A Compendium of Methods and Tools for Chemical Hazard Assessment

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Home and Personal Care Sector Working Group



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The Lowell Center for Sustainable Production is a research institute at the University of Massachusetts Lowell that promotes healthy work environments, thriving communities, and viable businesses.

We collaborate with citizen groups, workers, businesses, institutions, and government agencies to advance chemicals, materials, products, and practices that are healthy, humane, and respectful of natural systems.



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Executive Summary

The Sustainability Consortium is developing a Sustainability Measurement and Reporting System (SMRS) to enable the measurement and reporting of sustainability-related information associated with consumer packaged goods. The Home and Personal Care Sector Working Group seeks to identify a method or combination of tools that can be used to account for ecological and human health impacts of chemical-based products. To develop this aspect of SMRS, the Sustainability Consortium seeks a better understanding of the methods and tools that have been developed in recent years for chemical hazard assessment. In response to this need, the Lowell Center for Sustainable Production has prepared this compendium of methods and tools.

This compendium is not meant to be exhaustive, but rather to provide an overview of the methods and tools being used by governments, the for-profit private sector, and non-profit organizations to more effectively screen and prioritize chemical hazards and identify safer alternatives. We researched a range of methods that are designed to assess and reduce chemical hazards throughout the product life cycle. There are three general types of methods and tools: those that are designed to identify and screen out hazardous chemicals; those that are designed to compare alternatives; and those that are designed to identify preferred chemicals and products.

We used these three categories to catalogue the methods and tools that we have included in the compendium. Each method or tool is described and its strengths and limitations are identified. In addition, the different methodologies and tools are compared in a summary matrix. The methods and tools differ in the levels of expertise, data, and review required. However, all of them represent tools that can be used to assess and reduce chemical hazards in products.

The report discusses key drivers for reducing chemical hazards in the product life cycle including new regulations, particularly in the European Union and at the state level in the US, as well as retailer, manufacturer, and consumer demand for products that do not contain chemicals of concern Key issues to be considered in developing or analyzing any method or tool are discussed including: data gaps, decision rules/transparency, exposure evaluation in hazard assessment methods, and positive chemical attributes.

The report concludes by identifying some key elements that may be considered in determining whether a company is systematically working toward improving product sustainability with regards to chemical hazards throughout the product life cycle. These include: an inventory of chemical usage and disposition throughout the supply chain; a process for identifying high-hazard chemicals; a means of prioritizing chemicals to be substituted; a method for comparing alternatives; a process for implementing these changes; and a system for disclosing product ingredients. These elements can form the basis for sustainability performance indicators and can provide a means of differentiating among companies.

Introduction

The Sustainability Consortium is developing Sustainability Measurement and Reporting Systems (SMRS) to enable the measurement and reporting of sustainability-related information associated with consumer packaged goods. SMRS include reporting on human health, climate change, resource depletion, ecosystem quality, and social impacts. The Home and Personal Care Sector Working Group seeks to identify a method or combination of tools that can be used to account for ecological and human health impacts of chemical-based products. This Working Group includes the following categories of products: air care, dish care, cleaning accessories, laundry care, surface care, insect/pest/allergen control, cosmetics, fragrances, hair products, personal hygiene products, and skin products. Life cycle assessment (LCA) provides the basic framework for the SMRS. LCA and risk assessment are well documented methodologies for assessing the health and environmental impacts of chemicals and products. ¹² Chemical hazard assessment methods are a set of tools that have been developed by governments, non-governmental organizations and the private sector to efficiently screen out known chemical hazards, compare alternatives, and identify preferred chemicals, processes and products. To aid in developing sustainability indicators for this aspect of the SMRS, the Sustainability Consortium seeks a better understanding of the methods and tools that have been developed for chemical hazard assessment. In response to this need, the Lowell Center for Sustainable Production has prepared this compendium of methods and tools.

Methodology

To conduct this study, we reviewed government, industry and non-governmental reports, documents, and Web sites, as well as published literature where applicable. Using an internal group review process, we identified tools that were: (1) already used in the home and personal care sectors; (2) were or could be relevant to the sector; or (3) were useful models for chemical hazard assessment. We researched a range of methods that are designed to assess and reduce chemical hazards in products. Although it was not possible to ensure that this compendium includes all methods and tools in use (there are likely dozens of them including those developed by firms, governments, nonprofit and forprofit organizations), the major categories of methods and tools are included. We developed a standard format for characterizing each method or tool and collected data to complete this template. When possible, developers of the method or tool were contacted and requested to review the summary description for accuracy.

While there is some overlap between methods and tools, we distinguish between them as follows: methods include a decision-making framework and approach while tools provide information and data, but do not guide the user in decision-making. For example, the Chemicals Alternatives Assessment approach developed by the US EPA Design for Environment (DfE) program is a method, whereas a list of restricted substances is a simple tool that can be used to provide information on substances to avoid. There are three general types of methods and tools:

- methods/tools that are designed to *identify and screen out* hazardous chemicals
- methods/tools that are designed to compare alternatives
- methods/tools that are designed to identify preferred chemicals and products

We have used these three categories to catalogue the methods and tools that we have included in the compendium. It should be noted, however, that some tools can classified in more than one category. This report characterizes and analyzes the current landscape of methods and tools, including: government initiatives in the US and Europe; tools developed by the for-profit private sector, focused particularly on home and personal care products; and nongovernmental (NGO) efforts. Each method or tool is described and its strengths and limitations are identified. In addition, the different methodologies and tools are compared in a summary matrix. The methods and tools differ in the levels of expertise, data, and review required. However, all of them represent tools that can be used to assess and reduce chemical hazards in the product life cycle.

Most of the methods and tools described in the compendium consider both human health and environmental hazards. The US EPA screening-level tools ECOSAR and the PBT Profiler predict aquatic toxicity but do not screen for human health hazards. The Environmental Working Group's Skin Deep Cosmetics Database is focused primarily on human health, but does consider toxicity to fish, wildlife, plants and other organisms.

Drivers for reducing chemical hazards in the product life cycle

In recent years, there has been increased scientific, government, and public concern about hazardous chemicals that may be released during production, product use or in disposal, their build up in the environment and in human tissues, and their potential health impacts. While for particular chemicals there is scientific debate about the extent of chemical risks to consumers, government policy is changing and the marketplace is beginning to act. Key drivers for reducing chemical hazards in the product life cycle include new regulations, particularly in the EU (European Union) and at the state level in the US, as well as retailer, manufacturer, and consumer demand for products that do not contain chemicals of concern. Government bodies have begun to discuss reforms to chemical management policies to address concerns about the presence of chemicals in products that have not been well studied for their health effects on humans and ecosystems.

The European Union's (EU) Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) Regulation came into force in June 2007. It requires chemical manufacturers to provide toxicity information on the chemicals they produce and to seek authorization for continued use of the highest concern chemicals if no suitable alternatives exist. As of December 1, 2010 companies operating in the EU can no longer make or import high-volume or certain high-hazard chemicals unless they are registered with the European Chemicals Agency (ECHA). To date, 4,300 substances have been registered

In addition, the 2002 EU Directive known as RoHS (Restriction of Hazardous Substances –in electrical and electronic equipment) has been a key driver for the electronics and automotive sectors to eliminate from their products and find safer alternatives for lead, mercury, cadmium, hexavalent chromium, polybrominated diphenyl ethers, and polybrominated biphenyls.

In the US, the Toxic Substances Control Act is understood to be outdated and has not been fully effective for comprehensive chemicals management. To begin the process of TSCA reform, the US Senate introduced the Safe Chemicals Act in April 2010, with companion legislation introduced in the House of Representatives in July 2010 (the Toxic Chemicals Safety Act). A revised Safe Chemicals Act of 2011 was introduced in the US Senate in April 2011. The debate over how to reform TSCA is likely to take several years or more. In the interim period the US EPA has issued new policies regarding protection of Confidential Business Information, Chemical Action Plans, and chemical use reporting.

In the absence of federal policy reform, many states have developed their own chemical policies over the last decade. States have enacted legislation to:

- restrict specific chemicals such as lead, phthalates, bisphenol A (BPA), decabrominated polyphenyl ether (decaBDE), mercury, dioxin, perchloroethylene, and formaldehyde;
- regulate product categories such as children's products, cleaning products, personal care products, and packaging;
- require ingredient disclosure and labeling;
- encourage green chemistry and design for environment;
- require environmentally preferred purchasing;
- require alternatives assessment to identify safer alternatives to toxic chemicals.³

In January 2011, 30 states announced plans to introduce legislation on toxic chemicals. See Figure 1.⁴ These bills include legislation in 9 states to enact comprehensive chemicals policies. Legislation to phase out specific chemicals such as BPA, cadmium and deca BDE is planned in a number of states.

States Introducing Toxics Legislation in 2011



Figure 1. States Introducing Toxics Legislation in 2011.

Source: Safer Chemicals Healthy Families. January 18, 2011. www.saferchemicals.org

Other drivers for reducing chemical hazards in the product life cycle include pressure from consumer and environmental advocates to eliminate chemicals of concern in a wide array of products. Several organizations conduct testing of consumer products and have created databases to inform consumers about chemical hazards. These include sites such as healthystuff.org, the Skin Deep cosmetics database, Pharos (with information on building products), and GoodGuide.^a Some of these databases go beyond providing information on chemical hazards and include data on corporate social responsibility (GoodGuide) and renewable materials and energy (Pharos). In addition to these Web sites, there are more than 300 eco-labels worldwide.⁵ These labels are designed to inform consumers about environmental (and sometimes social) attributes of products. Environmentally preferred purchasing programs that are mandated by state or federal government often rely on these third-party certified eco-labels to select products.

Some large retailers have begun to require suppliers to share information on chemicals in products and to eliminate or reduce chemical hazards. In 2009, Walmart, Sears, and Kmart began requiring suppliers of chemical products to disclose all intentionally added chemical ingredients to a third-party service provider, the WERCS. The WERCS keeps the formulation data confidential but lets the retailers know whether the products are regulated under federal or state environmental laws and how they should be handled and disposed of. Walmart has taken this effort further by requiring suppliers to use the GreenWERCSTM chemical screening tool to evaluate ingredients for human and environmental health risks. Retailers can use this information to compare competing

^a See www.healthvstuff.org, www.cosmeticsdatabase.com,www.pharosproject.net, www.goodguide.com

products and encourage suppliers to substitute safer ingredients for harmful ones. GreenWERCSTM is also used by chemical manufacturers to assess their formulations.

These drivers taken together are spurring movement in the marketplace to understand chemical hazards and identify functional alternatives where concerns arise.

Methods and tools for chemical hazard assessment - overview and key issues

In response to the drivers described above, over the last decade scientists have developed a number of methods and tools to assist in efficiently identifying and screening out chemicals of concern and to compare and help choose alternatives that are commercially available, technically feasible and cost competitive. These tools assist companies to be in compliance with new laws and in some cases to get ahead of impending regulations by identifying, eliminating or reducing substances of concern. Comparative hazard assessment methods are particularly useful at the initial product design stage for formulated products that are chemical intensive. Some of these tools go beyond assessing chemical hazards to address other aspects of product sustainability such as energy use, packaging, and recyclability. These methods and tools are being developed by governments, NGOs, academia, and the private sector.

We have used three general categories to catalogue the methods and tools in the compendium:

- methods/tools that are designed to *identify and screen out* hazardous chemicals
- methods/tools that are designed to *compare alternatives*
- methods/tools that are designed to *identify preferred chemicals and products*

Some of the methods and tools can be used in several ways and therefore fit into more than one category. The largest number of methods and tools are found in the first category, that of identifying and screening out hazardous chemicals. There are several methods available for comparing alternatives (Category 2), and methods and tools are under development that are designed to identify preferred chemicals and products (Category 3). In reviewing these methods and tools, we have identified the following key issues that should be considered in developing or analyzing any method or tool.

Data gaps

One of the greatest challenges for assessing chemical hazards in the product life cycle is the lack of publically available data on a large percentage of the tens of thousands of chemicals in commercial use today. While availability of data is increasing, for many product manufacturers, obtaining information on upstream product chemistries may be difficult beyond Tier II as suppliers are difficult to identify and are not always willing or able to supply information on chemical content or toxicity. Limits to obtaining product

ingredient or toxicity data beyond MSDS sheets can pose a significant challenge for companies seeking to identify, assess, and reduce chemical hazards in their product life cycles. Some chemical manufacturers have developed Product Safety Assessments that provide information beyond what is typically found in a MSDS.⁶

In developing methods and tools to address hazards, this central issue of data gaps is handled in a variety of ways. In some cases, it is ignored – chemicals that do not appear on government lists of hazardous chemicals are not ranked as high hazard and are therefore directly or indirectly assumed to be safer. Some of the tools address data gaps by providing a score for data certainty/uncertainty, and others rate chemicals with no data as high hazard. The more sophisticated methods go beyond reviewing whether a chemical is on a government list of chemical hazards and include a review of the scientific literature for experimental data on chemicals of concern. An additional step involves the use of screening-level tools developed by the US EPA to evaluate chemicals for which there are no experimental data, applying structure-activity relationships. The use of these screening-level methods requires a significant understanding of both toxicology and chemistry with expert judgment required at many stages of the modeling process.

Decision rules and transparency

The majority of the methods and tools described in this compendium include decision rules that are embedded in the process. That is, the method includes criteria for determining whether a chemical should be ranked as high, medium or low hazard. These criteria are based on data, informed judgment, and on international scientific understanding and agreements. The range of hazard endpoints subject to these decision-rules varies significantly between tools; however, most include at least ecotoxicity, carcinogenicity, acute toxicity, and PBT characteristics. In some methods especially where alternatives are being compared, data for each chemical are arrayed by hazard category. The user determines the rules for decision-making by assigning a weight to each hazard category, such as cancer or neurotoxicity. In other cases, the tool assigns weights for each hazard category and thereby determines which chemicals should be deemed high hazard. Embedded decision rules make a tool easier to use by those untrained in toxicology and chemistry, but reduces the transparency of the analysis and decision-making process.

Transparency – of chemical ingredients and choices - is increasingly important for many consumer product manufacturers. In some cases developers of these methods and tools make the details of their methodologies public to enhance transparency. Methods that array a range of hazard information are the most transparent, but they generally require more research, data collection, and evaluation by the user.

Exposure evaluation in hazard assessment methods

The majority of the methods and tools described in this compendium are designed to evaluate a chemical based on its inherent hazards. The inherent hazard is the intrinsic properties of a chemical determined by its molecular structure. Understanding that a chemical can be hazardous to humans and ecosystems throughout a product life cycle and that exposure can occur in a variety of situations, these tools are designed to reduce the use of high-hazard chemicals and substitute alternatives that are not chemicals of concern.

Methods such as the US EPA's Design for Environment's (DfE) chemicals alternatives assessment evaluate chemicals for the same functional use, for example as a solvent, surfactant, or plasticizer. DfE scientists describe the functional use approach as a way to simplify the assessment and avoid the need for a full risk assessment because "where similar product and chemical use patterns are expected, exposure can be considered a constant." This assumption can be made except in cases where the alternatives under consideration exhibit different physical chemical properties such as dermal absorption potential or volatility or if the alternative is required at a higher concentration to achieve the same function, or if several chemicals are required to achieve the same function. These factors illustrate the challenges of identifying "drop-in" substitutes for chemicals of concern.

Therefore, in addition to understanding the inherent hazard of chemicals, it is important to understand exposure pathways and likely exposure scenarios in prioritizing management of chemical hazards and avoiding risk trade-offs. It may be useful to consider potential exposure to determine if use of an alternative chemical may increase the type or intensity of exposure to specific populations. Some of the tools described in the compendium directly or indirectly consider exposure to the chemical as part of the decision-making process. For example, Quick Scan considers how the chemical is being used as a surrogate for exposure. In Quick Scan, chemicals in open application or consumer use are considered of higher concern than chemicals in controlled industrial uses. The Column Model includes a consideration of factors that would increase or decrease potential exposure. In BASF's Eco-efficiency Analysis, exposure is evaluated according to the way that substances are handled, rather than determining actual exposure concentrations. The parameters considered to determine exposure are total production volume, use pattern and exposure route, and the vapor pressure of products. In these methods, an evaluation of exposure occurs after the inherent hazard of the chemical has been assessed as additional information in determining priorities for risk reduction. This is consistent with the concept of green chemistry where the first priority is to reduce intrinsic hazards of chemicals throughout their life cycles.

Positive chemical attributes

After high hazard chemicals are identified for reduction and elimination, the challenging question of determining positive attributes for alternative chemicals remains. Performance, cost, and technical feasibility play a key role in this determination along with properties such as low toxicity and biodegradability. Some companies have developed "positive lists" (sometimes referred to as white lists) of chemicals alongside lists of restricted substances (black lists) to better manage the purchasing and use of toxic chemicals. In many cases, companies may need to engage in research and development to identify safer chemicals for specific applications. The 12 Principles of Green Chemistry can be used to help foster the development of chemicals that have these positive qualities (Figure 2). These principles focus on the reducing the intrinsic hazards of chemicals, rather than applying controls after they are made into chemical products. The iSustain tool described below has been developed to assist companies using green chemistry principles to design safer chemicals.

Figure 2. The 12 Principles of Green Chemistry

- 1. Pollution Prevention
- 2. Atom Economy
- 3. Less Hazardous Synthesis
- 4. Design Safer Chemicals
- 5. Safer Solvents & Auxiliaries
- 6. Energy Efficiency
- 7. Renewable Feedstocks
- 8. Reduce Derivatives
- 9. Catalysis
- 10. Design for Degradation
- 11. Real-Time Analysis
- 12. Accident Prevention

Anastas, Paul T. and John C. Warner. **Green Chemistry: Theory and Practice**. Oxford

University Press: 1998.

The following discussion reviews the methods and tools described in the compendium. A summary matrix of these methods and tools is provided in Appendix A. More detailed descriptions of each method or tool and links to associated Web resources are included in Appendix B.

Tools designed to identify and screen out hazardous chemicals

The first category of methods and tools includes those have been developed to identify and screen out hazardous chemicals. There is increasing agreement that certain high-hazard chemicals - especially persistent, bioaccumulative and toxic chemicals (PBTs) and carcinogens, mutagens, and reproductive toxins (CMRs) - should be substituted, where technically and economically feasible. Over the last several decades, governments and

research institutes around the world have compiled lists of such high-hazard chemicals. In addition, there are recognized lists of asthmagens, suspected endocrine disrupters, ozone depleting substances, and neurotoxins. Many of the tools in this compendium evaluate chemical hazards based on whether chemicals are found on these lists. An obvious weakness of this approach is that chemicals for which few data exist or that have not been evaluated by government panels are not on these lists.

PRIO⁸

The Swedish Chemicals Inspectorate (KemI) developed PRIO to assist chemical producers and users such as product developers, company managers, and purchasers in eliminating high hazard chemicals from products to meet the government's goal of a "non-toxic environment" by the year 2020. This Web-based tool contains a database of chemicals that the Swedish Government has identified as being of high concern to human health or the environment. Hazard characteristics have been divided into two categories: "phase-out" or "priority risk reduction." "Phase-out" substances are considered to be of such high hazard that they should not be used. Criteria for "phase-out" substances include: CMRs, PBTs, vPvB (very persistent and very bioaccumulative), highly hazardous metals (mercury, cadmium, lead and their compounds), endocrine disruptors and ozone-depleting chemicals. For chemicals identified as "phase-out" substances, the PRIO tool provides a 7 step process for identifying safer alternatives.

Quick Scan⁹

The Dutch Ministry of Housing, Spatial Planning and the Environment developed the Quick Scan method as part of its effort to advance voluntary initiatives to substitute high hazard chemicals, recognizing that a rapid screening method was needed to avoid extensive animal testing. Quick Scan uses existing data, criteria and decision-making rules to evaluate substances and place them in five categories: very high concern; high concern; concern; low concern; and, provisionally very high concern if no data is available. The concern categories are adjusted based upon potential for exposure (a qualitative risk assessment) as determined by chemical uses and availability of alternatives. Four areas of substance use are evaluated: industrial use; site-limited intermediate use (in confined areas); open applications/professional use; and consumer applications. Although the Quick Scan method is no longer used now that REACH is in place, it provides a useful model for screening hazardous chemicals.

Substances in concern category on basis of hazard and useza)

FURNEURF	Use of substances as indication of exposure						
EXPOSURE ON BASIS CONCERN OF USE ON BASIS	Site limited intermediate substances	Substances in industrial applications	Open professional use of substances	Substances in consumer applications			
OF HAZARD	Low Exposure	Exposure	High exposure	Very high exposure			
Very high concern	High concern	High concern	Very high concern	Very high concern			
High concern	Concern	Concern	High concern	High concern			
Concern	Concern	Concern	Concern	High concern			
Low concern	Low concern	Low concern	Low concern	Concern			
No data, very high concern	Very high concern	Very high concern	Very high concern	Very high concern			

Figure 3. Quick Scan Model

Source: Dutch Ministry of Housing, Spatial Planning and the Environment. Implementation Strategy on Management of Substances – Progress Report and 2nd Progress Report. The Hague, 2002.

RISCTOX¹⁰

RISCTOX was developed by the Spanish Trade Union Institute for Health, Work and Environment to provide clear, organized, and easily accessible information about risks to human health and environment posed by chemicals in the workplace. For each hazard category, the database includes a description of the hazard and EU risk phrases and GHS hazard statements^b, what to do if that substance is found in the workplace, written practice guidelines, how the substance is classified, and current regulations. In addition to researching hazards posed by workplace chemicals, users can assess and compare alternative products using a tool in the database that is based on the Column Model described below.

US EPA Screening-Level Tools¹¹

The US EPA has developed a number of screening-level tools to address the problem of lack of experimental data for both newly developed and existing chemicals. Most of these tools require an understanding of toxicology and/or chemistry and are not designed for the lay user. These tools were developed as part of EPA's Sustainable Futures Initiative to encourage chemical developers to consider toxicity in the design and evaluation of new chemicals and find safer substances if hazards are identified. Companies that participate in the Sustainable Futures Initiative are eligible for an expedited EPA review of their pre-screened chemicals, which may shorten the time to market for new chemicals. These tools include:

^b Risk phrases (R-phrases), developed by the European Union, is a system of hazard codes and phrases for labeling dangerous chemicals and their compounds. R-phrases are being replaced by Hazard statements under the Globally Harmonized System (GHS) for classification and labeling.

- *EPI SuiteTM*, a software program that provides screening-level estimates of physical /chemical and environmental fate properties of chemicals
- *ECOSAR*, a software program that predicts toxicity of industrial chemicals released into water to aquatic life
- *PBT Profiler*, an online tool that screens chemicals for their potential to persist, bioaccumulate, and be toxic to aquatic life
- *OncoLogicTM*, a software program designed to predict the potential cancercausing effects of a chemical by applying Structure Activity Relationship (SAR) analysis
- Analog Identification Methodology (AIM), an online tool that helps locate data on closely related chemical structures to help users determine potential hazards of untested chemicals
- **Non-Cancer Screening Protocol**, a process for screening chemicals for non-cancer health effects in the absence of data

The EPA has also developed two exposure assessment tools: Exposure and Fate Assessment Screening Tool (E-FAST) and Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER).

Greenlist^{TM12}

In 2001, SC Johnson developed the GreenlistTM in partnership with the US EPA. This tool scores chemical ingredients used in SC Johnson products on the basis of health and environmental profiles. Chemicals are evaluated and scored in 19 functional categories, such as surfactant, solvent, or preservative. Chemicals with the lowest impact receive the highest scores and are considered preferable. The GreenlistTM has proven to be a useful tool for identifying problematic ingredients that require replacement and can also be used to compare substances to determine a preferred chemical or material. The GreenlistTM tool is now licensed for use through a third-party administrator and a few large, multinational companies are in the process of acquiring it.

Restricted Substances Lists (RSLs)

Restricted Substances Lists (RSLs) are a basic type of screening tool. RSLs generally include chemicals that are currently restricted by a government body anywhere in the world. The list may indicate whether the chemical is restricted widely or not. Chemicals that are of concern but are not yet regulated may also be included. Some companies maintain a separate "watch list" of chemicals under scrutiny by scientists and environmental advocates that are not yet regulated. Many companies have developed RSLs as well as some industry sectors, including the automotive, apparel, and electronic sectors, have also developed such lists. In addition to RSLs developed by the private sector, NGOs are creating lists of chemicals of concern to raise awareness about toxic chemicals in commercial use. For illustrative purposes, we have included an example of an industry-wide RSL, a cross-sector analysis of RSLs, a company-specific RSL, and a RSL developed by a nonprofit organization.

American Apparel & Footwear Association (AAFA) Restricted Substances List¹³:

The AAFA's RSL was developed as a practical tool to help companies undertake responsible chemical management practices in the home textile, apparel, and footwear industries. It provides information on chemicals that are restricted or banned in finished home textile, apparel, and footwear products anywhere in the world. For each chemical, the RSL identifies the most restrictive regulation. This tool is useful for assuring environmental compliance with global regulations and may also be used to call attention to substances that may be of emerging concern in this industry sector but are currently regulated by a few governments only.

Green Chemistry & Commerce Council^c Cross-Sector Compilation of Restricted Substance Lists¹⁴: To better understand the types of restricted chemicals and the drivers for their restriction, the Green Chemistry and Commerce Council compiled a cross-sector RSL using proprietary lists provided by 15 member companies and 4 sector-based RSLs that are made publicly available by their trade associations. Together these lists include the following sectors: retail, electronics, textiles, apparel, building products, personal care and cleaning products, automotive, flooring, commercial cleaning products, aerospace, and pharmaceutical.

The cross-sector compilation includes a table that identifies each restricted substance appearing on one or more of the 19 lists, its functional use (solvent, dye, etc), type of restriction applied (ban, restricted above a certain threshold, etc.), a description of what motivated the restriction, and the sector(s) in which the chemical is restricted.

Boots Priority Substances List (PSL)¹⁵: Boots UK has taken a precautionary approach to chemicals, stating that where there are reasonable grounds for concern that a chemical used in a Boots brand product could be harmful to human health or the environment, the company will take appropriate measures. The company is committed to conducting a systematic review of chemicals in all Boots brand products. It is updated annually and lists chemical ingredients of concern and their uses, regulatory actions that have been taken to restrict their use, the Boots UK position on each ingredient and any precautionary actions deemed necessary along with relevant timelines. Progress toward published targets is reported as part of the annual environmental performance update of the corporate social responsibility section of the company's Web site.

SIN (Substitute It Now!) List¹⁶: The SIN List was developed by ChemSec, a nonprofit organization based in Sweden. The first version of the list was released in September 2008 to engage with the REACH authorization process by identifying the most hazardous substances that should be prioritized for substitution and to encourage toxics use reduction by chemical producers and users. The SIN List includes only those chemicals that meet REACH criteria for Substance of Very High Concern (SVHC).

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^c The Green Chemistry & Commerce Council is a network of some 100 firms and other organizations committed to developing safer chemicals and materials. See http://www.greenchemistryandcommerce.org/home.php

These criteria include CMRs, PBTs, and vPvBs. It also includes other chemicals determined by toxicologists on a case-by-case basis to pose serious risks, such as endocrine disrupters. Building on the SIN List, a group of European trade unions have developed a European Trade Union restricted substances list. In May 2011, the SIN List 2.0 was released, adding 22 substances that are endocrine disruptors to the original SIN List.

Proprietary Chemical Management/Hazard Evaluation Tools

Another group of chemical screening tools that have been developed in response to the drivers described above are proprietary chemical management/hazard evaluation tools. All of these tools offer protection of confidential business information. A qualified third party reviews ingredient data without sharing it directly with customers or other interested parties. Users determine the weighting of the hazard categories and pay a subscription fee that varies based on the services provided. Many of these tools were developed initially to manage MSDSs but have been expanded to include hazard and risk evaluation. A description of GreenWERCSTM is included in the compendium and four other proprietary tools are briefly summarized.

GreenWERCS^{TM18}

The GreenWERCSTM chemical screening tool evaluates the human health and environmental hazards of chemical ingredients in products. It was originally developed to help Walmart increase its understanding of the chemicals in its products, with a long-term goal of reducing or eliminating carcinogens, mutagens and reproductive toxicants (CMRs) as well as persistent, bioaccumulative and toxic (PBT) chemicals from its products. Although GreenWERCSTM was originally developed for a retailer, the software is also used by manufacturers. Using ingredient data entered into a database, GreenWERCSTM analyzes the composition of individual products. Regulatory lists of hazardous substances are used to develop an aggregated score for each product, based on the weighting and scoring methodology of each company.



Figure 4. Example of GreenWERCS™ Output

Source: The Wercs Ltd (GreenWERCSTM Software) internal document.

Several other proprietary chemical management tools are briefly summarized in Appendix B. These include:

- SciVera Lens: Like GreenWERCSTM, SciVera Lens evaluates chemical ingredients in products for human health and environmental hazards. In addition, the tool considers exposure scenarios. If experimental data are not available, SciVera toxicologists use expert judgment and modeling to determine hazard.
- **3E Green Product Analyzer:** The 3E Green Product Analyzer evaluates chemical ingredients for health, safety and environmental compliance and can help in the selection of safer chemicals or products.
- IHS Chemical Inventory Greening Solutions: IHS Chemical Inventory Greening Solutions evaluates chemical products for their human health and environmental impacts, ranks these products, and suggests alternatives that have been approved by a qualified third party such as the EPA Design for Environment program, EcoLogo, or Green Seal.
- Actio Material Disclosure: The Actio Material Disclosure tool provides ingredient information about materials in a product supply chain for global compliance that can be accessed by retailers or manufacturers.

Methods and tools that are designed to compare alternatives

The second major category of methods and tools are those that are designed to compare alternatives, generally chemical alternatives, though P2OASys also considers alternative processes. These methods go beyond most tools in Category 1 as they include a methodology for comparing alternatives and, in some cases, provide a decision

framework to determine a preferred chemical. These methods tend to be more time consuming and require some understanding of toxicology and chemistry.

Chemicals Alternatives Assessment (CAA)¹⁹

The US EPA Design for Environment (DfE) program has developed this methodology for assessing alternatives to chemicals of concern. The tool uses existing primary data and predictive modeling to determine human health and environmental hazards of each chemical under evaluation. Life cycle thinking is used to consider chemical hazards throughout manufacture, use and disposal. This includes a comprehensive consideration of potential worker, consumer, and environmental exposure pathways. Data sources include publicly available empirical data, data received by EPA as confidential business information, structure activity relationship-based estimations using EPA screening-level methods, expert judgment that often relies on the experimental data for chemical analogues, and confidential experimental data supplied by chemical manufacturers.

The DfE program has developed hazard evaluation criteria that use thresholds to classify hazards as high, moderate or low. ²⁰ To easily compare alternatives, this analysis includes a summary table that arrays the hazard classifications of each chemical for human health effects, ecotoxicity, environmental impacts, and potential routes of exposure. The DfE program has used this approach to assess alternatives to brominated flame retardants used in furniture and printed circuit boards and is currently assessing alternatives to the use of bisphenol A (BPA) in thermal paper, among other projects.

Table 1 Example of how data are arrayed in a US EPA DfE Chemicals Alternatives Assessment

Screening Level Toxicology and Exposure Summary of Alternative Flame-Retardant Chemicals

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		Human Health Effects Ecotoxicity Environr			Human Health Effects			nmental	Potential Routes of Exposure												
		ation ³	ē	er	a	雪							ıtion	١	Norke	r		enera pulatio			
Company	Chemical	% in Formulation ³	Cancer Hazard	Skin Sensitizer	Reproductive	Developmental	Neurological	Systemic	Genotoxicity	Acute	Chronic	Persistence	Bioaccumulation	Inhalation	Dermal	Ingestion	Inhalation	Dermal	Ingestion	Aquatic	Reactive or Additive?
	SAYTEX RZ-243																				
	Proprietary E Tetrabromophthalate diol diester		L	L	L*	L^*	L	M^{k}	L	L	H	L?	L	N	Υ	Υ	N	N	Υ	Υ	Additive
	Proprietary B Aryl phosphate		L	L	М*	M*	M	M *	L	Н	H	L	M	N	Υ	Υ	N	Υ	N	N	Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	М	L	Н	H	L	L	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Additive
Ameribrom	FR513		ĺ			İ			İ					İ							
	Tribromoneopentyl Alcohol CAS # 36483-57-5		M	L	М	M	M	М	М	M	М	L	L	Υ	Υ	Υ	N	N	Υ	Υ	Reactive
Great Lakes	Firemaster 550																				
	Proprietary F Halogenated aryl ester		L	L	M	M	L	M	L	Н	Н	L?	L	N	Υ	Υ	N	Υ	Υ	Υ	Additive
	Proprietary G Triaryl phosphate, isopropylated		L	L	M*	M*	M	М*	L	Н	H	L	M	N	Υ	Υ	N	Υ	N	N	Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	Н	Н	L	L	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Additive
	Proprietary H Halogenated aryl ester		L	L	M	M	L	M	L	Н	H	L?	L	N	Υ	Υ	N	Y	Υ	Υ	Additive

L = Low hazard concern

M = Moderate hazard concern

H = High hazard concern

 \boldsymbol{L} , \boldsymbol{M} , or \boldsymbol{H} = Endpoint assigned using estimated values and professional judgment (structure activity relationships)

Source: US Environmental Protection Agency – Design for Environment Program. Furniture Flame Retardancy Partnership: Environmental Profiles of Chemical Flame-Retardant Alternatives for Low Density Polyurethane Foam. Volume 1. September 2005. Complete summary table is on pages 37-39.

The Green Screen for Safer Chemicals²¹

The Green Screen for Safer Chemicals was developed by Clean Production Action, a non-governmental organization seeking to translate the concepts of clean production into practical tools that industry and government can use to ensure greener, safer, and healthier products. Version 1.0 of the Green Screen, released in 2007, provides a free, publicly accessible tool designed to reliably and consistently screen and rank chemicals and materials for their human health and environmental hazards.

Like the DfE CAA method, the Green Screen includes threshold values to determine a level of concern for each hazard endpoint. These are derived from lists of chemicals of concern as well as criteria from the Globally Harmonized System (GHS) for Classification and Labeling. The Green Screen goes further in that it includes a set of four benchmarks that provide a decision framework for screening out chemicals that are associated with adverse health and environmental impacts. Chemicals that do not pass through Benchmark 1 are deemed chemicals of high concern and should be avoided; chemicals at Benchmark 2 are categorized as usable, but efforts should be taken to find safer alternatives; Benchmark 3 chemicals are those with an improved environmental health and safety profile but could still be improved. Chemicals that reach Benchmark 4 are considered safer chemicals and are therefore preferred.

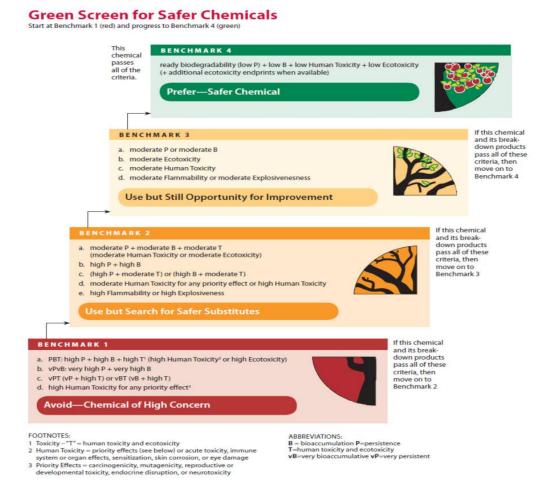


Figure 5. Benchmarks for Green Screen Evaluations

Source: http://www.cleanproduction.org/Green.php

Pollution Prevention Options Analysis System (P2OASys)²²

P2OASys was developed by the Toxics Use Reduction Institute at the University of Massachusetts, Lowell. It was created to help companies conduct systematic environmental and worker health and safety analyses of the pollution prevention (P2) and toxics use reduction (TUR) options they identify through their planning activities. It assists in identifying potential hazards associated with current and proposed processes and helping to choose the alternative that is most protective of worker health and safety and the environment. One unique characteristic of this tool is that it includes data associated with the process in which the chemical is used, to help determine potential occupational exposures.

The user must research and enter quantitative and qualitative data on the chemical toxicity, ecological effects, and physical properties of the current chemical/process and of alternative options. For each data point entered, the user also enters a "certainty score" from 0-100. For each hazard category, the tool provides side-by-side comparisons of the data calculated for current processes/chemicals and potential alternatives. A color-coding scheme makes the comparison easy to view. For categories in which there is no difference between the current and alternative process both fields will be colored yellow.

For those in which one is safer, that field will be green, and the other will be red. For fields with no contrasting data or blank fields, no color will be added. By arraying a wide range of criteria, the user can make judgments about categories of particular concern.

Table 2. P2OASys Summary Table

CATEGORY	Current Process	Alternative 1	Alternative 2	Alternative 3
Acute Human Effects				
Chronic Human Effects				
Physical Hazards				
Aquatic Hazard				
Persistence/Bioaccumulation				
Atmospheric Hazard				
Chemical Hazard				
Energy Resource Use				
Product Hazard				
Exposure Potential				

Source: Alternatives Assessment for Toxics Use Reduction: A Survey of Methods and Tools. The Massachusetts Toxic Use Reduction Institute (TURI), University of Massachusetts Lowell, 2005.

Column Model²³

The Institute for Occupational Safety of the German Federation of Institutions for Statutory Accident Insurance and Prevention developed the Column Model to provide industry with a practical tool for identification of alternative substances. While currently used primarily by German companies, it is being adapted for use with the Globally Harmonized System (GHS) for classification and labeling, which may lead to its use in other countries.

The Column Model evaluates the following acute health hazards: toxicity, reactivity, corrosivity, skin sensitization, ocular hazards and irritants. It evaluates the following chronic health hazards: carcinogenicity, mutagenicity, reproductive toxicity and bioaccumulation. The model also evaluates environmental concerns such as water pollution, and physical hazards such as fire and explosion. A column called "exposure potential" ranks chemicals according to vapor pressure (higher vapor pressure equals higher exposure risk). Finally, a column labeled "hazards caused by procedures," considers whether there is open or closed processing of the chemical, which is also a proxy for exposure.

Hazards are classified into five risk categories: very high, high, medium, low and negligible. These hazard rankings are based on R-phrases (or H-statements in the draft GHS Column Model). If the proposed substitute ranks as a lower risk in all columns, then the decision to make this change is straightforward. If the potential substitute ranks higher in some columns and lower in others, the user must evaluate which hazards are of greatest concern in a particular production process

Methods and tools that are designed to identify preferred chemicals and products

The third group of methods and tools builds on the approaches described in Categories 1 and 2. Some identify positive criteria for preferred ingredients and products. This category is the least developed, but in recent years some important new approaches have been created and are being utilized.

$Clean Gredients @ ^{24} \\$

CleanGredients® is an online database of cleaning product ingredients that meet established requirements for environmental and human health performance. Its goal is to encourage the design of cleaning products that are safer with respect to human and ecological health and safety and to provide a market-based incentive for chemical manufacturers to invest in green chemistry research and development. GreenBlue, a nonprofit institute that supports businesses in their sustainability efforts, develops these requirements through a consensus-based stakeholder process, in collaboration with the U.S. EPA's Design for Environment (DfE) program. Currently, surfactants, solvents, and fragrances are listed in the database, and some chelating agents are under review. Two independent organizations (NSF International and ToxServices) serve as third-party reviewers to evaluate manufacturers' ingredients and provide verified information on standard physical and chemical properties as well as relevant environmental and human health attributes.

Third-Party Eco-labels and Certifications

Third-party eco-labels and certifications have been developed by a variety of organizations. The compendium briefly summarizes the eco-label and certification programs of the US EPA Design for Environment program, Green Seal, EcoLogo and McDonough Braungart Design Chemistry (MBDC). Other organizations, such as Good Housekeeping, are developing new green product certification programs. In most cases, the criteria for achieving a particular eco-label are publicly available. In some cases, particularly when the certification is developed by a private organization, the criteria may not be transparent.

Safer Product Labeling Program²⁵: The US EPA Design for Environment (DFE) program has developed the Safer Product Labeling Program to identify and promote products that contain ingredients that are the safest in their chemical class. Products are evaluated based on standards for safer chemicals, within a functional class (such as surfactant, colorant, solvent). The standards, which are developed with stakeholder input, consider the human health, ecological toxicity and environmental fate characteristics of chemicals in the class, and establish thresholds that must be met for an ingredient to be allowed in a DfE-labeled product.

To earn the DfE label, product manufacturers must submit a list of all product ingredients to a qualified third party. The third party develops a hazard profile for each ingredient

and reviews the profiles against the DfE standards. Product manufacturers are provided with an assessment of their ingredients and whether they meet DfE's safer chemical criteria. To achieve the DfE label, a manufacturer must use the safest ingredients from each functional group and meet other product-level requirements, such as pH and performance. In addition, companies must sign a partnership agreement with EPA that formalizes their commitment to making safer products and improving them over time.

Green Seal²⁶: Green Seal is a non-profit organization that since 1989 has developed life cycle-based sustainability standards that cover almost 200 product and service categories, including standards for household and institutional cleaners. Green Seal includes product-specific health and environmental requirements in its standards. For example, Green Seal Standard 37 for Cleaning Products for Industrial and Institutional Use includes a list of prohibited ingredients and specifications regarding acute toxicity, skin and eye irritation, carcinogens, mutagens, reproductive toxins, asthmagens, skin sensitization and absorption, ozone depleting compounds, VOC content, inhalation toxicity, aquatic toxicity, persistence, bioaccumulation, etc.

Green Seal has recently issued a GS-C1, a Pilot Sustainability Standard for Product Manufacturers that includes requirements for safer chemistry planning and management, including a process for identifying and prioritizing hazardous chemicals and using a green screen to determine safer alternatives.

EcoLogo vas founded as an environmental certification program by the government of Canada in 1988 and is now recognized world-wide. The organization has developed standards for over 120 product categories. EcoLogo is managed by TerraChoice, which has recently been purchased by Underwriters Laboratories Canada. EcoLogo includes specific health and environmental criteria in its standards. For example, EcoLogo's standard for Personal Care Products, first published in 2000, is currently being revised. The original standard contains requirements related to biodegradability, carcinogenicity, acute toxicity, and also identifies some specific chemicals such as phosphates as being restricted.

Underwriters Laboratories Environment division (ULE) has recently issued a standard entitled Sustainability for Manufacturing Organizations, known as ULE 880. This standard gives points to companies that have in place a chemicals alternatives policy to address PBTs, CMRs, and endocrine disruptors.

MBDC²⁸: MBDC is a private sustainability consulting and product certification firm that has developed the Cradle to Cradle® certification for materials, products and systems. The certification program includes requirements for: product and materials transparency, human and environmental characteristics of materials, product and material reutilization, production energy, water use at the manufacturing facility, social fairness and corporate ethics.

MBDC has developed a protocol to score chemicals and materials for their impact on human and environmental health. The score is determined by identifying the hazard posed by the

chemical/material, possible routes of exposure, and intended use in a finished product. Chemicals/materials are classified as follows^d:

Table 3 MBDC Chemical Scoring Protocol

GREEN (A-B)	Little to no risk associated with this substance. Preferred for
	use in its intended application.
YELLOW (C)	Low to moderate risk associated with this substance.
	Acceptable for continued use unless a GREEN alternative is
	available.
RED (X)	High hazard and risk associated with the use of this
	substance. Develop strategy for phase out.
GREY	Incomplete data. Cannot be characterized.

Source: Cradle to Cradle® Certification Program Version 2.1.1. MBDC. Updated January 2010. http://www.mbdc.com/images/Outline CertificationV2 1 1.PDF

Cleaner Solutions Database²⁹

The Cleaner Solutions Database was developed by the Surface Solutions Laboratory (TURI Lab) at the Massachusetts Toxics Use Reduction Institute to share the results of laboratory tests on the performance of alternatives to hazardous cleaning solvents used in a variety of manufacturing practices. The TURI Lab tests how well these solvents perform when cleaning a range of contaminants from parts using different cleaning techniques (soaking, agitation, etc.). The parts are made from a variety of materials including metals, plastic or glass.

Companies seeking to replace problematic cleaning solvents with a safer alternative can search the database to identify cleaners that may work well as a replacement given the contaminant they need to clean, the intricacy of the parts needing to be cleaned, and their existing cleaning equipment. The TURI Lab encourages users of the database to seek alternative cleaners that are safer both for workers and the environment to avoid shifting risks between the workplace and environment/community.

iSUSTAINTM Green Chemistry Index³⁰

The iSUSTAINTM Green Chemistry Index was developed by the iSUSTAIN Alliance, which includes Cytec Industries Inc. (a specialty chemicals and materials company), Sopheon (a provider of software and services for product life cycle management), and Beyond Benign (a nonprofit organization dedicated to green chemistry education and training). iSUSTAINTM, launched in March 2010, is designed as an assessment tool for scientists in the research and development phase of a product life cycle.

^d See Cradle to Cradle® Certification Program Version 2.1.1. MBDC. Updated January 2010. http://www.mbdc.com/images/Outline CertificationV2 1 1.pdf

iSustainTM is an Internet-based tool that generates a sustainability score for chemical products and processes. It contains a set of sustainability metrics based on the 12 Principles of Green Chemistry (see figure 2), taking into account factors such as waste generation, energy use, health and environmental impacts of raw materials and products, and the safety of processing steps for the chemical being evaluated. The score allows a designer to understand areas where improvements are needed in the chemical design.

Green Chemistry Attribute	Score (0-100, higher is "greener")
Waste Prevention Atom Economy Safe Raw Materials Safe Product Safe Solvents Energy Efficiency Renewables Process Complexity Catalysis Biodegradability Process Control Safe Process	80 70 85 100 75 75 45 60 95 50 75 65

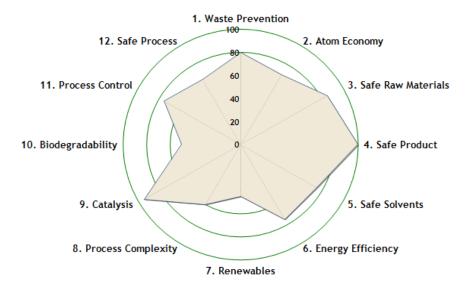


Figure 6. A Sample iSUSTAIN TM Scenario for Isopropyl Lactate

(scores rounded to the nearest 5):Source: Summary of sample scenario, Isopropyl Lactate, at https://www.isustain.com/Scenarios.aspx

BASF Eco-efficiency Analysis Tool – Toxicity Scoring System³¹

The chemical company BASF has developed the Eco-efficiency Analysis Tool to compare the sustainability of products and processes. Six elements are evaluated: raw materials consumption, energy consumption, land use, air and water emissions and solid waste, toxicity potential, and risk potential from misuse. In addition, the economic costs of products and alternatives are determined, taking into account material and energy flows. For this report, we summarize the scoring system that BASF has developed to determine potential toxicity.

The BASF toxicity scoring system uses the EU classification of 31 Risk phrases (R-phrases) that describe different health effects. BASF asked 42 toxicologists within its organization and at the University of Leipzig to review 25 chemicals with different risk phrases or combinations and score them according to the severity of the toxic effect. Interviewees were asked to score these chemicals on a scale from 0-1000. Using the results of the survey, a simple scoring system was developed for toxic properties.

Exposure is evaluated according to the way that substances are handled, rather than determining actual exposure concentrations. The parameters considered to determine exposure are total production volume, use pattern and exposure route, and the vapor pressure of products. When the toxicity potential data is entered into the Eco-efficiency Analysis tool, the process steps of production, use and disposal are weighted. Process steps with greater potential for direct contact are more heavily weighted than process steps for which there is unlikely to be exposure.

Skin Deep Cosmetics Database³²

A number of NGOs have created databases to inform consumers about toxic chemicals in products. Because this compendium is being prepared for the Home and Personal Care Working Group of the Sustainability Consortium, we have included in the compendium a description of the Skin Deep cosmetics database.

The Environmental Working Group, an environmental research and advocacy organization, developed the Skin Deep cosmetic database to give consumers access to hazard information about chemicals in personal care products. It contains hazard information about chemicals found in: makeup and other products for skin, hair, eyes, nails, oral care, sun protection, and baby products. Skin Deep relies on input from companies that have signed the Compact for Safe Cosmetics to report their ingredients. Additional ingredient information is gathered from willing manufacturers or product labels. The database gives users an overall hazard score for each product. More detailed information is available on the hazards of specific ingredients.

Discussion and analysis - methods and tools

These methods and tools are summarized in a matrix in Appendix A. The matrix provides the following information so that methods and tools can be easily compared: name of method/tool, developer, whether or not fees are applied, main purpose, ease of use, hazards evaluated, ranking and aggregation of hazard information, criteria weighting, exposure considerations, strengths and limitations.

Table 4 shows the primary and secondary purposes of the methods and tools in each of the three major categories. This table can help determine which method or tool may be most useful for a given purpose. For example, the tools shown in bright orange may be useful for screening out hazardous chemicals, the tools in dark green may be useful for comparative assessments, and the tools in brown can be used to identify safer and greener chemicals and products. Many of the methods and tools have a primary purpose but can also be used in other ways, as suggested by the lighter shaded boxes in the table.

Table 4 Methods and Tools: Primary and Secondary Purpose

Name of method/tool	Tools that are designed to identify and screen out hazardous chemicals	Tools that are designed to compare alternatives	Tools that are designed to identify preferred chemicals and products
PRIO			
Quick Scan			
RISCTOX			
US EPA screening tools			
AAFA RSL			
GC3 RSLs			
Boots PSL			
SIN (Substitute It Now!) List			
Greenlist TM			
GreenWERCS TM			
SciVera Lens TM			
3E GPA TM			
IHS Greening Solutions			
Actio Material Disclosure			
DfE CAA			
Green Screen			
P2OASys			
Column Model			
CleanGredients			
Eco-Labels and Certifications			
Cleaner Solutions Database			
iSUSTAIN™			
BASF Eco-efficiency tool			
Skin Deep			

Primary focus to identify/screen out hazardous chemicals	Secondary focus to identify/screen out hazardous chemicals
Primary focus to compare alternatives	Secondary focus to compare alternatives
Primary focus to identify preferred chemicals/products	Secondary focus to identify preferred chemicals/products

Many of the tools in the first category, such as PRIO, RISCTOX, the RSLs, and the SIN List are easy to use and provide a quick screening of high hazard chemicals. RSLs are most useful if they are reviewed and updated regularly. A potential problem with the RSL approach is that employees may become too reliant on them and assume that chemicals not appearing on the list are safer, which may or may not be accurate. For this reason, some companies are reluctant to create RSLs. Ideally, the use of an RSL is accompanied by in-depth procedures for evaluating chemicals that do not appear on an authoritative government list.

The GreenlistTM requires some expertise, but can be a useful tool both for screening out high hazard ingredients and comparing substances. The EPA screening-level tools are more challenging to use, but can be useful when experimental data do not exist. The proprietary chemical management software tools provide a means for companies to determine whether chemical ingredients are on regulatory lists and can also be used to identify safer alternatives. However, some of these tools do not provide analysis beyond evaluating formulations against authoritative lists of hazardous chemicals. The burden is on the user to weight hazard categories (e.g., cancer vs. endocrine disruption; human health vs. environmental impact). Some of the third-party proprietary tools offer toxicological and technical support services.

In the second category, the EPA DfE Chemicals Alternatives Assessment method, the Green Screen, and P2OASys provide in-depth approaches for comparing alternative chemicals. These methods are time and data intensive and require that users have some expertise in toxicology and chemistry. Both the DfE method and P2OASys array the hazard data for the decision maker, but do not provide decision rules for action based on the hazard. The Green Screen, in contrast, provides four benchmarks and associated decision rules for avoiding high-hazard chemicals and preferring low-hazard chemicals. The Column Model provides a more streamlined approach to comparing alternatives using R-phrases and H-statements from MSDSs. None of these methods describe "positive" attributes for safer chemicals.

In the third category, CleanGredients®, the EPA DfE Safer Product Labeling Program, and iSustain go farthest in identifying positive criteria and attributes for safer and greener chemicals and products. The Cleaner Solutions database can be used to find effective solvents that are safer for workers and the environment. The BASF toxicity scoring system can be used to quickly determine the toxicity of different chemicals and the Ecoefficiency Analysis tool (within which the toxicity scoring system is imbedded) includes an evaluation of use as a surrogate for exposure, which can provide additional information for decision-making in regard to hazardous chemicals. The Skin Deep cosmetics database can be used by consumers to screen out products with hazardous ingredients and to find products that do not contain known harmful ingredients. The ecolabel and certification programs discussed above provide a set of criteria for manufacturers to use in formulating preferred products for health and the environment.

Summary and conclusions

The Sustainability Consortium seeks to identify a method/approach or combination of tools that can be used to account for ecological and human health impacts of chemical-based products as part of its Sustainability Measurement and Reporting Systems (SMRS). To better understand the state of the science on approaches for accounting for these impacts, the Lowell Center for Sustainable Production was asked to review methods and tools for assessing and reducing chemical hazards. This compendium is not meant to be exhaustive, but rather to provide an overview of the methods and tools being used by governments, the for-profit private sector, and non-profit organizations to more effectively screen and prioritize chemical hazards and identify safer alternatives.

A key question in defining the sustainability of chemical-based products is: what are the safest chemicals that can be used throughout the product life cycle? This is a very difficult question to answer. Governments, companies, and NGOs have developed the range of methods and tools illustrated in this compendium to begin to address this challenge. Rather than there being one method or tool that comprehensively addresses this question, these methods and tools are often best used in combination.

In reviewing these methods and tools, and based on decades of experience in working with firms on chemical assessment and pollution prevention, we have identified some key elements that can be considered in determining whether a company is systematically working toward improving product sustainability with regards to chemical hazards throughout the product life cycle. These elements can form the basis for sustainability performance indicators in the SMRS and can provide a means of differentiating among companies. Some of these elements may be easier or more difficult to implement depending on the size of the company or technical and scientific resources available. For example, some companies may have extensive toxicological resources available in-house to evaluate chemical data or structure information while others may need to rely on software packages or lists to conduct reviews.

To more systematically identify and address chemical hazards in the supply chain, it is useful for manufacturers and their suppliers to have the following elements in place:

- an inventory of chemical usage and disposition throughout the supply chain
- a process for identifying high-hazard chemicals
- process for identifying chemicals and functional uses with the greatest potential for exposure particularly to vulnerable populations
- a means of prioritizing chemicals to be reduced or substituted, which includes consideration of both hazard and exposure potential
- a method for comparing alternative chemicals and processes, including criteria for identifying safer chemicals and products
- a process for implementing alternative practices, including chemical substitution and process changes
- a system for disclosing product ingredients to workers and the public

A first step in this process is an inventory of chemical usage throughout a product supply chain (including raw materials, potential byproducts and breakdown products). As noted earlier, this information can be challenging to determine, particularly beyond Tier II suppliers. Establishing systems to collect and manage such data can also be challenging at first but can help increase efficiency of chemicals management in the long-term.

To aid in identifying and prioritizing high-hazard chemicals, many companies are creating a Restricted Substance List (RSL) or participating in developing an industry sector RSL. This is valuable if the list is systematically updated and if there is a process for further researching chemical hazards when a chemical does not appear on a list. But because data are lacking on many chemicals in commerce, it is critical that the process of identifying hazards go beyond a simple review of government lists. In developing an RSL, a company may consider which criteria are most important for prioritizing chemicals to be substituted, such as carcinogenicity, neurotoxicity, persistence and/or bioaccumulation. This is a subjective determination and it is important that this weighting process be transparent. The home and personal care sector may want to consider the development of an industry-wide RSL, including a set of toxicological criteria that would lead to higher or lower concern about a substance and help identify safer substances. Such an RSL could further prioritize chemicals by uses of highest concern.

Once hazardous chemicals have been identified and prioritized, including a consideration of uses of highest concern, a company must determine a method to evaluate alternatives. This is most effectively done when comparing chemicals for the same functional use. The Green Screen provides a valuable method for companies and is being used by Hewlett-Packard and other companies for this purpose. The Green Screen asks users to take into consideration chemical breakdown products when evaluating chemicals against its four Benchmarks. In this way one aspect of the "embedded hazard" of the chemical is included in the hazard evaluation. Once a safer alternative is identified, a plan for implementation must be developed, particularly if the substitution affects production processes or work practices.

Beyond identifying high hazard chemicals and working toward their substitution it is critical that positive attributes of safer, greener chemicals and products be identified. The methods and tools in this arena that have been developed to date are quite valuable, though this area needs further development. Companies that choose to be strategic about a forward thinking chemicals management policies will benefit by determining these positive attributes. Certification and labeling programs that incorporate these elements can help to encourage the formulation of preferred products. In addition, these positive attributes can be built into new product development processes and tools, such as illustrated, for example, by the Boots Sustainability Product Assessment Tool. It may be useful for the home and personal care sector to develop a "positive list" of chemicals for specific functional uses.

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^e The "embedded hazard" of a chemical includes the attributes of its feedstocks, intermediates, byproducts and breakdown products.

In summary, the key elements of an approach for assessing and reducing chemical hazards throughout the supply chain should include: an inventory of chemical usage and disposition, a process for identifying high-hazard chemicals, a means of prioritizing chemicals to be substituted including a consideration of hazard and exposure potential, a method for comparing alternatives, a process for implementing these changes, and a system for disclosing product ingredients. These elements can serve as the basis for sustainability performance indicators and thereby recognize companies that are proactive in managing and reducing chemical hazards and moving towards implementation of green chemistry approaches.

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⁶ Further information on Product Safety Assessments can be found at: http://www.icca-chem.org/en/Home/ICCA-initiatives/global-product-strategy/

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¹⁷European Trade Union Confederation - Trade Union Priority List. See: http://www.etuc.org/a/6023

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²⁰ US EPA. November 2010. Design for Environment Program Alternatives Assessment Criteria for Hazard Evaluation.

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²¹ Rossi, M. and Heine. L. The Green Screen for Safer Chemicals: Evaluating Flame Retardants for TV Enclosures. Version 1. Clean Production Action. March 2007.

²² Toxics Use Reduction Institute. University of Massachusetts Lowell. See:

http://www.turi.org/toxics_use_home/hot_topics/cleaner_production/p2oasys_tool_to_compare_materials

²³ Institute for Occupational Safety of the German Federation of Institutions for Statutory Accident Insurance and Prevention. See: http://www.dguv.de/ifa/en/pra/spalte/spaltmod.pdf

²⁴ CleanGredients®. See: http://www.cleangredients.org/home. Developed by GreenBlue:

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25 US EPA. Design for Environment Program. Safer Product Labeling Program. See: http://www.epa.gov/dfe/pubs/projects/formulat/saferproductlabeling.htm

²⁶ Green Seal. See: <u>www.greenseal.org</u>

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MBDC. See: www.mbdc.com
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³² Skin Deep Cosmetics database. Developed by the Environmental Working Group. See: http://www.cosmeticsdatabase.com/

Appendices

Appendix A - Summary Matrix of Methods and Tools

Appendix B - Descriptions of Methods and Tools for Chemical Hazard Assessment

Appendix A - Summary Matrix of Methods and Tools

	Tools that are designed to identify and screen out hazardous chemicals											
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations		
PRIO	Swedish Chemicals Inspectorate (Keml)	No	Identify hazardous chemicals to be phased out or reduced.	Easy	Acute/chronic toxicity, CMR, PBT, vPvB, haz. metals – Hg, Cd, Pb and compounds, endocrine disruption, allergenicity, aquatic toxicity, ozone depletion.	Substances are divided into "phase-out" and "risk reduction" according to certain properties.	Criteria that identify "phase-out" substances are weighted as more significant than "risk reduction" criteria.	PRIO recommends that exposure be evaluated for "risk reduction" substances.	Easy to use on-line tool for screening out hazardous chemicals.	Many chemicals in use are not in database. Hazards such as explosive- ness, flammability are not considered.		
Quick Scan	The Dutch Ministry of Housing, Spatial Planning and the Environment	No	Prioritize the management and evaluation of chemicals in commerce, without greatly increasing animal testing.	Moderate	PBTs, health damage to humans, ecological impacts, CMRs, hormone disruptive effects.	Substances are classified according to hazard in 5 levels: very high concern; high concern; concern; low concern; no data, very high concern.	Tool includes decision rules to weight hazard categories. Concern categories are adjusted based on exposure potential.	Use type is used as a proxy for exposure: industrial use; site-limited intermediate use; open applications / professional use; and consumer applications.	Useful model for categorizing hazards and exposure potential and determining levels of concern.	Like other tools, Quick Scan is most useful when sufficient data are available to characterize chemical hazards. Chemicals with no data are categorized as very high concern.		
RISCTOX	The Spanish Trade Union Institute for Work, Environment and Health (ISTAS)	No	Provide information about risks to human health and environment posed by chemicals in the workplace. Users can also assess/ compare alternative products.	Easy	CMRs, endocrine disruption, neurotoxicity, ototoxicity, sensitizing agents, allergens, PBTs, vPvB, aquatic tox., air quality/ozone depletion/ climate change, soil cont., POPs.	Substances in database are evaluated for hazard categories based on government lists, peer-reviewed research; linked to EU R-phrases and H-statements.	N/A	N/A	Easy to use database to identify chemical hazards in workplace, compare chemicals, and research safer alternatives.	Information is for substances, not mixtures. Database is in Spanish.		

Tools that are designed to identify and screen out hazardous chemicals											
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations	
US EPA Screening-level models and tools	US EPA	No	Predict hazards and exposures based on structure. Evaluate the safety of new chemicals before they enter the market, identifying safer design options.	Moderate to difficult - varies with each tool	Tools evaluate a range of hazards including PBTs, carcinogenicity and non-cancer effects. Tools include: ECOSAR, EPI Suite™, PBT Profiler, OncoLogic™, Non-Cancer Screening Protocol, AIM.	These are screening-level predictive models. The PBT Profiler compares predicted values to PBT criteria.	N/A	Screening-level information from EPI Suite™, E-FAST and ChemSteer can be used as inputs to exposure assessments.	Screening level models provide information about untested chemicals when measured data is not available.	Measured data is generally preferred to results from screening-level models.	
Greenlist™	SC Johnson & Son, Inc.	Free. License required for use.	Designed to score chemical ingredients used in SC Johnson products based on health and environmental profiles. Other companies can license this framework for ingredient evaluation and customize it for their use.	Moderate	Aquatic toxicity, acute and chronic human toxicity, carcinogenicity, allergenicity, reproductive toxicity, endocrine disruption, biodegradability, PBT.	Threshold values for each criterion define score of 0-3. 3/best; 2/better; 1/acceptable; 0/use in limited quantities when no alternative exists.	Individual scores for each hazard category are averaged before being adjusted based on a review of other significant concerns that can be customized by user.	Considered when selecting an ingredient for inclusion in a product based on its anticipated use.	Ranking system that allows users to screen chemical ingredients; identify problematic ingredients, and replace with safer alternatives. Can be used to compare substances.	Effectiveness contingent on suppliers' willingness to disclose data needed to review ingredients.	
Restricted Substances Lists (RSLs)	Various organizations - individual companies, industry sectors, NGOs	No	Provide information on chemicals that are regulated anywhere in the world.	Easy	CMRs, heavy metals, phthalates, brominated flame retardants, PBTs, vPvB, acute toxicity, aquatic toxicity, etc.	N/A	N/A	N/A	Regularly updated RSL helps manufac- turers avoid chemicals of concern in global regulations.	RSLs generally include only regulated chemicals. May not include chemicals restricted in production processes. RSLs do not identify safer alternatives.	

	Tools that are designed to identify and screen out hazardous chemicals												
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations			
GreenWERCS™	The WERCS Ltd. & Wercs Professional Services LLC. Green WERCS™ is one example of a proprietary software tool for chemicals management and hazard evaluation.	Yes	Evaluate the human health and environmental hazards of chemical ingredients in products.	Moderate	CMRs, PBTs, potential endocrine disruptors, and chemicals regulated as hazardous waste. Can be customized to include additional health or environmental endpoints.	Hazard ranking is determined based on authoritative government lists.	Hazard categories are weighted by user. Data are aggregated into GreenWERCS score.	N/A	Customiz- able chemical screening tool that reviews formulations against government lists of hazardous substances. Proprietary information remains confidential.	User determines weighting of hazard categories so results may not be comparable across users. Review of chemical hazards is list-based and does not include review of scientific literature or modeling.			

	Tools that are designed to compare alternatives											
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations		
Chemicals Alternatives Assessment (CAA)	US EPA Design for Environment Program (DfE)	No	Conduct chemicals alternatives assessment to identify safer alternatives to known chemical hazards.	Moderate	CAA includes evaluation of a wide range of human health, ecotoxicity, and environmental impacts	DfE has developed criteria for hazard categories. Hazard endpoints are designated as very high, high, moderate, low, or very low concern based on the criteria.	Hazard information is arrayed for user in summary table. Categories are not weighted.	Methodology evaluates chemicals for same functional use, so exposure is considered to be relatively constant. Potential exposure routes are identified.	Compare and identify safer alternatives that are commercially available. When test data not available, screening-level tools are applied.	Biggest limitation in this methodology is data gaps.		

	Tools that are designed to compare alternatives											
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations		
Green Screen for Safer Chemicals	Clean Production Action	No for version 1. A fee for expert review under version 2 will apply.	Screen and rank chemicals and materials used in commerce for their human health and environmental hazards to support the transition to safer chemicals.	Moderate	Persistence, bioaccumulation , acute & chronic aquatic toxicity, CMRs, developmental toxicity, endocrine disruption, neurotoxicity, acute human toxicity, systemic or organ toxicity, immunotoxicity, eye irritant, respiratory sensitizer, reactivity, explosivity.	Threshold values are determined for each hazard category, which define levels of concern from very high to low.	4 bench- marks for decision making: #1- chemicals to be avoided; #2 -chemicals that can be used but search for safer alternatives; #3 -chemicals have improved EH&S profile but could still improve; # 4- preferred.	Not addressed specifically.	Useful method-ology for comparing alternative chemicals or materials that have the same purpose in a product. Chemicals and their breakdown products are evaluated.	Like other tools, Green Screen is most useful when sufficient data are available to characterize chemical hazards. Version 1 cannot be used with inorganic chemicals. Version 2 will modify criteria for application to inorganic chemicals.		
Pollution Prevention Options Analysis System (P2OASys)	Toxics Use Reduction Institute, University of MA, Lowell	No	Help companies conduct systematic environmental and worker health and safety analyses of the pollution prevention (P2) and toxics use reduction (TUR) options identified in their planning activities.	Moderate	Acute human effects, chronic human effects, physical hazards, aquatic hazards, persistence, bioaccumulation , atmospheric hazard, disposal hazard, chemical hazard, energy and resource use, product hazard.	Each endpoint is scored from 1-10. Higher score indicates higher hazard. User also enters certainty score from 0-100. Data for each end point are aggregated.	Data for each alternative are arrayed. Categories are not weighted.	Exposure potential is qualitatively estimated as high, medium or low.	Side by side comparison of current processes / chemicals and potential alternatives. Color coded for ease of use.	User must research and enter hazard data, which is time and labor intensive.		

	Tools that are designed to compare alternatives												
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations			
Column Model	Institute of Occupational Safety of the German Federation of Institutions for Statutory Accident Insurance and Prevention	No	Provide a practical tool for industry to compare chemicals currently in use and proposed alternatives.	Easy to moderate	Acute toxicity, reactivity, corrosivity, skin sensitization, ocular hazards and irritants. CMRs, bioaccumulation, water pollution, flammability and explosivity.	Hazard rankings based on EU R- phrases and GHS H- statements. 5 risk categories: very high; high; medium; low and negligible.	Hazard categories are not weighted.	Exposure potential from vapor pressure, and chemical processing taken into account.	Tool is a streamlined approach to array data and compare chemical alternatives, including exposure potential.	Data derived primarily from MSDS or SDS which may not provide sufficient information.			

	Tools that are designed to identify preferred chemicals and products										
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations	
CleanGredients [®]	GreenBlue	Yes	Identify verified ingredients with preferable EH&S attributes to encourage the design of cleaning products that are benign with respect to human and environmental health and safety.	Easy	Acute mammalian toxicity, carcinogenicity, developmental toxicity, PBT status, neurotoxicity, repeated exposure systemic toxicity, reproductive toxicity, biodegradability.	The U.S. EPA has established a set of criteria that identifies the minimum requirements for ingredients in a Design for Environment recognized product.	N/A	N/A	Helps suppliers market and formulators identify chemicals that will support recognition by the US EPA as a preferred product.	Currently limited to surfactants, solvents and fragrances in cleaning products. Chelating agents in review.	

Tools that are designed to identify preferred chemicals and products											
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations	
Eco-Labels and Certifications	Various organizations, such as: US EPA, Green Seal, EcoLogo, and McDonough Braungart Design Chemistry (MBDC)	No for EPA for Safer Product Labeling Program (except third party review); Yes for Green Seal, EcoLogo and MBDC	Provide institutional and individual consumers with information on environmental performance of products at point of purchase.	N/A. Evaluation by qualified third parties.	EPA DfE program has Criteria for Safer Chemical Ingredients. Green Seal includes product specific health and environmental requirements. EcoLogo includes product specific health and environmental criteria. MBDC identifies hazards, possible exposure routes and intended use.	EPA DfE has developed master criteria and specific criteria for functional classes. Green Seal and EcoLogo have criteria and list prohibited chemicals. MBDC classifies chemicals as little to no risk, low to moderate, high hazard/ risk, and incomplete data.	N/A	EPA DfE program focuses on functional use. Green Seal and EcoLogo do not consider exposure. MBDC considers possible routes of exposure.	Provide valuable information to consumers at the point of purchase.	Programs are voluntary and may not be widely used, though some may be required by government purchasing authorities. Single attribute labels do not provide a complete story of life cycle product impacts.	
Cleaner Solutions Database	Surface Solutions Laboratory, Toxics Use Reduction Institute, University of MA, Lowell	No	Share results of performance tests on cleaning solvents used in a variety of manufacturing practices to help companies replace problematic cleaning solvents with safer alternatives.	Easy	VOCs, global warming potential, ozone depletion potential, pH, occupational hazard.	A 10 point scale is used to evaluate each of the hazard criteria for a possible total of 50 points. A higher score indicates a potentially safer product. Data is aggregated.	Health impacts are weighted more heavily than other hazards.	Indirectly considered in the hazard evaluation.	Useful for comparing alternative cleaners and solvents in similar cleaning applications and equipment, and finding alternative solvents that are environmentally preferred and safer for workers.	Hazard information is primarily derived from MSDS and does not include detailed information about chronic health hazards or environ- mental concerns.	

Tools that are designed to identify preferred chemicals and products										
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations
iSUSTAIN™ Green Chemistry Index	iSUSTAIN Alliance	Basic access is free. Annual fee upgrade available.	Assist chemists in designing safer chemistries by developing sustainability score for chemical products and processes based on the 12 Principles of Green Chemistry.	Easy	12 metrics: waste prevention; atom economy; safety of raw materials; safety of products; safety of solvents; energy efficiency; renewable raw material; process complexity; catalysis; biodegradability; process control; and safety of process.	Each metric is rated from 0 to 100 with 0 representing low sustainability. Data is aggregated into a radial map that delineates areas that are "green" and areas that need improvement.	N/A	N/A	First tool based on the 12 principles of green chemistry that provides "what if" analyses during the design phase.	Tool launched in March 2010. Database is incomplete. More impact information will be added as it becomes available.
Eco-efficiency Analysis Tool Toxicity Scoring Method	BASF	N/A. Internal tool	Score chemicals for toxicity. Purpose of Ecoefficiency Analysis tool is to quantitatively compare products and processes for ecological and economic impacts.	Easy	Scoring system uses the EU classification of 31 R- phrases that describe a wide range of health effects.	Hazard categories are scored from 1- 1000. 1- weak effects; 2-local effects; 3-acutely toxic, irreversible effects, reproductive toxicity suspected; 4-severe irreversible effects, reproductive toxicity; 5-carcinogenic; 6-combination of effects	Hazard categories are not weighted but if chemical is assigned more than one R-phrase, it is upgraded one category.	Exposure is evaluated according to the way that substances are handled. Parameters include total production volume, use pattern and exposure route, and vapor pressure of products.	Easy to use scoring system to compare toxicity of different chemicals. Tool includes an evaluation of use as a surrogate for exposure, which can provide additional information for decision-making.	Method is most useful for well-studied chemicals that are clearly associated with R-phrases. Ranking system determined by 42 toxicologists from industry and academia is subjective.

	Tools that are designed to identify preferred chemicals and products											
Name of method/tool	Developed by	Fee for use	Main purpose	Ease of use	Hazards evaluated	How hazards are classified	Weighting of hazard categories	Exposure consideration	Strengths	Limitations		
Skin Deep	Environmental Working Group	No	Provide information about hazardous chemicals found in personal care products: makeup; products for skin, hair, eyes, nails, and oral care; sun protection; and baby products.	Easy	Cancer, reproductive / developmental toxicity, neurotoxicity, endocrine disruption, allergies / immunotoxicity, use restrictions, organ system toxicity, persistence / bioaccumulation , multiple / additive exposure, mutations, cellular / biochemical changes, ecotoxicity, occupational hazards, irritation and miscellaneous.	Each ingredient receives score of 0-100. 100 is high hazard. Data are aggregated into a color coded product score of 0-10: 0-2 low hazard; 3-6 moderate hazard; 7-10 high hazard.	Hazard categories are weighted from 0.1 to 1.	Occupational hazard is considered in the rating system. Score is adjusted based on absorption potential of a product or ingredient.	Easy-to-use online database for consumers provides general overview of the safety of cosmetics and personal care products, and detailed information on the hazards of specific ingredients and products.	Does not allow for side by side comparison of products or ingredients.		

Appendix B - Descriptions of Methods and Tools for Chemical Hazard Assessment

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Note: Each description notes whether certain decision rules are embedded in the tool. This includes two types of decision rules. The first type is the criteria used to determine whether a certain hazard endpoint ranks as high, medium, or low. The criteria for hazard ranking are generally determined by threshold values that delineate a level of concern. These thresholds are generally derived from authoritative government lists of chemicals of concern as well as criteria from the Globally Harmonized System (GHS) for Classification and Labeling. The second type of decision rule is the weighting of hazard categories, e.g., neurotoxicity vs. carcinogenicity. Some of the methods/tools do not weight categories, but instead array the hazard rankings and leave the weighting to the user. Other methods/tools include a decision framework that weights these categories for the user and indicates whether the substance is of higher or lower concern.

1. Tools that are designed to identify and screen out hazardous chemicals

A. PRIO

Developed by: Swedish Government - KemI, the Swedish Chemical Inspectorate

Where to find: http://www.kemi.se/templates/PRIOEngframes 4144.aspx

Fee for use: No

Background/purpose of tool: In 1999, the Swedish parliament adopted 16 environmental quality objectives to be achieved by 2020. One of these goals is a "nontoxic environment." PRIO was developed as a tool to assist chemical producers and users such as product developers, company managers, and purchasers in eliminating high hazard chemicals from products in order to meet this objective. PRIO is currently being revised to adapt to new EU regulations including REACH and a new regulation on Classification, Labeling, and Packaging. The criteria described below for "Phase out" substances are in line with substances defined by REACH to be particularly hazardous and requiring authorization. PRIO is not based on legislation but is concerned with the intrinsic health properties and environmental properties of substances. The database contains both substances that are regulated and those that are not covered by Swedish regulations.

Ease of use: Easy to use. Users can search for substances and obtain information on properties hazardous to the environment and human health; obtain information on prioritized health and environmental properties; identify substances contained in chemically characterized substance groups and product types; and obtain help in developing systems for purchasing, product development, and risk management. The tool contains a priority setting guide to assist in evaluating hazardous chemicals.

Decision rules embedded in tool: The Swedish Government has determined criteria for "phase out" and "priority risk reduction" chemicals, which is a weighting of hazard categories.

Hazard evaluation: This web-based tool contains a database of chemicals that the Swedish Government has identified as being of high concern to human health or the environment. Hazard characteristics have been prioritized into two categories: "phase out" or "priority risk reduction". "Phase out" substances are considered to be of such high hazard that they should not be used. Criteria for "phase out" substances include:

- CMR (carcinogenic, mutagenic or toxic to reproduction), categories 1 and 2
- PBT/vPvB (persistent, bioaccumulating and toxic/very persistent and very bioaccumulating)
- Particularly hazardous metals (mercury, cadmium, lead and their compounds)
- Endocrine disruptive

Ozone-depleting

For chemicals identified as "phase out" substances, the PRIO tool provides a 7 step process for identifying safer alternatives. Criteria for "priority risk reduction" substances include:

- Very high acute toxicity
- Allergenic
- Mutagenic, Category 3
- High chronic toxicity
- Environmentally hazardous, long-term effects
- Potential PBT/vPvB

Table 1 delineates criteria for "phase-out" and "priority risk reduction" substances.

Exposure evaluation: For "priority risk reduction" substances, PRIO recommends that the user conduct a risk assessment by evaluating potential exposure during production, product use and waste handling. The tool guides the user through a process to evaluate risk over the life cycle of a product containing the "priority risk reduction" substance, including: a consideration of exposure to this chemical in the production process, use phase, and in disposal; a weighing together of the risks; and, finally, a decision on continued use of the "priority risk reduction" substance. If it is determined that the chemical will continue to be used, the risk assessment is designed to aid in identification of measures to be taken to ensure that the substance does not pose unacceptable risk at any stage of the product life cycle.

Strengths/best for which applications: This tool can be used to help prioritize chemicals for elimination and risk reduction. Searches can be done in various ways, such as by product type, hazardous properties, substance group, or using the chemical name or CAS number.

Limitations: The database contains substances for which data exists for the criteria identified (usually because these substances have been classified in the EU). If the substance is in the database, the chemical will be identified as "phase out" or "priority risk reduction". A large number of chemical substances currently in use are not included in the database. If the chemical is not in the database the user can research the properties of the substance of concern and compare it to the PRIO criteria to determine whether it fits into the "phase out" or "priority risk reduction" category. To conduct this evaluation, environmental and health effects data must be available for the chemical of concern. Material Safety Data Sheets and other data sources may be needed to determine the constituents and hazard characteristics of chemical mixtures. If after review it is found that a substance is not associated with the hazards identified in the "phase out" or "priority risk reduction" categories, this may mean that the inherent hazards of this chemical are lower, relative to other substances. However, the database does not consider all types of hazards. For example, explosiveness and flammability are not included. Information on quantities and areas of use relate only to use in Sweden.

The bottom line: PRIO is a useful on-line tool for screening out hazardous chemicals. This database helps users determine what chemicals NOT to use, but does not directly provide information on safer alternatives. It does describe a process for evaluating alternatives to "phase out" substances.

Table 1 – Criteria for PRIO Phase-out and Priority Risk Reduction Substances

PHASE-OUT SUBSTANCES				
Property	Classification or other data to establish the property			
Carcinogenic (category 1 and 2)	R45 May cause cancer R49 May cause cancer by inhalation			
Mutagenic (category 1 and 2)	R46 May cause heritable genetic damage			
Toxic to reproduction (category 1 and 2)	R60 May impair fertility R61 May cause harm to the unborn child			
Endocrine disrupter	There are no generally accepted criteria as yet for endocrine-disruptive substances. An assessment is made on a case-by-case basis.			
Particularly hazardous metals and their compounds (Cd, Hg, Pb)	PRIO tool recommends the user to replace these substances with less hazardous substances			
PBT /vPvB – Persistent, Bioaccumulating, Toxic / very Persistent, very Bioaccumulating	The PBT/vPvB criteria of the PRIO tool are to a large extent equal to the criteria in REACH and the criteria in the European Commission's Technical Guidance Document (TGD) for risk assessment			
Ozone-depleting substances	R59 Dangerous for the ozone layer			

PRIORITY RISK-REDUCTION SUBSTANCES				
Property	Classification or other data to establish the property			
Very high acute toxicity	R26 Very toxic by inhalation R27 Very toxic by skin contact R28 Very toxic by swallowing R39/26 Very toxic: danger of very serious irreversible effects through inhalation R39/27 Very toxic: danger of very serious irreversible effects in contact with skin R39/28 Very toxic: danger of very serious irreversible effects if swallowed			
Allergenic	R42 May cause sensitization by inhalation R43 May cause sensitization by skin contact			
High chronic toxicity	R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation R48/24 Toxic: danger of serious damage to health by prolonged exposure in contact with skin R48/25 Toxic: danger of serious damage to health by prolonged exposure if swallowed			
Mutagenic (category 3)	R68 Possible risk of irreversible effects			
Environmentally hazardous, long-term effects	R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment R53 May cause long-term effects in the aquatic environment			

Potential PBT / vPvB	The potential PBT/vPvB criteria of the PRIO tool are to a large extent equal to the criteria in REACH and the criteria in the European Commission's Technical Guidance Document (TGD) for risk assessment
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Source: www.kemi.se

B. Quick Scan

Developed by: The Dutch Ministry of Housing, Spatial Planning and the Environment

Where to find: Background documents are no longer available on the Web

Fee for use: No

Background/purpose of tool: In the late 1990's the Dutch government committed itself to develop a new policy for managing chemicals, because of the lack of toxicological information on thousands of chemicals in commerce. The Dutch Ministry of Housing, Spatial Planning and the Environment developed the Quick Scan method as a means of prioritizing the management and evaluation of approximately 100,000 substances in use. The Quick Scan was developed in part to avoid a large increase in animal testing for toxicity, by evaluating existing data where possible. Animal testing results, scientific literature, expert judgment, and structure-activity models are used in the evaluation. The Quick Scan was designed to be implemented in five steps:

- Step 1: Develop hazard profile for each substance
- Step 2: Use specified criteria to classify the substance into hazard categories
- Step 3: Use decision-rules to combine and weight hazard categories and allocate substance to a category of concern (very high to low concern, no data is assumed to be very high concern)
- Step 4: Determine exposure potential based on chemical use and adjust concern category accordingly
- Step 5: Follow established policy for each category of concern.

Efforts by the Dutch government to implement requirements for using the Quick Scan were superseded by the REACH Directive and this tool is not actively used. It is included here as an example of a method that assesses chemical hazards and also includes an evaluation of how the substance is used, as a means of estimating likely exposure to workers, consumers, and the environment.

Ease of use: Moderate. User must research hazard data, using R-phrases developed by the European Union.

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 $^{^{\}rm f}$ See Dutch Ministry of Housing, Spatial Planning and the Environment. Implementation Strategy on Management of Substances – Progress Report and $2^{\rm nd}$ Progress Report. The Hague, 2002.

Decision rules embedded in tool: The Quick Scan uses existing data, criteria and decision-making rules to evaluate substances and locate them in five categories: *very high concern; high concern; concern; low concern; and, provisionally very high concern* because no data is available. A hazard such as carcinogenicity automatically translates into a "very high concern" category. The decision rules for persistent, bioaccumulative and toxic substances (PBTs) are more complex. In this case a chemical is assigned a concern category based upon the chemical's combined hazard level for persistence, bioaccumulative capacity and eco-toxicity. For example, a chemical that is highly persistent, bioaccumulative and toxic is considered of "very high concern," while a chemical that is persistent and somewhat bioaccumulative but only slightly toxic is considered of "concern". The concern categories are adjusted based upon exposure potential (considering chemical uses).

Hazard evaluation: Persistence, bioaccumulation, ecotoxicity, health damage to humans, carcinogenicity, mutagenicity, reproductive toxicity and hormone disruptive effects are evaluated. Criteria used to assign substances to one of four hazard levels are based on international agreements.

If available, experimental data are used in the evaluation process for each substance to determine hazard levels for each of the hazard categories listed above. These hazard levels locate the substance of concern in one of five categories. Substances are evaluated further using a matrix that considers both the degree of hazard and how these substances are used (see Figure 1).

When the Quick Scan was developed the Dutch government created policies for managing chemicals according to the categories of concern, as follows: substances in the *very high concern* category should no longer be used in any application unless very stringent conditions are followed to prevent exposure; substances of *high concern* cannot be used in consumer and open applications; and substances of *concern* and *low concern* can be used in all applications, as long as certain requirements are met. Substances with no data are considered *very high concern* and should not be used under any of the exposure conditions, without further information.

Exposure evaluation: The concern categories are adjusted based upon potential for exposure as determined by chemical uses. Four areas of substance use are evaluated: industrial use; site-limited intermediate use (in confined areas); open applications/professional use; and consumer applications.

Strengths/best for which applications: The Quick Scan, which considers risks to workers, consumers, and environment, was designed to fill the knowledge gap that exists about chemical risks. This method can be used to rapidly evaluate and compare human health and environmental risks from chemicals provided sufficient data is available so that substances can be properly placed into the evaluation matrix. This tool, designed to eliminate the use of high hazard chemicals, can also be used to encourage use of chemicals identified as low concern. Although exposure is not directly measured, the tool

considers different types of use as a proxy for exposure levels, allowing for prioritization of chemical uses as well as hazards.

Limitations: As with other tools, Quick Scan is most useful when sufficient data exists to characterize chemical hazards. Chemicals for which no data exists are placed into the very high concern category.

The bottom line: This is a detailed method for evaluating chemical risks using existing data. Although it is no longer in use by Dutch authorities, it provides a useful model for categorizing hazards and exposure potential and determining levels of concern.

Figure 1: Quick Scan Model

Substances in concern category on basis of hazard and use²²)

EMBORIUM	Use of substances as indication of exposure						
EXPOSURE ON BASIS CONCERN OF USE	Site limited intermediate substances	Substances in industrial applications	Open professional use of substances	Substances in consumer applications			
ON BASIS OF HAZARD	Low Exposure	Exposure	High exposure	Very high exposure			
Very high concern	High concern	High concern	Very high concern	Very high concern			
High concern	Concern	Concern	High concern	High concern			
Concern	Concern	Concern	Concern	High concern			
Low concern	Low concern	Low concern	Low concern	Concern			
No data, very high concern	Very high concern	Very high concern	Very high concern	Very high concern			

Source: Dutch Ministry of Housing, Spatial Planning and the Environment. Implementation Strategy on Management of Substances – Progress Report and 2nd Progress Report. The Hague, 2002.

C. RISCTOX

Developed by: The Spanish Trade Union Institute for Work, Environment and Health (ISTAS)

Where to find: http://www.istas.net/risctox/

Fee for use: No

Background/purpose of tool: RISCTOX was developed by the Spanish Trade Union Institute for Work, Environment, and Health to provide clear, organized, and easily accessible information about risks to human health and environment posed by chemicals in the workplace. It provides information on its classification and labeling requirements as well as applicable environmental and health and safety laws. In addition to

researching hazards posed by workplace chemicals, users can assess and compare alternative products using a tool in the database that is based on the Column Model described below. This tool requires additional information regarding flammability, how the chemical is used in a production process, vapor pressure, and physical state as the Column Model considers exposure potential based on this information.

The tool includes information on alternative chemicals and technologies that are commercially available. This section of the database can be searched by substances, applications/products, processes, or sectors.

Ease of use: Easy to use. Users can search for hazard properties using chemical name, CAS or other identification numbers, or by hazard category or environmental or occupational health and safety regulation. Approximately 30,000 chemicals are included in the database.

Decision rules embedded in tool: Substances in the database are evaluated for the hazard categories listed below, using authoritative government lists or peer-reviewed research findings and are linked to European and Globally Harmonized System of Classification and Labeling risk phrases and hazard statements. Hazard categories are not weighted.

Hazard evaluation: Chemicals are evaluated for the following hazards:

- Carcinogenicity, mutagenicity, and reproductive toxicity
- Endocrine disruption
- Neurotoxicity and ototoxicity
- Sensitizing agents and allergens
- PBTs, vPvB
- Aquatic toxicity
- Air quality/Ozone depletion/climate change
- Soil contamination
- Persistant organic pollutant (POP)

For each hazard category, the database includes the following: description of hazard and risk phrases, what to do if that substance is found in the workplace, written practice guidelines, how the substance is classified, regulations, Risk phrases and classification and labeling requirements under the Globally Harmonized System (GHS) of Classification and European Union guidelines, whether the substance is on the ISTAS black list of chemicals (http://www.istas.net/web/index.asp?idpagina=3447) and references used.

Exposure evaluation: The tool does not include an exposure evaluation.

Strengths/best for which applications: The RISCTOX database includes detailed hazard information on workplace chemicals for which data is publicly available. The database is easy to use, provides recommendations for action, and includes information

on practice guidelines and regulations. Users can also compare chemicals and research safer alternatives.

Limitations: The RISCTOX database is not comprehensive and may not include information on all risks to health and environmental that a particular chemical may pose. If a chemical is not in the database, it does not mean it is not hazardous, but rather that information does not exist or is not publicly available. The database includes information on individual substances, rather than mixtures. The database is in Spanish, but can be easily translated.

The bottom line: RISCTOX is a useful resource for identifying hazards of chemicals found in the workplace, comparing alternatives, and researching safer substances.

D. US Environmental Protection Agency (EPA) screening-level models and tools

Developed by: US EPA

Where to find: http://www.epa.gov/oppt/sf/tools/methods.htm

Fee for use: No

Background/purpose of tools: The EPA created the Sustainable Futures Initiative with a goal of making new chemicals safer, available faster, and at lower cost. To aid in evaluating the safety of new chemicals and designing safer chemistries, EPA has developed a series of screening-level models and tools. These tools are publicly available to chemical developers to evaluate new chemicals before they enter the market. If hazards are identified, developers are encouraged to find safer substitutes before submitting them for EPA review. Companies that complete training offered by the Sustainable Futures Initiative are eligible for an expedited EPA review of their prescreened chemicals.

The following tools are available (some can be downloaded from the link above and others are on-line tools):

Analog Identification Methodology (AIM): on-line tool that helps to identify publicly available experimental data on closely related chemical structures to help users determine potential hazards of untested chemicals. AIM was developed to identify analogs for neutral organic compounds and not for metals, inorganic substances, and organic salts.

*EPI Suite*TM: software program that provides screening-level estimates of physical /chemical properties (melting point, water solubility, etc.) and environmental fate properties (breakdown in water or air, etc.) that can indicate where a chemical will go in

the environment and how long it will stay there. EPI SuiteTM uses a single input to run 17 different estimation programs (including ECOSAR). It requires a good understanding of these models and their appropriate application.

ECOSAR: software program that predicts toxicity of industrial chemicals released into water to aquatic life (fish, algae and invertebrates). The model estimates acute and chronic toxicity by using structure activity relationships.

PBT Profiler: on-line tool that screens chemicals for their potential to persist, bioaccumulate, and be toxic to aquatic life. The program retrieves information on chemical structure using CAS registry numbers and provides easy to read color-coded comparisons of predicted values to PBT criteria. If the chemical exceeds thresholds for persistence, bioaccumulation or chronic fish toxicity, the designators are shaded red or orange. If thresholds are not exceeded the designators are shaded green. Inorganic chemicals, reactive chemicals, organic salts, high molecular weight compounds, chemicals with unknown or variable composition, mixtures, surfactants, and highly fluorinated compounds cannot be evaluated by the PBT Profiler. The tool does not include data to screen chemicals for human health hazards.

*OncoLogic*TM: software program designed to predict the potential cancer-causing effects of a chemical by applying the rules of Structure Activity Relationship (SAR) analysis and incorporating knowledge of how chemicals cause cancer in animals and humans. This program is an expert system that mimics the judgment of human experts on cancer causation.

Non-Cancer Screening Protocol: five step process (not computerized) useful for screening chemicals for non-cancer health effects in the absence of data. Steps are as follows: 1. Locate measured data on chemical/analog; 2. Determine if chemical/analog has familiar/well understood structures; 3. Search online for measured data; 4. Use appropriate screening-level models to predict human health effects; 5. Review of data by experienced toxicologist who assigns hazard concern level (high, moderate, or low).

Exposure and Fate Assessment Screening Tool (E-FAST): screening-level tool that allows users to estimate chemical concentrations in water to which aquatic life may be exposed, as well as generate human inhalation, drinking water ingestion, and fish ingestion exposures resulting from chemical releases to air, surface water, and land. In addition, the model may be used to assess inhalation and dermal exposures to chemicals that may result from the use of certain types of consumer products, such as hard surface cleaners, soaps, air fresheners, paints, gasoline, and motor oil. The exposed populations assessed by the model are either some segment of the general population or consumers. Worker exposures are not assessed in this model.

Chemical Screening Tool for Exposures and Environmental Releases

(Chem STEER): screening tool that estimates environmental releases and work

(*ChemSTEER*): screening tool that estimates environmental releases and worker exposures resulting from chemical manufacture, processing, and/or use in industrial and commercial workplaces. It is designed to be used in the absence of monitoring data. It provides screening-level data that may be used as inputs to the E-FAST model.

Ease of use: It varies by tool. For example, the PBT Profiler is easy to use while Oncologic[™], ECOSAR, and EPISuite[™] require significant expertise in ecotoxicology and organic chemistry and a detailed understanding of structure activity relationships.

Decision rules embedded in tools: These are primarily predictive models to assess hazard and exposure potential and do not assign weights to hazard categories. With predicted information on hazard and exposure, the data can be used in other assessment tools. For the PBT profiler the EPA has developed thresholds for persistence, bioaccumulation, and aquatic toxicity and the tool provides color-coded comparisons of predicted values to these PBT criteria.

Hazard evaluation: Screening-level information provided by these tools indicates a range of potential hazards, including persistence, bioaccumulation, and aquatic toxicity, carcinogenicity, and non-cancer effects. The following are hazard evaluation tools: ECOSAR, PBT Profiler, OncoLogicTM, and the Non-Cancer Screening Protocol.

Exposure evaluation: Screening-level information provided by these tools serve as inputs to exposure assessments. The following are tools to assist in exposure evaluation: Epi-SuiteTM, E-Fast and ChemSTEER.

Strengths/best for which applications: Screening-level models are valuable in providing information about untested chemicals when measured data is not available (or validating measured information). Adequate test data are generally preferred over predicted or estimated data. Before using any screening-level model, a thorough search for measured data should be conducted. When test data on a specific chemical are not available, test data on close analogs are preferred. If no test data can be located, use of screening-level models is appropriate.

Limitations: These are all screening-level models. The results are intended to be conservative in the absence of measured data, meaning that predicted hazards (for some endpoints) and exposures may be higher than what might be measured through actual data. Some endpoints where structure does not easily correlate to effect, such as endocrine disruption, may not be accurately predicted by the models, and exposure models may not account for cumulative or interactive effects of multiple exposures. Nonetheless, the models provide a useful means to prioritize chemicals of potential concern for additional testing or reductions.

The bottom line: These screening-level models are useful for conducting an initial screening evaluation to prioritize untested chemicals into groups that need further review

or action because they may be of potential concern. They can also be used to identify chemicals that may be of lower concern.

E. GreenlistTM

Developed by: SC Johnson & Son, Inc.

Where to find: Licensed for use through a third party administrator, Five Winds International: http://www.fivewinds.com/. A licensing option has been in place since 2009 and a few large, multi-national companies are in the process of acquiring the program. One company is currently using GreenlistTM to evaluate packaging materials rather than chemical ingredients.

Fee for use: Free license required.

Background/purpose of tool: Despite its name, GreenlistTM is not a list, but rather is a ranking system that scores chemical ingredients used in SC Johnson products based on their health and environmental profiles. Chemicals with the lowest impact on the environment or human health are given a score of 3 or "Best"; those scored as 2 are "Better"; 1 is "Acceptable"; and chemicals scoring 0 may only be used in limited quantities when no suitable alternatives exist. Chemicals that are in the acceptable or 0 categories require high level managerial approvals for continued use.

Developed in 2001 through a partnership with the US EPA, raw material suppliers, and scientists, GreenlistTM organizes ingredient rankings in a centralized database that also lists performance characteristics and costs. Chemists working at SC Johnson facilities worldwide can access this information when designing new products and can therefore choose the highest scoring chemicals available that meet performance and cost criteria. Ingredients are scored within 19 categories that describe the function the ingredient provides in the finished product:

- Surfactants
- Solvents
- Propellants
- Chelants
- Preservatives
- Waxes
- Insecticides
- Fragrances
- Inorganic acids
- Inorganic bases
- Resins
- Organic Acids
- Dves
- Colorants
- Thickeners
- Packaging materials

- Non-woven fabrics
- Silicones
- Sawdust and plant material

Ease of use: Moderate. Users are expected to have some expertise in toxicology.

Decision rules embedded in tool: There are threshold values for each criterion that determine whether a chemical scores from 0-3. The individual scores for each hazard category evaluated are averaged before being adjusted based on a review of "other significant concerns," described below. Hazard categories are not weighted.

Hazard evaluation: In the version of GreenlistTM used by SC Johnson, ingredients are scored individually against threshold values for 4-6 evaluation criteria specific to health and environmental concerns that are relevant to each of the functional categories described above.

The criteria for evaluation are chosen from the following categories:

- Aquatic toxin
- Acute human toxin
- Chronic mammalian/human toxin
- Carcinogen
- Allergen or sensitizer
- Reproductive toxin or teratogen
- Endocrine disruptor
- Biodegradability
- Persistence, bioaccumulative, toxic (PBT)
- EU Environmental Classification (also known as a risk-phrase or R-phrase)
- Vapor pressure
- Octanol/water partition coefficient
- Volatile Organic Compounds (VOC)
- Half life
- Formaldehyde donor (compounds with formaldehyde as a breakdown product)
- Mobilization of heavy metals in the environment
- The source and supplier of the material

The GreenlistTM includes a category of "other significant concerns" which are identified by the user prior to scoring. Regulatory or unofficial bans of the ingredient by market countries or appearance on chemicals of concern lists are examples of issues considered as "other significant concerns."

These concerns can be customized by the user, and where they apply to a chemical ingredient, may reduce a GreenlistTM score by one point. For example, a chemical that scores 2 (Better) may be given the final score of 1 (Acceptable) based on the severity of the concern identified. Theoretically, scores can be raised as new test data become available; however this scenario is less likely.

SC Johnson originally designed GreenlistTM as an internal tool for its company. Its approach to sharing the tool with other companies has been to provide a framework for ingredient evaluation that can be customized by the user. Companies in different sectors may wish to evaluate different hazard endpoints or identify additional significant concerns. The GreenlistTM can be customized to suit the needs of any user, as long as it remains in compliance with the fundamental intent of the program to identify safer chemical ingredients. Five Winds International will audit licensed users to ensure that customization does not impact the integrity of the original GreenlistTM framework.

Exposure evaluation: Not directly addressed; however exposure is considered when selecting an ingredient for inclusion in a product based on its anticipated use.

Strengths/best for which applications: GreenlistTM allows users to screen chemical ingredients and identify those are most problematic and need to be replaced with safer alternatives. GreenlistTM can also be used to compare substances to determine a preferred chemical or material.

Limitations: GreenlistTM can only be used effectively when chemical information is supplied for ingredients being reviewed. In instances where suppliers have been unwilling to disclose the data needed for review an ingredient, a default score of 1 is assigned. GreenlistTM is not intended to replace existing chemical management systems, but rather to complement approaches already in use.

The bottom line: GreenlistTM offers users a customizable framework for reviewing the safety of chemical ingredients.

F. Restricted Substances Lists (RSLs) – Examples

Restricted Substances Lists (RSLs) are a basic type of screening tool. RSLs generally include chemicals that are currently restricted by a government body anywhere in the world. The list may indicate whether the chemical is restricted widely or not. Chemicals that are of concern but are not yet regulated may also be included. Some companies maintain a separate "watch list" of chemicals under scrutiny by scientists and environmental advocates that are not yet regulated. Many companies have developed RSLs as well as some industry sectors, including the automotive, apparel, and electronic sectors, have also developed such lists. In addition to RSLs developed by the private sector, NGOs are creating lists of chemicals of concern to raise awareness about toxic chemicals in commercial use. For illustrative purposes, we have included an example of an industry-wide RSL, a cross-sector analysis of RSLs, a company-specific RSL, and a RSL developed by a nonprofit organization.

F.1 Green Chemistry & Commerce Council Cross-Sector Compilation of RSLs

Developed by: Green Chemistry & Commerce Council (GC3), a project of the Lowell Center for Sustainable Production

Where to find: GC3 web site:

http://greenchemistryandcommerce.org/downloads/RSLAnalysisandList_000.PDF

Fee for use: No

Background/purpose of tool: In an effort to demonstrate product safety, comply with multiple regional and national government regulations restricting the use of toxic chemicals, and anticipate future regulations, companies are increasingly developing screening programs and criteria to guide hazardous substance restrictions. The result has been the creation of multiple corporate and sectoral lists of restricted chemicals, known as RSLs. Despite their widespread use, corporate RSLs are often developed by an individual company or sector, and are generally not publicly available. In an effort to better understand the types of restricted chemicals and the drivers for their restriction, the Green Chemistry and Commerce Council compiled a cross-sector RSL using proprietary lists provided by 15 member companies and 4 sector-based RSLs that are made publicly available by their trade associations. Together these lists include the following sectors:

- Retail (2)
- Electronics (3)
- Textiles (1)
- Apparel (3)
- Building products (1)
- Personal care and cleaning products(2)
- Automotive (2)
- Flooring (1)
- Commercial cleaning products (1)
- Aerospace (1)
- Pharmaceuticals (1)
- Retailer that is also personal care product manufacturer (1)

This cross-sector compilation of RSLs includes a table that identifies each restricted substance appearing on one or more of the 19 lists, its functional use (solvent, dye, etc), type of restriction applied (ban, restricted above a certain threshold, etc.), a description of what motivated the restriction, and the sector(s) in which the chemical is being restricted. The table is accompanied by an analysis of the drivers for chemical restriction, and suggested implications for green chemistry and design for environment approaches to safer chemistry.

Ease of use: Easy to use. Chemicals are listed by Chemical Abstract Service (CAS) number when provided, and organized in a simple table. The document is in a PDF

format. Users can search for individual chemicals, uses, or other phrases using the search function provided in Adobe software.

Decision rules embedded in tool: N/A

Hazard evaluation: The vast majority of substances are listed because they appear on one or more authoritative government lists of hazardous chemicals or are regulated by a national government. These include:

- Carcinogens, mutagens, and reproductive toxins (CMRs)
- Specific substances including: lead, mercury, cadmium, hexavalent chromium, polybrominated diphenyl ethers (PBDE) and polybrominated biphenyls (PBB)
- Classes of chemicals including: phthalates, heavy metals, brominated flame retardants
- Very persistent (VP), very bioaccumulative (VB), or persistent, bioaccumulative and toxic (PBT) chemicals
- Chemicals that are acutely toxic
- Chemicals that are toxic to aquatic organisms

Exposure evaluation: N/A.

Strengths/best for which applications: The cross-sector compilation of RSLs provides a snapshot of some corporate efforts to identify and reduce the use of hazardous chemicals in products. It provides a broad overview of substances of concern in 12 sectors.

Limitations: This cross-sector RSL, like most RSLs, is limited to regulated and known chemical hazards. While valuable in assisting firms to avoid chemicals of concern, this tool does not help identify safer alternatives.

The bottom line: The cross-sector compilation of RSLs is presents chemicals being targeted for reduction or elimination by a range of US firms and their representative associations. The document provides a glimpse of trends in chemicals management that likely extends well beyond the relatively small number of companies that participated in the project.

F. 2 American Apparel & Footwear Association (AAFA) Restricted Substances List

Developed by: A working group of the AAFA's Environmental Task Force

Where to find: http://www.apparelandfootwear.org/Resources/restrictedsubstances.asp

Fee for use: No. Access to the RSL is free. The direct link to the latest version, # 7 September 2010, can be found at:

https://www.apparelandfootwear.org/UserFiles/File/Restricted%20Substance%20List/AA FARSLFinalRelease7.PDF

Background/purpose of tool: The AAFA's RSL was developed as a practical tool to help companies undertake responsible chemical management practices in the home textile, apparel, and footwear industries. The RSL provides information on chemicals that are restricted or banned in finished home textile, apparel, and footwear products anywhere in the world. For each chemical, the RSL identifies the most restrictive regulation. The RSL is updated on a regular basis.

This tool is useful for assuring environmental compliance with global regulations and may also be used to call attention to substances that may be of emerging concern in this industry sector but are currently regulated by a few governments only.

Ease of use: Easy to use. The RSL is a PDF file and the user is alerted to updates made since the previous version.

Decision rules embedded in tool: N/A

Hazard evaluation: For each substance the RSL identifies the following features:

- 1. CAS number
- 2. Common chemical or color name
- 3. Information on the restriction/limit on final product or tested component
 - a. Restriction level
 - b. Country where that restriction/limit is found
 - c. Test Method
 - d. Other countries that maintain equivalent or lesser restrictions
 - e. Comments (if applicable)

The substance categories included in Version 7 are: arylamines, disperse dyes, solvents, pesticides, asbestos, fluorinated greenhouse gases, dioxins & furans, flame retardants, metals, organotin compounds, miscellaneous chemicals, and phthalates.

Exposure evaluation: N/A.

Strengths/best for which applications: The goal of AAFA's RSL is to help manufacturers avoid the chemicals and substances that have been identified to be of concern through global regulations. Use of the AAFA's RSL is voluntary. Because of the industry's global supply chain, Version 7 has been translated into Vietnamese.

Limitations: The RSL does not include chemicals that are restricted in production processes; rather it identifies chemicals that are restricted in finished home textile, apparel, and footwear products. It does not include chemicals regulated in toys, automotive textiles, or other industrial textiles, nor does it include restrictions related to

the use of substances in packaging. Chemicals that are not on authoritative government lists are not included.

The bottom line: The AAFA RSL is a useful resource that identifies chemicals that are currently restricted in finished home textile, apparel, and footwear products.

F.3 Boots UK Priority Substances List (PSL)

Developed by: Boots UK Chemical Working Group (CWG). The CWG provides Boots senior management with direction on environmental values and priorities including a commitment to a precautionary approach to the use of chemicals. It is accountable for publishing and maintaining the PSL.

Where to find: http://www.boots-

uk.com/App_Portals/BootsUK/Media/PDFs/CSR%202010/priority_substances_list%20July%202010%20FINAL.PDF (priority list 2010)

Fee for use: N/A. Internal tool.

Background/purpose of tool: Boots UK has taken a precautionary approach to the use of chemicals, stating that where there are reasonable grounds for concern that a chemical used in a Boots brand product could be harmful to human health or the environment, the company will take appropriate measures. The company is committed to doing a systematic review of chemicals in all Boots brand products. The PSL is updated annually and lists chemical ingredients of concern and their uses, regulatory actions that have been taken to restrict their use, the Boots UK position on each ingredient and any precautionary actions deemed necessary along with relevant timelines. Progress toward published targets is reported as part of the annual environmental performance update of the corporate social responsibility section of the company's Web site.

Ease of use: Easy to use. This is a list-based tool. Substances are listed by name and are organized in a simple table. The document is in a PDF format. Users can readily see the status of each substance as well as the planned action and timeline.

Decision rules embedded in tool: N/A

Hazard evaluation: In assessing whether to use a particular chemical in a Boots brand product, consideration is given to:

- Immediate health hazards and longer term threats to health (bio-accumulation, etc.)
- Environmental impacts (cradle-to-grave)
- NGO priority lists (i.e., ChemSec's SIN list)
- Product efficacy

- Availability and cost of alternatives
- Regulatory constraints
- Customer concerns

Following this evaluation and further investigation a number of actions may be recommended, including:

- Immediate withdrawal of the chemical or use
- Phase out of the chemical or particular use over an appropriate time scale
- Actively seek a replacement of the chemical
- Restrict the use of the chemical to specific purposes and continue to monitor further developments
- Continue to use the chemical but maintain a watch in instances where the balance of evidence does not justify action
- Remove the chemical or use from the PSL

Once the action has been determined, it is noted on the PSL and specific guidelines for product development teams are developed.

Exposure evaluation: N/A.

Strengths/best for which applications: The Boots PSL is useful in identifying substances of concern to the company and the status of these substances, including regulatory status, actions to be taken and the timeline for these actions.

Limitations: Boots sells both its own brand and other brand products in its stores but the PSL is applicable only to Boots brand products. The PSL lists only the key chemicals that Boots considers to be of regulatory or public concern.

The bottom line: The PSL supports Boots UK's precautionary approach to chemicals and its sustainability principles by identifying chemicals of concern in products and tracking progress in adopting the actions identified for each chemical.

F. 4 SIN (Substitute It Now!) List

Developed by: ChemSec, the International Chemical Secretariat, based in Göteborg, Sweden. ChemSec is a non-profit organization founded in 2002 by four environmental organizations.

Where to find: http://www.chemsec.org/list/sin-database

Fee for use: No

Background/purpose of tool: The SIN list was developed by ChemSec to help ensure that the authorization process in REACH is used effectively to quickly identify the most hazardous substances for substitution and to encourage toxics use reduction by chemical

producers and users. In REACH, substances of very high concern (SVHC) are determined according to certain hazard criteria described below. When a substance is listed as a SVHC, it is subject to authorization provisions and its use may be restricted.

Ease of use: Easy to use. Users can search by name, CAS #, European Commission #, or phrase. Search filters include health and environmental classification, possible uses, EU SVHC lists, production volume, and appearance date on SIN list.

Decision rules embedded in tool: N/A

Hazard evaluation: Article 57 of REACH provides the following criteria for determining substances of very high concern:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR), meeting the criteria for classification in category 1 or 2 in accordance with Directive 67/548/EEC;
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation;
- Identified, on a case-by-case basis from scientific evidence as causing probable serious effects to human health or the environment of an equivalent level of concern as those above (e.g. endocrine disrupters).

ChemSec used these criteria to prepare the SIN List. Chemicals classified as CMRs, PBTs, and vPvB were fairly straightforward to identify. However, chemicals that pose an "equivalent level of concern" were more difficult to identify, as there is no authoritative list containing these substances. To determine which chemicals to include on the SIN List, ChemSec used the methodology described below and illustrated in Figure 2.

For CMRs, ChemSec began with the 905 chemicals fulfilling criteria for CMR category 1 or 2. This was reduced to 226 substances, after eliminating mixtures and other substances potentially exempted from the REACH authorization process. For PBTs and vPvB, ChemSec began with the PBT Working Group's finding that 27 substances fulfill EU criteria. This was reduced to 17 substances after determining that certain of the substances (such as pesticides and hydrocarbon distillates) were not subject to REACH.

The determination of substances posing an "equivalent level of concern" was more challenging. ChemSec began with a list of approximately 4000 substances compiled from many different lists. The Swedish Chemicals Agency searched their chemicals database to determine which of these substances were found in consumer products. This narrowed the list to 250 substances. ChemSec then reviewed data on high production volume (HPV) chemicals and narrowed the list to 150. The list of 150 chemicals was then screened to remove chemicals posing physical hazards only, those already identified as CMRs, PBTs, vPvB, or exempt from REACH. From this list, substances were prioritized if their risk phrases indicated CMR, PBT, or endocrine disrupting properties (EDC). As the last step in the process, toxicologists reviewed 60 substances to determine

if they met SVHC criteria. This review resulted in 30 substances being added to the SIN list.

The SIN List 1.0, released in September 2008, contained 267 substances. An updated SIN List 1.1 was released in October 2009, containing 356 substances. 89 substances were added because of an extension of substances classified in the EU as CMRs. In May 2011, the SIN List 2.0 was released, adding 22 substances that are endocrine disruptors to the original SIN List.

Exposure evaluation: No. The SIN list is based on a hazard evaluation.

Strengths/best for which applications: The SIN List is a tool that businesses, governments, and NGOs can use to identify chemicals that meet the REACH criteria for SVHC and therefore may be subject to restriction in the future, if they are not currently regulated. Businesses can share the SIN List with suppliers to encourage substitution to safer chemicals.

Limitations: The SIN List is primarily based on existing lists of toxic chemicals developed by government agencies. Chemicals for which little data exists are generally not included on these lists.

The bottom line: The SIN List was developed to help speed up the REACH implementation process, but it can also be used by a range of actors who wish to be proactive in phasing out toxic chemicals from their products.

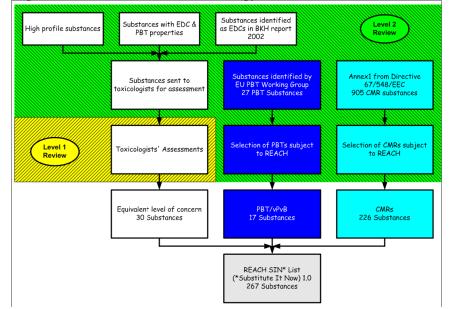


Figure 2 - Overview of Methodology and Selection Process for the SIN List 1.0

Source: Methodology for selection of substances included in the REACH SIN List 1.0. Page 9. Retrieved at: http://www.chemsec.org/images/stories/publications/Downloads/080917 SIN List methodology.PDF

G. GreenWERCSTM

Developed by: The WERCS Ltd. & Wercs Professional Services LLC.

Where to find: www.thewercs.com; www.greenwercs.com

Fee for use: Yes. There are three primary means to procure GreenWERCSTM:

- "Software as a Service" model monthly fee with tiered pricing based upon number of users. The software is hosted by The Wercs and the customer subscribes to use the software.
- Transactional fee structure companies pay \$20.00 to enter each product and have it scored.
- Perpetual seat license purchaser is granted full use of the software. This model tends to be used by product manufacturers. The software is installed at the customer's location.

Background/purpose of tool: The GreenWERCSTM chemical screening tool evaluates the human health and environmental hazards of chemical ingredients in products and links to other databases, such as those that are designed to generate a MSDS. It was developed to help Walmart gain a better understanding of the human health and environment impact of the products it sells, with a long-term goal to reduce or eliminate carcinogens, mutagens and reproductive toxicants (CMRs) and persistent, bioaccumulative and toxic (PBT) chemicals in products sold at Walmart. Although GreenWERCSTM was originally developed for a retailer, the software can also be used by a manufacturer to evaluate the chemical hazards in its products. GreenWERCSTM is currently used by Walmart/Sam's Club, West Marine, Halliburton and Allergan Pharmaceutical. GreenWERCSTM analyzes the composition of individual products from ingredient data entered into the database. It examines the potential impact on human health and the environment based on regulatory lists of hazardous substances, and plots an aggregated score based on a company's weighting and scoring methodology. A retailer using GreenWERCSTM can compare products within a category and make decisions about which to purchase based on its sustainability goals.

GreenWERCSTM protects a manufacturer's proprietary data, as the ingredient data is not shared directly with the retailer. Chemical product manufacturers can use GreenWERCSTM to better understand product formulations at the development stage and assess the potential human health and environmental impact of product ingredients. The tool can compare products and provide "what if" scenarios that allow users to see the impact of changing chemical formulations.

Ease of use: Moderate. A user logs in with a secure password and submits key product ingredient data (chemical composition and formulation) for its chemical products. These data are analyzed by GreenWERCSTM software and the pre-determined scoring method provides a score for each product. The data provided by the WERCS can be viewed and

synchronized with retailers' or manufacturers' internal systems, providing real-time, searchable access to information on the chemical make-up of each product. Figure 3 provides an example of the output generated by GreenWERCSTM.

Decision rules embedded in tool: Chemical ingredients are reviewed to determine if they appear on regulatory lists of hazardous substances. Each hazard endpoint is given a weight that is determined by the user. The scores are combined into a GreenWERCSTM product score.

Hazard evaluation: Chemical ingredients are evaluated against authoritative lists to determine if they are CMRs, PBTs, potential endocrine disruptors, or are regulated as hazardous waste.

The software can be configured for additional health or environmental endpoints or scoring parameters. In addition, GreenWERCSTM can be configured to include additional sustainability criteria that have been pre-calculated by other systems such as recycled content or energy use. These additional sustainability goals can be tracked, reported and displayed using the software.

Exposure evaluation: N/A.

Strengths/best for which applications: The GreenWERCSTM tool provides information on the human health and environmental hazards of chemical ingredients in products, by reviewing formulations against authoritative government lists of hazardous substances. Proprietary information remains confidential through the use of a third party.

Limitations: Chemical ingredients are evaluated to determine if they appear on regulatory lists. Analysis does not include a review of scientific literature or application of screening-level models. Each user determines its own weighting methodology so that products may not be comparable across retailers.

The bottom line: GreenWERCSTM provides a secure screening tool that protects proprietary information and allows chemical manufacturers, formulators, and retailers to evaluate the potential impact of product ingredients on human health and the environment.



Figure 3: Example of GreenWERCSTM Output³³

Source: The Wercs Ltd (GreenWERCSTM Software) internal document.

H. Brief summaries of other proprietary software tools for chemicals management and hazard evaluation

These tools have all been developed by private sector companies and are fee-based.

1. Name of tool: SciVera LensTM - Product Chemical Assessment Software

Developed by: SciVera http://www.scivera.com/

Where to find: http://www.scivera.com/dropbox/sciveralens-factsheet-2011.PDF

Background/purpose of tool: SciVera LensTM provides a secure web-based platform for automated hazard and risk assessment screening of chemical ingredients in materials and products. SciVera LensTM enables decision makers, with or without toxicology expertise, to determine toxicological information about chemical ingredients in their products. The system output is an easy to understand dashboard of hazard and risk scoring, usable by scientists and non-scientists for evaluation and management of materials and their constituent chemicals. It is a "software as a service" product that facilitates access to public scientific data, modeled data and toxicological expert judgment. Using this tool, manufacturers and their suppliers can explore various innovation scenarios that can improve a product's chemical hazard or risk profile and assist in identification of safer alternatives.

The scientific analysis provided by SciVera goes beyond the use of authoritative lists and regulations regarding toxic chemicals. SciVera's toxicologists review scientific literature and use expert judgment and data modeling as necessary. SciVera LensTM evaluates chemicals across 22 human health and environmental toxicology endpoints. The "default" hazard assessment framework consists of best practices from several governmental (OECD/GHS, US EPA DfE, etc.) and other endpoint-specific frameworks. SciVera LensTM includes an assessment of the potential exposure to a product or chemical ingredient that is customized for the specific user or industry. This may be particularly useful for article manufacturers to further prioritize products for risk management actions.

SciVera LensTM provides efficient, secure collection of product ingredient information throughout the supply chain. This information collection process protects companies' proprietary product or supplier information, while communicating the results of the assessment downstream to the requesting party.

This tool is subscription-based. Subscribers gain access to all features of the software for one year. Basic features include automated hazard and risk assessment of unlimited products, components and substances. More features are available for an additional fee, including ongoing enhancement of the software's user interface and increased functionality for securely communicating assessment information with suppliers and customers.

The bottom line: SciVera LensTM is a new tool that offers a toxicological hazard and risk assessment for chemical ingredients, materials and products that goes beyond the use of authoritative lists to identify chemical hazards, also including literature reviews, expert judgment and data modeling as necessary. The tool considers information on exposure as well as hazard. The developers have toxicological expertise to review product ingredients.

2. Name of tool: 3E Green Product AnalyzerTM (GPA)

Developed by: 3E Company http://3ecompany.com/

Where to find: https://sd.amazonaws.com/cdn.3ecompany.com/files/3E_GPA_final.PDF

Background/purpose of tool: The 3E Green Product AnalyzerTM (GPA) supports sustainability and green initiatives by providing access to the data needed to assess the environmental, health and safety (EH&S) compliance for chemical products, and aids in the development and selection of safer and more environmentally friendly products.

The 3E GPATM generates information that enables companies to assess the sustainability footprint of their raw materials or finished goods, compares products to evaluate more

environmentally friendly alternatives for greener purchasing decisions and provides a simple baseline methodology to measure improvement. Users can access 3E Company's chemical profiles and substance data to analyze and compare products by toxicity, environmental impact, use type and cost.

The 3E GPATM baseline scoring approach can be customized to suit the needs of a company or industry. Users define and weigh each area of concern within 3E's Green grading system. Each product receives a 3E Green Score, which is comprised of three components: the product's impact on people (employees and customers), property, and the environment. Products can be analyzed by each of these components to understand impacts. For example, an organization may choose to identify all products that contain known carcinogens. Using 3E's global CAS level regulatory profiles and chemical classification data, 3E GPATM will scan product inventory and identify all substances that are included on the REACH Carcinogens Category 1 or Category 2 lists and other authoritative lists. If the product contains one or more components on relevant lists, the resulting grade will reflect that information. Pricing is based on an annual subscription rate.

The bottom line: 3E GPATM is a new tool that provides assistance with EH&S compliance management and can support efforts to develop or purchase products with a reduced toxic footprint.

3. Name of tool: IHS Chemical Inventory Greening Solutions

Developed by: IHS http://ihs.com/

Where to find: http://global.ihs.com/news/temp/otc-2010/Chemical%20Inventory%20Greening.PDF

Background/purpose of tool: IHS has developed "Chemical Inventory Greening Solutions for a Non-toxic Business" to help companies identify safer alternatives to chemicals of concern in supply chains.

Using the IHS ecoanalysisTM comprehensive software tool, chemical products can easily and quickly be evaluated by use category and data can be sorted and analyzed by cost and hazard ranking (human and environmental) using complex algorithms and multiple endpoints. Product details are illustrated in graphs that allow for evaluation of new products versus current products, provide relative rankings for simplified decision-making, and identify third-party certified alternatives – including products with the following labels: US EPA Design for Environment (DfE), EcoLogo, or Green Seal.

With these data, a company can strategically eliminate and/or replace products based on chemical impacts, and select more favorable products. Users can measure results by tracking and reporting efforts, generating progress reports related to chemical impacts of specific products and product types.

The price for this service is based on the services required, which may include implementation support, field services, and software training.

The bottom line: IHS Chemical Inventory Greening Solutions tool identifies toxic ingredients in products and can help companies to strategize and implement preferred alternatives based on priority criteria and multiple analysis scenarios.

4. Name of tool: Actio Material Disclosure – Product Stewardship Program

Developed by: Actio http://www.actio.net/default/

Where to find: http://www.actio.net/default/index.cfm/products/material-disclosure/

Background/purpose of tool: Actio's Material Disclosure web portal is a supply chain communication tool that retailers and manufacturers can use to securely collect, store, and distribute regulatory and ingredient information about materials in a product supply chain for global compliance. It is designed as a robust, structured database platform to track, analyze and compare finished good and supplier product data against regulations.

Material Disclosure organizes product information by component and chemical ingredient and includes supporting documentation, such as Safety Data Sheets, technical data sheets, certificates of analysis, and food grade certificates, creating a single product record for each material. It consolidates data on toxic or potentially hazardous substances in the supply chain that may be contained in a company's products. Supplier product and materials data are compared against national, international, and local regulations and directives, along with any industry or client specific restricted substance lists. Criteria and information requirements can be customized to meet user needs. Securely, and by permission only, this tool collects, stores, and distributes information on finished goods and raw materials used in product manufacture.

Comprehensive material content information from the supplier is entered once and resides as a single product record, stored in a central repository. This information is immediately accessible to the retailer or manufacturer. Custom reports, using only the information designated by the supplier, can be generated and distributed to the customer. Customers must be granted access to see the information designated by the supplier.

This is a "software as a service" product with the fee structure dependent on customer revenues and a data needs analysis. Off-the-shelf and customized modules are also available.

The bottom line: Actio's Material Disclosure is designed to track raw material chemical components as they move through the supply chain, allowing suppliers to enter chemical composition information into a product record which can then be accessed, at the supplier's discretion, by manufacturers or retailers that are looking to evaluate or purchase the material.

2. Tools that are designed to compare alternatives

I. Chemicals Alternatives Assessment (CAA)

Developed by: US Environmental Protection Agency (EPA) Design for Environment Program (DfE)

Where to find: http://www.epa.gov/dfe/alternative_assessments.html

Fee for use: No

Background/purpose of tool: The US EPA Design for Environment (DfE) program has developed a methodology for chemicals alternatives assessment to identify safer alternatives to known toxic chemicals. The tool uses existing data and predictive modeling to determine human health and environmental hazards of each chemical under evaluation. CAA uses life cycle thinking to consider chemical hazards throughout manufacture, use and disposal, which provides a comprehensive consideration of potential worker, consumer, and environmental exposure pathways. The DfE program considers CAA to be a tool for informed substitution that minimizes the likelihood of unintended consequences because of its life cycle-based approach.

The DfE approach to CAA is underlined by seven principles:

- Alternatives must be commercially available or likely to become available
- Use must be technologically feasible
- Alternatives should deliver same or better value in cost and performance
- Alternatives should have an improved health and environmental profile
- Analysis should consider social and economic factors
- Stakeholders must be interested in participating in the assessment process with DfE
- Alternatives should have potential to result in lasting change

Ease of use: Moderate. CAA is an in-depth analytic methodology that must be conducted by those with sufficient expertise in toxicology and chemistry to interpret a range of scientific data.

Decision rules embedded in tool: The DfE program has developed alternatives assessment criteria for hazard evaluation, which can be found at: http://epa.gov/dfe/alternatives assessment criteria hazard eval nov2010 final draft2.PDF Hazard endpoints are designated as very high, high, moderate, low, or very low based on these criteria. Hazard categories are not weighted.

Hazard evaluation: There are six broad steps to implementing a chemicals alternatives assessment.

- Step 1 Determine needs: DfE initiates a CAA in response to policy or regulatory drivers and consumer and industry requests to identify safer alternatives. For example, when the flame retardant pentaBDE was voluntarily phased out by US manufacturers of furniture foam there was a need to identify safer chemical alternatives.
- Step 2 Gather information: DfE begins by developing an understanding of the chemical manufacturing process including feedstocks, contaminants and residuals from production, the range of functional uses of the chemical, and the available alternatives, including how well they are characterized. In consultation with stakeholders, DfE determines the functional uses of high concern, life cycle elements that are critical, and the availability of alternatives.
- Step 3 Involve Stakeholders: DfE works with stakeholders to design a methodology, monitor its implementation, and use the results to encourage the substitution of safer chemicals. Stakeholders include chemical and product manufacturers, retailers, nongovernmental organizations (NGOs), government agencies, academic researchers, end users, and waste management entities. With stakeholders, DfE makes the final decision on alternatives to be evaluated and functional use(s) to be addressed.
- Step 4 Assess hazard: DfE conducts a literature search and analyzes the available data to assign a value of very high, high, moderate, low, or low toxicity concern for each endpoint based on hazard thresholds. Data sources include publicly available empirical data, measured data received by EPA as confidential business information, structure activity relationship-based estimations using EPA screening-level tools, expert judgment that often relies on experimental data for chemical analogues, and confidential experimental data supplied by chemical manufacturers. Measured data is always preferred but DfE uses structure activity relationships and experimental data when measured data are not available.
- Step 5 Report information: When the hazard endpoints are fully profiled, DfE prepares a report to communicate hazard information to decision makers. A key element of this report is a summary table that arrays information gathered for each chemical about human health effects, ecotoxicity, environmental impacts, and potential routes of exposure, so that alternatives can be easily compared. Table 2 provides an example of a summary table.
- **Step 6 Apply information:** The CAA does not specify a preferred alternative; rather it arrays the data so that decision makers can assess trade-offs if no alternative is clearly preferable. These data are considered alongside cost and performance data.
- **Exposure evaluation:** The CAA is designed to focus on a chemical's functional use, which is the purpose that a chemical serves in a product or process. When considering functional use of a chemical, likely exposure pathways are identified. Because these exposure pathways are generally similar for a certain functional use, exposure can be considered to be relatively constant for a use within a class of products. Therefore the CAA focuses on comparing hazard endpoints among chemical alternatives, rather than

further assessing exposure. The CAA does include an evaluation of potential routes of exposure to workers and the general public.

Strengths/best for which applications: CAAs are valuable in identifying safer alternatives that are commercially available. This information can assist formulators and users in developing environmentally preferable products. The CAA may also reveal that viable alternatives are not available for certain chemical uses. This knowledge may aid innovation toward safer chemistries.

Limitations: The greatest limitation in this methodology is data gaps. The CAA approach addresses data gaps by prioritizing the use of measured data, but applies expert judgment and uses structure-activity relationship analysis and experimental data when measured data are not available.

The bottom line: The DfE CAA is an in-depth, detailed approach to identifying chemical hazards and assessing alternatives.

Table 2: Example of how data are arrayed in a US EPA DfE Chemicals Alternatives Assessment

Flame-Retardant Chemical Alternatives - Screening Level Toxicology and Exposure Summary

		Human Health Effects Ecotoxicity Environmental Potential Routes of Exposure			osure																
		ation3		rer	a	ם	<u> </u>				ıtion	Worker			General Population		П				
Company Albemarie	Chemical	% in Formulation³	Cancer Hazard	Skin Sensitizer	Reproductive	Developmental	Neurological	Systemic	Genotoxicity	Acute	Chronic	Persistence	Bioaccumulation	Inhalation	Dermal	Ingestion	Inhalation	Dermal	Ingestion	Aquatic	Reactive or Additive?
Albornario	Proprietary E Tetrabromophthalate diol diester		L	L	L*	L*	L	M*	L	L	Н	L?	L	N	Υ	Υ	N	N	Υ	Υ	Additive
	Proprietary B Aryl phosphate		L	L	M *	M*	M	M *	L	Н	H	L	M	N	Υ	Υ	N	Υ	N	N	Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	Н	Н	L	L	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Additive
Ameribrom	FR513		İ		ĺ																
	Tribromoneopentyl Alcohol CAS # 36483-57-5		M	L	M	M	M	M	M	M	M	L	L	Υ	Υ	Υ	N	N	Υ	Υ	Reactive
Great Lakes	Firemaster 550																				
	Proprietary F Halogenated aryl ester		L	L	M	M	L	M	L	Н	H	L?	L	N	Υ	Υ	N	Υ	Υ	Υ	Additive
	Proprietary G Triaryl phosphate, isopropylated		L	L	M*	M*	M	M*	L	Н	Н	L	М	N	Υ	Υ	N	Υ	N	N	Additive
	Triphenyl Phosphate CAS # 115-86-6		L	L	L	L	L	M	L	Н	H	L	L	Υ	Υ	Υ	Υ	Υ	Υ	Υ	Additive
	Proprietary H Halogenated aryl ester		L	L	M	M	L	M	L	Н	H	L?	L	N	Υ	Υ	N	Υ	Υ	Υ	Additive

L = Low hazard concern

M = Moderate hazard concern

H = High hazard concern

L, M, or H = Endpoint assigned using estimated values and professional judgment (structure activity relationships)

Source: US Environmental Protection Agency – Design for Environment Program. Furniture Flame Retardancy Partnership: Environmental Profiles of Chemical Flame-Retardant Alternatives for Low Density Polyurethane Foam. Volume 1. September 2005. Complete summary table is available on pages 37-39.

J. The Green Screen for Safer Chemicals

Developed by: Clean Production Action

Where to find: http://www.cleanproduction.org/Greenscreen.php

Fee for use: Green Screen version 1.0 is free and publicly accessible. Supporting documents and templates are available at the link above. Version 2.0 (expected to be available in 2011) will remain unrestricted when used internally within organizations, but will include trademark protections and require validation of publicly asserted Green Screen benchmark scores by an independent panel of experts. There will be a fee associated with this expert review.

Background/purpose of tool: The Green Screen for Safer Chemicals (Green Screen) is a method developed by Clean Production Action, a non-government organization seeking to translate the concepts of clean production into practical tools industry and government can use to ensure greener, safer, and healthier products. Version 1.0 of the Green Screen, released in 2007, provides a free, publicly accessible tool to consistently screen and rank chemicals and materials used in commerce for their human health and environmental hazards, with the intent of transitioning to safer chemicals. The Green Screen was developed through input from scientists, engineers, and experts in human health and ecotoxicity. The Green Screen is being used by Hewlett Packard to evaluate chemicals and materials for their preferred materials program.

This method evaluates and ranks possible replacements for a problematic chemical or material, allowing users to identify which option is the safest. Because users can then make more informed decisions about their chemical choices, the Green Screen reduces the possibility that multiple chemical substitutions will be necessary as additional data become available.

Ease of Use: Moderate. Users must have some toxicological expertise to conduct the hazard assessment.

Decision rules embedded in tool: The Green Screen includes threshold values to determine a level of concern for each hazard endpoint. These are derived from lists of chemicals of concern as well as criteria from the Globally Harmonized System (GHS) for Classification and Labeling. In addition, the Green Screen uses a set of four benchmarks to screen out chemicals and their breakdown products that are associated with adverse health and environmental impacts. This is a weighting of hazard categories. Chemicals that do not pass through Benchmark 1 are deemed chemicals of high concern and should be avoided; chemicals at Benchmark 2 are categorized as usable, but efforts should be taken to find safer alternatives; Benchmark 3 chemicals are those with an improved environmental health and safety profile but could still be improved; and chemicals that pass through all four benchmarks are considered safer chemicals and are therefore preferred. Figure 4 illustrates these 4 benchmarks.

Hazard Evaluation:

The Green Screen assesses chemicals for the following hazard endpoints:

- Persistence
- Bioaccumulation
- Evidence of long range transport
- Immunotoxicity
- Acute and chronic aquatic toxicity
- Eye Irritant/corrosive
- Carcinogenicity
- Skin Irritant/corrosive/sensitizer
- Mutagenicity
- Respiratory Sensitizer
- Reproductive toxicity
- Reactive
- Developmental toxicity
- Explosive
- Endocrine disruption
- Particle size
- Neurotoxicity
- Mobility
- Acute human toxicity
- Concerning metabolites or degradation products
- Systemic or organ toxicity

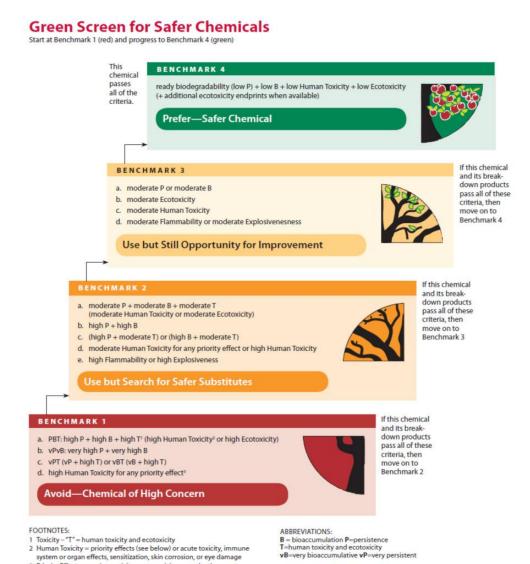


Figure 4: Benchmarks for Green Screen Evaluations

Source: http://www.cleanproduction.org/Green.php

3 Priority Effects = carcinogenicity, mutagenicity, reproductive or developmental toxicity, endocrine disruption, or neurotoxicity

Exposure evaluation: Exposure is not addressed specifically; however a component of determining bioaccumulation is whether the chemical in question has been found in biomonitoring studies of human or wildlife tissues. Persistence and bioaccumulation potential are related to environmental exposure.

Strengths/best for which applications: The tool is useful for comparing possible alternative chemicals or materials that have the same purpose in a product. For example, in 2007 Clean Production Action used the Green Screen to evaluate three flame retardant chemicals used in plastic television enclosures as possible alternatives to the controversial flame retardant decabromo-diphenyl ether (Deca-BDE). After applying the

Green Screen it was found that the alternatives ranged in score from a benchmark 1 (avoid) to benchmark 2 (use but search for safer substitutes).

Limitations: As with other tools, Green Screen is most useful when sufficient data exists to characterize chemical hazards. Version1 cannot be used with inorganic chemicals but Version 2 will modify criteria to apply to inorganic chemicals.

The bottom line: Version 1 of the Green Screen for Safer Chemicals provides a rigorous comparative chemical hazard assessment tool. The changes anticipated under Version 2 should provide further credibility for decision-making based on benchmarking scores and closer alignment with the revised Globally Harmonized System of Classification and Labeling and with the US EPA DfE program's alternatives assessment criteria for hazard evaluation.

K. Pollution Prevention Options Analysis System (P2OASys)

Developed by: Toxics Use Reduction Institute, University of Massachusetts, Lowell

Where to find:

http://www.turi.org/toxics_use_home/hot_topics/cleaner_production/p2oasys_tool_to_compare_materials

Fee for use: No.

Background/purpose of tool: The Pollution Prevention Options Analysis System (P2OASys) was developed by the Toxics Use Reduction Institute (TURI) at the University of Massachusetts, Lowell. It was created to help companies conduct systematic environmental and worker health and safety analyses of the pollution prevention (P2) and toxics use reduction (TUR) options they identify through their planning activities. It assists in identifying potential hazards associated with current and proposed chemicals and processes and helping to choose the alternative that is most protective of worker health and safety and the environment. One unique characteristic of this tool is that it includes data associated with the process in which the chemical is used, to help determine potential occupational exposures. The tool is publicly available on TURI's web site, but is not widely used.

P2OASys provides a means to assess the potential environmental, occupational, and public health impacts of alternative strategies for toxics use reduction. The tool helps companies to comprehensively examine impacts of process changes, including chemicals substitution, and to compare alternative processes.

Embedded formulae in P2OASys provide a numerical hazard score for the company's current process and identified options, which can then be combined with other information sources and professional expertise to make decisions on implementation of a toxic use reduction option.

Ease of use: Moderate. The user must research and enter quantitative and qualitative data on the chemical toxicity, ecological effects, and physical properties of the current chemical/process and of alternative options. These data are available in a variety of existing government databases, but it may be time consuming to collect the information. For each data point entered, the user must also enter a "certainty score" from 0-100. If no score is entered, the default value is 100. Data may be entered for each component of a process or product.

Decision rules embedded in tool: P2OASys normalizes the data entered by the user, by assigning a score of 1-10 for each data point. A lower score represents a lower hazard and a higher score represents a higher hazard. P2OASys uses the "max-min" principle, meaning that the highest value within any hazard category dominates that category of analysis (e.g., chronic toxicity, acute toxicity, etc.). The worksheet computes the scores in each category by multiplying score x certainty. Each category is then weighted by the user (default value is 10 for each category) and the score is multiplied by this weight. The final value for each alternative is a weighted average of the scores for each category. Table 3, the final hazard score table in P2OASys, illustrates how alternative chemicals can be compared in a side-by-side manner.

Hazard evaluation: To determine health, safety, and environmental hazards, eleven categories are considered:

- Acute human effects skin, respiratory and eye irritation as well as skin absorption.
- Chronic human effects-carcinogenicity, mutagenicity, neurotoxicity, reproductive or developmental effects, respiratory sensitivity or disease.
- Physical hazards- heat, noise, and vibration, ergonomic and psychosocial hazards.
- Aquatic hazards- harm to water quality, fish and aquatic plants.
- Persistence/Bioaccumulation.
- Atmospheric hazard- ozone depletion, greenhouse gas emissions, and contribution to acid rain. This also includes the emission standard for a chemical, if one exists,
- Disposal hazard- this includes the end-of-life for a chemical. The user indicates
 whether it will be landfilled, recycled, or incinerated. It also includes whether a
 chemical is listed in the Emergency Planning and Community Right-to-Know
 Act
- Chemical hazard- The chemical hazard section includes properties such as flash point, vapor pressure, solubility, corrosivity, and whether it is a volatile organic compound.
- Energy and resource use- This includes whether non-renewable energy is used in production, as well as overall energy and water use.
- Product hazard- this includes potential hazards that the product may pose in terms of disposal, use and upstream effects.
- Exposure potential- this section qualitatively estimates exposure to workers and/or consumers.

Exposure evaluation: As noted above, exposure potential is qualitatively estimated as high, medium, or low for each alternative.

Strengths/best for which applications: This tool is most useful for side-by-side comparisons of current processes/chemicals and potential alternatives. A color-coding scheme makes the comparison easy to view. By arraying a wide range of criteria the user can make judgments about categories of particular concern.

Limitations: The user must research the hazard data on each chemical and enter it into the database. The user also must all enter data on factors such as ergonomic hazards and exposure, making the use of this tool potentially time and labor intensive. This tool is best used by individuals who have some expertise in occupational and environmental health and in researching toxicological and other chemical databases.

The bottom line: This tool is useful for side-by-side assessment of alternative processes and chemicals. However, it requires a significant investment of time and effort to research and enter relevant data.

Table 3 – P2OASys Summary Table

CATEGORY	Current Process	Alternative 1	Alternative 2	Alternative 3
Acute Human Effects				
Chronic Human Effects				
Physical Hazards				
Aquatic Hazard				
Persistence/Bioaccumulation				
Atmospheric Hazard				
Chemical Hazard				
Energy Resource Use				
Product Hazard				
Exposure Potential				

Source: Alternatives Assessment for Toxics Use Reduction: A Survey of Methods and Tools. The Massachusetts Toxic Use Reduction Institute (TURI), University of Massachusetts Lowell, 2005.

L. Column Model

Developed by: The Institute for Occupational Safety of the German Federation of Institutions for Statutory Accident Insurance and Prevention

Where to find: http://www.dguv.de/ifa/en/pra/spalte/spaltmod.PDF

Fee for use: No

Background/purpose of tool: The German Hazardous Substance Ordinance states that an employer shall ensure that any worker, health or safety risk arising from any work activity involving hazardous substances is eliminated or minimized. In complying with this requirement, the employer shall prioritize use of a substitute substance or preparation. The Institute for Occupational Safety (BIA) of the German Federation of Institutions for Statutory Accident Insurance and Prevention developed the Column Model to provide industry with a practical tool for identification of alternative substances.

The Column Model is primarily used by German companies. It is currently being adapted for use with the Globally Harmonized System for classification and labeling (GHS), which may lead to usage in other countries. A draft of the GHS Column Model is available at: http://www.dguv.de/ifa/en/pra/spalte/ghs_spaltenmodell/index.jsp

Ease of use: Easy to moderate. The user relies primarily on information found in Safety Data Sheets (SDS) to complete the Column Model. German Safety Data Sheets include R-phrases, which are a European system for classifying chemicals according to their intrinsic hazards. The draft GHS Column Model uses information from Safety Data Sheets (SDS) that includes Hazard statements (H-statements) indicating physical and health hazards. These are intended to eventually replace R-phrases. If hazard information is not contained in the SDS, the user may need to search additional data sources for information to complete the columns.

Decision rules embedded in tool: The model assigns hazard rankings based on R-phrases (or H-statements in the draft GHS Column Model). The model classifies the hazards into five risk categories including: very high, high, medium, low and negligible (see Figure 1). If data are not available for certain hazards, the model assigns them a predetermined risk category as follows: if the test data for acute toxicity, skin irritation, mutagenicity, or skin sensitization are not available, the model instructs users to score substances as medium, low, high, and high risk respectively. See Table 4 for classification of acute and chronic health hazards. The columns are not weighted; rather, the user must make a determination of hazards that are most significant for a particular production process.

Hazard evaluation: The Column Model evaluates the following acute health hazards: toxicity, reactivity, corrosivity, skin sensitization, ocular hazards and irritants. It evaluates the following chronic health hazards: carcinogenicity, mutagenicity, reproductive toxicity and bioaccumulation. The model also evaluates environmental concerns such as water pollution, and physical hazards such as fire and explosion.

Exposure evaluation: The model includes a column called "exposure potential" that ranks chemicals according to vapor pressure (higher vapor pressure equals higher exposure risk). In addition, a final column, labeled "hazards caused by procedures," considers whether there is open or closed processing of the chemical, which is also a proxy for exposure.

Strengths/best for which applications: If data are available, the Column Model provides a useful way to array data and compare hazards. If the proposed substitute ranks as a lower risk in all five columns, then the decision to make this change is straightforward. If the potential substitute ranks higher in some columns and lower in others, the user must evaluate which hazards are of greatest concern in a particular production process or processes.

Limitations: The Column Model draws primarily from data found in a SDS, which may not be sufficient to complete the columns.

The bottom line: The Column Model is a useful tool for a side-by-side comparison of chemicals currently in use and proposed alternatives.

Table 4: Column Model - Acute and Chronic Health Hazards and Classifications

Risks	2a Acute health hazards (single affection, e.g. accident with chemicals)	2b Chronic health hazards (repeated affection)
Very high risk	 ◆ Very toxic substances/preparations (R26, R27, R28) ◆ Substances/preparations which may liberate very toxic gases when in contact with acids (R32) 	Carcinogenic substances of categories 1 or (Carc.Cat.1, K1, Carc.Cat.2, K2, R45, R49) Mutagenic substances of categories 1 or 2 (Mut.Cat.1, M1, Mut.Cat.2, M2, R46) Preparations containing carcinogenic or mutagenic substances of categories 1 or 2 in concentrations ≥ 0.1%
High risk	 Toxic substances/preparations (R23, R24, R25) Substances/preparations causing severe burns (highly corrosive) (R35) Substances/preparations which may liberate toxic gases when in contact with water or acids (R29, R31) Skin sensitizing substances (R43, Sh) Substances sensitizing the respiratory tract (R42, Sa) Preparations containing skin or respiratory tract sensitizing substances in a concentration ≥ 1% (in case of gases ≥ 0.2%) 	Substances toxic to reproduction of categories 1 or 2 (Repr.Cat.1, R _c 1, R _p 1, Repr.Cat.2, R _c 2, R,2, R60, R61) Preparations containing substances toxic (reproduction of categories 1 or 2 in conce trations ≥ 0.5% (in case of gases ≥ 0.2%) Carcinogenic substances of category 3 (Carc.Cat.3, K3, R40) Mutagenic substances of category 3 (Mut.Cat.3, M3, R68) Preparations containing carcinogenic or mutagenic substances of category 3 in concentrations ≥ 1% Substances which can accumulate in the human body (R33)
Medium risk	Substances/preparations harmful to health (R20, R21, R22) Substances, which may accumulate in breast milk (R64) Substances/preparations causing burns (corrosive) (R34, pH ≥ 11.5, resp. ≤ 2) Substances harmful to eyesight (R41) Non toxic gases; may cause suffocation by air displacement (e.g. nitrogen)	Substances toxic to reproduction of category 3 (Repr.Cat.3, R ₁ 3, R ₂ 3, R62, R63) Preparations containing substances of category 3 toxic to reproduction in concentrations ≥ 5% (in case of gases ≥ 1%)
Low risk	 ♦ Irritant substances/preparations (R36, R37, R38) ♦ Skin affections when working in wet environment ♦ Substances/preparations which may cause lung damage if swallowed (R65) ♦ Skin affecting substances/preparations (R66) ♦ Vapours causing drowsiness and dizziness (R67) 	Otherwise chronically affecting substance (no R-phrase, but nonetheless a hazardor substance!)
Negligible risk	Harmless substances by experience (e.g. water)	er, sugar, paraffin and similar)

The Institute for Occupational Safety of the German Federation of Institutions for Statutory Accident Insurance and Prevention, *The Column Model*, http://www.dguv.de/ifa/en/pra/spalte/ghs_spaltenmodell/index.jsp

3. Tools that are designed to identify preferred chemicals and products

M. CleanGredients®

Developed by: GreenBlue, a non-profit institute that supports businesses in their sustainability efforts. See: http://www.greenblue.org/. The US EPA Design for the Environment (DfE) program, ISSA, Reckitt Benckiser, and Lanxess are sponsors of CleanGredients® and provide financial support.

Where to find: http://www.cleangredients.org/home

Fee for use: Yes. There are two fundamental classes of subscription. A "formulator" subscription allows an organization to search CleanGredients® and view information about the listed ingredients. A "supplier" subscription allows an organization to search and list an unlimited number of ingredients. Subscription fees are based on annual chemical product sales for formulators, annual chemical sales for chemical suppliers, and annual operating budgets for non-profit organizations and government agencies.

Background/purpose of tool: The goal of CleanGredients® is to encourage the design of cleaning products that are safer with respect to human and ecological health and safety and to provide a market-based incentive for chemical manufacturers to invest in green chemistry research and development. CleanGredients® is an online database of cleaning product ingredients that meet established requirements for environmental and human health performance. GreenBlue develops these requirements through a consensus-based stakeholder process, in collaboration with the U.S. EPA's Design for Environment (DfE) program. Currently, surfactants, solvents, and fragrances are listed in the database, and some chelating agents are under review. Two independent organizations (NSF International and ToxServices) serve as third-party reviewers to evaluate manufacturers' ingredients and provide verified information on standard physical and chemical properties and relevant environmental and human health attributes.

The tool is designed to help formulators identify ingredients that have preferable environmental, human health and safety attributes and to help suppliers of cleaning product ingredients showcase chemicals with preferable environmental and human health and safety attributes.

Initial funding and support for CleanGredients® was provided by the U.S. EPA DfE Program in 2004, and DfE continues to collaborate closely to advance the project. CleanGredients® engages a range of stakeholders including government entities, environmental organizations, industry associations, cleaning product formulators and distributors, and chemical manufacturers and suppliers. Approximately 37 suppliers and 267 formulators subscribe to the tool.

Ease of use: Easy to use. CleanGredients® is organized by ingredient class and is searchable by chemical class, physical or performance properties, CAS registry number, manufacturer, and more. Users can compare candidate chemicals according to key human and environmental health attributes. Users can also view additional technical information, such as the manufacturer's contact information, recommended product uses, web sites, material safety data sheets, technical data sheets, additional human and environmental health information, and life cycle information.

The data entry process for ingredients is straightforward. Suppliers are encouraged to enter as much data as possible for all attributes.

Decision rules embedded in tool: For each chemical entered into the database, key human health and environmental attributes are reviewed by an independent, qualified third party. The key attributes for each ingredient class are recommended by a stakeholder committee through a consensus process. The U.S. EPA DfE program has established a set of criteria that identifies the minimum requirements that ingredients must meet to be acceptable for use in a DfE-recognized product (see below). These criteria provide a way for CleanGredients® to identify chemicals that are best in their class.

Hazard evaluation: Suppliers must provide ingredient information so that qualified third parties can evaluate whether chemicals meet established requirements for environmental and human health performance. Suppliers are encouraged to report specific chemical attributes depending on the ingredient type subject to specific requirements:

- Full information on all components of the product intentionally added or present above a certain threshold must be submitted to a third party for assessment and validation. Company derived toxicological and fate data may also be submitted.
- Ingredient biodegradability. All surfactant ingredients and components must be ultimately biodegradable (i.e., pass the threshold level of 60% mineralization in the prescribed test in 28 days) without degradation products of concern.
- Toxicological review of ingredients: all solvents must pass a minimal set of requirements for fate, human health and environmental toxicity (see http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm). Relevant attributes include: acute mammalian toxicity, carcinogenicity, developmental toxicity, environmental fate and toxicity (PBT status), neurotoxicity, repeated exposure systemic toxicity, and reproductive toxicity.

Exposure evaluation: N/A.

Strengths/best for which applications: The strengths of the CleanGredients® database for suppliers include: ease of analysis, review and listing as preferable; independent third-

party review of ingredients based on consensus-derived criteria; and recognition as a supplier of preferable ingredients.

For formulators the strengths include: access to information on safer alternatives in a central easy-to-access location; increased speed to market due to a reduction in product development time through centralized and standardized data on chemical attributes; and consistent and scientifically informed ingredient reviews due to the required third-party review. CleanGredients® helps formulators identify chemicals that will support formulation recognition by the U.S. EPA and streamlines their participation in the U.S. EPA DfE Formulator Initiative by listing ingredient chemicals that are "pre-screened" against U.S. EPA criteria.

Limitations: Currently CleanGredients® lists surfactants, solvents and fragrances, and some chelating agents are in review. Modules for additional ingredient classes and product types are in development.

The bottom line: The CleanGredients® database of cleaning product chemicals presents verified, ingredient-specific information on standard physical and chemical properties plus relevant environmental and human health attributes, enabling informed design decision-making. It is a useful tool for both suppliers and formulators.

N. Third-Party Eco-Labels and Certifications

Developed by: Various organizations, such as: US EPA, Green Seal, EcoLogo, and McDonough Braungart Design Chemistry (MBDC)

Where to find:

US EPA: http://www.epa.gov/dfe/pubs/projects/formulat/saferproductlabeling.htm

Green Seal: www.greenseal.org
EcoLogo: www.ecologo.org

Cradle to Cradle® Certification: www.mbdc.com

Fee for use: There is no fee paid to the US EPA for the Safer Product Labeling Program, but participants pay a third party reviewer to evaluate their products. Green Seal, EcoLogo and MBDC charge a fee for certification.

Background/purpose of tool: The purpose of eco-labels and certifications is to provide institutional and individual consumers with information on environmental performance of products at the point of purchase. Eco-labeling programs are voluntary though many state and private environmentally preferable purchasing programs require that products be certified or carry an eco-label. The International Organization for Standardization (ISO) has identified three broad types of eco-labels as follows:

Table 5: ISO Classification of Eco-Labels

Type I	Voluntary, multiple-criteria based, third party program that awards a license that authorizes the use of environmental labels on products indicating overall environmental preferability of a product within a particular product category based on life cycle.
Type II	Informative environmental self-declaration claims.
Type III	Voluntary programs that provide quantified environmental data of a product, under pre-set categories of parameters set by a qualified third party and based on life cycle assessment, and verified by that or another qualified third party.

Source: Understanding Eco-Labels. Federal Electronics Challenge.

12/31/07. http://www.federalelectronicschallenge.net/resources/docs/ecolabel.PDF

Credible eco-labels are verified by independent, qualified third parties to meet the standards associated with that label. Some eco-labels are single-attribute, for example, those that note recycled content or compostability. Eco-labels that are multi-attribute are most valid when they consider health, environmental, and social impacts throughout the life cycle of a product.

There are hundreds of eco-label programs world-wide. An index of 374 eco-labels is available at: http://www.ecolabelindex.com/ecolabels/. Several Type 1 eco-labeling/certification programs of relevance to the home and personal care sector are described below:

US EPA Safer Product Labeling Program: The US EPA Design for Environment program (DfE) has developed the Safer Product Labeling Program to identify and promote products that contain ingredients that are the safest in their chemical class. Products are evaluated based on standards for safer chemicals, within the functional classes (such as surfactant, colorant, solvent). The standards, which are developed with stakeholder input, consider the human health, ecological toxicity and environmental fate characteristics of chemicals in the class, and establish thresholds that must be met for an ingredient to be allowed in a DfE-labeled product. To earn the DfE label, product manufacturers must submit a list of all product ingredients to a qualified third party. The third party develops a hazard profile for each ingredient and reviews the profiles against the DfE standards. Product manufacturers are provided with an assessment of their ingredients and whether they meet DfE's safer chemical criteria. To achieve the DfE label, a manufacturer must use the safest ingredients from each functional group and meet other product-level requirements, such as pH and performance. In addition, companies must sign a partnership agreement with EPA that formalizes their commitment to making safer products and improving them over time.

Green Seal is a non-profit organization that since 1989 has developed life cycle-based sustainability standards that cover almost 200 product and service categories, including standards for household and institutional cleaners. In addition, the organization has recently issued a GS – C1, a Pilot Sustainability Standard for Product Manufacturers. (http://www.greenseal.org/GreenBusiness/CompanyCertification.aspx). This new standard

includes requirements for: transparency and accountability at the corporate level; aggressive goals and achievements in environmental and social impact areas; effective and accountable supplier management to ensure sustainable sourcing of materials; life cycle assessment of key product lines; and requirements for third party certification of products. GS – C1 includes requirements for safer chemistry planning and management, including a process for identifying and prioritizing hazardous chemicals and using a green screen to determine safer alternatives.

EcoLogo was founded as an environmental certification program by the government of Canada in 1988 and is now recognized world-wide. The organization has developed standards for over 120 product categories. EcoLogo is managed by TerraChoice, which has recently been purchased by Underwriters Laboratories Canada. Underwriters Laboratories Environment division (ULE), like Green Seal, has recently issued a standard entitled Sustainability for Manufacturing Organizations, known as ULE 880. (http://www.ulenvironment.com/ulenvironment/eng/pages/offerings/standards/organizations/). This standard includes metrics in five areas: sustainability governance, environment, workplace, customers and suppliers, and social and community engagement. ULE 880 gives points to companies that provide an inventory of chemicals used in its manufacturing operations and have in place a policy to reduce the use of PBTs, CMRs, and endocrine disruptors.

MBDC is a private sustainability consulting and product certification firm that has developed the Cradle to Cradle certification for materials, products and systems. The certification program includes requirements for: product and materials transparency, human and environmental characteristics of materials, product and material reutilization, production energy, water use at the manufacturing facility, social fairness and corporate ethics. Companies may apply for four levels of certification – basic, silver, gold, and platinum - and are encouraged to strive for continuous improvement. The certification applies to materials, sub-assemblies and finished products.

Ease of use: N/A. The evaluation is conducted by qualified third parties that have expertise in the particular certification program.

Decision rules embedded in tool: All of the programs described above have developed consistent criteria that chemicals, materials, and products must meet to receive designation as being environmentally preferable. In some cases these criteria are developed through consensus processes and are transparent but in some private eco-labels this is not the case.

Hazard evaluation:

The EPA DfE program has developed Criteria for Safer Chemical Ingredients that can be found at: http://www.epa.gov/dfeprojects/gfcp/index.htm#GeneralScreen. This includes master criteria and specific criteria for different functional classes of chemicals.

Green Seal includes product specific health and environmental requirements in its standards. For example, the Green Seal Standard 37 for Cleaning Products for Industrial and Institutional Use includes a list of prohibited ingredients and specifications regarding acute toxicity, skin and eye irritation, carcinogens, mutagens, reproductive toxins, asthmagens, skin sensitization and absorption, ozone depleting compounds, VOC content, inhalation toxicity, aquatic toxicity, persistence, bioaccumulation, etc.

EcoLogo includes specific health and environmental criteria in its standards. For example, EcoLogo's standard for Personal Care Products, first published in 2000, is currently being revised. The original standard contains requirements related to biodegradability, carcinogenicity, acute toxicity, and also identifies some specific chemicals such as phosphates as being restricted.

MBDC has developed a protocol to score chemicals and materials for their impact on human and environmental health. The score is determined by identifying the hazard posed by the chemical/material, possible routes of exposure, and intended use in a finished product. Chemicals/materials are classified as follows:

Table 6: MBDC Chemical Scoring Protocol

	51115			
GREEN (A-B)	Little to no risk associated with this substance. Preferred for			
	use in its intended application.			
YELLOW (C)	Low to moderate risk associated with this substance.			
	Acceptable for continued use unless a GREEN alternative is			
	available.			
RED (X)	High hazard and risk associated with the use of this			
	substance. Develop strategy for phase out.			
GREY	Incomplete data. Cannot be characterized.			

Source: Cradle to Cradle® Certification Program Version 2.1.1. MBDC. Updated January 2010. http://www.mbdc.com/images/Outline_CertificationV2_1_1.PDF

Exposure evaluation: The EPA DfE program focuses on functional use in evaluating chemical ingredients. This eliminates the need for a detailed exposure evaluation as exposure is considered to be relatively constant for similar chemical and product use patterns. Green Seal and EcoLogo standards do not generally include an exposure evaluation in their criteria, but may consider aspects such as skin absorption. The Cradle to Cradle® protocol considers possible routes of exposure when it scores a chemical from grey to green.

Strengths/best for which applications: Credible, third-party certified eco-labels provide valuable information to consumers at the point of purchase. They provide a simple means for a purchaser to chose "preferable" products. Eco-labels that are multi-attribute and consider environmental and social impacts throughout a product life cycle are more informative than those that focus on a single attribute.

Limitations: Eco-label programs are generally voluntary and may not be widely used by businesses or consumers. In some cases they are required by private or public

purchasing authorities. Single attribute eco-labels provide useful information, but do not provide a complete story of life cycle product impacts.

The bottom line: Eco-labels and certifications are a valuable mechanism for signaling consumers and the marketplace about greener products. They must be widely recognized and accepted by businesses and consumers to have a meaningful impact.

O. Cleaner Solutions Database

Developed by: Surface Solutions Laboratory at the Massachusetts Toxics Use Reduction Institute, University of Massachusetts, Lowell

Where to find: http://www.cleanersolutions.org/

Fee for use: Free

Background/purpose of tool: The Cleaner Solutions database was created by the Surface Solutions Laboratory (TURI Lab) at the Massachusetts Toxics Use Reduction Institute to share the results of laboratory tests on the performance of alternatives to hazardous cleaning solvents used in a variety of manufacturing practices. The TURI Lab tests how well these solvents perform when cleaning a range of contaminants from parts using different cleaning techniques (soaking, agitation, etc.). The parts are made from a variety of materials including metals, plastic or glass. Companies seeking to replace problematic cleaning solvents with a safer alternative can search the database to identify cleaners that may work well as a replacement given the contaminant they need to clean, the intricacy of the parts needing to be cleaned, and their existing cleaning equipment.

The TURI Lab encourages users of the database to seek alternative cleaners that are safer both for workers and the environment to avoid shifting risks between the workplace and environment/community. While developed to assist Massachusetts firms with their toxics use reduction goals, the Cleaner Solutions database is used throughout the world. Some 2,000 visitors use the database each month from the US, Canada, India and the European Union.

In addition to the results from testing done at the TURI Lab, the Cleaner Solutions database also includes a "vendor search" component that contains information provided by vendors. This portion of the database allows users to identify potential cleaners for a specific cleaning need and performance level. Through a searchable interface, users can find cleaners recommended by vendors for best results in specific situations. Search criteria include:

- Name of the company making the cleaner
- Trade name of the cleaner
- Category of cleaner (biobased, semi-aqueous, etc.)
- Whether the cleaner will be used to clean manufactured parts, in precision cleaning applications, or whether the cleaner will be used for janitorial cleaning
- Contaminant being cleaned

- Material from which parts are made
- Cleaning equipment used

Ease of use: Easy to use. Users can review the results of TURI Lab testing through four different types of search as follows:

- <u>Search for a cleaner</u>. Users can search for an alternative cleaner by contaminant, type of material from which the parts are made, or existing equipment used.
- <u>Search by currently used solvent.</u> Manufacturers currently using a solvent can search for cleaners identified as alternatives to a specific solvent.
- <u>Search by safety criteria</u>. Cleaners can be found by setting limits on environmental health and safety criteria and searching for cleaners meeting those limits.
- <u>Search by results of previous testing</u>. Cleaners can be identified through results of
 previous testing that are listed categorically by the sector for which the cleaner
 was reviewed.

Search results are linked to product-specific web pages, which offer more detail about the product score, the data that led to that score, and a Material Safety Data Sheet.

Decision rules embedded in tool: A 50 point scale based on hazard criteria is used to evaluate products. A higher score indicates a potentially safer product. For approximately 10% of the products included in the database a more detailed environmental health and safety evaluation is performed using P2OASys described above. The TURI Lab aims to eventually conduct this in-depth analysis for all products in the database.

Hazard evaluation: A 10-point scale is used to evaluate each of the following hazard criteria for a possible total of 50 points:

- The presence of volatile organic compounds (VOCs)
- Global warming potential
- Ozone depletion potential
- pH
- Occupational hazard

Threshold values are established for each criterion delineating different point values. Occupational hazard is evaluated using the Hazardous Material Information System (HMIS) and the National Fire Protection Association (NFPA) ratings. These ratings are combined to compare flammability, health impacts and physical hazard.

Exposure evaluation: Exposure is not directly assessed but is indirectly considered in the hazard evaluation.

Strengths/best for which applications: The Cleaner Solutions database is useful for comparing alternative cleaners and solvents in similar cleaning applications and equipment. The tool considers occupational health hazards, volatility, ozone depletion and global warming potential.

Limitations: The hazard information in the database is primarily derived from Material Safety Data Sheets and technical data sheets and does not include detailed information about chronic health hazards such as cancer, or environmental concerns such as aquatic toxicity, bioaccumulation or persistence in the environment.

The bottom line: The Cleaner Solutions database provides a valuable resource for businesses seeking safer cleaning solvents in their manufacturing processes. Companies can use the database to find alternative solvents that are both environmentally preferred and safer for workers.

P. iSUSTAINTM Green Chemistry Index

Developed by: iSUSTAIN Alliance. The Alliance includes Cytec Industries Inc. (a specialty chemicals and materials company), Sopheon (a provider of software and services for product life cycle management), and Beyond Benign (a non-profit organization dedicated to green chemistry education and training).

Where to find: https://www.isustain.com/

Fee for use: Basic access to the Web site is free. One analysis may be performed at a time; the results can be printed but cannot be saved. For an annual fee, an upgrade is available which offers more features, including the ability to save and recall analyses. Individual subscriptions cost \$199 per year; corporate enterprise subscriptions with multiple seats are subject to additional terms and conditions.

Background/purpose of tool: The iSUSTAINTM Green Chemistry Index, launched in March 2010, is designed as an assessment tool for scientists in the research and development phase of a product life cycle. It is an Internet-based tool that generates a sustainability score for chemical products and processes. It contains a set of sustainability metrics based on the Twelve Principles of Green Chemistry, taking into account factors such as waste generation, energy usage, health and environmental impacts of raw materials and products, and the safety of processing steps for the chemical being evaluated. The score allows a designer to understand areas where improvements are needed in the chemical design.

The iSUSTAINTM Index is not a life cycle assessment (LCA) tool. Rather, it is designed to provide a quick evaluation of a product and/or process using readily available information and requiring much less time and effort than a full LCA. As such, the tool currently provides a "gate-to-gate" assessment, looking upstream in a process to impacts of raw materials and then into the laboratory or production facility at the process being used to prepare the product under consideration. It is designed to allow use from a very early stage in the product development cycle (even before laboratory trials have begun), through to the later stages of commercial production.

The tool provides a baseline evaluation of sustainability and allows scientists and chemical manufacturers to track their progress over time in developing greener products and gain an appreciation of the factors within their control that can affect the overall sustainability of their processes. This focus on the design stage of a product life cycle allows for the elimination of hazards and pollution later in the product life cycle. It allows users to continuously improve on the environmental performance of a product at the design phase.

Ease of use: Easy to use. The user of the iSUSTAIN™ Green Chemistry Index generates a scenario for a particular process. The scenario contains information on: the materials going into the process (bill of materials in) such as water, solvent, catalysts, and reagents; information on the materials that come out at the end of a process (bill of materials out), such as wastewater, spent solvent, products, and waste chemicals; and the conditions used for the various steps in a process. Several alternative scenarios can be generated for the same product/process, making changes within them to evaluate their impacts on the overall sustainability score, thus allowing the user to do a "what-if" analysis.

Decision rules embedded in tool: The iSUSTAIN Alliance has determined criteria for the 12 sustainability metrics based on the 12 Principles of Green Chemistry. A full description of the intent and calculations used for each metric, plus supplemental information giving full details of algorithms, is provided.

Hazard evaluation: There are 12 metrics in the iSUSTAINTM application:

- waste prevention evaluates chemical processes based on overall generated waste
- atom economy measures the efficiency of utilization of raw materials into the product
- safe raw materials combines scorings of raw material impacts into a single Raw Material Impact number
- safe product uses human and aquatic toxicity endpoints of the product to generate an overall safe product score
- safe solvents combines scoring of solvent impacts into a single Auxiliary Material Impact number
- energy efficiency accounts for energy usage during heating and cooling and for application of high pressure or vacuum, for each step of an overall process
- renewable calculates the percentage of renewable raw material (RRM)
- process complexity calculates the number of reactors and other primary equipment that the bulk of the process stream passes through plus all in-process additions or removals
- catalysis calculates the use of a catalytic reagent versus a stoichiometric reagent using the mole percentage of the catalyst
- biodegradability generates a biodegradability score based on user inputs of the product biodegradation endpoints or based on estimated biodegradability generated through modeling software (i.e., US EPA BIOWIN)

- process control assesses whether the process is capable of forming hazardous side-products, whether there are adequate controls for monitoring reactions, with an estimation of the extent of control
- safe process assesses the potential for chemical accidents, including releases, explosions, and fires

Each metric is rated from 0 to 100, with zero indicating low sustainability and 100 being the highest score. These ratings are presented as a radial map that delineates areas that are "green" and areas that need improvement. Alternative scenarios can be developed for each chemical product or process, allowing users to make changes and see how process or product changes affect the rating. The metric scores can be exported into excel format in order to compare scenarios and overlay data. All data inputs and outputs are stored in the excel file. Figure 5 provides an example of the output from an iSustain analysis.

Exposure evaluation: N/A.

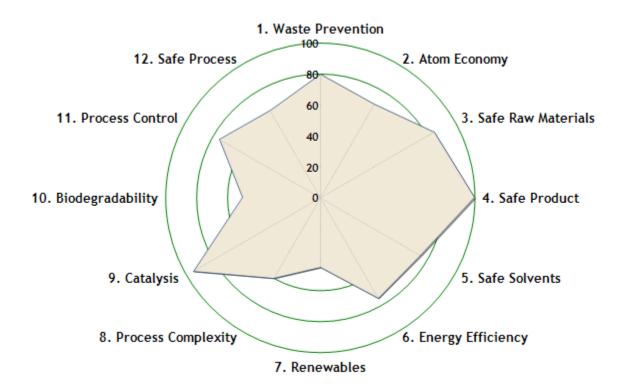
Strengths/best for which applications: iSUSTAIN™ is the first effort to develop a sustainability tool based on the 12 principles of Green Chemistry that covers all types of chemical products and processes. It is also the first time there is a readily available tool for scientists to do 'What if?' analyses and instantly review the results of their choices during the design phase of a new chemical or process.

Limitations: The index was launched in March 2010 and currently includes 5494 materials. If a material is not found when entering materials in a scenario, a user can either use a placeholder material (in which case certain scores will not be available), or request that a new material be entered into the raw materials database, for a small fee. The tool developers plan to include more detailed impact information in the iSUSTAINTM Index as it becomes more readily available. Some additional refinements will also be made to the process steps over time.

The bottom line: The iSUSTAIN™ Green Chemistry Index is a useful software application that provides a quantitative measure and graphical representation of the sustainability of chemical products and processes both to develop an initial sustainability baseline and provide guidance for process improvement. It is a quick evaluation that requires much less time and effort than a full life cycle assessment.

Figure 5: A Sample Scenario for Isopropyl Lactate (scores rounded to the nearest 5):

Waste Prevention	80
Atom Economy	70
Safe Raw Materials	85
Safe Product	100
Safe Solvents	75
Energy Efficiency	75
Renewables	45
Process Complexity	60
<u>Catalysis</u>	95
Biodegradability	50
Process Control	75
Safe Process	65



Source: Summary of sample scenario, Isopropyl Lactate, at https://www.isustain.com/Scenarios.aspx

Q. BASF Eco-efficiency Analysis – Toxicity Scoring System

Name of tool: Toxicity scoring system used in BASF's Eco-Efficiency Analysis tool

Developed by: BASF

Where to find: http://www.basf.com/group/corporate/en/sustainability/eco-efficiency-

analysis/

Fee for use: N/A. Internal tool.

Background/purpose of tool: BASF developed the Eco-efficiency Analysis tool to quantitatively compare products and processes for sustainability. BASF's Eco-efficiency tool evaluates the ecological and economic impacts of products. Six elements are evaluated: raw materials consumption, energy consumption, land use, air and water emissions and solid waste, toxicity potential, and risk potential from misuse. In addition, the economic costs of products and alternatives are determined, taking into account material and energy flows. For the purposes of this report, we describe the scoring system that BASF has developed to determine potential toxicity.

Ease of use: Easy to use. Users refer to table below to determine toxicity of chemicals being evaluated, based on EU Risk Phrases (R-Phrases). This tool is currently being updated to use the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals.

Decision rules embedded in tool: Yes. Scoring system for toxicity was determined through a survey of toxicologists within BASF and at the University of Leipzig. There are additional decision rules. The first step is to identify the highest ranking R-phrase of a substance under evaluation. If there is only one R-phrase, substance is assigned to this group. If the chemical is assigned more than one R-phrase, the substance is upgraded one group, unless it is a weak effect (group 1).

Hazard evaluation: The BASF toxicity scoring system uses the EU classification of 31 Risk phrases (R-phrases) that describe different health effects. BASF asked 42 toxicologists within its organization and at the University of Leipzig to review 25 chemicals with different risk phrases or combinations and score them according to the severity of the toxic effect. Interviewees were asked to score these chemicals on a scale from 0-1000. Using the results of the survey, a simple scoring system was developed for toxic properties.

For untested chemicals that have not been associated with R-phrases, scientists will evaluate whether similar compounds exist. Quantitative Structure Activity Relationships (QSARs) will be determined using established tools. If this analysis does not result in sufficient information, the substance will receive a default score of 1000.

Table 7: Scoring System for Toxic Properties described by R-Phrases

Group	Description	Toxic Effects given by R-Phrases	Score
1	Weak effects	R21, R22, R36, R38, R66, R67	100
2	Local effects	R34, R35, R37, R41, R43	300
3	Acutely toxic	R24, R25, R27, R28, R40, R42, R48,	400
	Irreversible effects	R62, R63, R64	
	Reproductive toxicity		
	suspected		
4	Severe irreversible	R23, R33, R39, R46, R48, R60, R61	550
	effects		
	Reproductive toxicity		
5	Carcinogenic	R26, R45	800
6		Only by combination	1000
+1	Up-grade by additional	Additional "strong" effects (all effects	
	effects	except those of group 1 and additional	
		exposure routes)	

Source: Landsiedel, R. and Saling, P. Assessment of Toxicological Risks for Life Cycle Assessment and Eco-Efficiency Analysis. International Journal of Life Cycle Assessment, 2002, pg. 6.

Exposure evaluation: Exposure is evaluated according to the way that substances are handled, rather than determining actual exposure concentrations. The parameters considered to determine exposure are total production volume, use pattern and exposure route, and the vapor pressure of products. The following use patterns are considered:

- Closed system, non-isolated intermediate
- Isolated intermediate, stored on-site
- Isolated intermediate with controlled transport
- Inclusion into or onto matrix
- Non-dispersive use, professional use
- Widely dispersive use
- Low, medium and high vapor pressure
- Specific factors for nano-particulates

Widely dispersive use is given a much higher score than closed system use. Exposure routes are evaluated to determine whether they are relevant for the process under evaluation.

When the toxicity potential data is entered into the Eco-efficiency tool, the process steps of production, use and disposal are weighted. Process steps with greater potential for direct contact are more heavily weighted than process steps for which there is unlikely to be exposure.

Strengths/best for which applications: Easy to use scoring system to compare toxicity of different chemicals. Tool includes an evaluation of use as a surrogate for exposure,

which can provide additional information for decision-making in regard to hazardous chemicals. Every product that has a Materials Safety Data Sheet can be evaluated.

Limitations: This methodology is most useful for well-studied chemicals whose effects can be clearly defined by R-phrases. The tool includes an element to rank the probability of an effect in untested chemicals compared to well known products. Chemicals for which data are lacking that cannot be adequately characterized by QSAR receive a default score of 1000. The ranking system determined by 42 toxicologists from industry and academia is subjective, as a different group of people may have ranked hazard endpoints differently. Endocrine disrupting chemicals can cause a multitude of effects, which are not fully taken into account by R-phrases.

The bottom line: BASF has developed a scoring system to assess toxicity of chemical ingredients in a product that is easy to use and takes into account use patterns. This system is most useful for well-studied chemicals and does not fully address all hazard parameters of concern, such as endocrine disruption.

R. Skin Deep Cosmetics Database

Developed by: Environmental Working Group

Where to find: http://www.ewg.org/skindeep

Fee for use: No

Background/purpose of tool: Skin Deep is a safety guide to cosmetics and personal care products developed by the Environmental Working Group, an environmental research and advocacy organization. This tool is an on-line database that contains information regarding the hazardous chemicals found in: makeup and products for skin, hair, eyes, nails, oral care, sun protection, and baby products.

The database is designed as a tool to give consumers access to hazard information about chemicals in personal care products. Skin Deep relies on input from companies that have signed the Compact for Safe Cosmetics to report their ingredients. Additional ingredient information is gathered from willing manufacturers or product labels.

Ease of use: Easy to use. User can search by product, company, brand, or ingredient.

Decision rules embedded in tool: Each ingredient is given a score from 0-100 based on the evidence from studies or other data sources. For example, a known human carcinogen would receive a score of 100, while a probable human carcinogen would receive a score of 55. For the categories of restrictions/warnings, multiple/additive exposure, impurities and miscellaneous the scores are simply added. For the other categories, the highest score found for an ingredient is used. The category scores are weighted and summed to produce a raw score. See Table 7 below for category weights. The raw score is then

weighted by the absorption category score, to take into account particle size and penetration enhancing ability.

To determine a product score, the highest scoring ingredient is added to an average of the rest of the ingredient scores (except absorption). For example the ingredient showing the highest score for cancer would be added to an average of other ingredients that have scores for cancer to get the product cancer score. All categories are weighted using Table 1 to get a raw product score. The raw score is then weighted again by the absorption category score. Products receive a color code and score of 0-10. 0 -2 (green) indicates low hazard; 3-6 (orange) indicates moderate hazard, and 7-10 (red) indicates high hazard.

Skin Deep also provides a rating for data availability (none, limited, fair, good and robust). The data availability rating is combination of two factors – the scope of ingredient safety data contained in the Skin Deep data base and the number of published studies in the scientific literature on a particular ingredient. The data availability rating for a product is the average of the data availability ratings of individual ingredients in the product.

Hazard evaluation: The following categories of hazard are evaluated: cancer, reproductive/developmental toxicity, neurotoxicity, endocrine disruption potential, allergies/immunotoxicity, restrictions/warnings, organ system toxicity, persistence/bioaccumulation, multiple/additive exposure, mutations, cellular/biochemical changes, ecotoxicity, occupational hazards, irritation, absorption, impurities, and miscellaneous (includes toxicity endpoints that do not fit into another category, efficacy scores, and scores for unidentified ingredients). The database also notes whether the company conducts safety testing on animals.

The tool uses the hazard information available from almost 60 sources including ACGIH, EPA, IARC, NIOSH, and NTP as well as scientific studies and other government, manufacturer, industry and NGO sources to assign a hazard score to each ingredient and product.

Exposure evaluation: The Skin Deep tool considers occupational hazard in its rating system. Ingredients and products are assigned a score based on 8 hour TLV's and PELS. It is important to note that some of this information is based on animal studies and has been converted to represent human occupational limits.

Skin Deep also adjusts scores based on the absorption potential of a product or ingredient. Those ingredients that contain a penetration enhancer or nano-scale ingredient will have their ingredient score increased by a scaling factor. Likewise ingredients that decrease absorption will be scaled down.

Strengths/best for which applications: Skin Deep is designed as an on-line database for consumers seeking information about toxic chemicals in cosmetics and personal care products.

Limitations: The user is not able to do a side by side comparison of products or ingredients. Also, many personal care products and ingredients have not been well assessed for safety and some have only limited assessments.

The bottom line: Skin Deep is an easy to use tool that provides a general overview of the safety of personal care products and includes detailed information on the hazard of specific ingredients or products.

Table 8: Skin Deep Hazard Categories and Weighting Factors

Category	Weighting factor	Description
Cancer	1.0	linked to cancer in government, industry, or academic studies or assessments.
Developmental/reproductive toxicity	1.0	linked to developmental and reproductive toxicity, a broad class of health effects that can range from infertility and reproductive organ cancers to birth defects and developmental delays for children.
Endocrine disruption	1.0	the body's natural hormones, the chemicals that carry messages across the body to manage growth, tissue repair, and reproduction.
Allergies/immunotoxicity	1.0	linked to immunotoxicity, or harm to the immune system, a class of health problems that manifest as allergic reactions or an impaired capacity to fight disease and repair damaged tissues in the body.
Miscellaneous	1.0	Includes toxicity endpoints that didn't fit in another category, efficacy scores (scores that might counteract toxicity scores), and scores for unidentified ingredients.
Neurotoxicity	1.0	linked to neurotoxicity, or harm to the brain and nervous system, a class of health problems that can range from subtle developmental delays to chronic nerve degeneration diseases.
Use restrictions	0.9	prohibited for use in cosmetics, or subject to concentration, use, or manufacturing method restrictions, according to industry safety guidelines and government requirements and guidance from the U.S., E.U., Japan, and Canada.
Organ system toxicity (non-reproductive)	0.5	linked to toxicity of one or more biological systems in the body (cardiovascular, stomach and digestive tract, respiratory system, etc.) through laboratory studies or studies of people.
Biochemical or cellular level changes	0.3	the ability to affect the body at a cellular or biochemical level that may have larger, but poorly understood health implications.
Multiple, additive exposure sources	0.3	also found as contaminants in tap water and food, as ingredients in other kinds of consumer products, or in people in biomonitoring studies that measure

		chemicals in blood, urine, and other fluids and tissues.
Mutations	0.3	linked to both cancer and developmental defects. Includes government, industry, or academic assays, studies and assessments.
Persistence and bioaccumulation	0.3	persistent and/or bioaccumulative, resisting normal chemical breakdown in the environment; building up in wildlife, the food chain, and people; and lingering in body tissues for years or even decades after exposure.
Ecotoxicology	0.2	linked to toxicity of wildlife that may include fish, wildlife, plants, or other wild organisms.
Occupational hazards	0.2	linked to hazards for workers exposed on the job, including acute dangers from chemical handling, or longer term health effects from routine occupational exposures.
Irritation (skin, eyes, or lungs)	0.1	linked to irritation of the skin, eyes, or lungs according to government assessments, industry reviews, and peer-reviewed studies.
Enhanced skin absorption	0.0	an enhanced capacity to absorb through this skin by virtue of chemical properties like penetration enhancing abilities or small particle size (including nanoparticles), or by virtue of where it is applied on the body (on infant skin, lips, or damaged skin).
Decreased skin absorption	0.0	a decreased capacity to absorb through this skin by virtue of chemical properties like penetration enhancing abilities or large particle size (including nanoparticles), or by virtue of where it is applied on the body (on infant skin, lips, or damaged skin).
Data gaps	0.0	linked to data gaps that constitute the absence of basic toxicity studies and safety assessments in Skin Deep's core databases, or that reflect findings of data deficiencies in government or industry assessments.
Contamination concerns	0.1 for ingredients 0.01 for products	may be contaminated with toxic impurities, many of which are linked to cancer, according to government and cosmetic industry ingredient safety assessments or peer-reviewed studies.

Source: Environmental Working Group: http://www.ewg.org/skindeep/site/about.php#5