

Magnesium Stearate and Stearic Acid Fact Sheet

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Some manufacturers of nutraceutical products try to differentiate themselves from their competitors by emphasizing that they do not use magnesium stearate in their products. Worse, in their effort to market their products, they cast a negative picture on magnesium stearate claiming that it is deleterious to health and that it affects bioavailability of nutrients. However, the scientific data to support their point of view is very weak and some of the scientific references cited are taken out of context to support their point of view.

What are Magnesium Stearate and Stearic Acid

Magnesium stearate ($C_{36}H_{70}MgO_4$) is the magnesium salt of stearic acid (octadecanoic acid; $C_{18}H_{36}O_2$), mainly derived from plant and animal sources. Magnesium stearate and stearic acid are among the most commonly used excipients in the pharmaceutical and food industry. An excipient is an inert, non-active ingredient to assist in the physical process of making tablets and capsules, either as fillers, glidants or lubricants. Many dry powder ingredients would not quickly and evenly (uniformly) flow into capsules without an excipient to enhance the free flow of the powder particles.

Safety and Toxicity of Magnesium Stearate and Stearic Acid

Magnesium stearate is a US FDA approved food and cosmetic ingredient and is classified as GRAS, *a food substance that is not subject to premarket review and approval by FDA because it is generally recognized, by qualified experts, to be safe under the intended conditions of use* (1). Of the more than 3,000 substances that comprise the US FDA EUFUS (Everything Added to Food in the United States) database, magnesium stearate has the notation “ASP” which means that a “fully up-to-date toxicology information has been sought” (2). An extensive search of the scientific literature did not unearth any documented toxic and safety concerns with magnesium stearate. One study that evaluated the effects of magnesium stearate on rats concluded that the no-effect-level is estimated to be 5% magnesium stearate in the diet, equivalent to an intake of 2.5 grams per kg body weight per day (3). This would be the equivalent of a daily intake of approximately 170 grams per day for a 150-pound individual.

Stearic acid, the parent compound of magnesium stearate, is also GRAS and has the same “ASP” notation in the US FDA EUFUS database (2). A search of published articles on stearic acid did not show articles documenting adverse effects of stearic acid to human health. Instead, there is an emerging body of literature supporting beneficial effects of stearic acid. One study showed that stearic acid-rich diet has positive effects on thrombogenic and atherogenic risk factors in males (4). In another study, food high in stearic acid favorably affected blood lipids and factor VII coagulant activity in young men (5). Stearic acid-rich diet did not result in significantly higher plasma cholesterol concentrations compared to low-fat diet (6).

Effect on Nutrient Bioavailability

A thorough search of published peer-reviewed literature did not show any published data showing that the presence of magnesium stearate has a negative effect on dietary supplement absorption due to poor dissolution. Dissolution refers to the rate and effectiveness at which a tablet dissolves. One study reporting lower dissolution with magnesium stearate as a lubricant was more due to the form of starch excipient used rather than magnesium stearate. The report goes to conclude that “the rate of dissolution was not affected when the drug and pregelatinized starch were mixed with magnesium stearate for a prolonged time due to the absence of magnesium stearate flaking and film formation” (7). In fact other studies with pharmaceutical drugs show that magnesium stearate has no significant effect on drug dissolution (8, 9). One dietary supplement manufacturer making an issue of magnesium stearate negatively affecting nutrient absorption made a case with niacin. It claims that niacin with magnesium stearate will cause the nutrient to be delivered to the small intestine, thus decreasing absorption. Granting that absorption of niacin happens in the stomach (in contrast to most nutrients that are known to be absorbed in the small intestine), Bechgaard and Jespersen in 1976 (10) concluded that “By using the GI tube technique, niacin was shown to be equally well absorbed from the stomach and the upper small intestine. . . Thus, the physiological prerequisites for a physically retarded niacin preparation were established.”

Prevalence of Stearic Acid in Foods

Stearic acid (C 18:0) is one of the most commonly occurring saturated fatty acids in animal and vegetable fats and oils. The stearic acid contained in one serving of various foods based on the USDA Agricultural Research Service database (11) and in a typical dietary supplement capsule and powder product is shown below:

TYPE OF FOOD	SERVING SIZE	STEARIC ACID (mg/serving)
Soybean oil, salad or cooking	1 tbsp (13.6 g)	517
Canola oil	1 tbsp (13.6 g)	245
Corn oil, salad or cooking	1 tbsp (13.6 g)	251
Olive oil, salad or cooking	1 tbsp (13.6 g)	266
Sunflower oil, high oleic	1 tbsp (13.6 g)	588
Coconut oil	1 tbsp (13.6 g)	381
Palm oil	1 tbsp (13.6 g)	585
Beef patty, 80% lean meat/20% fat, pan-broiled	85 g (3 oz)	1,599
Bacon, cured, broiled, pan-fried or roasted	8 g (1 slice)	343
Chicken drumstick, fried, bone and skin removed	42 g	248
Dietary supplement, capsule (@1% magnesium stearate)	500 mg	4.8*
Dietary supplement, powder (@1% stearic acid)	1,000 mg (1 g)	10

*Magnesium stearate is about 96% stearic acid.

Science First

Designs for Health is committed to making pure and effective products. We take our science-first underlying business principle very seriously and will never make products that will compromise the health of our customers. DFH uses either magnesium stearate or stearic acid that is 100% plant-derived in several of its dietary supplement capsule and powder products. When either is used, the application rate is about 1% (anywhere from 1 mg to 10 mg per capsule or serving of powder). As shown in the table above, the amount of stearic acid in a typical dietary supplement product is insignificant compared to what consumers get from food -- 266 mg stearic acid/1 tbsp of olive oil, 1,599 mg/85 g (3 oz) of pan-broiled beef patty, 343 mg/slice of cooked bacon, 248 mg/42 g of chicken drumstick meat, for example. In fact, there is a move in the food industry to enrich fats with stearic acid as an alternative to hydrogenation because of the beneficial effects of stearic acid on lipids and thrombosis (12).

The Designs for Health line is mainly capsules and powders. Most patients prefer to swallow capsules rather than tablets. Many health professionals choose Designs for Health powders that are, as often as possible, free of all excipients and allow for more aggressive dosing as desired for efficacy. We are proud of the results obtained with our product line and are gratified by the ability to help those in health crisis.

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