

Magnesium Stearate:

Is it safe - is it needed?

In order to alleviate the concerns of our customers we have extensively researched the topic.

We have reviewed both the available literature and drawn on our “real life” experience.

Here are the preliminary conclusions we have come to.

If any reader has conclusive evidence— as opposed to opinion- to the contrary we would be most grateful to be shown it and then we will correct our stand.

1. **No ethical manufacturer will put “unnecessary” ingredients into their products**, both due to safety reasons and because nobody would want to increase the manufacturing costs.
Flow agents are necessary to be introduced into most formulas since without them the manufacture of some products would be either impossible (the machines cake up, production stops all together) or the process would be so slow as to be practically impossible or too costly. Magnesium stearate is one such flow agent that has been used for decades in the manufacture of nutraceutical supplements and other pharmaceutical products. **The rumor that mag stearate is being added to supplements “for no reason” is nonsense.**
2. No studies have ever proven that in the *in vivo* animal and/or especially clinical trials mag stearate is damaging. The one isolated *in vitro*(*in the laboratory*) study on the effect of mag stearate on cultured, isolated T lymphocytes showing a negative effect is misleading in regards to the question of safety. The purpose of that study was to show the mechanism by which certain fats affect the walls of the T cells, not safety. The amounts used were grossly above any reasonable physiological levels because, to emphasize again, the mechanism had to be studied not the clinical usage of the substance.
3. Saying that there are “gaps in the research” regarding mag stearate is pure fear mongering. One can point to “gaps in the research” with any substance. This applies even to the study on the influence of water on the human organism!
4. The statement is being made that magnesium stearate potentially, or supposedly, lowers the absorption from the intestines of the ingredients contained in the nutraceutical product and is thus considered to be undesirable in nutritional supplements. Two aspects need to be observed here:
 - a. No pharmacologically validated human studies have been done that would show an appreciable lowering of plasma levels of an ingredient when mag stearate was added in appropriate amounts to a formula.

- b. Stearates are fats that are contained in a multitude of foods that we ingest on a daily basis. Thus if we already have many hundreds of mg's of mag stearate constantly existing in our intestines, a couple more of, literally, single units of mg's of stearates from the supplements probably do not make any difference.
Since stearates are fats obviously dissolving a cap or tablet in water in the lab is going to slow the process down. But the intestine is not a pool of water!
 - c. 100% absorption of Nothing is still Nothing. At the end of the day an ethical company- like True Botanica, and others- will put enough of the necessary ingredient PLUS a so called overage into their product so that the desired levels are reached.
5. One objection to using bovine source stearates as unacceptable for vegetarians has been overcome by the use of "non hydrogenated vegetable stearates."
6. **Some companies are trying to make a name for themselves by stating "we never have nor will we ever use mag stearate."** Aside from the comments 1-5 above, this is a highly disingenuous comment. Of course they also have to use a flow agent. In the case of one particular company, which is literally screaming this message from the roof tops, please note that most of their **formulas include the use of silicon dioxide as a flow agent. SiO₂ as opposed to mag stearate** has been known to cause significant illnesses in the human body when it reaches the tissues at considerable levels (auto immune diseases, chronic fatigue, etc). Since however most of the time SiO₂ is ingested from vegetables, etc it would be disingenuous on our part now too to claim that that is a health hazard. By the same logic as above a couple more mg's in the supplements on the background of much more ingested in the diet is probably not going to make any difference.
But a flow agent is needed!
(Incidentally, a flow agent is needed in only a very small number of formulas. In the case of True Botanica the vast majority of our products can be made without the assistance of any flow agent, mag stearate, silicon dioxide or other.)
7. **Can we make formulas that contain absolutely no flow agents, excipients, etc, even though the absence of such helpful additives makes the production much more labor intensive?**
Absolutely!
All the customer (personal or business) has to do is to be willing to pay the price for a handmade, small number of items. We estimate that the price per unit would be about 3-4 times the regular price.

So, in conclusion how can one tell a "good" supplement:

- a. **Read the product description and see if there are any distinguishing features to the formula.**
- b. **See if acceptable efforts have been made to ensure overall safety, truthful label disclosures, etc, (like third party tests, GMP certification, etc).**
- c. **Ask if you trust the source: as just one example, is the company led by physicians or by business people who think that this is a way to make a quick buck.**

Thank you for your careful attention.

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