

#### Magnesium stearate safety, side effects, toxicity, problems and review of studies by <u>Ray</u> <u>Sahelian, M.D.</u> Information on stearic acid safety Is magnesium stearate in supplement capsules safe? Are people overly concerned? Are there web sites that are spreading false safety concerns about this ingredient?

Stearic acid is a common fatty acid found in significant amounts in meat, poultry, fish, eggs, butter, grains, and milk products. Some websites have misleading information regarding the safety of magnesium stearate. Some of these sites claim magnesium stearate, even in as small an amount as a few milligrams. as found in dietary supplement capsules, is dangerous. There is no evidence this is true, particularly the tiny amounts found in supplements. I am not aware of any human studies that show MS, in the small amounts found in capsules, has any side effects or causes any harm. There is no evidence that small amounts of stearic acid are harmful. If anyone knows of a human study that indicates magnesium stearate, in the small amounts found in capsules, has shown to have harmful effects, email me. I have searched extensively and not seen any such clinical trials. I believe there is misinformation on web sites that claim this substance is harmful. Much of this mis-information is posted by companies who are trying to differentiate themselves from other vitamin companies by providing products that are free of mag stearate, perhaps because they are not able to compete solely on the actual effectiveness of their products. If anyone tells you magnesium stearate in the extremely small amounts found in capsules is harmful, challenge them to provide you with a human study that proves their point -- they will not be able to. For some consumers this whole issue has become almost a psychological obsession going way beyond any logical reasoning. Some people regularly eat a piece of pie, cookie, or other sweet or junk food, or consume chocolate (which has tons of stearic acid) without any concerns, but get all worked up about insignificant amounts found in capsules. It defies logic.

Most dietary supplement capsules have about 500 mg of herbs or nutrients and perhaps 10 mg or less of magnesium stearate. Since magnesium mineral is part of the overall weight of the molecule, the amount of stearate alone is even less than 10 mg. One kilogram equals 1000 grams, and one gram equals 1000 mg. A few milligrams is an insignificant amount compared to the millions of milligrams of food we consume a day.

I have been taking dietary supplements for more than thirty years and I know older patients who have been taking a handful of vitamin capsules with magnesium stearate every day for more than 40 or 50 years and they are in their 80s and 90s (even a few who are over a 100 years old) and in good health. If MS was so toxic as some claim, how come none of these vitamin users have become ill after consuming these ms-containing capsules daily for several decades?

#### What is it?

Magnesium stearate is a white substance that has two equivalents of stearate and one magnesium cation. It is safe for human consumption. It is often used as a filling agent in the manufacture of supplement capsules. This substance has lubricating properties and prevents ingredients from sticking to manufacturing equipment during the compression of chemical powders into capsules or

tablets.

Chocolate contains cocoa butter, which is high in saturated fat. About a third of the fat in chocolate is in the form of stearic acid.

## Stearic acid in food

Stearic acid is the most common of the long-chained fatty acids. It is found in many foods including vegetable and animal oils, beef fat, and cocoa butter. A person who eats a chocolate bar will ingest hundreds of times more stearic acid than someone taking a dietary supplement with magnesium stearate.

### Safety of magnesium stearate and stearic acid, risk or danger, side effects and toxicity?

I am not aware of any human studies that show MS, in the small amounts found in capsules, has any side effects, poses risks, danger, safety issues or causes any bodily harm. There is no evidence that small amounts of stearic acid are harmful. The studies below prove that stearic acid, even in moderate amounts, has not been shown to be harmful.

A stearic acid-rich diet improves thrombogenic and atherogenic risk factor profiles in healthy males. Eur J Clin Nutr. 2001. Department of Food Science, RMIT University, Victoria, Melbourne, Australia. To determine whether healthy males who consumed increased amounts of dietary stearic acid compared with increased dietary palmitic acid exhibited any changes in their platelet aggregability, platelet fatty acid profiles, platelet morphology, or haemostatic factors. Results from this study indicate that stearic acid (19g/day) in the diet has beneficial effects on thrombogenic and atherogenic risk factors in males. The food industry might wish to consider the enrichment of foods with stearic acid in place of palmitic acid and trans fatty acids.

Influence of stearic acid on hemostatic risk factors in humans.

Lipids. 2005. Tholstrup T. The Research Department of Human Nutrition, Centre of Advanced Food Research, The Royal Veterinary and Agricultural University, Frederiksberg, Denmark. Stearic acid has been claimed to be prothrombotic. Elevated plasma factor VII coagulant activity (FVIIc) may raise the risk of coronary thrombosis in the event of plaque rupture. Fibrinogen, an acute-phase protein, is necessary for normal blood clotting; however, elevated levels of fibrinogen increase the risk of coronary heart disease (CHD). Here I report the results of three controlled, human dietary intervention studies, which used a randomized crossover design to investigate the hemostatic effects of stearic acid-rich test diets in healthy young men. A diet high in stearic acid (shea butter) resulted in a 13% lower fasting plasma FVIIc than a high palmitic acid diet, and was 18% lower than a diet high in myristic and lauric acids after 3 wk of intervention. The present investigations did not find dietary stearic acid to be more thrombogenic, in either fasting effects compared with other long-chain fatty acids, or in acute effects compared with dietary unsaturated FA, including trans monounsaturated FA.

# Statement by chemical manufacturer Hummel Croton Inc., South Plainfield, NJ 07080

Hazards Identification regarding magnesium stearate:

Acute health effects: Irritating to the skin and eyes on contact. Inhalation will cause irritation to the lungs and mucus membrane. Irritation to the eyes will cause watering and redness. Reddening, scaling, and itching are characteristics of skin inflammation. Follow safe industrial hygiene practices and always wear protective equipment when handling this compound.

Chronic health effects: This product has no known chronic effects. Repeated or prolong exposure to this compound is not known to aggravate medical conditions.

Acute health effects: This product is not listed by NTP, IARC or regulated as a carcinogen by OSHA.

### **Absorption issues**

Some consumers having read on websites that have unreliable information that MS hinders absorption of the active ingredients. This is not true. People take their supplements with food (chicken, chocolate) that contains hundreds of times the stearic acid found in supplements, yet absorb the herbs or vitamins quite well. I have seen no evidence that the intake of the tiny amounts of mag stearate in capsules interferes with intestinal absorption of nutrients. Anyone who makes this claim needs to show scientific proof with several studies done in humans.

## Emails

Q. Thank you for your Passion Rx. It actually works! The report below on magnesium stearate concerns me. Here is a quote from a website, "The Truth About Vitamin Supplements: Check your vitamin labels. Do they contain Magnesium Stearate or Stearic Acid? Studies by the University of Texas Health Science Center and the East Carolina University School of Medicine reveal that these toxic excipients cause a rapid collapse of T-cell membrane function and cell death; therefore suppressing the immune system. (Immunology, 1990, July). It is estimated that 90% of the vitamin and mineral products consumed today contain stearates. These are used as binders in tablets and in the processing of gelatin capsules. Consumers often take handfuls of capsules and tablets to get vitamins, minerals and other key nutrients from supplements that contain stearates, and instead, in reality, get a powerful immune suppressive treatment. For more information on this topic and copies of the above-quoted studies as well as other studies and warnings concerning stearates, send an email to Quantum Nutrition Labs' nutritional supplements. Our products are 100% free of toxic excipients, including magnesium stearate or stearic acid."

Much of the misinformation about the safety or toxicity is posted by companies who are trying to make themselves different from other vitamin companies by providing products that are free of this ingredient. The study referred to by this company was actually done in a cell culture. Below is the study that is referred to and my comments.

Molecular basis for the immunosuppressive action of stearic acid on T cells.

Immunology. 1990; Tebbey PW, Buttke TM. Department of Microbiology and Immunology, East Carolina University School of Medicine, Greenville.

Studies were performed to determine the mechanism by which stearic acid (18:0) selectively inhibits T-dependent immune responses in vitro. Incubation of mitogen-activated B and T cells with stearic acid resulted in dissimilar patterns of incorporation of the saturated fatty acid into their membranes. High-performance liquid chromatography (HPLC) analyses of T cells showed an accumulation of disaturated 18:0-containing phosphatidylcholine (PC) that replaced normal cellular PC. Less significant quantities of the same PC species were seen to accumulate in B-cell membranes; rather, they increased their proportion of oleic acid (18:1)-containing PC. The different lipid compositions of the lymphocyte cell membranes after exposure to 18:0 were correlated with their plasma membrane potentials. In T cells, the accumulation of disaturated, 18:0-containing PC coincided with a rapid (within 8 hr) collapse of membrane integrity, as determined by flow cytometry. The collapse of membrane integrity was found to be time and dose dependent. No such depolarization was observed in B cells which, by virtue of their desaturating ability, were able to avoid incorporating large amounts of disaturated 18:0-containing phospholipids into their membranes. It is proposed that a lack of stearoyl-CoA desaturase in T cells precludes them from desaturating exogenously derived 18:0, thus leading to increased proportions of 18:0-containing disaturated PC in their cell membranes. The increased abundance of this PC species may enhance membrane rigidity to an extent that plasma membrane integrity is significantly impaired, leading to a loss of membrane potential and ultimately cell function and viability.

**Comments:** This study is totally irrelevant to what would occur in the human body from the tiny amounts of stearic acid ingested in capsules. If you directly put a particular nutrient, vitamin, fatty acid, amino acid, medication, herb or any substance in a high enough dosage directly in a cell culture you will get results that have nothing to do with what happens when a tiny amount is ingested as part of a medicine, supplement, or through diet and is diluted and distributed to trillions of cells. For instance, you can kill a cell if you put too high an amount of fish oil fatty acids near it in a cell culture, but that does not mean fish oil fatty acids, the omeag-3s, are harmful to you when ingested in reasonable amounts - in fact omega-3s are healthy fatty acids. People or companies who use this type of in vitro study to make such a leap either do not understand medicine or science, or are purposely misleading consumers for marketing reasons.

Q. Are these studies not valid? Please advise. "Stearic Acid inhibits T-cell dependent immune responses. Plasma membrane integrity is significantly impaired, leading to a loss of membrane potential and ultimately cell function and viability." Tebbey PW, Buttke TM, "Molecular Basis For The Immunosuppressive Action of Stearic Acid on T cells" (Immunology, 1990 July. When cells were exposed to stearic acids and palmitic acids, there was a dramatic loss of cell viability after 24 hours." Ulloth, JE, Casiano CA, De Leon M. Department of Microbiology and Immunology, East Carolina University School of Medicine. "T-helper cells become the target of stearic acid." "The addition of palmitate or stearate to cultured cells led to activation of a death program with a morphology resembling that of apoptosis. Palmitates and stearates caused cardiac and other types of cells to undergo programmed cell death."

Sparagna, GC, Hickson-Bick, DL, Department of Pathology and Medicine, University of Texas Health Science Center, Houston. American Journal of Medical Science, Jul 1999; pg. 15-21.

A. See my explanation written above. You can put an excess of any healthy substance, including fish oils, around cells in a Petri dish and the cells can die. This does not mean that fish oils are harmful when ingested in reasonable amounts. What happens in an isolated cell in a Petri dish has little relevance to the actual ingestion of that substance since the dilution of the substance that ends up in trillions of cells in the body makes it insignificant.

Q. Can you comment on these I found on some website? "Stearic Acid, Magnesium Stearate, Calcium Stearate, Palmitate, and Hydrogenated Vegetable Oils are lubricants which enable manufacturing equipment to run more efficiently but inhibit eventual dissolution of the nutrient. Stearic acid may prevent absorption by individuals with compromised digestive systems. Magnesium stearate and stearic acid also present the problem that delivery of the active ingredient may be considerably further down the intestinal tract than the site originally intended. This may result in the nutrient being delivered away from its optimal absorption site. Not only can this impede absorption, in some cases it might be harmful to the liver." Czap, AL. Townsend Letter For Doctors and Patients, July 1999. Consumers often take handfuls of capsules to get nutrients from supplements containing magnesium stearate or stearic acid and instead, get a powerful immuno suppressive treatment! Most retailers are not aware of this threat and mistakenly claim 100% purity for their products. Ask suppliers to provide a written statement that guarantees their supplements are free of stearates.

A. The statements above are probably written by someone who does not have a good understanding of the human body, physiology, metabolism and digestion.

Q. Thorne Research references in their catalog magnesium stearate affecting the solubility and bioavailability of nutrients and therefore does not use it in their product line. The study mentioned was in Pharmaceutical Technology. That's the only info I have. I would love to know differently as I am concerned about all the magnesium stearate in all the supplements I take and would like to get the full availability of a nutrient/supplement intended. I do enjoy your website and information and use it

often in my research since I am an herbalist.

A. I have a different opinion. In my experience, the use of magnesium stearate does not have any noticeable influence on nutrient or herbal absorption. I have taken countless products that have magnesium stearate and felt the potency of such products. For instance, I take Passion Rx which contains it and I notice the powerful effects of the herbs. There is quite a lot of misleading information and unnecessary concern about this topic.

Q. TI recently bought a hoodia product. When I got it I was disappointed to see magnesium stearate (from vegetable products ) on the label! Rival hoodia products claim hoodia containing magnesium stearate as POISON! I subsequently did some research on various sites ...including yours ...and was relieved to find out it was harmless in the manufacture of supplement tablets! Now I don't have to switch my hoodia for another brand!

Most of the time magnesium stearate is made by subjecting cottonseed or palm oil to high heat and pressure in the presence of a metal (in this case magnesium) catalyst for several hours. This creates a hydrogenated saturated fat. I did the math and it follows that if each 1000mg capsule has approximately 2% magnesium stearate in it ( this seems to be about average) that means 20 mg of the capsule is hydrogenated fat. If I take ten capsules a day I would be ingesting about 73,000mg of hydrogenated fat per year or about 2.5oz. Like most people who pay attention to their health and do take supplements, I take a lot more than ten capsules a day. As a person who reads labels at the grocery store and promptly rejects any foodstuff with hydrogenated oil in it, why would I take a supplement with hydrogenated oil in it?

The amount of stearate consumption is even less since magnesium is part of the weight. Therefore, even if there is 20 mg or so of magnesium stearate in a 1,000 mg supplement capsule, some of that weight is a healthy mineral. Some people can get guite obsessed about minutia that, practically speaking, have little or no influence on their health. One could get worried about these tiny amounts that is not likely to have any health effects yet have no concerns about getting in the car to drive to the local movie theatre. The risk of a car accident with bodily harm or inhaling pollutants while on the road are much more likely to occur than the minute amounts of magnesium stearate causing harm to health. If a person is that worried about every possible harm that could occur to them, then they would stay home and not even go out of the house. Then again that has its own risks since once could become vitamin D deficient due to lack of sunlight and possibly get depressed due to lack of human interaction. The amount of hydrogenated oils you mention as a result of ingesting 10 capsules a day about the same or less than eating half a donut over a period of one year. (See an email below that questions the presence of hydrogenated oils in mag stearate.) If your diet is so perfect (with absolutely no sugar, bad fats, cookies, cakes, ice cream, etc) that eating the equivalent of half a donut over a period of year would concern you, then you may look to find supplements that do not contain it. How many people can truly claim that throughout the whole year they do not ingest any ice cream, regular soda, cookies, pastries, a piece or birthday cake, white bread, more than a cup of coffee a day, cream added to the coffee, artificial sweeteners, margarine, or any type of unhealthy food? I think drinking several ounces of fruit juice at one time is a much more significant health issue since it raises blood sugar levels and promotes an excess insulin response. I am certain there are many people who are concerned about mag stearate in their capsules yet consume unhealthy foods on a regular basis without worrying about that. I think there are more important health issues to focus on. If a person is taking more than 10 capsules of supplements a day, there is a significantly higher risk of side effects from the active ingredients in all of these pills rather than the insignificant amount of fillers or lubricants. It often surprises me on how some people go to great lengths in trying to avoid ingesting something that has practically no harm to them yet do not realize there is a higher risk of

harm from so many other activities they do routinely, for instance driving for leisure or even going skiing.

Q. I work for a vitamin company and have been doing a little reading up on these substances, and have read your responses. Stearic acid / mag stearate, does not have any trans fatty acids in it. The person asking the question is making it sound as if there is a concern about this, and your response implies that there is so little, that it should not be a concern. It's my understanding, that there is 0 trans fatty acids. The trans fatty acids are formed when the oil is only partially hydrogenated. This Statement by Now Foods talks about it a little and says there are 0 trans fats. http://www.nowfoods.com/Quality/QualityNotes/M093528.htm

Perhaps you could change that response? This seems to be coming more of an issue.

A. Yes, you are right, I am assuming that there are are some hydrogenated oils in the magnesium stearate since high temperatures may be used in the preparation. I would still like to see an independent analysis to determine whether any of the stearic acid is hydrogenated,. Not that it matters much since the amounts that are consumed are so tiny to be practically irrelevant.

My Grandmother became worried when an associate told her she was killing herself because she took 30 to 60 capsules a day of MSM (Organic Sulfur) which contained magnesium stearate in each capsule. My Grandmother swears by this stuff; she's been taking it for years and her skin is flawless. She's 75 and looks 45...she's very active and doesn't have joint pain like most of her friends... If she's taking 30 to 60 capsules a day of MSM with MS in the capsules, is this toxic in your opinion?

I personally don't think it is toxic and the proof is in the pudding. She has been taking all these capsules for all these years and yet, as you mention, she is vibrant and 75 years old. If it were toxic she should have had some negative symptoms or side effects by now.

January 2009 - Dr. Mercola just sent out an email warning against using supplements that use magnesium stearate or stearic acid as filler. I have researched and there are other sources besides Dr. Mercola that also warn of toxicity. What is your stance on this?

I have a different viewpoint. I have personally taken supplements with magnesium stearate for 20 years without any ill effects. Some people worry about magnesium stearate but do not seem to be concerned about eating chocolate which has a high sugar and fat content along with a high stearic acid content, but, for some reason, the tiniest amount in capsules raises concern for them. Makes no sense.

Here is information taken from Dr. Mercola website, "Steer Clear of Magnesium Stearate, I realize that there is very little research published on this, and I am actually working on a special report to detail what is known. But the bottom line summary is actually quick and simple. Some highly respected clinicians like Dr. Klinghardt and others have extensive experience with this issue. Magnesium stearate is not a supplemental source of the mineral but it is a form of stearic acid and is used as a flow agent. The ONLY purpose of it in the supplement is to help the raw materials become more slippery and flow through the machines that create the supplements."

As with many health topics, politics, religion, etc, there are different viewpoints held by different people. It is up to each individual to read up as much as they can on this topic and others and then come to their own conclusion on whose opinion they trust.

While reading your article about Vegetable Magnesium stearate, you mentioned a small amount should be safe. However, I take about 45 supplements a day and most of them have that in them--do you think that is also safe?

I can't predict the response of any particular individual to any supplement or filler or additive, but

there is a high likelihood that adverse effects could occur from taking so many supplements from the active ingredients they contain. One should evaluate whether these many pills are required to be taken daily.

Source of this article: http://www.raysahelian.com/magnesiumstearate.html