

# Dietary Supplement Quality Reference Guide

A broad range of supplements of varying quality is available to consumers. While some consumers are savvier than ever, there is no substitute for an educated professional who can inform and guide customers in making educated decisions about their health. Many consumers rely on the knowledge of experts like Certified Dietary Supplement Professionals (CDSPs<sup>™</sup>). CDSPs<sup>™</sup> are trained and certified to recommend safe, physiologically effective, and cost-effective supplements. This developed trust creates repeat business.

Nutritional supplements are available in many forms, including liquids, gels, chewables, powders, tablets, and capsules. When recommending an appropriate dietary supplement for a customer, many factors come into play. Age, gender, nutrient form, contraindications such as pregnancy, known allergies, prescription medication interactions, and a general understanding of the customer's health condition or concern are all factors to consider.

An essential part of helping customers make informed choices is knowing how to identify supplement quality. Lower quality formulas and brands are ineffective, leaving customers frustrated or disillusioned that supplements "just do not work." Highquality supplement companies have been combatting such stigmas for years.



# Supplement Quality Considerations

Does the price make a difference? Preservatives & Shelf Life Proper Labeling Certificate of Analysis Raw Material Quality Herb Quality

# Does the price make a difference?

For the most part, the price of a good quality supplement is irrelevant and should not be the determining factor. A poorly formulated product will not produce the desired results. As nutritionist Dr. Jonny Bowden put it, "Never look for bargains on parachutes, tattoos, and nutritional supplements." In other words, low quality supplements are a waste of money.

# Preservatives & Shelf Life

A supplement should maintain maximum purity and potency from manufacture through the expiration date stamped on the bottle. Most products have a shelf life of 1–2 years, and the date is generally 18–24 months following the date of manufacture. Check the expiration date or manufactured-on date to determine the freshness and potency of a product. Discard any products within six (6) months following the expiration date. Probiotics tend to expire sooner, within twelve (12) months or less of the manufactured-on date.

Ideally, a product should maintain potency right up to the expiration date. Dispose of discolored products that have likely oxidized or spoiled. Exposure to light, heat, or moisture will degrade a supplement even inside the bottle. For these reasons, supplements should be stored in a cool, dry place, away from heat sources. Choose dark-colored or opaque containers whenever possible. Desiccant packs, made from silica, are included in most supplement bottles containing dry ingredients designed to absorb moisture and preserve the product.

# **Proper Labeling**

A good indication of quality lies in answering the following question: Does the product disclose the specific form of a nutrient, or does it merely state its general name? High quality products list as much information about the product, nutrients, and forms of nutrients as they can fit on the bottle. Lower quality manufacturers are not descriptive about the form of the nutrient, and sometimes do not even provide milligram amounts.

Another critical question is: Does the product contain what the label states? This has become a significant issue in the supplement industry. The U.S. Food and Drug Administration (F.D.A.) regulations require that manufacturers "meet label claims." Periodic auditing of bottles randomly selected from retail outlets and tested for label claims have revealed nutrient levels far below label claims. For example, they may not contain an herb, botanical, or nutrient said to be in the formula. These violations result in the F.D.A. issuing an official warning. The manufacturer is notified of the discrepancy, and it must immediately correct the violation. The F.D.A. has the authority to remove the product line from the shelves and even dissolve the business.

# Certificate of Analysis

High-quality companies regularly conduct audits of their products and their facility (or the subcontracted manufacturer they hire) to ensure quality control and accurate label claims. As mentioned in the "Proper Labelina" section, the F.D.A. conducts these audits as well. Highquality supplement companies will provide a certificate of analysis upon request, which shows that a product meets that company's quality standards. This document reports every constituent found in a specific product and at what level. The certificate may be provided by an in-house lab or by an independent laboratory. Reputable laboratories hold verifiable membership that they meet specific standardized testing requirements.

The certificate should detail the lot number of the product tested, which tests were administered, and how. Finished products typically are not a perfect match to the label claim, but they should be within 5–10 percent of the label claim. A discrepancy greater than ten (10) percent indicates a problem with quality control in manufacturing that product.

# **Raw Material Quality**

The raw materials used in high-quality nutritional supplements are carefully sourced and tested multiple times for active constituents and impurities such as microbes, heavy metals, parasites, pesticides, herbicides, bacteria, fungi, yeast, and mold. Raw materials that test at a certain level of impurity, which is dictated by the manufacturer, are rejected and sent back to the supplier.

While the F.D.A. does have laws to regulate manufacturing practices, the allowable limits of known contaminants [i.e., microbials and heavy metals] may not be considered acceptable according to higher quality supplement companies' standards. This is why high quality companies choose to test their raw material and end product repeatedly, so they can readily provide verified documentation of their product quality to concerned consumers on an as-needed basis. In contrast, most over-the-counter and even some professional brands do not test for contaminants, choosing to trust the raw material supplier. Higher levels of impurities are considered acceptable by some brands as long as they are within the F.D.A.'s allowable limits.



National Association of Nutrition Professionals Dietary Supplement Quality Reference Guide

# Herb Quality

The American Herbal Products Association (AHPA) is a reputable organization that collaborates with supplement companies to set quality standards for growing, harvesting, storage, and manufacturing herbal products. A supplement company that is an AHPA member must manufacture products with herbs that meet the AHPA quality standards to maintain their membership with the AHPA.

## Traditional Preparations vs. Standardized Extracts

There is debate within the supplement industry regarding traditional herbal preparations vs. standardized extracts. Standardized extracts isolate a specific herb component, rather than looking at all components of an herb. Some companies choose to use them because the chemical compositions of herbs can vary for various reasons, most of them due to growing conditions, some of which are environmental. Because of the natural variances that occur, Master Herbalists who specialize on the topic will be the first to admit that it depends on the herb. This is because certain herbs' traditional preparation requires they are made into an extract for viable active constituents. In contrast, other herbs require the whole herb being present or need a water infusion instead of an alcohol-based extraction to make the active constituents viable. This is why presuming an isolated active ingredient is a substitute for the whole herb is not always accurate.

Some herbalists believe that a single extracted constituent is superior to a blended formula. There is a belief amongst traditional herbalists that herbs work via gentle, subtle synergistic actions of the full complement. However, unlike drugs, herbs may not work via only one mechanism of action. In theory, whole herb compounds are generally free from side effects, suggesting complementary components of the herb protect against unwanted side effects. Assuming that an isolated active ingredient is a substitute for the full-spectrum compound is not accurate.

Using standardized extracts for a short-term duration to achieve the desired effect may be beneficial. Otherwise, people may benefit from using full-spectrum preparations for gentle balancing effects over the long term.

## U.S.A. Supplements Allowed for European Import

Supplements from U.S.A.-based companies imported to the European Union (E.U.) are generally a higher quality due to Europe's stricter quality standards and regulations. Countries in Europe, Asia, and India have integrated botanical medicine into healthcare, and often have strict government controls regarding these products (such as Germany's Commission E). These companies produce high-quality and wellresearched products.





# Natural vs. Synthetic Nutrients

Chemically-speaking, natural and synthetic nutrients contain the same molecular constituents. However, synthetic nutrients' molecular structure differs from natural nutrients in that the molecules are arranged a bit differently. They may have the same numbers and kinds of atoms, but they differ in their structure or organization. The manufacturers who use synthetic nutrients consider this difference insignificant, but the human body differentiates between natural vs. synthetic nutrients. For example, naturally derived vitamin E is three times more absorbable than its synthetic counterpart [Prasad 1994]. Additionally, naturally sourced nutrients usually contain cofactors, enzymes, and various phytonutrients, which provide a synergistic effect that benefits absorption and efficacy.

# Food-Based vs. Food-Derived & Food-Grown Nutrients

## **Food-Based**

A marketing term used to make products appear more natural. Products with the term "food-based" on the label have added food extracts such as wheatgrass, rose hips, or herbs to a product containing synthetic nutrients.

**How to Identify Food-Based Products:** The "Supplement Facts" label will have synthetic nutrients listed and a combination of food extracts. The food extracts are usually grouped while the synthetic nutrients are listed separately.

### **Food-Derived**

One of the most bioavailable forms of nutrients are whole food concentrates made from vegetables, juices, green foods, or other whole foods extracted, freeze-dried, and placed into capsules. Flash or low heat processing can also be used to dry the product. This method guarantees that all the nutrient cofactors [i.e., phytonutrients] and other nutrients are preserved. Synthetic nutrients do not include these cofactors. Pasteurization destroys enzymes but leaves the original structure of nutrient and nutrient ratios intact.

**How to Identify Food-Derived Nutrients:** The food from which a nutrient is derived will be adjacent to the nutrient in parenthesis. See visual example for context: "Iodine (from kelp)."

### **Food-Grown**

Because some nutrients naturally occur in such minute quantities that it is not feasible to derive them from food, Food-Grown nutrients' technology was developed; made by adding a synthetic nutrient to fertilize or "feed" a healthy growth matrix. For example, synthetic B vitamins are "fed" to legume, grain, or vegetable sprouts, or a living yeast such as Saccharomyces cerevisiae. When the growth matrix consumes the synthetic nutrient, it is converted to the form naturally occurring in nature, with the correct molecular structure. Food-grown nutrients using yeast as the growth matrix may be contraindicated for individuals with yeast issues.

**How to Identify Food-Grown Nutrients:** Due to F.D.A. regulations, the synthetic form of the nutrient must be listed on the supplement label in tandem with the growth matrix in parenthesis, which can be confusing if one does not know how to interpret what they are seeing. See visual examples for additional context.

# Supplement Facts Serving Size 1 Tablet Servings per Container 30

Amount per S	erving	% DV
Thiamin (B1) (thiamine HCI with S. cerevisiae)	9 mg	750
Riboflavin (B2) (with organic brown rice)	9 mg	692
Niacin (niacinamide with S. cerevisiae)	45 mg NE	281
Vitamin B6 (pyridoxine HCI with S. cerevisiae)	10 mg	588
	) mcg DFE folic acid)	
Vitamin B12 (cyanocobalamin with S. cerevisiae	e) 50 mcg	2083
Biotin (with organic brown rice)	30 mcg	100
Pantothenic Acid (d-calcium pantothenate with organic brown rice)	45 mg	900
Crganic Kale	125 mg	
** % Daily Value (DV) not established		
Other Ingredients: Cellulose, Silica, Stearic Acid.		

# Supplement Facts

Serving Size: 4 Tablets Servings Per Container: 30

	Amount Per Serving	% Daily Value
Calcium (as calcium citrate)	200 mg	15%
lodine (from kelp)	150 mcg	100%
Magnesium (as magnesium citrate, glycinate and gluconate)	100 mg	24%
Zinc (as zinc citrate and gluconate)	15 mg	136%
Selenium (from vegetable culture †)	50 mcg	91%
Manganese (as manganese gluconate)	2 mg	87%
Chromium (from vegetable culture †)	50 mcg	143%
Molybdenum (from vegetable culture †)	10 mcg	22%
Potassium (as potassium chloride and gluconate)	99 mg	2%
Boron (as calcium borogluconate) 1 mg*, Rubidium (from veg Lithium (from vegetable culture †) 20 mcg*, Vanadium (from ve Betaine hydrochloride 30 mg*, Superoxide Dismutase (from ve Catalase (from vegetable culture †) 20 mcg*	egetable culture	t) 5 mcg*
* Daily Value not established		

Other ingredients: Stearic acid (vegetable source), modified cellulose gum and food glaze.

Supplements with Food-Derived and Food-Grown nutrients have lower potencies than products with synthetic nutrients due to the naturally occurring cofactors and phytonutrients. There are differences of opinion in the supplement industry regarding which is better or worth the money.





# **Manufacturing Practices**

Good Manufacturing Practices

# Good Manufacturing Practices

To keep quality standards consistent, the F.D.A. has created a minimum standard for supplement manufacturers to adhere to called Good Manufacturing Practices (G.M.P.s). These standards are mandated for the entire dietary supplement industry. Any manufacturers out of compliance will face legal action and the F.D.A's potential to be shut down.

The objective of G.M.P.s is to ensure that the consumer is provided with a minimum level of safety when purchasing dietary supplements. G.M.P.s ensure dietary supplements are not adulterated or misbranded by requiring constituents to be easily identifiable and measurable on the label and meet the legal specifications of the supplement label. G.M.P.s entail all aspects of manufacture: the molecular composition of raw materials, sanitation of buildings and facilities, equipment used in manufacture, production and processing controls, warehousing, distribution procedures, and personnel training. The highest quality companies choose manufacturing practices that are even more stringent than those mandated by the F.D.A.'s Good Manufacturing Practices. A supplement company that offers a guarantee is an indication that the company has confidence in its products.

Conventional medicine professionals often hold the mistaken belief that dietary supplements are unregulated or even dangerous; clearly, this is untrue. Additionally, higher-quality brands and the manufacturing facilities that produce them have their products regularly reviewed and tested to ensure products meet either the F.D.A. standards or even higher-quality company-specific standards.

## In-house vs. Contracted Manufacturing

A small percentage of supplement brands manufacture their own products. The advantage of a supplement brand company manufacturing its products is managing and overseeing its standards of quality control. In contrast, most supplement brands contract with an outside manufacturing facility to make their products. Additionally, many manufacturers purchase raw material from a tiny group of suppliers. Unfortunately, most of the market's supplements are made from the same raw material, many of which are cheap, low quality, and ineffective.

A little-known fact is that supplement manufacturers **are not required** to disclose ingredients that may have been added to raw material(s) by the supplier. A manufacturer must only disclose ingredients that they have added to a formula, such as excipients. This is why choosing high quality dietary supplement companies is critical for assuring the integrity of a product.



# **Other Considerations**

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# Health claims

Health claims cannot be included on a supplement label. Manufacturers of dietary supplements are not legally permitted to make even implied claims for a supplement regarding cure, treatment, or disease prevention. Legislation passed in 1994—the Dietary Supplement Health and Education Act (DSHEA)—allows "structure/function claims." Such statements describe the way a natural substance alters or helps maintain a bodily function or structure. Examples of structure-function claims-"helps maintain normal vision" for vitamin A or beta carotene-containing products, or "helps balance a healthy woman's monthly cycle" for herbal products that support the female reproductive system.

# **Delivery Form**

As mentioned previously, dietary supplements are available in a wide range of forms: capsules, tablets, soft gels, powders, liquids, chewable wafers, sublingual tablets, and liquid sprays and topical gels. Many of these nutrients are available in time-release or rapid dissolution forms. Several factors apply to the selection of the desired form. It should optimize the nutrient delivery and absorption (taking into account both the product's dissolution rate and the client's digestive health).

Convenience also plays a role. A product that offers two (2) capsules' recommended serving is preferable to one that recommends eight (8) tablets to achieve the same serving size. Children, the elderly, the very sick, and those who dislike swallowing pills will benefit from using liquids, powders, or chewable products. These products are ideal for those with compromised digestive systems, who have trouble breaking down tablets or capsules. Unfortunately, they are rapidly absorbable and generally high in sweeteners (to mask unpleasant tastes) and often contain additives, preservatives, and emulsifiers.

**Tablets** are the most common delivery form because they are easy to store and have a longer shelf-life than powders or liquids. However, because they are pressed during manufacturing, they may be difficult to break down for those with poor digestive function. Furthermore, the use of heat in the tableting process may destroy nutrients.

**Capsules** generally dissolve and release their ingredients quickly and easily. Like tablets, they are convenient and easy to store, though they may be more expensive.

**Entero-coated capsules or caplets** (capsule-shaped tablets) dissolve in the intestine, not in the stomach. They are best used to deliver nutrients that cannot withstand stomach acid.

**Gelcaps** are soft gelatin capsules that many people find easier to swallow than regular capsules and tablets.

Sublingual tablets, sprays, and topical products are absorbed trans-dermally and enter directly into the bloodstream. While this delivery has the advantage

of bypassing digestion, it may place an additional burden on the liver. Normal digestion and absorption from the gut deliver small amounts of nutrients at a time. The rapid entry of these delivery systems may overload the liver's capacity to process the nutrients.

Time-release products are designed to release nutrients over 6 to 12-hours slowly. They are made by coating a nutrient in tiny micro-pellets and then combining these with a special base. The cost can be higher than regular supplements. If a time-release product travels through the gastrointestinal tract before releasing its nutrient, it may bypass the absorption site.

While time-release supplements may be the right choice for water-soluble nutrients, they are contraindicated for fatsoluble nutrients.

#### Sustained-release products are

designed to keep blood levels of vitamins high for several hours. Research has demonstrated that nutrients have specific absorption sites within the small intestine.

# Timing of servings

Customers will likely seek out the advice of CDSPs™ in recommending an effective serving schedule for their supplement(s). Many fat-soluble nutrients peak in the bloodstream at 4-6 hours post-ingestion and return to homeostasis twelve (12) hours later. These are best taken twice daily. Water-soluble nutrients, on the other hand, are rapidly degraded in the body. Maintaining sufficient blood levels of water-soluble nutrients requires more frequent administration: at least three (3) times daily.

# Absorption

It is essential to select a product with a high level of absorption. However, unabsorbed nutrients do have some effect. It is not necessarily true that excess nutrients are simply excreted and therefore wasted. Research has shown that many nutrients have essential roles to play by remaining in the intestine lumen rather than being absorbed for use systemically ("Bioavailability of Nutritional Supplements – Criteria to Use When Comparing<sup>®</sup> 2019). For example, vitamin C and calcium in the large intestine offer protection against some cancers by inhibiting agents' conversion into carcinogens and enhancing healthy flora [Prasad 1994].

# Chelated nutrients

Chelation (meaning claw) is when a mineral is bonded to an amino acid. Because the body easily absorbs amino acids (including dipeptides and tripeptides), the chelation process may enhance poorly absorbed minerals. However, the bioavailability and metabolism of mineral chelates differ depending on the properties of the chelating agent. Products labeled "amino acid chelates" may not be true chelates if they are produced from metal salts, hydrolyzed protein, or amino acids derived from hydrolyzed protein. If a mineral supplement contains true amino acid chelates, the label should list the amino acid's name and to which mineral it is chelated.

A quick way to determine quality when selecting a multiple vitamin-mineral product is to look at the mineral form. Inorganic minerals such as chloride, hydroxide, oxides, phosphates, and sulfates are inexpensive and not as absorbable as chelates. Products containing more absorbable mineral chelates will cost more but are worth it. While it is important to choose an absorbable chelate, some offer more comprehensive benefits due to the attached substrate. For example, magnesium chelated to the amino acid taurine may be an excellent choice for a customer looking to support heart health. Minerals chelated to Krebs Cycle intermediates would be a good selection for a customer with fibromyalgia or chronic fatigue looking to support healthy sleep, healthy joints, and positive energy levels.

# How to choose an appropriate formulation

The metabolic (pH) effect of a product is an important consideration. For example, vitamin C (as ascorbic acid) has an acidic effect. It is best taken with meals to enhance needed digestive acids. It may be best to take buffered vitamin C products away from meals (so as not to buffer digestive secretions). ("Vitamin C Prevents and Treats Osteoporosis," 2020) Buffered vitamin C may be preferred by those who are metabolically acidic.

Another example: calcium supplied in an alkaline salt form (calcium carbonate, calcium phosphate, calcium sulfate) requires adequate gastric acidity for proper absorption. If the individual is hypochloridic (achlorhydric: does not produce sufficient stomach acid), these forms will be poorly absorbed. However, these forms will be balancing and beneficial for a hyperchloridic person (who produce excess stomach acid). The acidifying calcium citrate form is a better choice for a hypochloridic person. Research indicates achlorhydric subjects absorbed calcium citrate ten times better than calcium carbonate (Werbach,1997: 88). When making supplement recommendations with consideration for optimum nutrient forms and formulations. consult Foundations of Nutritional Medicine by Melvyn Werbach, MD, and The Encyclopedia of Nutritional Supplements by Michael Murray, ND.

# Supplements & prescription/over-thecounter drug interactions

Nutrients interact with other nutrients, and interactions can also occur between nutrients and prescription or over-thecounter medications. There are not many studies that address specific interactions. An excellent resource for determining the safety of particular nutrients for customers taking pharmaceutical preparations is **The People's Guide to Deadly Drug Interactions: How to Protect Yourself**  from Life-Threatening Drug/Drug, Drug/ Food, and Drug/Vitamin Combinations by Joe and Teresa Graedon (New York, St. Martin's Press, 1995).

# Choosing the right product

The first step in achieving nutritional goals using supplements is to choose the appropriate product. Considerations include:

- Does the product contain allergens to which the customer may be sensitive?
- Are the forms of nutrients used suitable for the customer's needs?
- Is/are the product(s) within the customer's budget?
- Is there a product that combines several nutritional needs while still providing the needed amounts of nutrients?
- Is the delivery form suitable (i.e., chewable or liquid for children)?

The best way to determine the appropriate form of a nutrient, serving amount, and recommended duration for supplementing with a given formula, is to consult 3rd party research studies. Valuable information is included in these 3rd party resources, guiding the CDSP<sup>™</sup> within their Scope of Service.

# **3rd Party Resources**

Whenever possible, consult 3rd party research studies (<u>https://pubmed.ncbi.</u> <u>nlm.nih.gov/</u> or other reputable published and referenced sources) related to the nutrient(s) a customer is interested in purchasing. The CDSP™ can check for studies conducted on that nutrient and review what type of product achieved the study's results. Consumer purchases can be made based on information outlined in the study that most closely correlates with the nutrient(s) in the product(s) being considered. Consulting the study to uncover the form, serving, frequency, and duration of administration and the delivery method is the best strategy to replicate a study's (positive) outcome.

To illustrate this point, consider this hypothetical example: a study reports the effective alleviation of headaches with 400IU of the dl-alpha-tocopherol form of vitamin E, taken three (3) times daily for four (4) weeks. Consumers cannot reasonably expect someone taking 200 IU of dl-alpha-tocopherol twice daily for one week to achieve the same pain-relieving results. Different forms of the same nutrient may have other biochemical effects in the body. The product under consideration should be manufactured similarly and should contain the same concentration of ingredients as the product featured in the research study. Any additional or combined nutrients included in the study are best duplicated in the formula under consideration to achieve the full synergistic benefit based on the study. For example, if a study utilized ginseng combined with astragalus, your formula should provide both herbs in the correct amount and ratios.



# Excipients

How to Identify

Categories of Excipients

Flavorings

# **Excipient:** An inactive ingredient used in the manufacturing process of dietary supplements

The delivery form (e.g., capsules, tablets, soft gels, liquids, or powders), active ingredients used, and the manufacturing process dictate which types of excipients are used in a product. To be clear, adding excipients to a product is not required in making supplements. Excipients are added to products to give them a specific consistency, size, or to benefit the manufacturing process.

# How to Identify

Excipients are usually listed under the "Supplement Facts" of a product label as "Other Ingredients." The number of "Other Ingredients" included in a product is one of the easiest ways to identify higher-quality supplements. Companies that use little to no excipients are the exception rather than the rule and indicate a higher quality product. Supplement manufacturers are not required to disclose ingredients that may have been added to raw material(s) by a supplier. Therefore, there are instances when inactive ingredients are not included on a product label, as mentioned in the "Manufacturing Practices" section of this guide.

The most common raw materials used to make excipients are corn, soy, grains, and nightshade vegetables (potatoes). The raw material from which excipients are made can cause digestive issues or histamine reactions in those who have sensitivities, intolerances, or allergies to that material.

Product labels may also make claims about substances a product is free of, such as "gluten-free" or "this product does not contain yeast, corn or G.M.O.s." However, these claims are not regulated by the F.D.A., only by the company making the product. The use of the ingredients milk, eggs, fish, shellfish, tree nuts, wheat, peanuts, and soybeans must be disclosed under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). The law requires manufacturers to disclose these top eight (8) allergens on the labels of food products (including dietary supplements).



# Categories of Excipients

## **Binders**

Hold ingredients of a tablet together to give cohesiveness to powdered materials. Tablets would fall apart without binders.

### Carrier

A liquid used to hold active constituents of a supplement in suspension—for example, an herbal extract or tincture, or a liquid vitamin.

### Coatings

Used to protect a tablet from moisture, mask unpleasant tastes or odors, and allow for easier swallowing. Other examples: capsules, soft gels

## Coloring

Used for product identification and cosmetic appearance. Coloring agents may be mixed in with the blend of active ingredients or excipients or included as a color coating. Coloring can be naturally or artificially derived.

### Disintegrants

Used to facilitate tablet breakdown or disintegration after ingestion.

#### **Emulsifier**

Used to keep water and fat-soluble ingredients from separating.

### **Enteric coatings**

Coating is used to control where a supplement will be released in the digestive tract.

#### **Fillers**

Increase bulk to make tablets a suitable size for the active nutrient[s] manufacturing process and consumption.

#### Flavoring

Ingredients used in chewables, liquids, and powders to mask unpleasant tastes.

#### **Flow agents**

Ingredients used to prevent powders from clogging manufacturing equipment.

#### Lubricants

Used to prevent ingredients from clumping together and sticking to tablet punches or capsule filling machines and ensuring the tablet's or capsule's ejection.

#### **Preservatives**

Used to keep active ingredients from oxidizing, rancidifying, or breaking down.

#### Solvent

Used to release the active constituents of an herb.

#### Time-release agents

Coating is used on beadlets or granules of active ingredients to facilitate controlled time-release of the active ingredient(s).

# Examples of Common Excipients

- Acacia gum (Arabic gum, Acacia, Gum Arabic, Gum sudani, Senegal gum) Binder, time-release agent Natural gum from the hardened sap of various species of the acacia tree.
- Beeswax Binder, disintegrant, emulsifier (and as stiffening agents in cosmetics)
- Benzoic acid (Potassium Benzoate, Benzene, Sodium benzoate [salt form]) Preservative (antimicrobial) Benzoic acid in the acid form is quite toxic, while the sodium salt is much less toxic.
- **Bisphenol A (B.P.A.) Preservative** Xenoestrogenic industrial chemical has been used to make plastics and resins since the 1960s.
- Brazil wax Coating Derived from palm trees
- Butylated hydroxyanisole (BHA) Preservative
  Used to prevent edible fats from going rancid.
  National Institute of Health considers it and the related
  BHT, below "reasonably anticipated to be a human
  carcinogen."
- Butylated hydroxytoluene (BHT) Preservative Stabilizes fats and is used to <u>retain food smell, color,</u> <u>and flavor</u>. (Helmenstine, Ph.D., 2019)
- Calcium phosphate (Calcium phosphate, Dicalcium phosphate, Tricalcium phosphate, Ditab)
   Filler Powdered mineral rock. Unabsorbable source of calcium.
- Calcium stearate Flow agent Calcium is bound to stearic acid, which creates a white waxy powder classified as a calcium soap.
- Caramel color Colorant Usually made from highdextrose corn syrup, often combined with ammonium compounds, acids, or alkalis. A possible carcinogen.
- Carrageenan (Irish Moss) Preservative, natural emulsifier ingredient derived from red seaweed.
- Cellulose (Microcrystalline cellulose [or MCC], Hydroxypropyl cellulose, Hydroxypropyl methylcellulose, Hypromellose, 2-hydroxypropyl methyl ether cellulose) Binder, disintegrant, coating, filler, flow agent Most commonly derived from corn, cotton, or wood pulp. Some forms are derived from wheat. Vegetarian capsules are usually made from cellulose.
- Chlorophyll Colorant The pigment that makes plants green. Extracted and used as a natural colorant.
- Citric acid (Citrate when bound to another molecule) Preservative, flavoring An acid naturally found in citrus and other fruits, but usually synthesized from corn when used in supplements—commonly used in chelated mineral formulas. Affects the pH of a product.

#### The most common names used Other common names used on labels

Excipient categories

- Croscarmellose (Croscarmellose Sodium, Acdisol, Primellose) Disintegrant Vegetable fiber is usually derived from corn modified by being molecularly bound to sodium.
- Dextrin Binder & Coating Low molecular weight carbohydrates typically derived from corn, potato, arrowroot, rice, tapioca, or wheat.
- Erythritol Filler, binder, flavoring Sugar alcohol, typically derived from corn. Lower occurrence of digestive distress compared to other sugar alcohols.
- FD&C-numbered colors Colorant Used in food and supplements to enhance color. May cause allergic reactions or may be considered carcinogenic.
- Gelcaps (Gelatin capsules) Coating Capsules used to hold liquid ingredients that would otherwise break down vegetable-based capsules. An animal by-product is made from hydrolyzed collagen protein extracted from fresh beef or pork skin.
- Glycerin (Glycerol, Glycerine, Glyceryl monooleate) Solvent, emulsifier, flavoring, and carrier Polyol compound of esterified commercial oleic acid, typically synthesized from soy, palm, or petroleum.
- Glycols (Propylene glycol) Preservative Potentially toxic to the kidneys and possibly other organs.
- Guar gum Binder, disintegrant, emulsifier Polysaccharide extracted from guar beans.
- High fructose corn syrup (HFCS, Maize syrup, Glucose, Glucose syrup, Glucose-fructose syrup, Fruit fructose, Crystalline fructose, Isoglucose, Corn syrup, Dahlia syrup) Filler, sweetener Metabolized differently than other carbohydrates due to high fructose content, HFCS can contribute to increased liver fat. For this and other reasons, high fructose corn syrup is considered unhealthy and best avoided.
- Hydrogenated oils (Partially hydrogenated oils, Trans fats) Binder, lubricant The chemical process of hydrogenation turns liquid oils into solid, unhealthy trans fats. Trans fats raise LDL and lower HDL, doubling the risk of heart disease.
- Lactose Filler, binder, disintegrant Milk sugar.
   Contraindicated for individuals who react to dairy.
- Lecithin (Lecitina, Ovolecithin, Phospholipid, Vegilecithin, Vitellin, Vitelline) – Emulsifier Commonly derived from soybeans, sunflower seeds, and egg yolks. Has been used in medicine to support liver disease.
- Locust bean gum (Carob gum) Binder, flavoring Galactomannan vegetable gum extracted from the carob tree's seeds.
- Magnesium stearate Flow agent Magnesium bound to stearic acid. A sticky, fine white powder that is greasy to the touch.

- Maltitol Filler, binder, flavoring Sugar alcohol usually derived from corn. It can cause digestive distress.
- Nitrates/Nitrites (sodium nitrite, sodium nitrate)
   Preservative Added to processed foods, most commonly cured meats. When cooked at high heat and exposed to high acid conditions in the stomach, nitrites can form nitrosamines (the same carcinogens found in cigarette smoke).
- Pharmaceutical glaze (Shellac) Coating Resin secreted by the female lac bug to form a cocoon. Impervious to stomach acid. Those with digestive maladies are sometimes unable to break down the shellac coating.
- <u>Polyacrylate</u> Time releasing agent Synthetic polymer commonly used in baby diapers and detergents. View the hyperlink for more information.
- <u>Polyvinylpyrrolidone</u> (PVP, Povidone, Polyvidone) Binder Synthetic water-soluble polymer. View hyperlink for more information.
- Salt (Sodium, Sodium Chloride, sea salt)
   Preservative Used to preserve food before the advent of refrigeration and is still used as a preservative today.
- Silicon dioxide (Sodium silicate, Cabo-Sil M-5, Flogard, Silica) Filler, flow agent Naturally occurring mineral. Serves as an anti-caking agent to avoid clumping. Research shows ingested silica does not accumulate in the body; the kidneys flush it out.
- Sorbic acid Preservative Controls the growth of yeast and molds synthesized by combining crotonaldehyde and ketene for widespread use in food and supplements.

- **Starches Fillers** Rice flour, potato starch, corn starch, tapioca, and starch/flour.
- Stearic acid (Vegetable stearine) Binder Plantderived fatty acid usually made from hydrogenated soy but can be derived from palm or coconut oil. Stearic acid in supplements is manufactured through a method of hydrolysis, which leaves stearic acid in an oily form.
- Talc Filler Added to cosmetics, food processing, and dietary supplements to create a silky feel and absorb moisture.
- Time-sorb<sup>™</sup> Time release agent [trademarked] High- and low-viscosity hydroxypropyl methylcellulose [usually sourced from corn] molecularly combined with magnesium citrate [corn] laurate. Used instead of plasticizers, magnesium stearate, and waxes.
- Titanium dioxide Colorant Naturally occurring mineral used as a bright white pigment in supplements.
- Vegetable stearin Lubricant Similar to vegetable shortening, such as Crisco®.
- Xanthan gum Binder Synthetic gum made from fermenting simple sugars with the bacteria Xanthomonas campestris.
- Zein (Vegetable protein coating) Coating Corn derived protein that provides a clear film-coating agent.

# Flavoring

Flavorings are generally added to liquids, chewable tablets, and powder mixes.

## **Natural Flavoring**

The phrase "natural flavorings" can be confusing. There is no official definition for "natural flavorings," so it can include most anything because the term "natural" has not been officially defined and is not regulated. While loosely defined as "natural," natural flavors are highly processed and contain many chemical additives. As an example, monosodium glutamate (M.S.G.) is classified as a "natural flavoring." These flavorings are extremely common in foods, beverages, and chewable or drinkable supplements. The flavoring can be created using derivatives from plant or animal sources combined with chemicals to create specific flavor profiles. "Natural flavors" are only added to enhance flavor and do not contribute to nutritional value.

#### **Sweeteners**

Commonly used sweeteners include fructose, high fructose corn syrup, malt dextrose, sorbitol, and maltose, many of which are synthesized from corn. Chewable vitamin C wafers and children's chewable products usually include substantial quantities of sweeteners.

#### **Artificial Sweeteners**

Artificial Sweeteners come in many

different forms. Some are derived synthetically, as chemicals in a laboratory setting. Others are a combination of naturally occurring organic compounds that have been molecularly manipulated in a lab. Artificial sweeteners are noncaloric but still initiate an insulin response due to the body registering a sweet taste on the tongue. Examples of the most common artificial sweeteners include:

- Acesulfame potassium (Acesulfame-K, Ace-K, Sweet One®) An artificial sweetener that may lead to harmful changes in human metabolism, mainly by disrupting glucose regulation. Use has been associated with higher body weight.
- Aspartame (NutraSweet®, Equal®) Consists of the amino acids aspartic acid and phenylalanine.
   Phenylketonuria (PKU) is a rare genetic disease that makes an affected person unable to metabolize phenylalanine properly. It can cause severe reactions in those affected by Phenylketonuria.
- Saccharin (Sweet 'N Low®, Sugar Twin®) A sulfonamide compound can cause allergic reactions in people who cannot tolerate sulfa drugs.
- Sucralose (Splenda®) Sucrose molecularly bound to chlorine.

## Sugar Alcohols – (Polyols)

Sugar alcohols have a unique chemical structure. As the name implies, sugar alcohols are hybrids of sugar molecules and alcohol molecules. Despite the mention of "alcohol," they do not contain ethanol, the compound in alcoholic beverages, and are safe for people who abstain from alcohol. Several sugar alcohols are found naturally in fruits and vegetables. However, most are processed from other sugars, such as glucose from corn or fructose from high fructose corn syrup.

The most significant difference between sugar alcohols and artificial sweeteners is that the artificial sweeteners contain zero calories, whereas sugar alcohols contain about 2.6 calories per gram.



National Association of Nutrition Professionals Dietary Supplement Quality Reference Guide Sugar alcohols can cause bloating, flatulence, and diarrhea. This is due to the digestive system lacking the ability to completely break down and digest the sugar alcohol, which causes fermentation to occur in the intestines. It is highly recommended that customers are encouraged to use products with sugar alcohols in moderation. Examples of sugar alcohols include:

- Erythritol Produced from glucose commonly sourced from corn by fermentation with yeast. It has a lower incidence of causing gas and bloating compared to other sugar alcohols.
- Isomalt An equimolar mixture of two disaccharides, each composed of two sugars: Glucose and mannitol, glucose, and sorbitol. They are commonly derived from corn.
- Lactitol (Lacty®) Used medically as a laxative.
- Maltitol (Lesys<sup>™</sup>, Maltisweet<sup>®</sup>, SweetPearl<sup>®</sup>) A disaccharide produced by hydrogenation of maltose obtained from starch [i.e., corn or potato starch].
- Mannitol (d-Mannitol, mannite, manna sugar) An isomer of sorbitol. It is contraindicated in people with anuria. Adverse effects include hyponatremia and volume depletion leading to metabolic acidosis.
- Sorbitol (Glucitol) Synthesized from high fructose corn syrup and used in diet foods as a "nutritive sweetener" because it has four calories in every gram, just like table sugar and starch but is metabolized much more slowly. Often labeled as "sugar-free" or "no sugar added" though it can raise blood glucose.
- Xylitol Originally sourced from birch. Currently, it is more commonly synthesized corn unless the ingredients specify "birch derived." Found in some dental care products because research shows consumption helps prevent bacteria from sticking to the teeth, protecting from tooth decay.

#### **Natural Sweeteners**

While refined simple carbohydrates in all forms are best limited in the diet, choosing naturally occurring sweeteners is preferable over synthesized or artificial sweeteners. Examples of naturally occurring sweeteners include:

- Beet Sugar
- Cane Sugar (Evaporated cane juice, sucrose, sucanat)
- Coconut palm nectar and crystals
- Date sugar
- Honey
- Maple syrup and sugar

- Molasses
- Monk fruit
- Rice syrup
- **Stevia** The F.D.A. prohibits this herb from being labeled as a sweetener, which is why it's common for stevia products to contain fillers such as maltodextrin or sugar alcohols.
- Yacon syrup



# Topical and Other Excipients

Skincare ingredients must be listed in order of volume or weight on the product label, with the largest first and the smallest last.

- Sodium copper chlorophyllin Derived from chlorophyll and used as a colorant and deodorizing agent in skincare products. Has been shown to repair photoaged skin.
- Artificial fragrance A "cluster ingredient" that can consist of up to 4,000 different chemicals. Companies are not required by the F.D.A. to list the chemical compounds used in artificial fragrances.
- Benzene Antimicrobial preservative.
- Bisphenol A (B.P.A.) An industrial chemical found in polycarbonate plastics and epoxy resins. Made by combining a phenol and propanone (acetone), using an acid catalyst such as hydrochloric acid. They are polycarbonate plastics, often used in food and beverage containers.
- Dairy (artificial butter flavor, butter, butterfat, buttermilk, butter oil, casein, caseinates (forms include ammonia, calcium), half & half, hydrolysates (forms include casein, milk protein, protein, lactalbumin phosphate, lactoglobulin, lactose, lactulose), milk (forms include condensed, derivative, powder, dry), whey (forms include delactosed, demineralized.)) Ingredients found on a label indicate the presence of milk protein.
- Dimethicone (polydimethylsiloxane) Made from dimethyldichlorosilane, which is produced by powdered silicon (silicon dioxide) and methyl chloride. An anti-foaming agent in skin and hair conditioners. Prevents water loss by forming a barrier on the skin.
- EDTA (Edetate disodium, ethylenediaminetetraacetic acid, calcium disodium.) A chelating agent capable of removing heavy metals from the blood. It is used to lower blood levels of calcium when dangerously high.
- Ethanolamines (M.E.A. -monoethanolamine, D.E.A. -diethanolamine, T.E.A. -triethanolamine) Ammonia compounds used in cosmetics as emulsifiers or foaming agents. Clear, colorless, viscous liquids with ammonia-like odors that have the combined properties of alcohols and amines. Found in many consumer products ranging from cosmetics, seven (7) personal care products, and household cleaning products. (Miracolo, n.d.)
- Formaldehyde and derivatives (formalin, formic aldehyde, methanediol, methanol, methyl aldehyde, meth-ylene glycol, methylene oxide.)
   A colorless, toxic, potentially carcinogenic, watersoluble gas, (CH2O)6, usually derived from methyl alcohol by oxidation: used chiefly in aqueous solution, as a disinfectant and preservative. ("Definition of formaldehyde | Dictionary.com," n.d.)

- Gluten (Triticum vulgare (wheat), Triticale (a cross between wheat and rye), Hordeum vulgare (barley), Secale cereale (rye), Triticum spelta (spelt, a form of wheat), wheat protein/hydrolyzed wheat protein, wheat starch/hydrolyzed wheat starch, wheat flour/bleached flour, bulgur (a form of wheat), malt (made from barley), couscous (made from wheat), farina (made from wheat), pasta (made from wheat unless otherwise indicated), seitan (made from wheat gluten), wheat or barley grass (will be cross-contaminated), wheat germ oil or extract (will be cross-contaminated). Used to intensify the absorption and assist in the breaking down and digestion of the supplement.
- Isopropyl alcohol (rubbing alcohol) Alcoholic mixture intended for external use as an antiseptic.
- Parabens (propylparaben (propyl 4-hydroxybenzoate), butylparaben (butyl 4-hydroxybenzoate), ethylparaben (ethyl 4-hydroxybenzoate,) heptylparaben (heptyl 4-hydroxybenzoate), methylparaben (methyl 4-hydroxybenzoate.) Parabens are esters of parahydroxybenzoic acid. Part of a family of preserva-tives used to keep formulas free from bacteria, mold, and fungi and extend the shelf life of items containing water.
- P.E.G.s (polyethylene glycols) Petroleum-based compounds used in cosmetics as thickeners, solvents, softeners, and moisture-carriers are commonly used as cosmetics cream bases.
- Petroleum (mineral oil, [see P.E.G.s (polyethylene glycols) above], [see phthalates below], white oil, paraffin oil, liquid paraffin (highly refined medical grade), liquid petroleum, baby oil (perfumed mineral oil) a liquid by-product of refining crude oil to make gasoline and other petroleum products. ("Mineral oil", 2020) Used in commercial moisturizing products for dry, cracked skin, dandruff and also used for relieving constipation.
- Phthalates (DBP (dibutyl phthalate), DNOP (di-n-octyl phthalate), DiNP (diisononyl phthalate), DEP (diethyl phthalate), BBP (benzyl butyl phthalate), DEHP (di 2-ethylhexl phthalate), DiDP (diisodecyl phthalate), DnHP (di-n-hexyl phthalate), DMP (dimethyl phthalate), DnOP (di-n-octylphthalate.)
   Petroleum derived, used as plasticizers to keep plastic from becoming brittle and breaking.



- Plasticizers (Bis(2-Ethylhexyl) adipate (DEHA) Dimethyl adipate (DMAD) Monomethyl adipate (MMAD) Dioctyl adipate (DOA) Dibutyl sebacate (DBS) Dibutyl maleate (DBM) Diisobutyl maleate (DIBM) Bis(2-Ethylhexyl) phthalate). (See also phthalates above.) It is used to improve the softening and deformation of a material, as desired in nail polishes, lip gloss, and shampoos.
- Silicates /silicones Derived from heat and chemical resistant silicone rubber. Silicon is a naturally occurring element; silicone is human-made from a synthetic polymer made of silicon, oxygen, carbon, and hydrogen. (Castro, 2013) Generally, a liquid or a flexible, rubber-like plastic gives beauty products a silky feel and spreadable texture. (Also see Dimethicone above.)
- Sodium Lauryl / Lauryl Sulfates (Sodium Lauryl Sulfate (S.L.S.), and Sodium Laureth Ether Sulfate (SLES.) Created by combining lauryl alcohol with petroleum or with coconut or palm oil. An anionic detergent and surfactant found in personal care products. Sodium Laureth Ether Sulfate is considered more toxic because of its process to make it less harsh called ethoxylation. Ethoxylation is a process that results in two contaminants, ethylene oxide and 1,4-dioxane, linked to cancer. (Bondi et al. 2015)



# Questions to Ask a Supplement Company

Nutritional supplements are not intended to replace high-quality food. That is why they are called supplements. They are intended to supplement a nutritious diet. There are many challenges to the most health-sensitive, including the relatively poor food supply in the United States, toxins, pesticides, estrogen-mimicking chemicals, depleted soil, and polluted water. Many health professionals have determined that it is no longer possible for consumers to obtain all the nutrients they need, in the amounts necessary, entirely from food sources.

Consumers can now benefit from the education and expertise of the Certified Dietary Supplement Professional™ to assist them in selecting the highest quality supplements that support their nutrition goals and optimize their health.

- 1. What are the quality standards for your products?
- 2. What quality control measures do you have in place to ensure your products consistently meet your own quality standards?
- 3. Does your company manufacture its own products?
- 4. If you contract out your products' manufacturing, how do you ensure that your products regularly meet your quality standards?
- 5. Do you have documented evidence that products regularly meet your quality standards, such as Certificates of Analysis?
- 6. Can I get a Certificate of Analysis for a specific product (lot # \_ \_ \_ )?
- 7. How long does it take for the raw materials you purchase to become a finished product on the shelf?
- 8. Can you give me a complete listing of all the raw materials used in your products, including all excipients? If not: Can you give me a list of all the raw materials your products are guaranteed \*not\* to contain? For example, free of G.M.O.s, dairy, gluten, soy, heavy metals, etc.?
- 9. Can you provide documentation that your raw material and end products are all tested to be free of these substances?
- 10. Are the nutrients in your products naturally derived, synthetic, or a combination of the two?
- 11. Please share the reasons why your company decided to use the specific nutrient forms in your products.
- 12. Do you have studies on the efficacy of your products?
- 13. Does your company have affiliations with other companies (perhaps overseas)?
- 14. Does your company donate a percentage of profits annually toward research or otherwise demonstrate a commitment to research?
- 15. Do you have research abstracts or technical sheets available for practitioners?

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