Guidance Manual for the Safer Choice Certification Process

This manual provides businesses with comprehensive details on the Safer Choice certification process for new products or ingredients, including preparation, anticipated timeline, and costs.



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The Certification Assistance Program (CAP) was coordinated by the Pollution Prevention Resource Center(PPRC) and Oregon Department of Environmental Quality (ORDEQ), from 2021 through 2024. CAP supported the U.S. environmental Protection Agency (EPA) to increase Safer Choice Certified products and ingredient availability.







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This document has not been formally reviewed by EPA. The views expressed are solely those of PPRC and Oregon DEQ. Neither EPA, ORDEQ, or PPRC do not endorse any products or commercial services mentioned.

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Introduction

The Environmental Protection Agency's (EPA) Safer Choice Program reviews and recognizes best-inclass product formulations and ingredients that meet its stringent criteria for less hazardous ingredients and products.

The nationally-recognized EPA Safer Choice label helps consumers and commercial buyers identify and select products with safer chemical ingredients, without sacrificing quality or performance. Most products are intended for cleaning applications, with a few other examples including water treatment, descalers, drain maintainers, and fire suppressants.

The Safer Choice program is supported by many retailers, non-profits, governments, and manufacturers, which focus on using and promoting non-toxic products.

From 2021 through 2024, the Oregon DEQ and the Pollution Prevention Resource Center (PPRC) supported product and ingredient manufacturers to obtain the Safer Choice label through technical assistance and subsidizing the assessment fee. This program served xx product and ingredient manufacturer, outreached to over 100 manufacturers, certified xx products and xx ingredients.

This *Safer Choice Product Certification Guidance Manual* provides a summary of the certification process and helpful tips for those interested manufacturers to better understand the time and resources needed to obtain the label and become a Safer Choice Partner.

Benefits of Obtaining the EPA Safer Choice Label

Using Safer Choice labeled products protects workers, families, pets, marine life, and the environment. The Safer Choice label cuts through confusion and greenwashing, and lets customers know a product has undergone a rigorous review against a broad set of toxicological endpoints as well as performance criteria.

EPA's Safer Choice logo - on product packaging - means that EPA and third-party toxicologists have evaluated every ingredient in the product to ensure the product and ingredients meets Safer Choice's criteria. The product as a whole is evaluated for different functional uses selected (e.g., degreaser, hand soap, etc.).

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Each ingredient in the product is evaluated under criteria for the specific functional use of the chemical in the final product (e.g., surfactant, solvent).

The Safer Choice certification also ensures the product meets the standard's sustainable packaging requirements, and that certified products perform equivalent to other products on the market.

Statistics on Safer Choice products and the Safer Choice Ingredients List (SCIL) as of July 2024 are as follows:

- Over 2,100 unique Safer Choice products in the marketplace
 - Around half of these are categorized as consumer products, and half are business and/or institutional or industrial (I&I) products
 - Many are categorized for both consumer and business
- 51 different product categories (e.g., all-purpose, degreaser, dish soaps, carpet cleaners, etc.)
- Over 350 manufacturers representing 46 states, have labeled products and are Safer Choice Partners
- o Around **400 products** meet the Safer Choice fragrance-free criteria
- Over 100 products meet the Safer Choice criteria for outdoor use
- Over 700 ingredients are listed on EPA Safer Choice Ingredients List (SCIL)¹
- o **852 tradename ingredients** certified on CleanGredients²

The benefits of the Safer Choice label for product manufacturers to certify products include:

¹ The SCIL is available in <u>English</u> and <u>Spanish</u>. New ingredients are periodically added as they are approved for use in Safer Choice products and is searchable by CAS number, or by ingredient name, and/or by its functional use (e.g., chelating agent).

² <u>CleanGredients</u> is a subscription database of tradename ingredients approved for use in Safer Choice products and is searchable by CAS number, manufacturer name,

- Market recognition and potential new customers
- Numerous larger retailers, and more and more smaller retailers (including online) proudly stock and promote Safer Choice
- Credible and respected label
- o Reduced toxic chemical exposure for employees and customers.
- Promotional and branding assistance from EPA, and listing in the searchable, online Safer Choice Products Directory (English or Spanish).

Benefits of Listing Ingredients on SCIL or CleanGredients

The benefits for ingredient manufacturers to list ingredients on SCIL or certify to CleanGredients include:

- Access to over 350 Safer Choice product formulators and hundreds more that utilize the EPA SCIL or CleanGredients to identify safer ingredients for their products
- Reduced toxic chemical exposure for manufacturing staff, as well as product users
- Reduced toxic releases to the environment

Benefits to formulators that use ingredients listed on Safer Choice Ingredients List (SCIL) and/or CleanGredients, is that they have a high level of confidence that their product will be Safer Choice certifiable.

Access to Approved Ingredient Lists

As of 2024, there are 679 individual ingredients approved on EPA's SCIL. The 15 functional use classes for ingredients are as follows:

- Antimicrobial Actives
- Chelating Agents
- Colorants
- Defoamers
- Emollients
- Enzymes and Enzyme Stabilizers
- Oxidants and Oxidant Stabilizers
- Polymers
- Preservatives and Antioxidants
- Processing Aids and Additives
- Skin Conditioning Agents
- Solvents
- Specialized Industrial Chemicals
- Surfactants
- Uncategorized

Some ingredients have more than one functional use. Also note that EPA does not list fragrances or individual fragrance components (for example, pine oil or sweet orange oil), on the SCIL. There are about 2,000 approved fragrance materials.³

The SCIL lists the chemical name, the CAS Registry Number, and its functional use class for Safer Choice. Note that the listing identifies the chemical, but not a particular tradename or supplier.

The SCIL also provides a ranking of the chemical with a yellow triangle, half-green circle, or full green circle. The definition of the ranking, per EPA, is shown below.

- Green circle The chemical has been verified to be of low concern based on experimental and modeled data.
- Green half-circle The chemical is expected to be of low concern based on experimental and modeled data. Additional data would strengthen our confidence in the chemical's safer status.
- ▲ Yellow triangle The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See <u>Safer Choice Criteria</u>). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.

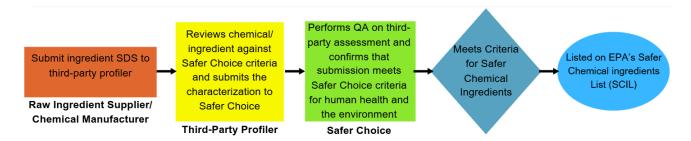
Source: EPA SCIL webpage

For green circle and half-green circle, the ingredients are allowed at full concentration, with some restrictions, such as for VOC (volatile organic compound) and pH limits for the full product, and/or certain restrictions for Safer Choice products selected for outdoor use (called "direct release").

The yellow triangle ingredients are allowed up to 10% concentration in a product, with some exceptions, such as concentration limits for some high VOCs, sensitizing chemicals, and a few specific ingredients (e.g., d-limonene). Similar to green-circle ingredients, some yellow-triangle ingredients will also have restrictions for use in "direct release" Safer Choice products.

³ To determine if a chemical is on the fragrance approved list, contact the EPA Safer Choice program, and/or access is available to those who begin the certification process, through the Safer Choice data entry portal, called the Safer Choice Community.

The diagram below illustrates the typical process for reviewing and adding a chemical to SCIL. (Source: EPA)



About CleanGredients

A subscription database, called CleanGredients, (www.cleangredients.org) is a list of ingredients from specific suppliers (aka tradenames), for which the supplier and the ingredient have been third-party certified as acceptable in Safer Choice products. The difference between CleanGredients and SCIL is that in CleanGredients, the actual supplier of the ingredient has been assessed along with their certified ingredient. There are currently 827 certified ingredients listed (as of July 2024). CleanGredients also uses a functional use class, very similar to those options noted in SCIL.

The intent of CleanGredients is to have pre-approved suppliers of specific ingredients and thereby streamlining the toxicological third-party assessment process for products containing these chemicals.

The CleanGredients database is used by many product formulators, beyond those interested in Safer Choice, as its listings offer safer ingredients for any product formulator.

Summary of Safer Choice Certification Process for Products

The first step in the Safer Choice certification journey is to learn about the program, the criteria, and the Safer Choice Standard. A brief training video is available here.

Additional materials (linked below) that may be helpful include EPA's educational webinars, documents, and Safer Choice webpages:

- Safer Choice Partner Community: What Formulators and Suppliers Need to Know
- Safer Choice Standard
- Safer Choice Product-Class Criteria
- Safer Choice Ingredient Criteria
- Ingredient disclosure FAQs
- Packaging FAQs
- Product performance FAQs
- Safer Choice Partner Community: What Ingredient Suppliers Need to Know

The EPA Safer Choice staff, and/or the EPA-approved third-party profilers, and/or <u>PPRC</u>, are able to answer specific questions. The three profilers are the Gradient Corporation, NSF International, and ToxServices, LLC. (Links are provided below).

The following diagram depicts a high-level summary of typical steps to move forward with certification of a product. Each step is explained in more detail below.



Step 1) Establish the Formulation, Applicable Product Category(ies), and Specialty (or Supplemental) Labels

At the **ingredient level** once the formulation is set, it's best to cross-check the ingredients to determine if:

- 1) Each ingredient is listed the EPA SCIL, and that the function of the ingredient (e.g., solvent) in the product matches the functional class of said ingredient on SCIL
- Its ranking (green circle, half-green circle, yellow triangle). Yellow triangles may have limits on concentration in the formula
- 3) For any ingredients that are not listed in SCIL or CleanGredients, the EPA Safer Choice staff or a profiler can consult on whether they see any red flag. (If the profiler and EPA ultimately concur that the ingredient meets the criteria, it has the possibility to be added to the SCIL
- 4) Full disclosure of all ingredients and composition to the profiler and to the EPA is required, under an NDA. Proprietary ingredients, however, are not necessarily required for public documentation, such as on the safety data sheet or product label

Additional information on ingredient functional classes and criteria resources:

- Criteria for Safer
 Chemical
 Ingredients for
 functional-class criteria
 (e.g., solvents,
 surfactants, chelating
 agents, and fragrances).
- Master Criteria for chemicals where specific functional-class criteria have not yet been defined.

At the **product level**, each product must be categorized under at

least one current product category, e.g., all-purpose cleaner, dish soap, laundry detergent, etc. A full list of current product categories (as of 2024) is presented in Appendix 1.

There are two specialty labels, Direct Release, and Fragrance-Free. If a product is intended for outdoor use, or direct release, meaning it may be used outdoors and then directly release to air, land, or waterways during use, additional criteria applies.

In addition to the categories shown in the Appendix, these specific product categories have additional criteria (at linked topics).

- Ice-melt products
- Inorganic- and mineral-based products
- Microorganism-based products
- Personal care products
- Safer marine lubricants
- Specialized industrial products⁴

Step 2) Verify Packaging Requirements

Safer Choice requires a written statement from the packaging supplier to ensure it meets the following criteria. More information is available in Section 4.2.5 of the EPA Safer Choice standard.

- Packages must either be recyclable and be made of a certain percentage of postconsumer recycled content or be designed to be reused.
- Product labels must not impact recyclability.
- Packaging may not contain heavy metals,
- The following chemical ingredients may not be intentionally introduced into packaging materials or coatings: per- and polyfluoroalkyl substances (PFASs); bisphenol-based and several phthalates.

Step 3) Verify Product Performance

Safer Choice products must meet a baseline measure of performance for the intended use, demonstrating equivalent performance to similar products on the market. Applicants must submit appropriate test results or other demonstration of performance agreed upon by EPA.

More information is available in Section 4.2.1 of the EPA Safer Choice standard.

Step 4) Select a Third-Party Profiler

⁴ Specialized industrial products are a distinct subgroup of products that meet tailored criteria under the Safer Choice Program to distinguish them based on performance requirements from other, more common industrial and institutional products, and/or to indicate ingredients and/or the product has special, high-performance functionalities.

The EPA Safer Choice program has authorized three third-party profilers (profilers):

- Gradient
- NSF International
- ToxServices, LLC

Applicants can submit a quote request to all three profilers to ensure the lowest assessment fees. Submitting a request to all three allows the applicant to get to know a little more about each profiler.

If the request is sent through the Safer Choice Community⁵, it is only entered one time and can be sent to all three at one time. Alternatively, in some cases, a quote can be requested through online direct communication.

The profiler(s) will provide a price quote for the review, and the applicant selects the profiler, and solidifies the contract. The profiler will then guide on how to submit additional product or ingredient information and establish an account to the Safer Choice Community (henceforth, the "Community").

Typical information profilers need for a quote include:

- Trade name(s) of the product(s)
- Consumer type: Home or Business or Both, and if Business, Industrial, or Institutional
- If multiple products, Is it the same base product with an alternate fragrance
- Product form (liquid, aerosol, solid, powder)
- Type of product (all purpose, degreaser, etc.)
- Number of ingredients in each product?
- If a current CleanGredients Subscriber, If, how many of the ingredients are currently listed on CleanGredients
- Number, if any, of proprietary ingredients
- Request for certification as fragrance-free
- Request for certification for direct release (or outdoor use)
- If the product is a wipe, pod, or solid (such as a laundry sheet)

Profilers will provide quotes, and the applicant then accepts a quote from one profiler and proceeds with the formal product review.

Step 5. Submit Additional Information for Formal Review

For **ingredients**, typically just an SDS and compositional analysis information may be required.

For **products**, the additional elements required for the formal submission include some basic company information, certain product properties relevant to Safer Choice (e.g., flash point), the range of the concentration of each ingredient, production volume, and known residuals and

⁵ The Safer Choice Community is the data entry portal used by applicants and their profiler to submit, and review (respectively) the required product information needed in Safer Choice reviews.

impurities and byproducts. (An SDS is not required for these residuals).

For wipes, the substrate ingredients and percent of product composition must be included. For pods, the film ingredients and percent of product composition are required.

The following attachments must be uploaded.

- Ingredient disclosure form
- Artwork for labeling, including the Safer Choice logo
- Safety data sheet (SDS) for all ingredients and the product itself compliant with ANZI Z400.1, and complete with product safety information (See <u>Section 3.4 of Safer Choice Standard</u>).
- Packaging supplier(s) documentation
- Performance equivalency testing data

The ingredient disclosure options are a full ingredient list directly on label, and/or website link, and/or a toll-free phone number. An example is shown below.

Ingredient	CAS#
Water	7732-18-5
Dodecanol ethoxylate	68131-39-5
Anionic surfactant (plant-based)	proprietary
Alanine	164482-16-2
Acrylic polymer	proprietary
Fragrance	proprietary
2-Phenoxyethanol	122-99-6

Step 6. Review by Profiler

The profiler will review all ingredients against Safer Choice criteria, contact suppliers to obtain necessary information related to proprietary or trade-name ingredients, and review performance data and packaging verification. They review the product as a whole, against the Safer Choice criteria for that product. The review typically takes about six weeks.

When the profiler has completed the assessment, they provide a formal report to the applicant. If the product and ingredients meet the Safer Choice criteria, the report is then sent to EPA for final review.

If changes are necessary, those changes can be made, and the application resubmitted.

Step 7. Entering Safer Choice Partnership

For qualifying products, EPA Safer Choice and the applicant discuss the elements of a partnership agreement, including key user and environmental benefits, ingredient disclosure, branding guidelines, and company signatory. If all parties are in agreement, the EPA partnership agreement is signed, and label use is allowed. The product is added to the Safer

Choice Product Directory.

The purpose of the partnership agreement is to set forth the basis, terms, and goals of the voluntary partnership between the partner and EPA. The partnership agreement includes provisions covering the following:

- How the partner formulates the qualifying products,
- Environmental and human health benefits; and
- How the partner and EPA Safer Choice will work together to continually improve the health and environmental profile of the qualifying products and educate consumers on the importance of safer products.

Audits and Renewal

After obtaining the label, annual audits of the manufacturer are conducted by the profiler. Year 1 is typically an in-person audit, and year 2 is typically a desk (or remote) audit. Safer Choice products must then renew every three years.

Typical Timeline to Certify a Product or Ingredient

Review and approval time varies based on several factors including whether the product is existing or a new formulation, the number of ingredients in the product, the number of ingredients that are Cleangredients or already listed on the SCIL, if there are any proprietary and/or multi-compositional ingredients or fragrances, and, if the product is seeking approval for outdoor use (aka "direct release"). Additional factors, and potential other factors.

The expected timeline from initiation of the profiling to the final EPA review varies greatly depending on how much of the product information is readily available, and whether any reformulation or other delays might occur. Excluding any delays, and once a product formulation is ready for profiling, an estimated timeframe may range from 15 to 25 weeks.

Table 1: Expected Time to Obtain Product Certification

<u>Activity</u>	Expected Timeframe
Select which profiler(s) to request a quote from. Gather required	2 – 3 weeks
information and prepare SDS*.	2-4 weeks
(Some profilers may provide a quote prior to entering any product information into the Safer Choice Community)	
Receive and review quote	1 – 2 weeks
Establish and account with profiler and add and upload all	1-2 weeks
required product information	
Profiler review	4 – 6 weeks
Review profiler report, approve for submittal to EPA for final review	1 week
EPA final review	4 – 6 weeks
Establish partnership with EPA (product added to Safer Choice	1 week
Directory)	

For ingredients, the expected timeline from initiation of the profiling to the final EPA review varies, likely from about 11 weeks to 19 weeks.

Table 2: Expected Time to Obtain Ingredient Certification

Activity	<u>Time</u>
Familiarize with Safer Choice standard, and ingredient criteria	0– 2 weeks
Request and receive quote from profiler(s)	2 – 3 weeks
Evaluate and select profiler, submit SDS (Possibly via the Community, possibly via direct electronic communication)	2 – 3 weeks
Profiler review	3 – 5 weeks
Review profiler report, approve for submittal to EPA for final review	1 week
EPA final review	3 – 5 weeks

Direct Cost to Certify a Product or Ingredient

The minimum cost range for profiler assessment for one product is typically around \$3,000, per product. Some of these factors may increase the assessment fee.

- Number of ingredients in the product or formulation
- Number of multi-compositional ingredients, especially fragrances, in the formulation
- Number of proprietary ingredients
- Number of ingredients that are <u>not</u> already listed in SCIL, CleanGredients or in EPA's Safer Choice proprietary database
- Direct release products
- Enzyme-based ingredient(s)

There are cost efficiencies, for companies submitting multiple products with some of the same ingredients. For instance, an all-purpose cleaner with an orange scent, and an "free & clear" all-purpose cleaner with the same formulation minus the fragrance.

If performance data is not available, performance testing by an outside lab may run ~\$500 to \$2,000.

After becoming a Safer Choice partner, annual audits occur. This applies to product manufacturers only, not ingredient manufacturer. Audit fees⁶ may vary from profiler to profiler, with the onsite audit costing around \$1,600 to \$2,000, with possible addition for consultant travel. The remote, or desk audit, may cost around \$700 (covering up to five products total).

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⁶ Estimated fees are from 2024.

Formulation: Key Points

- 1. When formulating a new product, or reformulating an existing product, selecting ingredients already on SCIL or in CleanGredients can result in a less complex assessment process, and higher potential for meeting the Safer Choice criteria.
- 2. For direct release products, some SCIL ingredients are not allowed, including fragrances, d-limonene, certain oxidants or oxidant stabilizers, and some ingredients that have at have aquatic toxicity values <10 mg/L. (See the supplemental criteria here).
- 3. Ingredients with a yellow-triangle designation must not cumulatively exceed 10% of a certified product as sold. Some yellow triangle designations have additional limitations, such as:
 - Yellow triangle d-limonene content must be less than 1.36% concentration and not allowed in direct release products
 - Yellow triangle phosphoric compounds are <u>only</u> allowed as an oxidant stabilizer, and at less than 0.5%.
 - Other limits may apply for certain yellow triangle ingredients.
- 4. Residuals of concern are limited to 0.01% in the product as sold. (Residuals are defined as trace amounts of chemicals that are incidental to manufacturing, and are not part of the intended chemical product)
- 5. At the **product level**, there is a limit to the Volatile Organic Compound (VOC) content of a product as sold. The product must adhere to VOC restrictions as prescribed by the Ozone Transport Commission under the federal Clean Air Act, sections 176A and 184) and the California Air Resource Board (CARB) VOC criteria.
- 6. The pH of a product, as sold, must be greater than 2.0 and less than 11.5 (even if pH is within these limits at the recommended dilution rate).

Potential Challenges Along the Certification Journey

Responses from manufacturer recipients under the Certification Assistance Program, when asked about challenges during the certification process are presented below. Some of these challenges were overcome with help from the CAP program, the profilers, and/or EPA's Safer Choice team.

- "We expected our products to easily pass with flying colors. We did need to do some reformulating throughout the certification process. We did ask our suppliers for alternative ingredients that were on SCIL or CleanGredients."
- "It does take some time to calculate the percent composition range (min and max) of all ingredients, which is required by EPA, to account for variations in the manufacturing process."
- From a soap manufacturer using organic food-based ingredients: "We wrongly anticipated all our ingredients, being food or plant-based, would fall into the category of ingredients that would be automatically approved. They all seemed very innocuous to us."
- "As a small business, we are uncertain if the cost associated with certification will
 offset our projection for increased sales".
- "Finding an acceptable fragrance that did not have unacceptable additives, (e.g., unallowable preservatives."
- "I did not realize we had to include all of our supplier names for each ingredient."
- "Changing the packaging to accommodate the specifications."
- "We were hoping to formulate a few industrial parts cleaning products, but the stringent criteria prohibited design of formulations that could perform as well as traditional solvent-based or caustics, for industrial contaminant removal, especially with the yellow triangle 10% limit."
- "Since our products did not fit in an existing product category, but fell under personal care, the certification process became more expensive and involved than if our products fit in an existing category. Especially since our products are intended for application to the skin, ("leave-on"), the dermal application, additional steps and costs would have been necessary." (For additional information on additional criteria for personal care, see Safer Choice's webpage).

Appendix: Safer Choice Product Categories

(Current as of 2024)

Air Conditioner Coil Cleaners

All-Purpose Cleaners Appliance Cleaners Athletic Field Paints

Automatic Dishwasher Products Biological-Based Products:

Bioremediators Biological-Based Products: Drain Maintainers Biological-Based Products: Grease Trap/Lift Station Maintainers

Biological-Based Products: Septic System

Treatments

Biological-Based Products: Wastewater Inoculants Brick and Masonry Cleaners

Brush Washes Car Care Products

Carpet Care Products: Carpet Cleaners Carpet Care Products: Spot Removers

Degreasers Deicers Descalers Dish Soaps

Dry Erase Board Cleaners
Dust Control Products

Floor Care Products: Floor Cleaners Floor Care Products: Floor Finishes Floor Care Products: Floor Strippers

Granite/Stone Cleaners

Hand Soaps

HVAC Maintenance Kitchen/Countertop

Cleaners Laundry Products:

Boosters

Laundry Products: Fabric Softeners

Laundry Products: Laundry

Detergents Laundry Products: Pre-

Treaters Leather Cleaners

Marine/RV Cleaners

Medical Instrument Cleaners Metal Cleaner/Polishes

Odor Removers

Other Business Products
Other Home Products

Oven/Grill/Barbeque Cleaners

Parts Washers Pet Care Products

Rinse Aids

Stainless Steel Cleaners Toilet Bowl Cleaners Tub/Tile Cleaners Upholstery Cleaners Window/Glass Cleaners

Wood Cleaners