult to distinguish between irritation and sensitization. We therefore suggest that if there is a question of irritancy or sensitization with a product, that testing on an appropriate use dilution of 2-5% be conducted.

Response: Although direct contact with the concentrated hand soap may be minimal, there is still direct contact. Criteria in this and other Green Seal and Environmental Choice environmental standards have tended to favor the most likely route of exposure. For example, the aquatic toxicity criterion recognizes that the product and associated rinse water will go down the drain and allows for the 1:200 dilution provided by the rinse water used. In the case of the hand soap, the user may simply wet their hands and then proceed to wash them using the recommended/dispensed amount of hand soap. Despite the small amount of dilution provided by the initial wetting of hands, the rinsing and additional dilution may not come until 15 or 20 seconds later if proper handwashing techniques are used.

There are also heavy duty and institutional hand cleaners that may be used with water or "waterless," in which case no dilution with water is involved.

17. [Commenter]… consider adding a restriction on high pH hand cleaners. Many studies have demonstrated that repeated hand washing with soap/ detergent and water raises the pH of skin and as the pH of skin increases there is a notable increase in skin ailments. See "Hygiene of the Skin: When is Clean Too Clean" E. Larson. Emerging Infectious Diseases. 2001.Vol 7. No 2

Response: The target market for these hand soaps is not the medical setting described in the paper. In other words, frequent and repeated use of the soaps does not accurately describe how these products are used. The existing restrictions on skin irritation and skin sensitization are enough to protect skin of users.

Instructions for Use

18. Do you mean general instructions, such as "Apply to soiled hands and rub in thoroughly. Add water and continue rubbing hands. Rinse with water and dry hands"?

    Response: Yes.

Packaging

19. If an exemption is given for flexible packaging, the packaging should not be made with PVC or other toxic materials.

20. The *carte blanc* exclusion of bag-in-box packaging ignores the fundamental benefit of this type of packaging, and the progress made over the last decade to reduce its environmental footprint even further. Bag-in-box and other flexible pouch systems have achieved a dominant position in institutional soaps due to their many advantages. They are recognized as more hygienic than traditional bulk, refillable systems (see "how should hand care products be stored" at Centers for Disease Control Prevention website, http://www.cdc.gov/oralhealth/infectioncontrol/faq/hand.htm). [National Center for Chronic Disease Prevention and Health Promotion, Oral Health Resources for patients and health care personnel] In addition, bag-in-box packaging is more space and labor efficient, less likely to be overused (portion- controlled), and presents a relatively low waste profile in landfills. However, from a green perspective, the standard 800 mL bag-in-box system can be improved, and these improvements should serve as the basis for eco-label considerations.

    The industry standard for flexible packaging of hand soaps is the 800 mL bag-in-box (BIB) system with a lightweight film (bag) inside a rigid cardboard box. The box is serrated with a tear-off to expose a portion of the bag for viewing when placed inside a dispenser. The bag:soap product ratio in a typical 800 mL BIB is approximately 12g/liter. Although the box is typically high post consumer recycle paper, newer BIB type systems offer improved environmental impact. Some systems require the bag to be completely removed from the box prior to placement in the dispenser. The box is then easily placed in the normal paper recycle stream. Other systems eliminate the box entirely but may use somewhat more material in the overall packaging to compensate. Again though, the paper components are more readily recycled. Finally, some larger volume refill (e.g., 1000 – 2000 mL) containers are possible wherein the ratio of packaging material to soap is significantly improved vs. the 800 mL system.

    <u>Proposed change:</u>
    3.e. If the primary product container is rigid plastic, it shall be recyclable;
    3.f. If the primary product container is lightweight, sanitary-sealed, flexible packaging (e.g. pouches or bags), it shall represent a significant reduction in material compared to the industry standard 800 mL bag-in-box packaging. Such reduction can include: a) use of a cardboard carton (box) that must be removed prior to use of the bag, b) elimination of the box, and/or c) a

meaningfully lower ratio of packaging material to soap product;
3.g. As demonstrated by the due diligence of the manufacturer, efforts have been made to ensure packaging with post-consumer recycled content;

21. Packaging: Data cannot be generated to represent a significant reduction in flexible packaging material (at least 30X less plastic per volume of product) when compared to rigid packaging. A true representation is 3-5 times less packaging materials, due to the nature of the product (it is a RTU), and the way it is dispensed.

22. [Commentor] believes that bag in box packaging should still be considered a viable packaging option for hand cleaner products. The proposed standard seeks to restrict products in this type of packaging, as listed in *3e not to be packaged in bag in box packaging*.

    Product waste is currently listed as a case against bag in box due potential waste resulting from the potential of product to be replaced before necessary due to limited view of level of product inside the container.

    3f permits the use of *lightweight flexible packaging that represents a significant reduction in material when compared to rigid packaging.* An outer box would provide protection for such flexible bag in transit and in storage, reducing the chance of product waste through puncture or leakage.

23. Studies of bulk soap containers have shown bacterial growth in the soap containers over time with the combination of open, bulk containers and non-antimicrobial soaps. The reservoirs are seldom cleaned and different soaps could be placed in the same dispenser. The use of Bag-in-a-Box (BIB) packaging would prevent the growth of bacteria because it is a closed system, plus it is made from partially recycled materials and can be recycled. The Chipboard is from recycled material, the BIB itself is Polyethylene which is recyclable, and the Valve can be removed. Therefore, we suggest the allowance of BIB packaging with the prevision that instructions are given to recycle after use.

24. From a health and safety issue, we do not feel that bulk soap dispensers provide health and safety advantages for the customer. There are no assurances in place that the integrity of the product has not been compromised due to contamination (switch out different soaps), lock–out (dilute with water), etc. How will this issue be addressed from a health and safety aspect?

    Response: This standard does not focus on products used by medical facilities and any special requirements for hand cleaners and dispensing equipment used in them.

    The majority of hand soap manufacturers surveyed market products packaged in several formats, including in bulk form designed to refill dispensers, in bulk containers that also function as the dispenser via the addition of a pump, in rigid plastic cartridges for use with dispensers, in bags and in bag-in-the-box (BIB) packaging. There are clearly, based on the marketplace, situations and facilities where a bulk dispensed product can be safely used.

    A survey of BIB and bag packaging showed many to use multi-layer, multi-material bags that are non-recyclable (coded as Society of the Plastics Industry code “7-Other”). In addition, the nozzle or dispensing nipple is typically an integral part of the bag assembly and not easily

removed. If the bag and nozzle are also contained in a box, the entire assembly becomes difficult to take apart and recycle, assuming those materials are readily recyclable in most communities. Simply providing instructions to recycle would not necessarily make the packaging more environmentally responsible. When the visual challenge of viewing the product inside a bag inside a box is considered, the potential added product waste must also be considered.

Flexible packaging does have several environmental benefits compared to the equivalent rigid container across several parameters, which may include:

- weight of the flexible package versus a rigid container
- manufacturing energy required for a pouch versus rigid container
- amount of overall plastic material in the pouch versus a rigid container
- evacuation efficiency of the pouch versus rigid container
- transportation savings (e.g., less energy to transport empty pouches, more filled pouches in the same amount of cargo space).

The intent of the specific percentage reduction in the proposed standard (at least 30X less plastic per volume of product) is to eliminate hand cleaners packaged in "bags" that are overpackaged and therefore use as much or more material per volume of product delivered as rigid packaging, but without the option of recycling the empty package. Based on available data, the final standard for hand cleaners will require a minimum 20% reduction in material use for flexible packaging when compared with rigid packaging, and the final standard language reads:

4. (f) be packaged in recyclable packaging. An exception shall be made for lightweight flexible packaging (e.g., pouches or bags) that represents at least 20% reduction in material use when compared with rigid packaging

Antimicrobials

25. We agree with the restriction on antibacterial ingredients.

26. The proposed change in wording accomplishes the same intent as the original language but adds a bit more specificity. It clarifies that this standard applies specifically to general use, non antimicrobial soaps, but also acknowledges the mandated use of antimicrobial products for infection control purposes in health care and food handling settings. Antimicrobial soaps are defined by the use of specific antimicrobial active ingredients (such as triclosan, triclocarban, quats, etc.) at defined levels. These products are well defined and regulated in both the US and Canada. These government standards provide a clear and consistent basis for the definition of antimicrobial soaps.

    Antimicrobial soaps are under the domain of FDA, and no products in this category are registered under EPA (FIFRA). The FIFRA reference is unnecessary and may be confusing.

    Proposed change:
    Antimicrobial Soaps -
    3.h. Soap products shall not be formulated with antimicrobial drug active ingredients nor make antibacterial, antimicrobial, or antiseptic product claims (e.g., the product must not: a) contain

ingredients or make claims that subject it to US Food and Drug Administration OTC monograph requirements for hand antiseptics; b) have or be required to have registration under Health Canada's Therapeutic Products Directorate; or c) require a Drug Identification Number (DIN). Antimicrobial soaps required for healthcare and food handling settings, as well as non soap hand rubs/sanitizers are outside the scope of this standard.

27. The discussion of antimicrobials on page two of the introduction and background document seems to have confused the controversy regarding use of antimicrobial hand products in the home by consumers with the use by institutional users in health care settings. Many of the resources that have been footnoted do not support the statements in this section either. We recognize there is still a great deal of debate regarding the benefits of antimicrobial hand wash products in the home. The FDA Nonprescription Drugs Advisory Committee has recommended that more study be done in this area. However, caution should be taken to use this debate as a means of making decisions on all antimicrobial hand soap products. CDC has developed a guideline for hand hygiene in health-care settings that includes the use of antimicrobial products in these settings. The Canadian Centre for Occupational Health and Safety has indicated that use of antimicrobial soaps may be appropriate in certain health care settings. We feel this further supports our recommendation that there be a comment in the introduction that this standard is not intended for products used in health care, day care or food service settings.

28. Again, are we talking about products for Heavy Duty soil removal only, or are you including all products? If for HD products, this is agreed (many reasons why this makes sense, as antibacterial claims for a HD product is redundant). However, if not, why are you disallowing Eco labeling for DIN product, where it is absolutely critical and demanded by some market segments to have such products (i.e. – healthcare providers, food processing, etc.) Does this also preclude future innovations in anti-bacterial ingredients that conclusively prove not to be any kind of detriment to the environment, and fall under the NHPD (Natural Health Products Directorate)?

    Response: The standard does not focus on the use of hand cleaners in households, food preparation operations, or medical facilities.

    The prohibition on antimicrobial ingredients has been simplified and the final standard language reads:

    4. (h) make no antibacterial, disinfecting, antiseptic or sanitizing product claims

29. Hand soaps typically require preservatives to prevent bacteria and/or fungal growth; that is, they cannot maintain shelf life without the use of antimicrobial preservatives. As currently stated, all antimicrobial ingredients would be eliminated from these products. There is a wide range of in-can preservatives approved by EPA and PMRA that perform this function with little-to-no environmental impact, including bioaccumulation.

    Response: The use of small amounts of preservatives in cleaning products is acceptable, provided the preservatives comply with the requirements in the environmental standard and the hand cleaner makes no antibacterial, disinfecting, antiseptic or sanitizing product claims.

Fragrances

30. We prefer elimination of fragrances. Some institutions are going "fragrance free", and more and more people are developing chemical sensitivities.

    Response: Industry estimates between 90 and 95% of the hand soap products contain fragrances. This criterion follows the approach taken in other Green Seal and Environmental Choice standards to recognize responsible use of fragrances. By requiring that fragrances meet the criteria in the environmental standard and disclosure on the label and MSDS that a fragrance has been added, purchasers can make an informed decision regarding the use of hand soaps and fragrances.

Volatile Organic Compounds

31. At this time, there is no regulatory limit for institutional hand cleaners in the US or in Canada. The California Air Resources Board has only adopted an 8% limit for heavy duty hand cleaners and soaps, such as those used in automotive or industrial settings. There is no technical rational given as to why a 1% limit has been chosen or whether it is even technologically feasible. The ARB adopted these limits based on the technological feasibility of having efficacious products that meet the requirements. We recognize that there are varying limits between states and federal EPA, therefore it would be more appropriate to advocate that products meet the most stringent VOC requirement. This would also take care of the continuously changing regulatory standards.

32. We do not have formal comments but thought that you should be aware that there are some differences in the exempted compounds in the federal volatile organic compound (VOC) definition cited in the proposed standard and CARB's Consumer Product Regulation VOC definition (section 94508(a) (144) of Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Article 2). This difference may be relevant if CARB 310 is used to certify a product. Also, you should be aware that CARB Method 310 allows subtraction of low vapor pressure VOCs (LVP-VOC) as defined in section 94508(a)(91). If Method 310 is used, some products could have significant levels of LVP-VOCs and still meet your certification standard. In particular, some heavy duty hand soaps could contain low vapor pressure hydrocarbon compounds such as some of the Isopars.

33. VOC levels in institutional soaps are generally quite low. They do not contain solvents that are sometimes employed in heavy duty cleaners used in industrial settings. A series of regulatory initiatives on the federal, provincial, state and local level increasingly restrict VOC levels in hand cleaner and hand soap products. These will ultimately minimize or eliminate VOC’s in these products. Green Seal should seek to harmonize with these key regulatory initiatives.

    <u>Proposed change:</u>
    VOC levels of institutional products (as defined in this standard) are almost universally lower than those of industrial products. Moreover, Green Seal does not propose to pre-empt key VOC regulatory initiatives at the local, state, and federal level and will rely upon on-going compliance with regional VOC limits as the basis for certification. Nonetheless, any institutional product with one percent or less VOC will be considered to have met the VOC requirements of this standard.

Response: Green Seal and ECP believe 1% VOCs by weight is a feasible upper limit for institutional hand cleaners and 8% VOC by weight for industrial cleaners based on our survey of currently available products.

Using CARB Method 310, even though the definitions would permit some low vapor pressure VOCs that might be otherwise ineligible with EPA VOC definitions, is acceptable for this product group for three reasons: 1) Method 310 is referenced in other Green Seal and Environmental Choice standards for similar product types, 2) the 8% limit for industrial hand soaps is identical to the limit set by CARB and attainable using CARB Method 310, and 3) for institutional hand soaps, users are exposed to the product for only short periods of time and less volatile low vapor pressure VOCs are considered less of a danger for volatilizing, reaching and affecting users.

Biodegradability

34. Would it be possible to make an exemption for the biodegradability of polymers that are used for rheology modification/thickeners in hand soaps, (similar to the exemption given to polymers in floor finishes/polishes)? Allowing the use of polymers would provide an environmental benefit as it can significantly reduce the amount of surfactant in the formulation as often high surfactant levels are used to build viscosity in hand soaps when polymers are not used. This would lower the environmental impact, (i.e. less BOD, reduced aquatic toxicity) and address the need for sustainable cleaning as society moves forward. It is known that these polymers, (i.e. xanthan gums, carboxymethyl cellulose, polyacrylates) used have low aquatic toxicity and are efficiently removed from sewage treatment plants. These polymers that are used in these personal care products are also non-senzitizing and do not contribute to irritation.

    Response: The environmental impact of these products during disposal is a key impact and therefore biodegradability of all ingredients is important. Publicly available formulations with polymers do have approximately 15 to 50% less surfactant compared to formulations without a polymer. These savings are significant but not consistent and at least one of the thickeners mentioned by the commenter is considered readily biodegradable, so the biodegradability requirement for all ingredients will remain.

Aquatic Toxicity

35. [Commentor] supports the use of a 200 to 1 dilution (5 mL of product diluted in 1 L) for <u>liquid products</u> as a basis for Aquatic Toxicity.

    Due to the development of alternate delivery systems such as foam, [Commentor] requests that an additional dilution of 0.8 -0.9 ml per 1 Liter be added as a dilution criterion for foaming hand cleaners.

    It appears that Green Seal intention is to require whole product testing for aquatic toxicity, rather than permitting component data as in previous standards.

[Commentor] supports permitting component data in addition to an option to submission of whole product data if such data already exists for components against the organism *Photobacterium phosphoreum.*
[Commentor] also supports submission of aquatic toxicity data against alternate aquatic organisms, should such data exist.
Requiring submission of whole product testing could create economic hardship for smaller companies.

36. Would like some additional information on the test.

Response: The EPS RM 24 / Microtox method is relatively inexpensive ($100 to $200 per sample), fast (15 minute test), and accurately quantifies the toxicity of the product. There are many laboratories qualified to perform aquatic toxicity testing under the Canadian Association of Environmental Analytical Laboratories http://www.caeal.ca/caeal_directories.html. To find labs use the search option for either "Method 13" or for parameter "Microtox."

We recognize the characteristics of foam soaps might make the 1: 200 dilution inappropriate for all types of products. The aquatic toxicity criterion has been modified and the final standard language reads:

4. (u) based on standard use, not be toxic to aquatic life defined as IC_{50} > 1000 mg/L as measured by whole formulation short-term sensitive toxicity test performed on the bacteria Photobacterium phosphoreum. Aquatic toxicity shall be measured by one of the following test methods: Biological Test Method: Toxicity Test Using Luminescent Bacteria (Photobacterium phosphoreum), Report EPS 1/RM/24, November 1992, Environment Canada, ASTM D5660-96 or ISO 11348.

where "standard use" is defined in definition section as "the amount of product directed for use and diluted in 1 litre of tap water. If no dose is suggested, 5 ml of liquid hand soap shall be used and 0.9 ml of foam soap shall be used."

Other Ingredients

37. There is nothing in the standard about the use of coloring agents in the product. The TURI document "Ten Ways to Find Safer Cleaners" recommended that "If colors are used to differentiate cleaning products, these should be safe, too, (such as those used for Food, Drug and Cosmetic purposes)."

Response: Dyes are frequently used in hand soaps to differentiate products, to minimize an underlying color from active ingredients that may not be appealing, and to mask ordinary color changes of ingredients from natural sources (e.g., soaps). A criterion addressing dyes has been added to the final standard that is consistent with the criteria used for dyes in similar product types.

4. (q) if formulated or manufactured with dyes, be formulated with only food grade dyes