Design for the Environment Safer Product Recognition Program Elements:
A Discriminating and Protective Approach to Cleaning Product Review and Recognition

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Situated in the U.S. EPA's Office of Pollution Prevention and Toxics (OPPT), the Design for the Environment (DfE) Safer Product Recognition Program (also known as the Formulator Program) is a product formulator's gateway to OPPT's unique chemical expertise, information resources, and guidance on greener chemistry. The program gathers hazard information on chemical ingredients and works with OPPT's science experts to assess this information and compare the relative safety of chemicals.

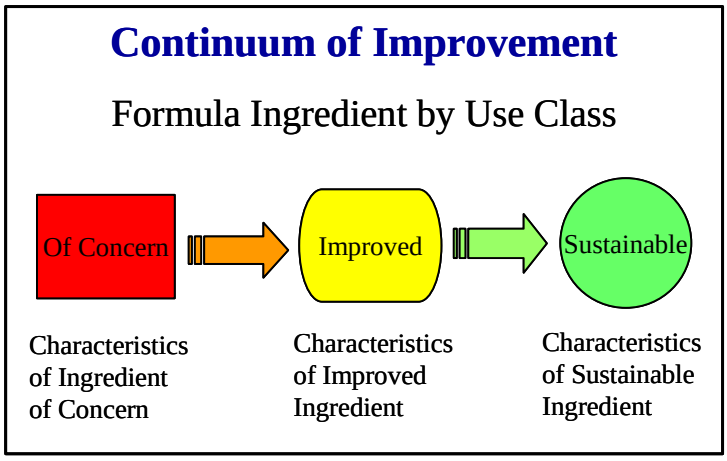
The DfE Program promotes green chemistry through informed substitution, the considered transition from a chemical of particular concern to safer chemicals or non-chemical alternatives. DfE informs substitution by bringing together key stakeholders and the best available information to address critical areas of environmental and health protection. DfE works with the cleaning industry and other industry sectors to compare and improve the human health and environmental profiles of existing and alternative products, while maintaining high performance and cost competitiveness.

Since 1997, DfE has offered recognition to those companies who design for the environment and human health by using only safer chemicals. To date, over 900 chemical products have been recognized by the program. A complete list of partner companies and products can be found at: http://www.epa.gov/dfe/pubs/projects/formulat/formpart.htm.

What Makes DfE Safer Product Recognition Review Unique? The DfE Program is distinct from all other product recognition or ecolabeling programs because of two defining characteristics: its assessment methodology and its technical review team. The DfE technical review team has many years of experience and is highly skilled at assessing chemical hazards, applying predictive tools, and identifying safer substitutes for chemicals of concern.

The review team applies the DfE assessment methodology by carefully reviewing each product component[1], starting with the chemical component's structure, to determine its key health and environmental characteristics. (The review includes all chemicals, including those in proprietary raw material blends, which manufacturers share with DfE in confidentiality). The review team then compares an ingredient's characteristics to other chemicals in the same use class[2], considers possible negative synergies between ingredients, and places the ingredient on a continuum of improvement relative to other similar chemicals.

[1] A *component* is a chemical as identified by its Chemical Abstract Service (CAS) number. An *ingredient* may be one component or a blend of multiple components.
[2] Ingredient class refers to the functionality of the product, e.g., surfactant, solvent, dye fragrance, etc…



Through its review team and methodology, DfE provides information to formulators that helps them select from among the safest chemicals in an ingredient class. The approach is adaptable to changing circumstances and new information, emphasizing continuous improvement as the opportunities for safer formulations grow with chemical innovation.

How Does DfE's Component-Based Review Compare with Other Product-Based Approaches? The following examples showcase some of the key benefits of DfE's component-based review and the extra measure of protection it often provides:

DfE uncovers chemicals of concern that can be masked by raw material blends or by dilution in water. By focusing at the component level and on key inherent characteristics, DfE is able to carefully scrutinize formulations and make meaningful calls on potential concerns. For example, a surfactant that is acutely toxic to aquatic organisms and environmentally persistent can appear to pose a low concern when blended with other less toxic and less persistent surfactants. Similarly, water, typically the largest percentage ingredient even in concentrates, can mask the effects of a hazardous chemical.

DfE spots negative synergies between product components. These potentially dangerous chemical combinations pose concerns for both acute and longer-term effects. For example, oxidizing agents, such as peroxides, can react with certain terpenes commonly used as fragrances and solvents; the products of these reactions have tested positive for dermal sensitization in rodent studies and human patch testing. In another example, mixing nitrosating agents with amines will create nitrosamines, potent carcinogens.

DfE uses its expert knowledge and predictive tools to supplement lists of chemicals of concern. Few chemicals in commerce have been adequately tested, especially for chronic effects, like cancer and developmental toxicity and thus lists of chemicals with these effects are partial at best. DfE uses its knowledge of the structural similarities between chemicals and its predictive models to flag product components with similar potential effects.

DfE screens all fragrances and dyes for chemicals that may pose serious health or environmental effects. Some of the chemicals of most potential concern in cleaning products are those in fragrances and dyes. Chemical ingredients in these classes can include sensitizers, carcinogens, and environmentally toxic and persistent compounds. Small quantities don't

necessarily mean small hazards: A person, once sensitized to a chemical, can have an allergic response even if exposed at levels below those that initially induced sensitization.

DfE recommends safer substitutes for chemicals of concern. Sustainability requires innovation and continuous improvement. The DfE program works directly with EPA's Green Chemistry specialists to identify and recommend safer chemicals to its formulator partners, continuously raising the bar and redefining the meaning of environmentally preferable products.

DfE General Screen for Safer Ingredients

As of January 2009, DfE has completed its General Screen for Safer Ingredients. With the development of the General Screen, the core of the DfE review process and the standard to which it applies is transparent and ready for third-party implementation. In establishing thresholds for green ingredients, the General Screen delineates the safer or "low-concern" end of the ingredient spectrum, guiding and ensuring best-in-class ingredient choices for DfE-recognized products. The General Screen covers the following human health and environmental attributes:

- Acute mammalian toxicity
- Carcinogenicity
- Environmental toxicity and fate
- Genetic toxicity
- Neurotoxicity
- Repeated dose toxicity
- Reproductive and developmental toxicity
- Respiratory sensitization
- Skin sensitization.

All components in DfE-recognized products will be screened against the General Screen or against the ingredient-class screen, as available and appropriate. Ingredient-class screens define and more fully explore the green end of specific ingredient-class continuums. Using the general screen as a template, the ingredient-class screens tailor the health and environmental endpoints in the General Screen in a way appropriate to the specific class, designating key, distinguishing characteristics and adjusting thresholds, as necessary. Developing the screens improves the general understanding of the characteristics of safer ingredients in the class and helps identify green-chemistry opportunities and successes.

DfE currently has specific ingredient-class screens for surfactants and solvents. An ingredient-class screen for fragrances will be available sometime in 2009.

DfE Screen for Solvents. With cleaning solvents, there are potential concerns for the following endpoints: carcinogenicity, acute mammalian toxicity, reproductive and developmental toxicity, repeated-dose toxicity, neurotoxicity, and environmental fate and toxicity. Phase I of the solvents screen should be applied only to alcohols, esters, ethylene glycol ethers, and propylene glycol ethers. DfE's next step is to expand the solvents screen to additional solvent classes used in cleaning products, such as terpenes, amines, and amides; these will be known as Phase II solvent classes.

Phase I Solvent Classes	Alcohols
	Esters
	Ethylene Glycol Ethers (EGEs)
	Propylene Glycol Ethers (PGEs)
Attributes of Concern for Phase I Solvents	Carcinogenicity
	Neurotoxicity
	Acute Mammalian Toxicity
	Reproductive and Developmental Toxicity
	Repeated-Dose Toxicity
	Environmental Fate and Toxicity

DfE Screen for Surfactants. Surfactants in cleaning products are distinguished by their rate of biodegradation and level of aquatic toxicity. The DfE Screen for Surfactants combines those two hazard characteristics, and requires that surfactants with higher aquatic toxicity demonstrate a faster rate of biodegradation. Surfactants that meet the relevant screen for product use are acceptable for use in a DfE-recognized cleaning product.

	Acute Aquatic Toxicity Value (L/E/IC50)[a,b]	**Persistence** (Measured in terms of level of biodegradation)	**Bioaccumulation Potential**
1	If ≤1 ppm…	…then may be acceptable if the component meets the 10-day window as measured in a ready biodegradation test[c] without degradation products of concern[d]…	…and BCF <1000.
2	If >1 ppm and ≤10 ppm…	…then if the component must meet the 10-day window as measured in a ready biodegradation test without degradation products of concern[d] …	
3	If >10 ppm and <100 ppm…	…then the component must meet the 28-day pass level as measured in a ready biodegradation test without degradation products of concern[d]…	
4	If ≥100 ppm…	…then the component need not meet the 28-day pass level as measured in a ready biodegradation test if there are no degradation products of concern[d] and half-life < 180 days…	

[a] *In general, there is a predictable relationship between acute aquatic toxicity and chronic aquatic toxicity for organic chemicals, i.e., chemicals that have high acute aquatic toxicity also have high chronic aquatic toxicity. [18] Since acute aquatic toxicity data are more readily available, the DfE Screens use these data to screen chemicals that may be toxic to aquatic life. Where measured chronic toxicity data is available, it will be assessed with other data and applied in the screen based on the relationship between acute and chronic aquatic toxicity.*

[b] *Data, whether estimated or measured, are required for each of the following groups of organisms algae, aquatic invertebrates and fish (all fresh water). Data for marine species may be added when available.*

[c] *A case-by-case approach focusing on rate of biodegradation and degradation products of concern will be implemented for chemicals toxic to aquatic organisms at ≤ 1ppm.*

[d] *Degradation products of concern are compounds with high acute aquatic toxicity (L/E/IC50 ≤ 10ppm) which mineralize <60% in 28 days.*

DfE Screen for Direct Release Surfactants and Other Ingredients. Certain products that are intended for use outdoors are likely to bypass sewage treatment, shortening the time for degradation prior to entering sensitive environments. For these products, like boat cleaners and graffiti removers, DfE has raised the bar in its standard surfactant screen to address the potential for immediate contact with aquatic life. **Any ingredients (including surfactants, preservatives, solvents, etc.) that have acute aquatic toxicity median lethal values <1 mg/L are not allowed in DfE-recognized direct release products.**

	Acute Aquatic Toxicity Value (L/E/IC50)[1]	Persistence (Measured in terms of rate of biodegradation via a ready biodegradation test)	Status
1	≤1 ppm		Not acceptable
2	>1 ppm and ≤10 ppm	Biodegradation[2] must occur within a 10-day window without products of concern[3]	Could be improved
3	>10 ppm and <100 ppm	Biodegradation[2] occurs within 28 days without products of concern[3]	Could be improved
		Biodegradation[2] occurs within a 10-day window without products of concern[3]	Acceptable
4	≥100 ppm	Biodegradation[2] occurs within 28 days without products of concern[3]	Acceptable

1. In general, there is a predictable relationship between acute aquatic toxicity and chronic aquatic toxicity for organic chemicals, i.e.
chemicals that have high acute aquatic toxicity also have high chronic aquatic toxicity. Since acute aquatic toxicity data are more readily available, the DfE Screens use these data to screen chemicals that may be toxic to aquatic life.
2. Generally, >60% mineralization (to CO2 and water).
3. Products of concern are compounds with high acute aquatic toxicity (L/E/IC50 ≤ 10ppm) and a slow rate of biodegradation (greater than 28 days).

Additional Considerations. The following matrix highlights additional elements reviewed by the DfE Formulator Program team. The matrix should help purchasing entities and others understand what DfE considers in its review, what its recognition means, and how they should view products that carry the DfE logo. DfE compares and balances product characteristics in determining the appropriateness and type of DfE recognition.

Review elements	Assessment Approach	Comments
Alkylphenol ethoxylates (APEs)	DfE-recognized products do not contain APEs. APEs, like all surfactants, are compared based on their key distinguishing characteristics: 1) Rate of biodegradation, 2) Aquatic toxicity, and 3) Degradation products. APEs do not have acceptable profiles because they degrade to products that are increasingly toxic and have potential for interaction with the endocrine system.	DfE has identified surfactants that are safer than APEs, and have comparable performance and price. In the context of its product reviews, DfE provides this information on safer substitutes to its formulator partners. See also the section titled 'Surfactants'.
Chelating and Sequestering Agents	A stakeholder group is developing a Screen for Safer Chelating Agents in Cleaning Products. The Chelant Screen will be based on the DfE General Screen, but will reflect the key health, environmental, and performance characteristics of chelants. Until such a screen is finalized (in 2009), DfE prefers chelating agents with low toxicity and rapid biodegradation. Currently, inorganic phosphates that contribute to eutrophication, and NTA, a potential carcinogen, are not acceptable in DfE recognized products. Other chelants/sequesterants that are not readily biodegradable, may be accepted under continuous improvement.	See 'Eutrophication' for explanation of phosphate criterion. Continuous improvement means that the chemical is of borderline concern by DfE standards and should be formulated out of the product within the three year Partnership Agreement timeline .
Compostability	DfE considers wipe composition and ability to decompose under mesophilic conditions (20˚ - 45˚C) as key characteristics for disposable cleaning wipes when they are the intended method of application for a cleaning formulation. At a minimum, wipes must be made entirely of compostable material.	'Compostable' and 'mesophilic' are defined in section 3.1.2 of the ASTM Standard Guide to Assess the Compostability of Environmentally Degradable Nonwoven Fabrics D6094-97.
Concentrates	Liquid laundry detergents must be at least a 2X concentrate to achieve DfE recognition.	Many manufacturers are producing products in concentrated form to reduce their transportation footprint and reduce greenhouse gas emissions. DfE commends this approach.

Review elements	Assessment Approach	Comments
Energy Efficiency	DfE-encourages the use of energy saving technologies including the use of concentrates and detergents that work in cold water. DfE considers energy efficiency by comparing product efficiency to that typical of the class, recognizing the importance of reducing energy use and generation of greenhouse gases. DfE expects that energy effiecient products would continue to meet all other program criteria.	
Flammability	DfE takes note of *product* flashpoint as appropriate and seeks to ensure low concerns for combustibility.	Flashpoint is generally not a concern when dealing with water-based mixtures. Flammable liquids are regulated by: ➢ 49CFR173.120 (a) (5) - Flammable Liquid Definition ➢ 49CFR173.150 (e) Aqueous Solutions of Alcohol ➢ 40CFR261.21 (a) (1) Characteristic of Ignitability
Fluorosurfactants	Based on EPA's concerns for persistence, bioaccumulation in humans, and potential toxicity, DfE-recognized products do not contain any fluorosurfactants that have a fluorinated chain of eight or more carbons (C8). All fluorosurfactants that do not have a C8 or longer chain will be reviewed on a case-by-case basis by DfE.	The ideal, green chemistry surfactant and surface treatment chemical, including wetting and leveling agents, would be a chemical that readily degrades to non-toxic degradants, has low toxicity, does not persist, or metabolize to chemicals of concern in humans or other species, and performs well when compared to traditional wetting agents.
Flushability	To be an acceptable wipe for a DfE-recognized formulation, a wipe must be "flushable". Flushablility is established if the wipe can pass through the toilet and drainline system, be transported in wastewater conveyance systems, and be compatible with wastewater treatment systems where they exist, or in some regions, discharges of untreated wastewater. An example of an acceptable test protocol is the Guidance Document for Assessing the Flushability of Nonwoven Consumer Products, published by INDA, the U.S.-based association of nonwoven fabrics industry and EDANA, the European-based international association serving the nonwovens and related industries.	

Review elements	Assessment Approach	Comments
Formulary Efficiency	DfE considers formulary efficiency by evaluating the functionality of each ingredient, its contribution to product performance, and the opportunity for elimination of unnecessary ingredients.	The principle of informed substitution recognizes the value of formulary efficiency, which might include the replacement of chemicals of concern with safer chemicals or non-chemical alternatives (e.g., biological or mechanical), provided that product performance is not compromised.
Fragrances	DfE works directly with fragrance houses to improve their formulations. C*omponents* are screened for: 1) Sensitization, 2) Carcinogenicity, 3) Mutagenicity, 4) Reproductive toxicity, 5) Environmental persistence, 6) Aquatic toxicity, and 7) Other hazard characteristics.	Following IFRA's Code of Practice may not be sufficiently protective when a fragrance is added to a cleaning product. A stakeholder group convened by GreenBlue has proposed a set of criteria for defining safer fragrances in cleaning products. Those criteria are under review at EPA. A final screen should be proposed in 2009.
Irritation and corrosivity	To minimize potential for dermal and eye irritation or injury, product pH should be ≥ 2 and ≤ 11.5. Depending on percentage in the formulation, DfE limits *components* that are suspected or known severe skin and eye irritants.	Most cleaning products have ingredients, like surfactants, that are expected skin and eye irritants, especially at concentrated levels. OSHA requires product-level irritation information on all MSDSs, if any positive results are available.
Labeling Requirements	Our partnership agreement requires each partner company to provide its customers with information on environmental and worker safety matters.	OSHA, DOT, and other authorities require manufacturers to provide handling and other worker safety information.
Laundry Systems	A cleaning system, such as a laundry system, is not eligible for recognition unless every component meets the DfE Criteria. DfE recognition of the system is void and in violation of the partnership agreement if DfE-labeled components are used in combination with non-labeled components.	

Review elements	Assessment Approach	Comments
d-limonene	d-limonene is a terpene often used as a solvent. Its oxidation products have tested positive for dermal sensitization but may be used in a DfE-recognized product in concentrations at which the potential oxidation products may be present at 20 millimoles per liter (mmol/L) or less (corresponding to a d-limonene concentration of 1.36 % or less, as a percent by weight) in an overall formulation. Because of their high potential toxicity to aquatic organisms, d-Limonene should not be used in products that will be directly released to the environment. Also, products that contain d-Limonene should not also contain oxidizers, like hydrogen peroxide, which may accelerate the formation of d-Limonene oxidation products and harm product integrity.	For more information, see short profile on d-Limonene.
Ozone-depleting compounds	DfE-recognized products do not contain ozone-depleting compounds. http://www.epa.gov/ozone/science/ods/index.html	The Montreal Protocol (1987) initiated the phase-out of HCFCs and banned almost all CFCs, including those used as propellants in cleaning products.
Packaging	Product manufacturers must explain how packaging is designed for increased sustainability by addressing recycled content, recyclability, reduced-space packaging, refillable packaging, or other parameters.	For more information see http://www.sustainablepackaging.org/
pH	Product pH should be ≥ 2 and ≤ 11.5.	
Phosphates	DfE-recognized products do not contain inorganic phosphates (known to be present or intentionally added), because of their potential to cause eutrophication.	Certain inorganic phosphates have produced exponential growth of green algae at levels as low as 50 parts per billion. Testing may be used to rebut the presumption that phosphates accelerate algal growth.

Review elements	Assessment Approach	Comments
Photochemical Smog, Tropospheric Ozone Production, and Indoor Air Quality	DfE seeks to minimize VOCs and limits components that are also Hazardous Air Pollutants (HAPs) or are on EPA's Toxics Release Inventory (TRI). DfE strives to optimize the health and environmental preferability of products. The lowest possible VOC-level may not correspond to the safest formulation. At a minimum, DfE limits product VOC content as prescribed by EPA's Office of Air and Radiation, as applicable (see 40 CFR 59, Subpart C).	
Phthalates	DfE-recognized products do not contain phthalates of concern.	
Product Performance Testing	To ensure a baseline measure of performance, DfE asks all partners to demonstrate that their products perform effectively. Potential partners may submit appropriate test results as specified in Appendix I or provide equivalent performance tests agreed upon by DfE.	
Residuals	Residuals of concern shall be limited to less than 0.01% (by weight) or 100ppm in the formulation. For ingredients known to contain residuals of concern, DfE's goal will be to limit those residuals to the lowest practicable levels. Dilution will not be considered in calculating the percentage of residuals in concentrates. Formulators should understand that residuals may be present and should encourage chemical manufacturers to carefully monitor and control processes to limit residuals of concern. A residual is a "residual of concern" if it fails to meet the criteria in the General Screen for carcinogenicity, mutagenicity, reproductive toxicity and other human health effects, or fails to meet the criteria for persistence, bioaccumulation and toxicity, as defined by the Final PB&T Rule (http://www.epa.gov/fedrgstr/EPA-WASTE/1999/October/Day-29/f28169.htm).	
Toxic elements	DfE-recognized products do not contain toxic elements, for example lead, cadmium, arsenic, zinc and copper.	Unavoidable, *de minimis* levels may be present, e.g., from inorganic materials mined from the earth.

Review elements	Assessment Approach	Comments
Training	Our Partnership Agreement requires each partner company to provide its customers with information on environmental and worker safety matters.	OSHA, DOT, and other authorities require manufacturers to provide handling and other worker safety information.
Verification	The Partnership Agreement between EPA/DfE and the partner company affirms that those ingredients disclosed to EPA during the product review process are in fact the only ingredients intentionally added or known to be present. DfE uses multiple quality assurance steps in its product review process. These steps include profiling by a qualified third party, expert Agency workgroup assessment, and detailed technical review oversight.	Under the terms of the Partnership Agreement, DfE may require partners to submit bills of lading to verify product ingredients.
Wipes	Wipes that are used for applications of cleaning products must meet criteria for the cleaning chemicals and for the materials composing the wipes. See details under 'Compostability' and 'Flushability'.	

Appendix I: Product Performance Testing under EPA's Design for the Environment Formulator Program

DfE believes performance testing requirements should be product category specific, and will accept any valid and scientifically sound method of demonstrating product performance. Examples of performance requirements that are acceptable to DfE include but are not limited to:

Carpet Cleaners – Perform equal to or better than nationally recognized carpet cleaners in the same category using CSPA DCC-03 and AATCC Test Method 171-1995 or equivalent method agreed upon by EPA DfE.

Compostability - Meets user requirements for the compostability of environmentally degradable nonwoven fabrics as described in ASTM D6094-97.

Glass Cleaners – Meets user requirements for cleaning, streaking and smearing when tested according to CSPA method DCC-09 or equivalent method agreed upon by EPA DfE.

General Purpose Cleaners – Meets user requirements for soil removal on relevant substrates when tested according to ASTM method D4488-95, ASTM G122 - 96(2002), CAN/CGSB 2-GP-11, Method 20.3, or equivalent method agreed upon by EPA DfE.

Hand Dishwashing Detergents – Meets user requirements for foam stability when tested according to the CSPA method DCC-10 or equivalent method agreed upon by EPA DfE.

Laundry Detergents – Meets user requirements for home laundering pre-wash spotter stain removal as specified in DCC-11 or equivalent method agreed upon by EPA DfE.

Oven Cleaners - Meets user requirements for the efficacy of oven cleaners as described by CSPA DCC-12 or equivalent method agreed upon by EPA DfE.

Resilient Floor Cleaners - Meets user requirements for soil removal on Resilient Flooring and Washable Walls as specified by ASTM D4488 - 95(2001)e1.or ceramic tile as specified by ASTM D5343 – 06 or equivalent method agreed upon by EPA DfE.