

# USANA Technical Bulletin

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## Excipients

### Technical Background

Excipients are non-medicinal ingredients used in manufactured products to impart desirable characteristics important for manufacture, convenience of use, and product efficacy. Most excipients are inert materials that are blended with the active ingredients prior to manufacturing or tableting. Excipients may be classified as follows according to their general function.

- **Binders** are added to hold a tablet together after it has been compressed. Without binders, tablets would break down into their component powders during packaging, shipping, and routine handling.
- **Coating Agents** are used to impart a finished look and a smooth surface to tablets, and to mask any unpleasant flavors the tablet ingredients may have. Coating agents are applied (in a separate operation) after tablet pressing.
- **Disintegrants** are used to ensure that when a tablet is ingested, it breaks down quickly in the stomach. Rapid disintegration is a necessary first step in ensuring that the active ingredients are bioavailable and readily absorbed.
- **Emulsifying agents** are widely used as dispersing, suspending, and clarifying agents. They are used to stabilize blends of liquids that are not mutually soluble, and to improve the bioavailability of some lipid-soluble compounds.
- **Lubricants** are required during manufacture to ensure that the tableting powder (i.e. the raw ingredient blend) does not stick to the pressing equipment. Lubricants improve the flow of powder mixes through the presses, and they help finished tablets release from the equipment with a minimum of friction and breakage.
- **Sweetening and Flavoring Agents** are commonly added to chewable tablet formulations to improve taste, texture, and overall palatability.

### Excipients Used in USANA Products

Several excipients are used in USANA formulations. They are selected for their non-toxicity and contribution to the overall integrity and performance of the product. All have excellent safety profiles and meet the requirements of the U.S. Pharmacopeia guidelines. Many serve multiple functions (e.g. disintegrant and binder). All are “high performance,” meaning that minimal amounts can be added to achieve the desired effects. Descriptions of each follow.

- **Annatto seed extract** is a natural yellow food colorant obtained from the seeds of the Bixa Orellana tree. It is used in gencaps as an opacifier.
- **Ascorbyl Palmitate** is used primarily as a lubricant; it improves the flow of tableting powders in the presses during manufacture and facilitates ejection of tablets from the

equipment following compression. While more costly than standard lubricants, ascorbyl palmitate (a fat-soluble form of vitamin C) also provides some additional vitamin C activity.

- **Beeswax** is a natural wax that functions as an emulsifier. It is used to blend and stabilize liquids that are not mutually soluble, as well as improve the bioavailability of certain lipid-soluble compounds.
- **Citric and Malic Acid** are used primarily as flavoring agents (due to their tartness). Citric acid is found mainly in oranges, lemons, and limes. Malic acid is found in a wide variety of fruits, including apples and cherries. These acids may also function as antioxidants in certain types of formulations.
- **Colloidal Silicon Dioxide** is an extremely fine form of silicon dioxide. (Silicon dioxide occurs naturally as quartz or sand.) It is a white powdery material that is used in formulations to promote flow of tableting powders and to prevent their sticking in tablet presses. It also promotes tablet disintegration.
- **Croscarmellose Sodium (Sodium Carboxymethyl Cellulose)** is called a “super disintegrant” because it is very effective – even at very low concentrations – at promoting the breakdown of tablets following ingestion. It is manufactured from cellulose (plant fiber) which has been processed to have a high affinity for water.
- **Dextrose** is a simple sugar used in some formulas as both a binder and disintegrant, but in most tablets it is contained in very small amounts as part of the coating mixture.
- **Fructose and Xylitol** are used in chewable tablets as sweetening agents, where they serve to mask the unpleasant taste of vitamins and minerals and to improve overall texture. These natural sweeteners are extracted and purified from plant sources (particularly from fruits). In addition, these ingredients have good binding properties and aid in tablet formation and integrity.
- **Gelatin** is a refined and purified protein that functions as a stabilizer, binder, and gelling agent. It is commonly used in soft and hard gel capsules.
- **Glycerin (vegetable derived)** functions as a humectant and a solvent and is essential to the pliability and stability of gelcaps.
- **Glycerin mono-oleate** functions as an emulsifier, and is derived from glycerine and fatty acids (such as oleic acid).
- **Guar Gum** functions as a strong binder. It helps to keep the tablets from disintegrating during packaging, storage, and handling. It is derived from the seed kernel of the guar plant.
- **Honey powder** is a purified natural sweetener used in chewable tablets for sweetening and flavor.
- **Lecithin** functions as an emulsifier. It is used to stabilize blends of liquids that are not mutually soluble, and to improve the bioavailability of certain types of lipid-soluble compounds. It is generally derived from soybeans.
- **Lemon oil** is a natural oil used to reduce undesirable aftertaste in fish oil capsules.
- **Medium-Chain Triglycerides (MCTs)** are derived from coconut oil and are more readily digested, absorbed, and metabolized than either animal fats or vegetable oils (which contain mainly long-chain triglycerides). MCTs are an excellent delivery system for fat-soluble elements – such as vitamin E – especially for individuals with fat malabsorption disorders. MCTs do not contribute to a rise in blood cholesterol.

- **Microcrystalline Cellulose** serves multiple functions in tablet formulas. It is an excellent binder and disintegrant. It is derived from plant fiber.
- **Modified Food Starch (Dextrin)** functions as a stabilizer and a binder. It may also help improve tablet solubility and texture. It is produced from starch.
- **Natural caramel color** is used in the Palmetto Plus capsule as an opacifying agent. It protects the active ingredients from exposure to light and improves appearance consistency.
- **Natural citrus flavors**, like citric and malic acid, are used as flavoring, and for tartness in chewable tablets.
- **Salt** is used in the Usanimals for flavoring purposes. It is a purified sea salt.
- **Soybean oil** is used in some gelcaps as a carrier for active ingredients, including mixed tocopherols (vitamin E).
- **Starch and Pregelatinized Starch** are used primarily as binders to improve tablet durability and integrity. Both are derived from corn. Pregelatinized starch is partially hydrolyzed and dried to make it flow better during tableting. It also has superior binding characteristics. Starch and pregelatinized starch are also used as disintegrants. After ingestion, these starch granules swell in the fluid environment of the stomach and force the tablet to break apart.
- **Titanium Dioxide** is a naturally-occurring white pigment that functions as an opacifier and white food coloring agent. It occurs naturally in minerals, and is used in a wide variety of consumable products.
- **Tri-calcium phosphate** is a form of calcium and phosphorus used as an anti-caking agent in the TenX bar.
- **Vanilla (natural flavor or extract)** is a natural water-based flavor used to mask undesirable taste in the chelated mineral, and for general flavoring in the chewable calcium tablets.