Hello everyone,

There has been a lot of unfounded bad press circulating about magnesium stearate (an ingredient found in many dietary supplements). The articles below are attached for your convenience.

Thanks,

Annette


Whether you've had customer inquiries or received e-mail alerts, there have been concerns raised regarding the safety of stearic acid and magnesium stearate in dietary supplements. Stearic acid is a saturated fatty acid found in many foods, including animal and vegetable fats and oils, and cocoa and flaxseed. Magnesium stearate is a magnesium salt of stearic acid—a compound containing two stearic acids and one magnesium.

In the body, stearic acid is primarily converted into oleic acid (a monounsaturated fatty acid). Oleic acid comprises the majority of olive oil, and may also be found in substantial quantities in grape seed oil, sea buckthorn oil and the açai berry. In addition, oleic acid may be responsible for the blood pressure-reducing effects of olive oil. Consequently, even though stearic acid is a saturated fat, studies have suggested it has no negative effect on blood cholesterol levels since such a high proportion is converted to oleic acid. In fact, some research indicates stearic acid actually lowers low-density lipoprotein (LDL) cholesterol. After magnesium stearate is broken down into its component parts in the body, its fat is essentially the same as that of stearic acid, except the magnesium molecule supplies the body with this essential mineral.

Both compounds have become more commonly used in dietary supplements. Stearic acid is commonly used as a binder in tablets, and it has lubricant properties. Magnesium stearate is a lubricant commonly used in tablet formulations. After achieving a homogenous blend of powdered ingredients, adding a small amount of magnesium stearate enables the powder blend particle surface to be sufficiently coated while limiting penetration of the lubricant within the particle matrix. This allows tablets to be punched without sticking to the machinery, or capsules to glide shut easily and eject from the machinery.

The amounts of stearic acid and magnesium stearate typically used in a tablet are relatively minute. Stearic acid typically ranges between 0.5 and 10 percent of the tablet weight, while magnesium stearate typically represents 0.25 to 1.5 percent of the tablet.
weight. Therefore, in a 500 mg tablet, the amount of stearic acid would probably be about 25 mg, and magnesium stearate about 5 mg.

**Addressing Concerns**

Given the small amounts used in supplements, what are the concerns being raised? There are basically two objections to the use of stearic acid and magnesium stearate in dietary supplements. The first objection is that, in some way, these ingredients will interfere with absorption of the nutrients in the tablet. The problem is that the method by which the interference is supposed to occur has not been clearly explained. Further, it would be easy to consume far more stearic acid in a regular meal than via a dietary supplement. For example, one piece of roasted chicken thigh delivers around 359 mg of stearic acid. Likewise, one-half bar of milk chocolate (about 112 calories) includes 1,283 mg of stearic acid. Following this concept to its logical conclusion means it would be necessary to avoid all food that contains stearic acid when taking supplements. However, people routinely take their supplements with meals, yet still absorb the nutrients provided by those supplements.

The other objection to stearic acid and magnesium stearate in dietary supplements is related to a possible negative effect on immunity. The primary source for this concern is the scientific journal article, “Molecular basis for the immunosuppressive action of stearic acid on T cells.” Researchers relate the results of an in vitro experiment where stearic acid suppressed immune activity of T cells.

Brad Douglass, Ph.D., education manager at Jarrow Formulas, reviewed the article, and raised some concerns. “It is important to consider that previous studies have shown T-cells lack the enzymatic machinery to metabolize stearic acid, which makes the findings of that study a bit suspicious,” he said. “Second, the total concentration of free fatty acids in the plasma of a healthy adult is about 100 times less than the amount of free stearic acid it took to kill the T-cells in vitro. In other words, in real life this couldn’t really happen.”

Further to Dr. Douglass’ point, the study was in vitro, which means it was done in the equivalent of a test tube, not in a human being, or even an animal. This is important since what happens in a test tube will not necessarily happen inside the body. For example, in 1991, some researchers found when vitamin C was mixed in a test tube with some fatty acids, there was a pro-oxidant effect that damaged DNA and which could, theoretically, be a step toward forming cancer cells. However, when tested in actual human beings, the opposite was found to be true; vitamin C protected against DNA damage and cancer.

So would these in vitro results be similar in humans? Likely not. Consider a study in which immune competence was tested by a battery of T- and B-lymphocyte stimulation tests and also by natural killer (NK) cell activity in a group of 94 men receiving different fatty acids, including stearic acid. Stearic acid was actually found to have a positive effect on immunity, particularly NK cell activity. In any case, whether the effects on immunity were positive or negative, the amount of stearic acid and magnesium stearate found in dietary supplements is still too insignificant to matter.
The take home message? Do not be concerned with potential negative effects from stearic acid and magnesium stearate in dietary supplements. The objections raised are not borne out by research. Both of these substances are safe and essentially harmless in the amounts used in dietary supplements.

References:
Stearic Acid and Magnesium Stearate

By Neil E. Levin, board certified clinical nutritionist (CCN) with diplomate in advanced nutritional laboratory assessment (DANLA), Nutrition Education Manager, NOW Foods

Most people concerned about the tiny amount of stearic acid in a capsule actually consume far more from healthy food sources, safely. Meat, coconut oil and chocolate (cocoa butter) are particularly rich sources. Additionally, researchers do not consider stearic acid to be a lipid that is harmful to cardiovascular health.

NOW’s magnesium stearate is derived solely from palm oil. It is a magnesium salt of fatty acid [C16 to C18], and contains no trans-fatty acids. It is non-GMO, free from BSE/TSE and may be used, if desired, as part of a vegetarian or vegan diet.

Stearic acid is a waxy oil fraction that acts as a lubricant to fill capsules when a dry powdered ingredient (or ingredient mix) is uncooperative, based on issues involving density, stickiness, flowability under pressure, etc. It is also used as an ingredient that helps tablets hold together and break apart properly.

Stearic acid (also called Octadecanoic Acid) is one of the most common long-chain fatty acids, found in both natural animal and vegetable fats, known also by its structural description of being an 18-carbon chain fatty acid (18:0) with a chemical structure of \( \text{C}_{36}\text{H}_{70}\text{MgO}_4 \).

Magnesium stearate is a combination of stearic acid and the essential mineral magnesium. Magnesium stearate contains the equivalent of not less than 6.8 percent and not more than 8.3 percent of MgO (Magnesium oxide), and is a mixture of pure stearic acid and palmitic acid where the content of stearic acid is not less than 40.0% and the sum of the two acids is not less than 90.0%. The British Pharmacopoeia 1993
describes magnesium stearate as consisting mainly of magnesium stearate with
variable proportions of magnesium palmitate and magnesium oleate.

NOW uses USP grade stearates tested to US Pharmacopeia standards; known as
pharmaceutical grade, the highest purity.

Stearic acid is naturally present in many foods in far greater quantities than in
supplements. Stearic acid is also the immediate precursor of oleic acid, an important
fatty acid found in healthy olive oil.

NOW uses stearic acid and magnesium stearate that are sourced from vegetable oils
obtained from palm and other natural sources. These ingredients are widely considered
to be safe, and are suitable for vegetarians and vegans.

An American Journal of Nutrition published review of beef’s effect on cholesterol
reported that, “Beef products are the most common source of dietary stearic acid in the
United States. Because beef fat is 19% stearic acid, the cholesterol-raising potential of
beef is not as great as predicted by its total saturated fatty acid content...Data suggest
that lean beef is no more hypercholesterolemic than chicken or fish and, therefore, lean
beef need not be eliminated from cholesterol-lowering diets.” ¹

Stearic acid is also one of the main fats in cocoa butter, and this particular fatty acid is
considered safer than others present in cocoa butter. A report from the University of
Texas Southwestern Medical Center confirmed this: “It has been known for some time
that cocoa butter, although rich in saturated fatty acids, does not raise total serum
cholesterol concentrations as much as expected from its total saturated fatty acid
content...In a recent experiment cocoa butter did not raise LDL cholesterol as much as
predicted by its total saturated fatty acid content.” ²

The Encyclopædia Britannica reports that, “In nature stearic acid occurs primarily as a
mixed triglyceride, or fat, with other long-chain acids and as an ester of a fatty alcohol. It
is much more abundant in animal fat than in vegetable fat; lard and tallow often contain
up to 30 percent stearic acid.” ³

Researchers at the University of Nebraska noted, “The observation that dietary stearic
acid does not raise plasma cholesterol concentration is well documented, although the
regulating mechanisms are not completely understood...the data suggest that reduced
plasma cholesterol concentration in hamsters fed high 18:0 [ed. note: stearic acid] diets
may be influenced by reduced cholesterol absorption and increased excretion of
endogenous [ed. note: produced by the body] cholesterol.” ⁴

The USDA cites this study regarding the use of magnesium stearate as a functional aid
in the manufacture of tablets: “Stearic acid is the predominant fatty acid in
triacylglycerols of beef fat and coconut oil (present as the ester). The free acid is used
routinely in many commercial products in addition to foods. It is used in polymer
formulations as an extrusion aid. As the magnesium stearate in tablets, it helps keep
the solid ingredients from falling apart in the bottle, and it also enables the tablet to break apart and release the active ingredient when the tablet is swallowed.”  

For softgel capsules containing liquid extracts, NOW does not typically use stearic acid as an excipient. Other excipients are more suitable for use in a softgel capsule and will appear on the label, such as vegetable oils, lecithin, and natural coloring/opacity agents such as annatto seed extract (red color), carob pod extract (brown), zinc oxide (opaqueness) and titanium dioxide (opaqueness).

The FDA has affirmed that stearic acid is GRAS (Generally Regarded As Safe) and can be added to foods in accordance with Good Manufacturing Practices (GMP). NOW is a GMP-certified manufacturer.

The FDA’s Select Committee on GRAS Substances has also reported on magnesium stearate safety, concluding that, “There is no evidence in the available information on magnesium carbonate, magnesium chloride, magnesium sulfate, magnesium hydroxide, magnesium oxide, magnesium stearate…that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current and in the manner now practiced, or which might reasonably be expected in the future.”

This science assures us that stearic acid is a safe fatty acid found in healthy foods and that magnesium stearate is a safe analog of stearic acid. NOW uses them only as necessary for the functionality of a particular dietary supplement, in tiny amounts (often less than one milligram, per capsule) compared to the amount of stearates found in common foods.

REFERENCES:


There are some common myths about stearates. Please allow me to describe the stearates that are utilized in making nutritional supplements, and how they are used, and other pertinent information on their safety and use in dietary supplements and foods.

Stearic acid is converted into oleic acid \textit{in vivo}, so becomes a similar fat as is found in olive oil. In fact, one jumbo olive is estimated to contain 13 milligrams (.013 g) of stearic acid (C 18:0), many times more than is used in any pills or capsules.

http://www.oliveoilsource.com/olivechemistry.htm “Stearic acid is well absorbed by the gut and is transported in chylomicrons and remnant particles before being picked up by the liver. Once there, an interesting paradox occurs in that excess stearic acid is simply converted to the 18-carbon monounsaturated oleic acid via a desaturase enzyme in the liver (3) and then recirculates in lipoprotein complexes as oleic acid, which is not hypercholesterolemic. Thus, conversion to oleic acid may explain why stearic acid does not elevate plasma cholesterol concentrations.”

Supplement manufacturers never use more than 2% and usually far less or none at all, even though common foods contain much more (beef fat is 19% stearates; cocoa butter is 30%) and stearates are Generally Recognized As Safe (GRAS). It is unusual that they would use even 1-2% in a product, and when they do use them it is typically used in microgram amounts to help process only sticky or non-flowing materials. It is so little that it would not be required to be labeled as a trans fat \textit{even if that were true}, which it is not (0.5 g, or 500 milligram or 500,000 microgram, is the threshold for labeling a fat; we use less than 1/1,000 of that, at most). The hydrogenation process is not used for the stearic acid in the magnesium stearate. It is possible to convert oleic acid to stearic acid by hydrogenation, but that is not necessary (or desirable) with sources that are already high in stearic acid and low in oleic acid. Lipase-catalyzed interesterification is a viable alternative to hydrogenation these days, for example, if one were to want to convert oleic acid to stearic acid.

No manufacturer coats their products or materials with stearates, to my knowledge. That is a completely artificial, bogus argument; as that process is not found in real life supplement manufacturing.

GMP-certified manufacturers test for proper disintegration/dissolution of every lot of every product in tablets or capsules to assure that they will deliver their contents.
properly. Using proper USP methods, one manufacturer allows only 45 minutes for tablets and 30 minutes for capsules to break apart, with all products required to meet or exceed those limits. Food will remain in the stomach for quite a bit longer than that, so that amount of time is reasonable and the capsule/tablet contents are then as bioavailable as the food itself.

No consumer should be inhaling stearates, so the issue of being hazardous is also a bogus one that should be relegated to producers and manufacturers. You can actually say far worse about the hazards of inhaled enzymes, for example. Most supplement materials have MSDS handling sheets that mention the dangers of inhalation. There are no known significant dangers from normal oral consumption or skin contact.

The reason dietary stearic acid is considered benign is based on its failure to elevate plasma cholesterol concentrations (1, 2).

Foods naturally rich in stearic acid and other saturated fats include:

Red meat (beef, pork, or lamb)
High-fat dairy products (whole milk, cheese, butter, and ice cream)
Chocolate
Lard
Coconut oil

For more on stearates, please see: [http://www.nowfoods.com/index.php?action=itemdetail&item_id=93528](http://www.nowfoods.com/index.php?action=itemdetail&item_id=93528). Also, the accompanying chart has the percentages of stearic acid in common foods (4). As you can see, stearic acid is far more abundant in olive oil, butter and lard than in dietary supplements as a percentage, with grams in foods and micrograms (possible low milligram levels) in only certain dietary supplements:

A common reference is to a 1990 study in the journal Immunology, but the reference is hardly satisfactory as a demonstration of the alleged harm of stearic acid. This was a test tube study that has not been replicated in living beings, with an artificial situation providing high concentrations of stearic acid exposed to isolated immune cells for hours at a time. It was actually done as a way to investigate whether prolonged high dose stearic acid administration could possibly be used to suppress the immune system for an autoimmune disease treatment. (5) It was definitely NOT a demonstration that this would work the same way with dietary supplements or with foods containing stearic acid. The effect was dose- and time- dependent; with a sustained, prolonged exposure over an 8-hour period that is impossible to replicate in the living human body. For a test tube study, it would first have to be shown that the mechanism was valid in vivo before it could be considered reasonable to extrapolate it to actual living organisms. This study did not do that; nor has any other, to date.

In conclusion, since this mechanism has not been proven in humans or had additional
verifying studies, since humans have much more complex metabolic activities, since stearic acid is easily absorbed from the gut and then readily converted to oleic acid in the liver (in vivo), since manufacturers use far less than this study gave and with only a brief exposure, and since people get stearic acid in many common oil-containing foods in far greater amounts than are used in dietary supplements, I conclude that the fears about the use of stearates in dietary supplements are unproven and speculative at best, slanderous and unscientific at worst.

For a second opinion, please see the website of Ray Sahelian, M.D. at http://www.raysahelian.com/magnesiumstearate.html

REFERENCES