

Information Collection Request

Supporting Document

for

**EPA's Design for the Environment
Formulator Product Recognition Program**

6/22/2009

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INFORMATION COLLECTION REQUEST FOR EPA'S FORMULATOR PRODUCT RECOGNITION PROGRAM

PART A

1 IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection:

EPA's Design for the Environment (DfE) Formulator Product Recognition Program.

ICR Numbers: EPA ICR No. 2302.01 OMB Control No. 2070-NEW

1(b) Short Characterization / Abstract

DfE's Formulator Product Recognition Program (Formulator Program) recognizes safer products where all ingredients have an environmental and human health profile showing that they are the safest in their functional use class. Under the encouragement of the current Formulator Program, leading companies have already made great progress in developing safer, highly effective chemical products. Since the program's inception in 1997, formulators have been using the program as a portal to OPPT's unique chemical expertise, information resources, and guidance on greener chemistry. DfE Formulator partners enjoy Agency recognition, including the use of the DfE logo on products with the safest possible formulations. In the next three years, DfE expects much greater program participation due to rising demand for safer products. This ICR would enable DfE to accommodate participation by more than nine formulators each year and enhance program transparency.

DfE participates in the development of CleanGredients™, a database of safer cleaning product ingredients, which identifies safer formulations and makes forming partnerships easier. Organized by product functional use class (e.g., surfactants, solvents, etc.), CleanGredients™ facilitates a green marketplace where formulators can select functionally appropriate and safer ingredients.

The redesign of chemical products offers opportunities to:

- Remove hazardous chemicals from formulations before they can enter the workplace, home, or environment.
- Advance energy and water efficiency, resource conservation, and innovative technologies.
- Qualify for environmentally preferred product status, increasingly sought by government, retailer and consumer purchasers.

Companies formulate products from a broad range of chemicals with a variety of applications. The Formulator Program is particularly involved with safer cleaning products, holding tank treatments/deodorizers, industrial coatings, and inks. Cleaning products make up the majority of partnership products, and cleaning product manufacturers make up the lion's share of demand for program participation by potential partners. Third-party profilers review all cleaning product applications prior to DfE submission. All other product applications are submitted directly to DfE for review.

The review team applies the DfE assessment methodology, as described in Attachment B, by carefully reviewing each product component. A literature review, and when appropriate, structural activity relationships, are used to understand each chemical's health and environmental characteristics. The review includes all chemicals, including those in proprietary raw material blends, which ingredient suppliers share with DfE in confidentiality. The review team then compares an ingredient's characteristics to other chemicals in the same use class, considers possible negative synergies between ingredients, and places the ingredient on a continuum of improvement relative to other similar chemicals. Through its review team and methodology, DfE provides

information to formulators that helps them select from among the safest chemicals in an ingredient class. Only formulations containing exclusively safer ingredients are recognized by DfE.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

Authority for the Formulator Program derives from Section 6604(b)(5) of the Pollution Prevention Act (PPA), 42 U.S.C. 13103(b)(5) [see Attachment A], which directs EPA to facilitate the adoption of source-reduction techniques by businesses, and the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), which encourages safety in technological innovation in chemistry. In recognition of this statutory directive, and through consultation with a broad range of stakeholders, EPA developed the Formulator Program.

Formulator Program information collection activities will assist the Agency in meeting the goals of the PPA by providing resources and recognition for businesses committed to promoting and using safer chemical products. In turn, the Formulator Program will help businesses meet corporate sustainability goals by providing the means to, and an objective measure of, environmental stewardship. Investment analysts and advisers seek these types of measures in evaluating a corporation's sustainability profile and investment worthiness.¹ It is not surprising then that EPA has heard from many organizations that Formulator Program partnership is an important impetus for prioritizing and completing the transition to safer chemical products. The Formulator Program is also needed to promote greater use of safer chemical products by companies unaware of the benefits of such a change.

DfE has carefully tailored its request for information, and especially the Formulator Program application, to ensure that it only asks for information essential to verifying applicants' eligibility for recognition.

2(b) Practical Utility/Users of the Data

The information collected by the Formulator Program is not designed or intended to support regulatory decision-making by EPA. EPA uses the information collected in the Formulator Program application to: (1) review products and their components; (2) complete chemical profiles for each product component to determine its key health and environmental characteristics; and (3) establish a partnership agreement with the company outlining how the company and EPA/DfE will work together to continually improve the health and environmental profile of the product(s).

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

Respondents will not be asked to provide information that has been or is currently being collected by EPA, other federal or state agencies, or proprietary sources. The information collected by the Formulator Program is unique and is not duplicative of previous information collection requests. As due diligence, EPA also checked with trade associations and potential partners to confirm that the information being collected by the Formulator Program does not exist elsewhere.

3(b) Public Notice Required Prior to ICR Submission to OMB

In proposing to issue this ICR, EPA provided a public notice and 60-day comment period that ended on August 18, 2008 (73 FR 34726; 06/18/2008). EPA did not receive any comments during the public comment period.

¹ "Green to Gold: How Smart Companies use environmental strategy to innovate, create value, and build competitive advantage" by Daniel Esty and Andrew Winston, Yale University Press, New Haven, 2006

3(c) Consultations

OMB regulations require agencies to consult with potential ICR respondents and data users about specific aspects of ICRs (5 CFR 1320.8(d)(1)). In accordance with this regulation, EPA consulted with four potential respondents who manufacture cleaning and other products made of chemical mixtures by telephone to get feedback on the reasonableness of EPA's cost and burden estimates. EPA asked the following questions:

- Please provide your best estimate regarding how long it would take to complete the application in terms of total hours.
- We are also interested in how many personnel (i.e., clerical, technical, and managerial) it would take for applicants to review the program information, obtain approval from senior management and complete the form.
- In addition, please provide us with any constructive criticism / comments you might have regarding the application itself, questions posed, instructions, description of the program, etc.

EPA received feedback from the following individuals:

- Jim McCabe, Clorox, 925-425-6674
- Charles Reeves, Sentry Chemical, 770-723-7040
- Victoria Finley, Osprey Biotechnics, 941-351-2700 ext. 111
- Richard Cottrell, SYSCO, 281-584-1793

These individuals were supportive of the ICR and said the burden estimates appeared reasonable. These four respondents are typical of the types of respondents expected under this ICR. Therefore, EPA made no changes to the information in this supporting statement.

3(d) Effects of Less Frequent Collection

Formulator Program applications will be received on an ongoing basis over the three years covered by this ICR. The applications are designed to be one-time information submissions for organizations that wish to participate in the Formulator Program, with the opportunity to renew the partnership agreement at the end of the three-year partnership period. This means that once every three years, the organization will submit a renewal application to confirm that no changes have been made to ingredients; this step is done in response to correspondence from DfE that reminds organizations of the terms of their partnership agreements. Without this information collection mechanism, DfE will not have the ability to assist formulators in developing safer, highly effective chemical products or to formally recognize formulators who have successfully done so.

3(e) General Guidelines

The information collection activities discussed in this renewal ICR comply with all regulatory guidelines under 5 CFR 1320.5(d)(2).

3(f) Confidentiality

Some information collected by EPA under the Formulator Program involves confidential business or trade secret information. The Formulator Program handles all information claimed as such as confidential business information in accordance with Agency confidentiality procedures (see 40 CFR part 2, subpart B). The Formulator Program uses information provided by formulators solely for purposes related to forming the partnership and discloses the information only to EPA employees and EPA contractors cleared for confidential information with a specific need to know.

3(g) Sensitive Questions

The information collection activities discussed in this document do not involve any sensitive questions.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents and NAICS Codes

The Formulator Program seeks partners from establishments engaged in the formulation of end-use, for-sale chemical products.

Below is a list of North American Industry Classification System (NAICS) codes and associated industries that may be affected by information collection requirements covered under this ICR. This list is intended to be illustrative; entities from other industries may elect to apply for recognition through the Formulator Program. However, EPA expects that most applications will come from the following industries:

<u>NAICS Code</u>	<u>Affected Industry</u>
325510	Paint and Coating Manufacturing
325611	Soap and Other Detergent Manufacturing
325612	Polish and Other Sanitation Good Manufacturing
325910	Printing Ink Manufacturing
325992	Photographic Film, Paper, Plate, and Chemical Manufacturing
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing

4(b) Information Requested

Once a company with an interest in partnership with the Formulator Program reviews the program materials and decides to apply, the next step for the organization is to submit the appropriate application.

(i) Data items:

Applicants for this voluntary program submit information items that vary depending upon the class of product. The items include:

Partnership Applications for Cleaning Products

Cleaning product manufacturers will submit ingredient information, as described here, to a qualified third-party profiler before submittal to EPA. Although third-party profilers may develop their own applications to facilitate the collection of these data elements, EPA does not require that a specific format be used.

Information submitted to 3rd parties:

- Company name and Web site URL;
- Name, title, address, phone number, fax number, and e-mail address of the candidate's primary contact person;
- Signature, name, and title of senior company authority (e.g., CEO, or vice president for health and environment);
- Description of all chemical ingredients in product;
- Other product information, including product packaging description, product flashpoint, and flushability / compostability;
- An MSDS for the product and each ingredient;
- Product performance testing (any method of demonstrating product performance is acceptable as long as it is a commonly used industry standard);
- If available, any supplemental product or ingredient environmental health and safety information., such as:
 - Biodegradation tests on individual ingredients

- Acute aquatic toxicity tests on product as a whole or individual ingredients
- Human health and safety tests
- Description of the type of training the company provides to customers on environmental and worker safety matters;
- Production volume of all products submitted for recognition.

Information submitted to EPA:

- Summary report, containing same data items as above

Partnership Applications for Non Cleaning Products

Holding tank treatment/deodorizing, industrial coating, ink products, and other manufacturers of innovative and environmentally safer products will the following information directly to EPA.

Information submitted to EPA:

- DfE Ingredient Worksheet (EPA Form 6800-08) (See Attachment C)

(ii) Respondent activities:

Applicants for Cleaning Product Formulation Partnerships

- Review program information, including instructions on submitting information to 3rd party profilers.
- Submit information described in section 4(b)(i) of this supporting statement to 3rd party profiler
- Establish agreement with 3rd party profiler
- Submit summary report to DfE
- Negotiate / establish Partnership Agreement with DfE
- Renew partnership, with no changes needed
- Site audit

Applicants for Non-Cleaning Product Formulation Partnerships

- Review program information
- Fill out and submit DfE Ingredient Worksheet (EPA Form 6800-08)
- Negotiate / establish Partnership Agreement with DfE
- Renew partnership, with no changes
- Site audit

5. THE INFORMATION COLLECTED – AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

Under the Formulator Program, EPA engages in the following activities related to the Formulator application and decision process.

- Distribute applications to potential participants, and maintain downloadable PDF versions on the Formulator Program Web site;
- Answer questions posed by potential applicants regarding recognition under the Program;
- Receive the completed applications, review for accuracy, and place any necessary follow-up calls;
- Apply EPA's chemical tools and expertise to understand toxicological characteristics of chemical ingredients and to ensure that they are the safest within their functional use class; and
- Approve candidates for recognition and notify both successful and unsuccessful applicants of the decisions.

5(b) Collection Methodology and Management

Cleaning product manufacturers may obtain applications for providing ingredient information for the chemical summaries that will be developed by third-party profilers by downloading them directly from the Web site of the third-party profilers, if they have developed such forms for this use. Non-cleaning product manufacturers will be able to obtain the DfE Ingredient Worksheet (EPA Form 6800-08) in hard copy from EPA or by downloading it from the Formulator Program Web site. The completed applications can be faxed, mailed, or, if they do not contain CBI or Trade Secret information, they can be scanned and emailed to EPA.

In collecting and analyzing the information associated with this ICR, EPA will use a telephone system, personal computers, and applicable database software. EPA will ensure the accuracy and completeness of collected information by reserving the right to request proof of the list of ingredients (e.g., bills of lading, invoices) or other relevant documentation at any time to confirm that candidates have achieved the criteria for recognition.

5(c) Small Entity Flexibility

EPA expects that some of the participants in the Formulator Program will be small entities. EPA has designed its application form to minimize respondent burden while obtaining sufficient and accurate information. In addition, given the voluntary nature of the collection, EPA expects that respondents will participate only if the benefits of participation outweigh the information collection burden.

5(d) Collection Schedule

Organizations may submit an application for recognition at any time.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

The average response burden is estimated to be about 22 hours per product application (see Exhibit 6.2) for both cleaning product formulators and non-cleaning product formulators. Cleaning product manufacturers may experience slightly higher burden if they bundle several products together for recognition in a single submission to EPA (potentially requiring a longer administrative review), but the estimated burden *per product* is the same (i.e., additional burden from bundling information for several products into a single package would be self-

imposed). EPA used professional judgment to arrive at a burden estimate and then consulted representatives from the participant categories to make sure the burden estimates were reasonable (see section 3(c)).

EPA expects that for a typical cleaning product formulator, program and application review will take about 2 hours (1 managerial, 1 technical). Filling out and submitting third-party information request forms will take about 5 hours (4 technical, 1 clerical), and then establishing an agreement with the third party will take about 3 hours (1 managerial, 1 technical, 1 clerical). Submitting a summary report to DfE will take about 2 hours (1 managerial, 1 technical). Finally, establishing a Partnership Agreement DfE will take 3 hours (1 managerial, 2 technical).

For a typical non-cleaning product formulator, program and application review will take 2 hours (1 managerial, 1 technical). Filling out and submitting the DfE ingredient worksheet (EPA Form 6800-08) will take about 5 hours (4 technical, 1 clerical). Finally, establishing a Partnership Agreement with DfE will take 5 hours (1 managerial, 4 technical).

In addition to the burden associated with first-time submission of applications, each formulator has the opportunity to renew its Partnership Agreement at the end of the three-year partnership period. This means that once every three years, the formulator re-submits its application for each partnership product to confirm that no changes have been made to ingredients. EPA then evaluates the application. EPA estimates that the partnership renewal process will take 5 hours (4 technical, 1 clerical) for cleaning and non-cleaning product formulators. For purposes of this ICR, EPA expects that 96 (see Section 6d on estimating the respondent universe) cleaning and non-cleaning product formulators will choose to renew their partnerships. Furthermore, EPA anticipates that one in ten cleaning and non-cleaning product formulators over the three-year period of this ICR will need to make improvements to their formulations so that they contain the safest ingredients within each functional use class; in these cases, a new partnership approval process, as described above, will be triggered. The associated burden for completing the new partnership approval process is assumed to be the same as first-time submission. For purposes of estimating annual cost and burden in Exhibit 6.2, it is assumed that one-third of the 96 formulators (or 29 cleaning product and 3 non-cleaning product formulators) over the three-year period of this ICR will renew their partnership agreements each year. It is also assumed that over the three-year period of this ICR, one in ten formulators (or 3 cleaning product and 1 non-cleaning product formulators) will need to go through a new partnership approval process, which on an annual basis translates into two formulators per year (1 cleaning product and 1 non-cleaning product formulator).

As part of the application process, the third-party certifier will also reserve the right to visit site facilities to verify that each partnership product contains the same ingredients, in the same volumes, that are reported by the company as part of the DfE recognition process. The site auditor will review batch tickets associated with each recognized product to ensure that ingredient claims are accurate. For purposes of estimating annual cost and burden in Exhibit 6.2, it is assumed that about 33% of formulators will get audited each year over the three-year period of this ICR (i.e., 10 cleaning product and 1 non-cleaning product formulators). Each audit is estimated to require two hours of a technical person's time and one hour of a clerical person's time.

6(b) Estimating Respondent Costs

EPA estimates an average loaded hourly labor rate (base hourly rate plus fringe and overhead) of \$68 for managerial staff, \$55 for technical staff, and \$27 for clerical staff. These three labor rate estimates are based upon manufacturing industry wage data from the Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation, Supplementary Tables* from September 2007. The hourly labor rates include a 17% overhead; this overhead rate is used for consistency with OPPT economic analyses for two major rulemakings: *Wage Rates for Economic Analyses of the Toxics Release Inventory Program* and the *Revised Economic Analysis for the Amended Inventory Update Rule: Final Report*. In addition, the hourly labor rates have been rounded for the purposes of this ICR. The type of staff needed to complete the Formulator's applications and their associated hourly labor rates were verified by contacting representatives from the participant categories. The derivation of labor rates for managerial, technical, and clerical staff are shown in Exhibit 6.1.

Exhibit 6.1. Derivation of Loaded Wage Rates

Labor category	Wage	Fringe Benefit	Fringes as % wage	Overhead % wage	Fringe + overhead factor	Loaded Wages	Loaded Wages (rounded)
	(a)	(b)	(c)=(b)/(a)	(d)	(e)=(c)+(d)+1	(f)=(a) × (e)	
Managerial ¹	\$41.40	\$19.74	47.68%	17%	1.65	\$68.18	\$68.00
Professional/ Technical ²	\$33.25	\$16.54	49.74%	17%	1.67	\$55.44	\$55.00
Clerical ²	\$16.40	\$8.28	50.49%	17%	1.67	\$27.47	\$27.00

In exhibit 6.2 we show the breakdown of burden costs, assuming 20 hours for cleaning product manufacturers and 17 hours for non-cleaning product manufacturers. The third-party verification process for cleaning products also adds a operating and management (O&M) cost of about \$13,200 per company per application. This cost estimate is from NSF International, which has experience conducting third-party analysis of ingredient characteristics. For this ICR, it is assumed that the typical cleaning product manufacturer will submit four products in an application. Each product is assumed to contain 2 ingredients at \$500 each, 2 proprietary ingredients at \$1,000 each, and 1 CleanGredients™ ingredient at no charge, for a total of \$3,000 per product. In addition, a \$300 administrative fee per product is assumed. The total will be \$13,200 per company per application. It is assumed that the typical non-cleaning product manufacturer will submit one product per application. No additional capital or O&M costs are incurred by respondents under this ICR.

¹ Bureau of Labor Statistics (BLS) *Employer Costs for Employee Compensation, Supplementary Tables*. From Supplementary Table 2, Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Private industry workers in manufacturing industries, by occupational group, establishment size and bargaining status, September 2007. Available at: <http://www.bls.gov/ncs/ect/sp/ecsuptc4.pdf>

Exhibit 6.2. Estimated Annual Burden and Costs to Respondents

Collection activity	Hours and Costs Per Respondent							Total Hours and Costs		
	Mgr. \$68/Hr	Tech. \$55/Hr	Cler. \$27/Hr	Response Hours/Yr	Labor Cost/Year	Capital Cost	O & M Cost*	Number of Respon.**	Total Hours/Yr	Total Cost/Yr
Cleaning Products										
• Review program information	1	1	0	2	\$123	0	--	30	60	\$3,690
• Respond to 3 rd party information request for summary report initiation	0	4	1	5	\$247	0	--	30	150	\$7,410
• Establish agreement with 3 rd party	1	1	1	3	\$150	0	\$13,200	30	90	\$400,500
• Submit summary report to DfE	1	1	0	2	\$123	0	--	30	60	\$3,690
• Negotiate / establish Partnership Agreement with DfE	1	2	0	3	\$178	0	--	30	90	\$5,340
• Renew partnership, with no changes needed	0	4	1	5	\$247	0	--	29	145	\$7,163
• Site audit	0	2	1	3	\$137	0	--	10	30	\$1,370
<i>Subtotal***</i>	4	15	4	23	\$1,205	0	\$13,200	29	625	\$429,163.00
Non-Cleaning Products										
• Review program information	1	1	0	2	\$123	0	0	4	8	\$492
• Fill out and submit DfE ingredient worksheet	0	4	1	5	\$247	0	0	4	20	\$988
• Negotiate / establish Partnership Agreement with DfE	1	4	0	5	\$288	0	0	4	20	\$1,152
• Renew partnership, with no changes	0	4	1	5	\$247	0	0	3	15	\$741
• Site audit	0	2	1	3	\$137	0	0	1	3	\$137
<i>Subtotal***</i>	2	15	3	20	\$1,042	0	0	3	66	\$3,510
TOTAL								32	691	\$432,673

* The cost for third-party review and verification assumes that the typical application submitted by a cleaning product manufacturer will contain four products. Each product will contain 2 ingredients at \$500 each and 2 proprietary ingredients at \$1,000, for a total of \$3,000 per product. Also assumes a \$300 administrative fee per product. The total will be \$13,200 per company per application.

**This column reports the number of annual respondents after accounting for the partnership renewal process and site audits. Assumes that one in ten formulators over the three-year period will need to make changes to their formulations and go through a new partnership process which includes same collection steps. On an annual basis, this translates to 1 of 29 cleaning product formulators (for a total of 30) and 1 of 3 non-cleaning product formulators (for a total of 4). Also assumes that about 33% of cleaning product formulators (i.e., 10) and non-cleaning product formulators (i.e., 1) will be subject to site audits each year. See Section 6(a) for additional explanation.

*** Some numbers may not add due to rounding.

6(c) Estimating Agency Burden and Costs

Exhibit 6.3 presents the estimated Agency burden hours and costs associated with the information collection activities under this ICR. EPA based its burden estimates on its experience managing other voluntary programs.

Agency labor costs are calculated based on hourly basic rates for federal employees in the Washington-Baltimore area published by the Office of Personnel Management effective January 2008². The average hourly labor rate for managerial staff is estimated as the rate for a GS-13 Step 5 employee, for technical staff as a GS-10 Step 10 employee, and for clerical staff as GS-5 Step 1. These GS-level assumptions are consistent with those used in past EPA OPPT ICRs. The hourly rates were multiplied by an assumed loading factor of 1.6 to reflect Federal fringe benefits and overhead. This loading factor is from an EPA guide, *Instructions for Preparing Information Collection Requests (ICRs)* (OPPE, 1992, page 30, footnote 9).

The resulting average hourly labor rates, rounded to the nearest dollar amount, are \$72 for managerial staff, \$53 for technical staff, and \$24 for clerical staff. The Agency expects most activities related to this ICR to be performed by managerial staff (25 percent) and technical staff (75 percent).

² OPM, 2008. Salary Table 2008-DCM. Available at http://www.opm.gov/oca/08tables/pdf/dcb_h.pdf

Exhibit 6.3. Annual Agency Burden/Cost

Collection activity	Hours and Costs Per Respondent						Total Hours and Costs		
	Mgr. \$72/Hr	Tech. \$53/Hr	Agency Hours/Yr	Labor Cost/Year	Capital/ Startup Cost	O & M Cost	Number of Respon.*	Total Hours/Yr	Total Cost/Yr
Cleaning Products									
• Review program information	0	1	1	\$53	0	0	30	30	\$1,590
• Review 3 rd -party summary	0	7	7	\$371	0	0	30	210	\$11,130
• Negotiate / establish Partnership Agreement with formulator	2	4	6	\$356	0	0	30	180	\$10,680
• Review partnership renewal, with no changes needed	1	1	2	\$125	0	0	29	58	\$3,625
<i>Subtotal</i>	3	13	16	\$905	0	0	29	478	\$27,025
Non-Cleaning Products									
• Review program information	0	1	1	\$53	0	0	4	4	\$212
• Review product submissions and complete chemical profiles	0	29	29	\$1,537	0	0	4	116	\$6,148
• Negotiate / establish Partnership Agreement with formulator	2	6	8	\$462	0	0	4	32	\$1,848
• Review partnership renewal, with no changes needed	1	1	2	\$125	0	0	3	6	\$375
<i>Subtotal</i>	3	37	40	\$2,177	0	0	3	158	\$8,583
TOTAL							32	636	\$35,608

*This column reports the number of respondents after accounting for the partnership renewal process. Assumes that one in ten formulators will need to make changes to their formulations and go through a new partnership process which includes same collection steps – i.e., 1 of 29 cleaning product formulators (for a total of 30) and 1 of 3 non-cleaning product formulators (for a total of 4).

6(d) Estimating the Respondent Universe and Total Burden and Costs

EPA estimates that 96 formulators will submit applications over the three-year life of the clearance. EPA expects the participation will ramp up over the three year period, but for the purposes of estimating annual cost and burden in Exhibit 6.2, it is assumed that 32 formulators will submit applications per year. This estimate is based on historical data and the assumption that participation will increase over the next three years in response to greater consumer demand for green products. Furthermore, EPA estimates that of the applications, about 90 percent (or 29 per year) will be cleaning products, with the remainder being non-cleaning products. The annual burden hours and cost associated with this information collection are 691 hours and \$432,673 respectively.

6(e) Bottom Line Burden Hours and Cost Tables

a. Respondent Tally

Exhibit 6.4 below summarizes the total annual estimated respondent burden and cost. These estimates represent the average burden in any given year over the three years covered by this ICR.

Exhibit 6.4. Total Annual Estimated Respondent Burden and Cost Summary

Total # of Respondents	Average Burden Hours	Annual Cost
32	691	\$432,673 (labor) + \$382,800 (M&O) = \$815,473

b. Agency Tally

Exhibit 6.5 below summarizes the total annual estimated agency burden and cost. These estimates represent the average burden in any given year over the three years covered by this ICR.

Exhibit 6.5. Total Annual Estimated Agency Burden and Cost Summary

Burden Hours	Annual Cost
636	\$35,608

6(f) Reasons for Change in Burden

Since this is a new ICR, change in respondent burden is not applicable.

6(g) Burden Statement

The annual public burden for this collection of information is estimated at 23 hours per response for formulators of cleaning products and 20 hours per response for formulators of non-cleaning products, including time for reviewing instructions, gathering information, and completing and reviewing the application. According to the Paperwork Reduction Act, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection it includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not

conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appears above. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the [Federal Register](#), are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

The Agency has established a public docket for this ICR under Docket ID No. EPA-HQ-OPPT-2008-0219, which is available for online viewing at www.regulations.gov, or in person viewing at the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280. You may submit comments regarding the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden, including the use of automated collection techniques.

Submit your comments, referencing Docket ID No. EPA-HQ-OPPT-2008-0219 and OMB Control No. 2070-NEW, to (1) EPA online using www.regulations.gov (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407T, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB by mail to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPPT-2008-0219. These attachments are available for online viewing at www.regulations.gov or otherwise accessed as described in section 6(g) of the supporting statement.

- Attachment A:** **42 USC 13103 - Pollution Prevention Act Section 6604.** Also available at online at the US House of Representatives' Office of the Law Revision Counsel's [US Code website](#)
- Attachment B:** **Design for the Environment Formulator Program Elements: A Discriminating and Protective Approach to Cleaning Product Review and Recognition**
- Attachment C:** **DfE Formulator Program: Ingredient Worksheet (EPA Form 6800-08)**

ATTACHMENT A

Pollution Prevention Act Section 6604(b)(5)

42 U.S.C. 13103(b)(5)

[Electronic copy available as part of the electronic copy of the ICR's Supporting Statement.]

SEC. 6604. EPA ACTIVITIES.

(a) **AUTHORITIES.**—The Administrator shall establish in the Agency an office to carry out the functions of the Administrator

under this subtitle. The office shall be independent of the Agency's single-medium program offices but shall have the authority to review and advise such offices on their activities to promote a multimedia approach to source reduction. The office shall be under the direction of such officer of the Agency as the Administrator shall designate.

(b) **FUNCTIONS.**—The Administrator shall develop and implement a strategy to promote source reduction. As part of the strategy, the Administrator shall—

- (1) establish standard methods of measurement of source reduction;
- (2) ensure that the Agency considers the effect of its existing and proposed programs on source reduction efforts and shall review regulations of the Agency prior and subsequent to their proposal to determine their effect on source reduction;
- (3) coordinate source reduction activities in each Agency Office and coordinate with appropriate offices to promote source reduction practices in other Federal agencies, and generic research and development on techniques and processes which have broad applicability;
- (4) develop improved methods of coordinating, streamlining and assuring public access to data collected under Federal environmental statutes;
- (5) facilitate the adoption of source reduction techniques by businesses. This strategy shall include the use of the Source Reduction Clearinghouse and State matching grants provided in this subtitle to foster the exchange of information regarding source reduction techniques, the dissemination of such information to businesses, and the provision of technical assistance to businesses. The strategy shall also consider the capabilities of various businesses to make use of source reduction techniques;
- (6) identify, where appropriate, measurable goals which reflect the policy of this subtitle, the tasks necessary to achieve the goals, dates at which the principal tasks are to be accomplished, required resources, organizational responsibilities, and the means by which progress in meeting the goals will be measured;
- (8) ¹ establish an advisory panel of technical experts comprised of representatives from industry, the States, and public interest groups, to advise the Administrator on ways to improve collection and dissemination of data;
- (9) establish a training program on source reduction opportunities, including workshops and guidance documents, for State and Federal permit issuance, enforcement, and inspection officials working within all agency program
- (10) identify and make recommendations to Congress to eliminate barriers to source reduction including the use of incentives and disincentives;
- (11) identify opportunities to use Federal procurement to encourage source reduction;
- (12) develop, test and disseminate model source reduction auditing procedures designed to highlight source reduction opportunities; and
- (13) establish an annual award program to recognize a company or companies which operate outstanding or innovative source reduction programs.

ATTACHMENT B

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



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

April 2009

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.

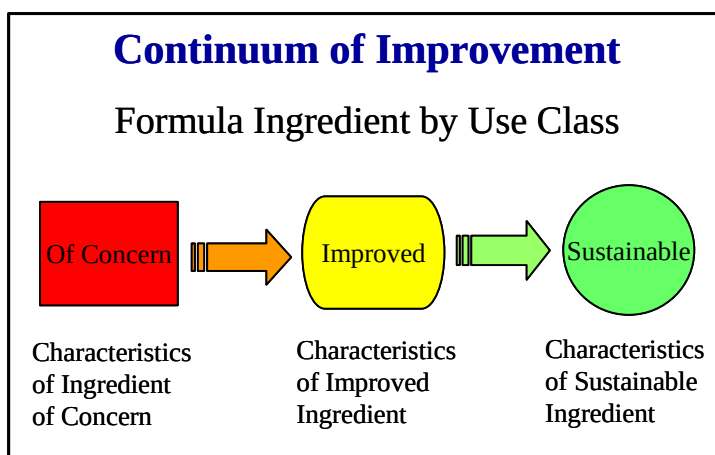
Since 1997, DfE has offered recognition to those companies who design for the environment and human health by using only safer chemicals. To date, over 900 chemical products have been recognized by the program. A complete list of partner companies and products can be found at: <http://www.epa.gov/dfe/pubs/projects/formulat/formpart.htm>.

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 component¹, 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 class², 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 ^dand 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...	
<p>^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.</p> <p>^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.</p> <p>^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 ≤ 1 ppm.</p> <p>^d Degradation products of concern are compounds with high acute aquatic toxicity (L/E/IC50 ≤ 10 ppm) which mineralize <60% in 28 days.</p>			

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)	<p>DfE-recognized products do not contain APEs. APEs, like all surfactants, are compared based on their key distinguishing characteristics:</p> <ol style="list-style-type: none"> 1) Rate of biodegradation, 2) Aquatic toxicity, and 3) Degradation products. <p>APEs do not have acceptable profiles because they degrade to products that are increasingly toxic and have potential for interaction with the endocrine system.</p>	<p>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.</p> <p>See also the section titled ‘Surfactants’.</p>
Chelating and Sequestering Agents	<p>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.</p> <p>Other chelants/sequesterants that are not readily biodegradable, may be accepted under continuous improvement.</p>	<p>See ‘Eutrophication’ for explanation of phosphate criterion.</p> <p>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 .</p>
Compostability	<p>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.</p>	<p>‘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.</p>
Concentrates	<p>Liquid laundry detergents must be at least a 2X concentrate to achieve DfE recognition.</p>	<p>Many manufacturers are producing products in concentrated form to reduce their transportation footprint and reduce greenhouse gas emissions. DfE commends this approach.</p>

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 efficient products would continue to meet all other program criteria.	
Flammability	DfE takes note of <i>product</i> 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: <ul style="list-style-type: none"> ➤ 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". Flushability 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. <i>Components</i> are screened for: <ol style="list-style-type: none"> 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 <i>components</i> 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	<p>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.</p> <p>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).</p>	
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	<p>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.</p> <p>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).</p>	
Toxic elements	DfE-recognized products do not contain toxic elements, for example lead, cadmium, arsenic, zinc and copper.	Unavoidable, <i>de minimis</i> 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	<p>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.</p> <p>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.</p>	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.

ATTACHMENT C

**DfE Formulator Program: Ingredient Worksheet
EPA Form 6800-08**

**OMB Control No. 2070-NEW
Approval expires XX/XX/XX**

The public reporting and recordkeeping burden for this collection of information is estimated to average 20 hours per response for formulators of cleaning products and 17 hours per response for formulators of non-cleaning products, including the time for reviewing instructions, gathering information, and completing and reviewing the application. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed application to this address.

DfE Formulator Program: Ingredient Worksheet



Company Name:

Product:

Product Information

Is the product registered with EPA Office of Pesticides? (Y/N)

Is the product an aerosol? (Y/N)

Enter pH of product

Enter Date of Form Submittal

	Chemical Name	CAS Registry #	Trade Name	% by weight in formula
Surfactant				
Hydrotrope				
Builder				
Sequestrant				
Dispersant				
Solvent				
Sanitizer				
Enzyme/ Micro- organism				
Preservative/ Biocide				
Fragrance				
Colorant				
Other				
				Total = 100%