

Supplement Formulation Extension for MADE WISE Certified™

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MADEWORKS™
Intelligence

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The MADE WISE certification program is an independent third-party review designed to eliminate 15,000 of some of the most harmful chemicals from consumer goods, driving transparency and accelerating the shift to safer, more sustainable production. Unlike vague “clean” or “green” claims, MADE WISE sets a science-based standard that exceeds both the US and EU regulations.

Earning the MADE WISE certification means a company proactively avoids more than 15,000 harmful chemicals as intentionally added ingredients, including:

- Toxic antibacterials and antimicrobials
- Harmful artificial colors and dyes
- Bisphenols
- Carcinogens
- Endocrine disruptors
- Developmental and reproductive toxicants
- Neurotoxicants
- Formaldehyde releasers
- Heavy metals
- High-risk pesticides
- PCBs
- PFAS
- Paraffin oil, paraffin wax, petrolatum, and liquid paraffinum ingredients
- Parabens
- Phthalates
- Harmful UV blockers and filters
- Harmful VOCs

Note: Some substances may have category specific allowances or technically unavoidable content, in which case either additional testing, threshold requirements, or other specifications may apply.

Participating in the MADE WISE program demonstrates a company's commitment towards transforming how products are made for a safer and more sustainable future. By minimizing the intentional use of harmful chemicals, we can decrease demand and ultimately reduce their prevalence in the marketplace. When all companies adopt the MADE WISE certification as a starting commitment to sustainability, we will have cleaner air, water, and soil – for everyone.

The MADE WISE Screening Process

- 1. Company Signs Agreement:** Company signs screening agreement and Non-Disclosure Agreement to begin work. This provides confidentiality during the screening process; MADEWORKS understands that the substance information submitted is sensitive, confidential, and sometimes proprietary in nature.
- 2. Company Submits Ingredients/Materials:** To help establish product transparency, companies are responsible for submitting all known substances added to a product, including fragrances and flavors, for review.
- 3. Company Submits Animal Welfare Documentation:** Effective as of January 2027, the MADE WISE Standard will include the following animal welfare requirements. In keeping with MADEWORKS' commitment to the wellbeing of the ecosystem and the creatures that live in it, these requirements are intended to promote consideration of animal welfare across ingredient sourcing and product production. Companies will be required to submit relevant attestations and supporting documentation to MADEWORKS demonstrating compliance with the requirements below:

Humane Treatment of Animals: MADE WISE certification requires that animals are not subjected to abuse, neglect, or inhumane conditions. For certified products containing animal-derived ingredients or materials, the company attests that it has actively verified compliance with relevant suppliers for the specific certified product to confirm that animals are not caused unnecessary pain, suffering, or injury, and that applicable animal welfare laws and humane handling practices are followed in facilities and operations in which they are raised, transported, handled, or slaughtered.

Minimization of Animal Testing: MADE WISE certification minimizes animal testing through the application of the Ecosystem Approach to evaluate ingredient eligibility through company verification and supplier compliance. The company attests that supplier due diligence has been conducted for the ingredients and materials used in the certified product to verify that, wherever possible, scientifically satisfactory methods or testing strategies not entailing the use of live

animals are used instead of animal testing, and that suppliers rely on existing data and established safety profiles whenever available.

Where ingredient safety data is incomplete or uncertain, MADEWORKS applies the Ecosystem Approach to screening, which evaluates potential impacts across human health, environmental persistence, bioaccumulation, and aquatic and terrestrial toxicity. This approach supports the identification and selection of safer alternatives and helps reduce the need for additional animal testing.

4. The MADE WISE Screen: Reported substances are first screened against the MADE Banned List. This list is a compilation of dozens of authoritative lists from around the world. The lists cover a wide array of toxicity endpoints that include both human health and environmental health. While the sources that comprise the entirety of the list are proprietary, some example sources are listed below:

- Agency for Toxic Substances and Disease Registry (ATSDR) Substance Priority List
- California Proposition 65
- ChemSec SIN List
- Environment Canada Persistence, Bioaccumulation and Inherent Toxicity
- European Chemicals Agency (ECHA) Cosmetic Products Regulation, Annex II - Prohibited Substances
- European Chemicals Agency (ECHA) Endocrine Disruptor Assessment List
- European Union European Commission Carcinogenic, Mutagenic Or Toxic for Reproduction (CMR) Substances
- European Union European Commission Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Substances of Very High Concern (SVHC)
- European Union European Commission Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Annex XVII
- Health Canada Cosmetic Ingredient Hotlist
- International Agency for Research on Cancer (IARC) Monographs on the Identification of Carcinogenic Hazards to Humans
- Pesticide Action Network International List of Highly Hazardous Pesticides
- Silent Spring Institute Mammary Carcinogens List

- State of Washington Department of Ecology Chemicals of High Concern to Children (CHCC)
- Stockholm Convention on Persistent Organic Pollutants (POPS)
- U.S. Food & Drug Administration (FDA) Prohibited & Restricted Ingredients in Cosmetics

If a substance is found on the MADE Banned List, it is typically not eligible for certification. If a substance is not found on the MADE Banned List, it progresses and undergoes additional screening in the subsequent review steps (below). Restricted substances are held to applicable standards. Restrictions may include concentration limits, testing requirements, contamination specifications, etc. Some substances may have category specific allowances or technically unavoidable content, in which case either additional testing, threshold requirements, or other conditions may apply.

- 5. Substance-Specific Requirements:** Reported ingredients must meet substance-specific requirements. Substance-specific requirements are determined based on the unique characteristics of a specific substance. For example, these characteristics may include: manufacturing processes, raw materials, contamination risks, and more.

Companies must provide documentation for each ingredient demonstrating compliance with requirements.

- Complete composition declaration: Required for all ingredients and materials. Documentation that accounts for the entire composition of an ingredient or material, including sub-ingredients and carriers. This document should explicitly list each sub-ingredient or verify the substance is only one single substance or material.
- Extraction method documentation: Required for select ingredients and materials, including botanicals. Documentation must disclose all extraction method(s) used in manufacturing.
- Non-nanomaterial documentation: Required for select ingredients and materials. Documentation that demonstrates that the material in question is not a nanomaterial. Lab testing must demonstrate that the material's primary particle size is larger than 100 nanometers.
- Final product pH: Required for select ingredients and materials. Documentation disclosing the final pH of the product undergoing screening.
- Other documentation: Additional documentation may be required on a case-by-case basis.

- 6. Final Report:** The company undergoing screening is issued a final report containing results on the product's approval for MADE WISE certification.

For products not eligible for MADE WISE certification, the final report will contain feedback on which ingredients are not permitted in the program. Companies can then reformulate and then resubmit for rescreening. Companies may reformulate on their own or may contract with our Transformation Partners Program for bespoke reformulation guidance and assistance. In special cases, companies may also be granted Provisional Use of the Seal contingent on Phase Outs or changes in ingredient suppliers.

For products that pass all screenings, the MADE WISE seal is awarded. Companies may work with the MADEWORKS team to announce certification.

Transparency and Disclosure Policies

Disclosure:

We require full disclosure of all intentionally added ingredients to MADEWORKS as part of our screening process. Without full disclosure, we cannot make a determination on the substances' eligibilities for certification. Documentation that accounts for the entirety of every intentionally added ingredient is required. For more information, see the Substance-Specific Requirements section above.

Transparency:

To bolster transparency and empower consumers to make the best possible decisions for themselves and their families, all fragrance and flavor ingredients present at 100 parts per million or higher must be disclosed in MADE WISE Certified products. MADEWORKS also requires disclosure of fragrance and flavor ingredients on packaging. If packaging disclosure is not feasible, the company can disclose ingredients on the product's webpage. Ingredients may also be disclosed in a fragrance or flavor library, but this option is not preferred. Providing shoppers with a list of fragrance and flavor ingredients builds customer trust and allows consumers to make the best possible decisions for themselves and their families.

Confidentiality:

We understand that companies rely on confidential business information and trade secrets for protection. That is why MADEWORKS can work with contract manufacturers, fragrance houses, or other third-party entities under NDA to protect this sensitive information. We do not typically require disclosure of ingredient concentrations to us; rather, we require a comprehensive list of all ingredients that are used in the relevant formulation. We also require relevant substance-specific documentation (see above) as part of our vetting process. We have successfully worked with numerous third parties in the past in a way that both protects intellectual property and allows us the visibility we need to conduct our comprehensive screening. We welcome the opportunity to discuss our confidentiality practices.

Maintaining Certification

In addition to our screening process, substance determinations and certified products are reviewed annually through two mechanisms: Annual Product Compliance and the MADE Banned List Amendment Process.

MADE Banned List Amendment Process:

Each year in Q3 and Q4, substances requiring reassessment will be gathered and reviewed by the MADEWORKS Science & Research Team. After completing the reassessment, if any determinations are changed (meaning a designation changes from permitted to restricted, or vice versa), an amendment will be made to the MADE Banned List powered by MADEWORKS. All companies working with MADEWORKS will be notified of all new MADE Banned List Amendments once they are finalized in Q1. At that time, all companies using newly prohibited Amended Substances have until the end of Q1 of the next year to reformulate and remove the ingredient, unless otherwise specified. Some substances may be given longer phase-out periods. All companies using substances with updated documentation or use case requirements must furnish documentation as soon as possible; the final deadline is 3 months from the date of notification.

Annual Product Compliance:

Certified products are reviewed each year beginning in Q2 to ensure that they comply with MADE WISE standards in terms of transparency, labeling, seal usage, formulation changes, and applicable phase-out of substances as a result of the MADE Banned List Amendment Process from the previous year. In addition to Annual Product Compliance, our team will review a product at any point in the year when companies inform us that changes in formulation or supply chain have or will occur. MADEWORKS can, at any time, require additional substance or product documentation or testing, including where concern over contamination exists. (All tests are done at the certified company's expense.)

MADE WISE Program Claims & Legal Disclaimer:

The MADE WISE certification process screens products against our database of 15,000 substances flagged for safety concerns, select regulatory restrictions, and/or manufacturing quality issues. This certification confirms ingredient transparency and adherence to MADE WISE screening standards but does not evaluate or endorse health benefits, therapeutic effects, or product efficacy. Please refer to the MADE WISE Seal Use Guidelines for more information on accepted claims, trademark compliance, seal use and terminology.

Supplement Standard for MADE WISE Certification

MADE WISE is a rigorous certification standard designed to eliminate some of the most harmful chemicals from consumer goods, including dietary supplements. For supplements seeking certification, all ingredients- including active ingredients, excipients, fillers, binders, colorants, preservatives, solvents, carriers, and coatings- must undergo full screening. Each product is reviewed for the presence of over 15,000 harmful substances as intentionally added ingredients and must adhere to strict documentation and disclosure requirements.

This section provides ingredient-specific guidance for companies developing supplements intended for MADE WISE certification, including best practices to ensure transparency, compliance, and alignment with our science-based evaluation process.

Prohibited and Restricted Ingredients and Practices

Based on extensive toxicological evidence and current regulatory shortcomings, several categories of ingredients or practices that MADE WISE either flags for review or outright prohibits in our certified supplements are listed below.

Artificial Dyes & Colorants: Synthetic ingredients used to color supplements

Background:

Synthetic dyes are often added to supplements purely for aesthetic appeal, but have no functional or nutritional benefit. Many artificial colors have been linked to a range of health concerns, including potential carcinogenicity, hyperactivity in children, and environmental issues.

Formulation Guidance for MADE WISE Compliance:

Artificial dyes identified on the MADE Banned List are ineligible for use in certified products due to their documented associated risks. While not all artificial colorants are included on the MADE Banned List, removing all artificial colorants will fast-track the product towards certification.

To identify potentially ineligible artificial colorants, look for the term FD&C followed by a number on labels (such as FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Blue No. 1) or looking for vague terms that include a color and sometimes a number (such as Brilliant Blue 1, Solid Green FCF, etc.).

Ethoxylated ingredients:

Ingredients that undergo a manufacturing process called ethoxylation and serve a wide range of functions in supplements.

Background:

These ingredients undergo a process that utilizes ethylene oxide, an ingredient linked to cancer, in manufacturing that can give rise to contaminating by-product 1,4-dioxane, another substance associated with cancer.

Formulation Guidance for MADE WISE Compliance:

Due to potential contamination, ethoxylated ingredients are ineligible for use in certified supplements. Because ethoxylation is a manufacturing process, it's not always easy to identify impacted ingredients. Look for and avoid PEGs and polysorbates (see section below) or ingredients with the suffix “-eth” (as in “laureth” and “ceteareth”). Another common potentially ethoxylated ingredient used in supplement formulation is hypromellose (aka HPMC), which can serve as a capsule shell, tablet binder, and more. This ingredient is not always ethoxylated, so

documentation demonstrating that this process is not used in manufacturing is required for certification.

Inactive ingredients / other ingredients:

Ingredients that are typically not intended to provide a specific effect or benefit. On product labels they can be listed as “other ingredients” and can include excipients, binders, fillers, and more used in the product.

Background:

Because the function these ingredients serve is varied, so are the ingredients that can appear on this portion of the label. Some problematic categories include PEGs, polysorbates, talc, synthetic colors, undisclosed flavors, ethoxylated ingredients, and more.

Formulation Guidance for MADE WISE Compliance:

All inactive ingredients must meet the same requirements as active ingredients. Companies must submit full composition disclosure for excipients, fillers, and binders, including any sub-ingredients. Documentation must verify that these materials are not members of prohibited categories such as PEGs, polysorbates, talc and synthetic dyes, and meet all other requirements.

PEGs and polysorbates:

Ethoxylated compounds used as emulsifiers, stabilizers, delivery agents, or other functions.

Background:

The production process used to manufacture PEGs and polysorbates, called ethoxylation, can leave behind residues like 1,4-dioxane and ethylene oxide, both associated with cancer.

Formulation Guidance for MADE WISE Compliance:

These ethoxylated ingredients are prohibited for use in certified formulations. To spot them in formulations, look for the terms PEG and polysorbate, typically followed by a number (Ex: PEG 400 and polysorbate 80).

Plant oils, extracts, and isolates:

Ingredients extracted from plants, which can occur in many forms including fixed oils, essential oils, extracts, isolates, hydrosols, and more.

Background:

These may use hazardous extraction solvents in processing. Even ingredients with strong safety support can become problematic if extracted with toxic solvents.

Formulation Guidance for MADE WISE Compliance:

Extraction method must be disclosed for plant ingredients in the certification process to ensure the use of compliant solvents and processes. We highly recommend sourcing ingredients extracted using mechanical processes like cold-pressing and expeller pressing or that use safer chemicals like CO₂ or ethanol.

Proprietary blend / proprietary formula:

A mix of ingredients grouped under a single name without individual quantities or identities disclosed.

Background:

Within the supplement industry, it is commonplace to conceal the concentration and/or identity of ingredients under umbrella terms like “proprietary blend”, “matrix”, or other copyrighted ingredient names. This means it is impossible to know what or how much of each substance is ingested – a serious issue if one of those ingredients is linked to health concerns or has little to no safety data at all.

Formulation Guidance for MADE WISE Compliance:

Composition disclosure, documentation verifying the identity of a substance and any added sub-ingredients, is required in certification. If the intentionally added ingredients cannot be identified, the product is ineligible for certification. Companies must also be compliant with all labelling requirements, including ingredient disclosure, to achieve certification.

Preservatives:

Ingredients used to extend the shelf-life of supplements.

Background:

Preservatives are necessary to prevent the growth of harmful bacteria and yeast, especially in formulations that contain water. However, some preservatives have been linked to human health and environmental concerns.

Formulation Guidance for MADE WISE Compliance:

Banned preservatives include: ethoxylated ingredients (see above for more information), BHT, BHA, parabens, and propyl gallate. Some acceptable preservatives include: ascorbic acid, potassium sorbate, citric acid, sodium benzoate, and vitamin E. Please note that the mixture of sodium benzoate and vitamin C ingredients or citric acid is not recommended; documentation to demonstrate compliance is required.

Standardized botanical extract:

A botanical extract that is adjusted to contain consistent amounts of a specific compound.

Background:

Some extracts are standardized using specific extraction methods and solvents, or by the addition of carriers or additives. The substances used in the standardization process are not typically disclosed on labels, making their identities inaccessible to consumers.

Formulation Guidance for MADE WISE Compliance:

In the certification process, we require disclosure of the extraction method, any extraction solvents, as well as the composition of the extract to account for additives and carriers. We highly recommend sourcing ingredients extracted using mechanical processes like cold-pressing and expeller pressing or that use safer chemicals like CO2 or ethanol.

Talc:

Mineral used as anti-caking agent.

Background:

Talc is a naturally-occurring mineral that can be contaminated with asbestos, a known human carcinogen. Even when suppliers claim their talc is “asbestos-free,” this cannot be guaranteed. This concern is especially important for products that are ingested or inhaled. It is not a nutritionally necessary substance and safer alternatives are readily available.

Formulation Guidance for MADE WISE Compliance:

The use of talc is prohibited in certified products. Companies must ensure talc and talc-derived materials are excluded from formulations. Alternative anti-caking agents are recommended.

Titanium dioxide:

A naturally occurring mineral found in the earth’s crust.

Background:

Titanium dioxide is widely used in supplements as a whitening or opacifying agent, especially in capsules and tablet coatings. While valued for aesthetics, titanium dioxide has been flagged for potential safety concerns. Although still permitted for use in the United States, the European Union has banned its use in food due to suspected genotoxicity and long-term ingestion risks.

Formulation Guidance for MADE WISE Compliance:

Titanium dioxide is not permitted in MADE WISE Certified supplements. Companies must source alternative capsule and coating materials that do not use titanium dioxide for whitening, opacifying effects, or other functions. Capsule and coating composition must be fully disclosed, including all colorants and additives.

Undisclosed flavors, colors, or fragrances:

Vague umbrella terms used to denote trade secret formulations on product labels that contain undisclosed flavor, color, or scent ingredients.

Background:

These terms can legally obscure dozens — sometimes hundreds — of individual components undisclosed on the label. Current U.S. federal regulations do not require manufacturers to break down these mixtures on labels, which means consumers have no way to know what they're actually ingesting. This lack of transparency can pose significant health concerns, as undisclosed ingredients have been linked to various health concerns like allergies, reproductive toxicity, and endocrine disruption.

Formulation Guidance for MADE WISE Compliance:

Components of flavor and fragrance formulations must be disclosed to 100 ppm in order to achieve certification. MADEWORKS also requires the same level of disclosure on packaging. If packaging disclosure is not feasible, the company can disclose ingredients on the product's webpage. Ingredients may also be disclosed in a fragrance or flavor library, but this option is not preferred.

This guidance document is designed to help companies achieve MADE WISE certification standards while navigating the complex regulatory landscape of the supplement industry. By adhering to these expectations, companies can bring products to market that reflect consumer demand for safety, transparency, and accountability.

Please note that this document is not an exhaustive list of certification criteria; other documentation, testing, or other requirements may be necessary to achieve certification. The company undergoing certification is solely responsible for all expenses incurred for required laboratory testing, third- party documentation services, or requirements.

MADEWORKS Intelligence™ (formerly MadeSafe.org) has been driving marketplace change since 2015. We are building a bridge to a safer, more sustainable future for all. Using the Ecosystem Approach, MADEWORKS Intelligence generates insights that support better product development and advance systemic change. By bringing together science, industry leadership, and informed consumer choice, we help turn meaningful information into action, transforming the marketplace for a healthier world.