IBEL Content – Work Group Packet

April 9, 2010

This document has been developed for use during the April 9th IBEL workgroup call, scheduled from 12-2 PM Eastern. To participate, please use the following call-in information. Thanks.

(218) 936-1100 Access Code #105445.

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IBEL Content- Working Menu

The following is a working list of potential IBEL content. Entries in the table indicate proposed categories and the associated IBEL metric(s) to be measured or reported. Please note: Not all metrics will necessarily apply to all products. This list will evolve through the decisions of work groups, and will be updated after each work group meeting to reflect the most recent status. When completed, this list will constitute a **MENU** of metrics against which product data can be reported. Individual metrics will be selected from this menu to assemble the product label content for each product category in future calls. **Purple shaded entries in the table are to be considered on the April 9, 2010 work group call. Changes since last call are displayed in Blue text. Approved criteria are shaded in green.**

Human Health & Environmental

Category	Reportable IBEL Metric	Status
Asthmagen content		**May 13**
Acute Chemical Concern - Oral	Oral LD50, GHS	**Recommended (Mar 9)**
Acute Chemical Concern - Inhalation	Inhalation LC50, GHS	**Recommended (Mar 9)**
Acute Chemical Concern - Dermal	Dermal LD50, GHS	**Recommended (Mar 9)**
Corrosivity to Skin		**May 24**
Skin Sensitizer		**May 24**
Product Absorption via Skin		**May 24**
Volatile Organic Compound Content		**May 13**
Chronic Chemical Concern - Oral		
Chronic Chemical Concern - Inhalation		**May 13**
Chronic Chemical Concern - Dermal		**May 24**
Phosphorus Eutrophication	Phosphorus Content – Wt % Phosphorus Content – grams /use (at most conc dilution)	**Modified – Open for Comment on BB (Apr 6)**
Biodegradable Content – Aquatic	% of product content considered biodegradable	**Under development – Will be reconsidered on future call**
Bioaccumulating content		**April 9**

Toxicity to Aquatic Life	Acute LC50 (for all 3 species - Fish, Daphnia, and Algae)	**Modified – Open for Comment on BB (Apr 6)**
Product Embodied Energy		
Product Embodied Water		

Product Performance

Category	Reportable IBEL Metric	Status
Product Performance (specific to product type)		**Under Development (Mar 11)**
Energy Efficiency		
Water Efficiency		

Additional Product/Packaging

Category	Reportable IBEL Metric	Status
Reportable Product Content		**April 9**
Trace contaminants – CMRs (unintentionally added)		
Fragrance	Fragrance Added (No/IFRA/DfE/Other)	**Open for Comment (Feb 19)**
Color and dyes	Colorant added (Yes/No)	**Open for Comment (Feb 19)**
Combustibility	Flash point, (^{o}F)	**Open for Comment (Feb 19)**
Post-Consumer Material content	PC Packaging content (%)	**Approved**
Renewable /Biobased Material content (Includes product and packaging)	Renew/Biobased Product Content (%) Renew/Biobased Packaging content (%)	**Revised – Open for Comment** (WG Call - Feb 9)
Recyclable Product Content (packaging only)	% of Product Recyclable	**Revised – Open for Comment** (WG Call - Feb 9)
EOL – Product Takeback (packaging only)		
EOL- Biodegradable/compostable Content – Land disposal		
Labeling content		

Corporate Performance Categories

Category	Reportable IBEL Metric	Status
Sustainability Reporting		**May 19**
Environmental Mgmt program		**May 19**
Supply Chain mgmt program		**May 19**
Sustainable Energy Use		**May 19**

Bioaccumulation - Aquatic

IBEL Proposed Metric(s)–

1. **Product Performance**
   - **IBEL Reported Value – 1)** Product Content Bioaccumulates – Y/N
   - **Method for Reporting /Measurement** – Determination of the potential of each individual product ingredient to bioaccumulate. See the definition of bioaccumulating below for details.
   - **Verification** – The following documentation must be provided by manufacturer, if requested, to prove conformance with reported value(s).
     - On a per ingredient basis, the rationale and supporting documentation of evidence sufficient to support a conclusion of non-bioaccumulating. Acceptable documentation includes literature data and citation, test data and method performed (if tested), or proof of readily biodegradable (see verification requirements for Readily Biodegradable)
   - **Rationale for inclusion in IBEL –** Bioaccumulating compounds are particularly destructive in aquatic environments.
   - **Reporting Context- NA**

Definitions

Bioaccumulating – an ingredient having a bioconcentration factor (BCF) greater than 100 when tested according to one of the following tests:

• Code of Federal Regulation 40CFR797.1520,
• ASTM E-1022-94 Standard Practice for conducting bioconcentration test with fishes and salt-water bivalve mollusk, or
• OECD Guidelines for Testing of Chemicals, 305C, Bioaccumulation: Degree of bioconcentration in Fish

The following ingredients are considered non-bioaccumulative and do not have to be tested for BCF:
• those that are readily biodegradable;
• those that have a water solubility greater than 1500 mg/L when tested using a method consistent with ASTM E1148-87, *Standard Test Method for Measurement of Aqueous Solubility*, and
• those that have an octanol-water partition coefficient of log P less than 3 when calculated, or tested using the *OECD Guidelines for Testing of Chemicals*, method 117 or 107.

Bioconcentration Factor – the ratio of chemical concentration in an organism to that in surrounding water

Misc Information/Comments: Green Seal has slightly more restrictive requirements in that they do not allow exemptions for chemicals using KoW or water solubility, nor is the CFR test recognized.

Reportable Product Content

The following is a list of potential reportable content, offered for consideration by the workgroup as content often cited by purchasers and/or labeling organizations. Not all content will apply to all products. The selection/application of criteria for specific products will be taken up on a future work group call.

IBEL Proposed Metric(s)–

2. **Reportable Content**
   - **IBEL Reported Value –** Does the product contain any of the following content:
     1. Carcinogens – Y/N
     2. Mutagens – Y/N
     3. Reproductive toxins – Y/N
     4. Endocrine disruptors- Y/N
     5. Optical Brighteners – Y/N
     6. Asthmagen – Y/N
     7. Ozone Depleting Compounds – Y/N
     8. Heavy Metals – Y/N
     9. Chlorinated Plastics – Y/N
     10. Phthalates – Y/N
   - **Method for Reporting /Measurement** – Varies (see below)
   - **Verification** – The following documentation must be provided by manufacturer, if requested, to prove conformance with reported value(s).
     - Disclosure of product formulation (confidential)
     - Manufacturer declaration of conformance to the above list in support of manufacturer claims about product
   - **Rationale for inclusion in IBEL –** Each of these are points of emphasis in product standards and existing labeling schemes because of their various human health and environmental concerns.
   - **Reporting Context** – Use of the **GHS system** for categorizing chemicals to provide context for the LC_{50} values reported. The GHS would list product in categories as described below ??

Definitions

Asthmagens – Substances designated as asthma causing agents by the AOEC, which after review by AOEC have met the AOEC sensitization criteria.

- AOEC Asthmagens

Carcinogens – Chemicals listed as a known, probable, reasonably anticipated, or possible human carcinogen by the IARC (Groups 1, 2A, and 2B), NTP (Groups 1 and 2), EPA IRIS (weight-of-evidence classifications A, B1, B2, C, carcinogenic, likely to be carcinogenic, and suggestive evidence of carcinogenicity or carcinogen potential), or by OSHA (as carcinogens under 29 CFR 1910.1003(a)(1)).

- Cal Prop 65
- IRIS Carcinogens (Integrated Risk Information System Database)
- Cancer Monographs (Monographs On the Evaluation of Carcinogenic Risks to Humans)

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

- Endocrine Disrupters Strategy (EU Community Strategy for Endocrine Disrupters - Priority List) Category 1

Heavy Metals – Report whether any of the following heavy metals have been intentionally added: Arsenic, Cadmium, Cobalt, Hexavalent Chromium, Lead, Manganese, Mercury, Nickel, and Selenium.

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 GHS.

Optical Brightener – Additives designed to enhance the appearance of colors and whiteness in materials by absorbing ultraviolet radiation and emitting blue radiation. These compounds are also known as fluorescent whitening agents.

Ozone-Depleting Compound – A compound with an ozone-depletion potential greater than 0.01 (CFC 11=1) according to the EPA list of Class I and Class II Ozone-Depleting Substances.

- US Environmental Protection Agency, Ozone Layer Depletion Program (US EPA Ozone)

Reproductive Toxin – A chemical listed as a reproductive toxin (including developmental, female, and male 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., also known as Proposition 65).

- Cal Prop 65

Aquatic Biodegradation (Revision 2) – Modifications in Red

IBEL Proposed Metric(s)–

3. **Product Performance**
    - **IBEL Reported Value – 1)** Readily Biodegradable Product Content - %
    - **Method for Reporting /Measurement** – Calculated as mass of Readily Biodegradable content in product divided by the total mass of the product, expressed as a percent. Product ingredients may be considered Readily biodegradable when:
        - Sufficient data exist to demonstrate that the component of the product is readily biodegradable using an acceptable test method (A list of acceptable test methods will be developed), or
        - In the absence of sufficient pre-existing data, results of testing of the individual chemical ingredient in the product, ***as used***, by an independent, accredited testing laboratory using an appropriate test method (e.g. OECD method 301 A) indicate the ingredient is Readily Biodegradable.
        - All inorganic content is non-biodegradable.
    - **Verification** – The following documentation must be provided by manufacturer, if requested, to prove conformance with reported value(s).
        - source documentation of all evidence supporting the classification of readily biodegradable for each component in the product formulation
        - Results and method of testing conducted by independent third party testing laboratory of product ingredients for which insufficient data exist.
        - ~~If tested by whole product testing, biodegradation test results and the test method used from an independent, third party lab .~~
    - **Rationale for inclusion in IBEL –** Rapid biodegradation prevents the build-up of the chemicals in the environment to potentially harmful concentrations, and lowers the potential for bioaccumulation of the chemicals in aquatic species.
    - **Reporting Context- ??**

Definitions

Readily biodegradable – for a component, is determined using any of the six test methods described in *OECD Guidelines for Testing of Chemicals*, 301A-301F. For a whole formulation, it is determined using one of the methods described in *OECD Guidelines for the Testing of Chemicals*, provided that all measurements and calculations are based on the carbon content of the mixture and its degradation, i.e. dissolved organic carbon(DOC) removal (301A or 301E), CO2 evolution (301-B) or oxygen consumption in the presence of aninhibitor of nitrogen metabolism (301C, 301D or 301F). (Source: Ecologo CCD-146)

Readily biodegradable under anaerobic conditions - is determined using the test method described in ASTM E 1199-92: Standard Test Method for Determining the Anaerobic Biodegradation Potential of Organic Chemicals. (Source: Ecologo CCD-146)

Misc Information/Comments: NA

Both Green Seal and Ecologo use the same basic approach to biodegradation, requiring that products meet the requirements for being readily biodegradable as determined by whole product testing, using the OECD Guidelines for testing chemicals (301A or 301 E) . Both also allow for bypassing such testing for products where each component can demonstrate evidence of being readily biodegradable using OECD methods 301A-F. Green Seal expands this list to allow other proof for individual components to include ISO 7827, 9439, 10707, 10708, 9408, 14593 in addition to the OECD 301 test methods.

Specific language directly from the Green Seal Standard is as follows:

"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 DOC > 70%
- BOD > 60%
- % of BOD of ThOD > 60%
- % CO2 evolution of theoretical > 60%

Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. 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 DOC removal > 90%.

An exception shall be made for an organic ingredient that does not exhibit ready biodegradability if it has low aquatic toxicity, is not bioaccumulating (4.12), 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 section, low aquatic toxicity is defined as having an acute *and* chronic aquatic toxicity >100 mg/L where chronic aquatic (fish) toxicity is measured per OECD Method 204.

Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases. In the absence of experimental data, QSAR data from EPA's BioWin (EpiSuite) models may be considered. "