IBEL Content – Work Group Packet

March 9, 2010

This document has been developed for use during the March 9th, IBEL workgroup call, scheduled from 3-5 PM Eastern. To participate, please use the following call-in information. Thanks.

(218) 936-1100 Access Code #105445.

-- Jack

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. **Shaded entries in the table are to be considered on the March 9, 2010 work group call. Changes since last call are displayed in Blue text.**

Human Health & Environmental

Category	Reportable IBEL Metric	Status
Asthmagen content		
Acute Chemical Concern - Oral		**Scheduled Mar 9th**
Acute Chemical Concern - Inhalation		**Scheduled Mar 9th**
Acute Chemical Concern - Dermal		**Scheduled Mar 9th**
Corrosivity to Skin		**April**
Skin Sensitizer		**April**
Product Absorption via Skin		**April**
Volatile Organic Compound Content		
Chronic Chemical Concern - Oral		
Chronic Chemical Concern - Inhalation		
Chronic Chemical Concern - Dermal		
Phosphorus Eutrophication		**March 23**
Biodegradable Content – Aquatic		**March 23**
Bioaccumulating content		**March 23**
Toxicity to Aquatic Life		**March 23**
Product Embodied Energy		
Product Embodied Water		

Product Performance

Category	Reportable IBEL Metric	Status
Product Performance (specific to product type)		**March 11**
Product Duration		**Removed**
Energy Efficiency		
Water Efficiency		

Additional Product/Packaging

Category	Reportable IBEL Metric	Status
Prohibited Product Content		
Trace contaminants – CMRs (unintentionally added)		
Fragrance	Fragrance Added (No/IFRA/DfE/Other)	**Recommended (Feb 19)**
Color and dyes	Colorant added (Yes/No)	**Recommended (Feb 19)**
Combustibility	Flash point, (°F)	**Revised (Feb 19)**
Post-Consumer Material content (packaging only)	PC Packaging content (%)	**Recommended (Feb 9)**
~~**Reclaimed Material content –**~~		**Combined with PC Content (Feb 19)**
Renewable /Biobased Material content (Includes product and packaging)	Renew/Biobased Product Content (%) Renew/Biobased Packaging content (%)	**Revised – Posted for comment on IBEL site** (WG Call - Feb 9)
Recyclable Product Content (packaging only)	% of Product Recyclable	**Revised – Posted for comment on IBEL site.** (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		
Environmental Mgmt program		
Supply Chain mgmt program		
Sustainable Energy Use		

IBEL Acute Toxicity- Oral /Dermal /Inhalation

The following approach applies to each of the exposure routes above, with exceptions noted in the text below.

IBEL Proposed Metric(s)–

1. **Acute Toxicity- Oral**
   - **IBEL Reported Value – 1) Oral** Lethal Dose 50 (LD50) (or dermal/inhalation)
     2) GHS Category
   - **Method for Reporting /Measurement** – Results of testing by an independent, accredited testing laboratory using an appropriate test method (e.g. OECD Acute Oral Toxicity Test -TG 401). *Alternatively*, testing is not required if sufficient acute oral toxicity data exist for each ingredient to allow calculation of toxicity on a component level basis using the method displayed below.

$$TP = \left(\sum_{i=1}^{n} \frac{wt_i}{TV_i} \right)^{-1}$$

Where,
TP = toxicity of the product
wt_i = the weight fraction of the ingredient
TV = the toxicity value for each ingredient (LD_{50})
n = number of ingredients

(Source: GS-37)

Toxicity will be measured on the product as a whole and in undiluted form. Inhalation toxicity shall be determined from all ingredients with a vapor pressure greater than 1 mm Hg at ambient conditions (1 atm pressure and 20-25° C). Please note: We will not specifically require animal testing to report values.

   - **Verification** – The following documentation must be provided by manufacturer, if requested, to prove conformance with reported value(s).
     - Method of determination and the calculations made, if any.
     - Source documentation of all toxicity values used in the determination of the product oral LD50, as well as formulation data sufficient to define the chemical identities and concentrations in the undiluted product (this is kept CBI), or if testing,
     - Oral LD50 test results from an independent and accredited lab along with a description of the test method.
   - **Rationale for inclusion in IBEL –** The use of some cleaning chemicals can result in exposures with the potential to pose an acute toxicity concern
   - **Reporting Context** – Use of the **GHS system** for categorizing chemicals to provide context for the LD50 values reported. The GHS would list product in one of 6 categories as described below.

Definitions

Acute Toxicity: Refers to those adverse affects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.
(Source: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/English/03e_part3.pdf)

LD 50/ Lethal Dose: The dose of a toxicant or microbe that will kill 50 percent of the test organisms within a designated period. The lower the LD 50, the more toxic the compound.
(Source: http://www.epa.gov/OCEPATERMS/lterms.html)

Dermal Toxicity: Ability of a chemical to cause injury when in contact with skin.

Oral Toxicity: Ability of a pesticide to cause injury when ingested.

Toxicant: A harmful substance or agent that may injure an exposed organism. (Source: http://www.epa.gov/OCEPATERMS/tterms.html)

Toxicity: The degree to which a substance or mixture of substances can harm humans or animals. *Acute toxicity* involves harmful effects in an organism through a single or short-term exposure. *Chronic toxicity* is the ability of a substance or mixture of substances to cause harmful effects over an extended period, usually upon repeated or continuous exposure sometimes lasting for the entire life of the exposed organism. *Subchronic toxicity* is the ability of the substance to cause effects for more than one year but less than the lifetime of the exposed organism. (Source: http://www.epa.gov/OCEPATERMS/tterms.html)

Misc Information/Comments:

GHS- *Globally Harmonized System of Classification and Labeling of Chemicals* was developed under the UN to define the health, physical and environmental hazards of chemicals. It creates a classification process based on available chemical data for comparison with defined hazard criteria, and provides guidance on communicating hazard information and protective measures on labels and Safety Data Sheets. The GHS can be accessed at http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

GHS Categories for Acute Oral/Dermal/Inhalation Toxicity can be found on the Table at the end of this document.

Established Criteria - The following products have established minimum criteria.

Table 1. Acute Toxicity Criteria of Established Ecolabels

Category	Oral (LD_{50})	Dermal (LD_{50})	Inhalation (LC_{50})
Green Seal	5,000 mg/kg	NA	20 mg/L all
EPA DfE	2,000 mg/kg	2,000 mg/kg	5,000 mg/L (gas) 20 mg/L (vapor) 5 mg/L (dust)
Ecologo 146	2,000 mg/kg or higher (prod specific)		5 mg/L (gas) 10 mg/L (vapor) 5 mg/L (dust)

Note: Values represent minimum thresholds, with higher values are better.

Ecologo CCD-146 lists thresholds for individual products. Examples include:

- cleaners for glass (LD_{50} > 10,000 mg/kg),
- boat and bilge (LD_{50} > 4,000 mg/kg),
- cooking appliances (LD_{50} > 4,000 mg/kg), and
- low potential for environmental illness (LD_{50} > 5,000 mg/kg).

Test methods

Each standard specifies different reference methods for determination of values. Green Seal references the same testing guidelines as the current CCD-146, while EPA DfE cites additional Office of Pollution Prevention and Toxic Substances (OPPTS) Harmonized Guidelines and OECD guidelines.

Animal Testing

Toxicity will be measured on the product as a whole and in undiluted form. In lieu of whole product toxicity testing on animals, the standard allows for verification of acute toxicity on a component level basis providing sufficient toxicity data exist for each of the products ingredients, and the correct procedure for calculating toxicity as described in the above referenced guidance is adhered to strictly. Acceptable data include those developed following the OECD Guidelines for Testing of Chemicals, including Acute Oral Toxicity Test (TG 401), Acute Inhalation Toxicity Test (TG403), and Acute Dermal Toxicity Test (TG402).

Strawman & Comments

The following is a subsection of the original IBEL strawman and all comments submitted for each relevant metric under discussion during this call.

Acute Chemical Concern – Oral	Acute potential – Oral (LD50) Method of determination (test/calc) Test method (if applicable)

COMMENTS:

Roger McFadden

Relying on MSD Sheets is problematic. Some companies do a great job of using MSD Sheets to communicate chemicals of concern and others do not. It has been reported that a high percentage of MSD Sheets have information that is missing, fragmented, ambiguous, biased and not founded on sound science with huge data gaps or weak arguments for confidential business information protection.

Libby Sommer

The UN, under GHS, has developed a method for classifying mixtures based upon the acute toxicity of the mixture constituents. This method, however, does not provide an exact value for the acute toxicity of said mixture. Rather, GHS bins mixtures into toxicity groupings. To EPA's knowledge, there is no scientific, generally accepted method of calculating the acute toxicity of a mixture from its constituents. Binning provides another advantage; purchasers will likely not understand the significance of differences in toxicity values (e.g. is an acute toxicity of 2500 mg/kg significant in comparison to a value of 2000 mg/kg?). GHS categorization provides a framework for understanding those differences.

Don Versteeg

This is fine, quantitative. Personally, I would prefer to assess chronic toxicity as a good acute toxicity score may be meaningless chronically, and visa versa. Should we use different routes of exposure for different products? For spray products, use inhalation and oral, for hand dish products use dermal, for laundry product that are pumped into washing machines use oral (or nothing since there is little chance for exposure?).

3.1.2 Classification criteria for substances

3.1.2.1 Substances can be allocated to one of five toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in the table below. Acute toxicity values are expressed as (approximate) LD_{50} (oral, dermal) or LC_{50} (inhalation) values or as acute toxicity estimates (ATE). Explanatory notes are shown following Table 3.1.1.

Table 3.1.1: Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories

Exposure route	Category 1	Category 2	Category 3	Category 4	Category 5
Oral (mg/kg bodyweight) *See notes (a) and (b)*	5	50	300	2000	5000 *See detailed criteria in Note (g)*
Dermal (mg/kg bodyweight) *See notes (a) and (b)*	50	200	1000	2000	
Gases (ppmV) *See notes (a), (b) and (c)*	100	500	2500	20000	*See detailed criteria in Note (g)*
Vapours (mg/l) *See notes (a), (b), (c), (d) and (e)*	0.5	2.0	10	20	
Dusts and Mists (mg/l) *See notes (a), (b), (c) and (f)*	0.05	0.5	1.0	5	

Note: Gases concentration are expressed in parts per million per volume (ppmV).

Notes to Table 3.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} where available;

(b) The acute toxicity estimate (ATE) for a substance in a mixture is derived using:

(i) the LD_{50}/LC_{50} where available; otherwise,

(ii) the appropriate conversion value from Table 3.1.2 that relates to the results of a range test; or

(iii) the appropriate conversion value from Table 3.1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposures should be by dividing by a factor of 2 for gases and vapours and 4 for dusts and mists;