KLAIRE LABS®

TECHNICAL NOTES

Magnesium Stearate

What is Magnesium Stearate

Magnesium stearate ($C_{36}H_{70}MgO_4$) is the magnesium salt of stearic acid, an 18-carbon fatty acid found in many foods. It is widely used in the production of cosmetics, nutraceuticals, and pharmaceuticals, and was present in 108 of the top 200 drugs from the year 2003.[1] It is an excipient—an inert ingredient in a capsule or tablet that acts as a carrier for the active ingredient, to provide suitable consistency or form.[2,3,4] Magnesium stearate (MgSt) is useful in the manufacture of pharmaceutical and nutraceutical capsules and tablets by acting as a lubricant. By promoting the smooth flow of ingredients through manufacturing equipment, magnesium stearate helps ensure the uniform distribution of active ingredients in capsule fills and tablets, thereby assuring consistent and accurate dosing.

Magnesium stearate and stearic acid are used by the vast majority of reputable dietary supplement and drug manufacturers to improve product quality and consistency. A publication by Rutgers University, entitled "Effects of Magnesium Stearate on Tablet Properties," reports that tablets containing 1% magnesium stearate have the least dose deviation, the most uniformity in composition, and maintain the highest percentage of drug release.[5] The substance is biologically inactive and is considered safe enough to be used by numerous routes of administration, including oral capsules, inhaled powders,[6,7] oral powders, tablets, sublingual tablets, vaginal suppositories, topical preparations, intravitreal implants, and injections.[2] It is widely used, not only in the production of dietary supplements and pharmaceuticals, but also in many food products, including candy, spices and baking ingredients.

Safety and Toxicity of Magnesium Stearate

Magnesium stearate is considered to be non-toxic,[2,4] and is Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration (FDA).[8] It is approved for use in food and dietary supplements as a lubricant and release agent, emulsifier, binder, thickener, anticaking and anti-foaming agent.[2,4,9] In addition to the United States, it is accepted as a safe food additive in Europe, the UK, and Canada. A specification for magnesium stearate is also included in the Food Chemicals Codex (FCC), a collection of internationally recognized standards for the purity and identity of food ingredients.[10] According to the FDA, there is no evidence to suggest that magnesium stearate causes adverse effects when used "at levels that are now current and in the manner now practiced, or which might reasonably be expected in the future."[11] Animal research shows that orally-administered magnesium stearate is non-toxic far beyond the commonly used amounts.[12] Additionally, as recently as 2015, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) conducted a safety assessment of magnesium stearate and found no concerns regarding its continued use or safety.[13]

It is important to read critically any claims of harm attributed to a substance that is Generally Recognized As Safe (GRAS) by the FDA. You will notice that many such articles fail to provide scientific references for their claims, which means they are essentially unsubstantiated opinion pieces. In contrast, the information in this bulletin has been fully substantiated and is corroborated by consensus of the scientific and medical communities.

Effect on Nutrient Bioavailability and Absorption

MgSt is a fat-soluble (water-insoluble, or hydrophobic) molecule. In the body it is broken down to its constituent fat (stearic acid) and magnesium. Stearic acid (a fatty acid) is subsequently broken down into harmless mono- and di-glycerides. In one manufacturer-sponsored video, it was claimed that magnesium stearate adversely affected the absorption of dietary supplement ingredients.[14] What was actually demonstrated was the comparative water- and fat-solubility of vitamin C and MgSt. Hydrophilic ("water-loving") Vitamin C readily dissolved as expected, while magnesium stearate did not, because it is fat-soluble, not water soluble. The conclusion that MgSt inhibited the solubility of vitamin C was incorrect and misleading. A glass of water does not replicate the conditions in the human digestive tract, but it is possible to do so. In fact, MgSt dissolves readily in the fluids of the stomach and small intestine, a medium that is replicated by GMP quality analytical testing for dissolution of dietary supplements.[15]

The process of digesting fats and oils starts in the mouth, continues in the stomach, and culminates in the small intestine with the aid of lipase and bile salts. Such conditions within the human body are required for the digestion of MgSt and other fat-soluble nutrients. Although the Vitamin C demonstration created a visual effect, it is irrelevant to human digestion and nutrient absorption. In fact, there is no published research in the scientific literature, in humans or in animals, to support the claim that magnesium stearate reduces nutrient absorption when used appropriately in tablet or capsule manufacturing.

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

In fact, magnesium stearate has been shown to *enhance* the delivery of some dietary ingredients. For example, chemists seeking to improve the absorption of calcium by improving its release in the intestine found that magnesium stearate was superior to other excipients in optimizing the delivery of a time-release formulation.[16] It is also worth noting that in vitro and in vivo studies have shown that increasing the concentration of magnesium stearate in tablets does not affect the release of active ingredients.[17,18,19] In a bioavailability study in human subjects, pharmaceutical tablets containing varying amounts of magnesium stearate (0.5–2.0%) produced nearly identical peak plasma levels of the active drug, and investigators concluded that the preparations were bioequivalent.[13]

Prevalence of Stearic Acid in Foods

Magnesium stearate is about 96% stearic acid and 4% elemental magnesium. Stearic acid is a common, naturally-occurring saturated fatty acid— found in high levels in quality foods such as salmon, olive oil, beef, eggs, etc.—and is a common component of a healthy diet. The table below shows amounts of stearic acid in one serving of various foods, based on the USDA Agricultural Research Service database, versus that found in a typical dietary supplement capsule and powder product.[20]

TYPE OF FOOD	SERVING SIZE	STEARIC ACID (mg/serving)
Olive oil	1 tbsp (13.6 g)	517mg
Sunflower oil, high oleic	1 tbsp (13.6 g)	588 mg
65% dark chocolate	1-2 squares (7g)	930mg
Coconut oil	1 tbsp (13.6 g)	381 mg
Almonds, raw	1 oz (28.4g) 23 whole almonds	19mg
Brazil Nuts	1 oz (28.4 g) 8 medium whole Brazil nuts	164mg
Dietary supplement, capsule (@1% magnesium stearate)	500 mg	4.8* mg

**Magnesium stearate is about 96% stearic acid.*

Formulating With Magnesium Stearate

Our clean label philosophy dictates that formulations will only include excipients as absolutely necessary, and then only safe excipients are used, in the smallest amounts required to achieve a consistent quality product. When required to ensure the uniform distribution of active ingredients, Klaire Labs' formulation scientists may judiciously include 100% plant-derived magnesium stearate as a lubricant. As a capsule lubricant, magnesium stearate has no peer. Other lubricants are occasionally used in various formulas, such as the amino acid leucine, or the antioxidant ascorbyl palmitate, but these substances do not have comparable properties to MgSt and are not appropriate replacements in all circumstances. When added as an excipient, a 1% concentration of MgSt is typical, but may range from 0.5% to 5% depending on the formula. It is important to emphasize that the amount of stearic acid in a typical dietary supplement is insignificant compared to what is routinely consumed from food (e.g., 1 tablespoon of olive oil contains 266 mg of stearic acid). In fact, the food industry has developed methods to *enrich* fats with stearic acid as an alternative to hydrogenation, because of beneficial effects of stearic acid on blood lipids and clotting.[21]

Our Commitment

At Klaire Labs our focus on simplicity is paired with an unwavering commitment to hypoallergenicity, product purity, and rigorous quality control. At the core of our approach stands the uncompromising dedication to making effective, scientifically validated dietary supplements that work for the most sensitive individuals. Judicious and safe use of MgSt among other ingredients to ensure quality, consistency, and bioavailability is consistent with this commitment.

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