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What the Science Says About Magnesium Stearate

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It's often been said that scientific studies can be used to support just about anything. But discoveries are never made one study at a time. Only when science is viewed as a process and the sum of these studies are added together can a solid conclusion be reached and used to support patients. When an individual ignores the larger body of research in favor of a single study with a particular finding, they bias their search for evidence and do a disservice to patients.

Magnesium stearate is a perfect example of how selective interpretation of research can lead to errors in clinical application. Magnesium stearate is an excipient – a substance with minimal biological activity based on the amounts used. Excipients are added to foods, supplements and drugs to prevent ingredients from clumping or sticking to equipment. To make a stearate excipient, calcium or magnesium is combined with stearic acid from vegetable oils.

The Food and Drug Administration has responded to the significant scientific evidence on magnesium stearate and found that it is *not* problematic for human health. Also, magnesium and stearic acid are found naturally in the diet. Despite this, there are claims based on one study or another suggesting that magnesium stearate should be avoided.

Let's examine one such claim, the idea that magnesium stearate can damage the immune system. This theory seems to be largely based on a 1990 study titled, "Molecular Basis for the Immunosuppressive Action of Stearic Acid on T Cells." In fact, this paper has nothing to do with orally ingested magnesium stearate in food, supplements or drugs. Instead, it demonstrates that exposing T cells to physiologically impossible concentrations of stearic acid (which is different from magnesium stearate) can suppress the immune response in the context of preventing the rejection of transplanted organs.[1]

But couldn't this suggest that magnesium stearate could affect T cell activity? The answer is no. The majority of consumed stearic acid is converted to oleic acid in the body, suggesting there is no reasonable

amount of dietary stearic acid that would be sufficient to suppress T cells in humans.

Another paper published in a 1985 edition of *Pharmaceutical Technology* has been used to suggest that magnesium stearate impacts absorption of nutrients. In fact, this paper examines crospovidone, an excipient used to help drugs (ketorolac tromethamine in this case) dissolve in water. The findings of this study are only relevant to food, supplements or drugs containing crospovidone. It has no bearing on items that use only magnesium stearate.[2]

Additionally, the dissolution rate of any substance in pure water cannot be used to make predictions about its digestion and bioavailability in the gut. Our digestive system involves tens of thousands of proteins and other molecules with a vast capacity to break down and absorb both water-soluble and fat-soluble molecules. Thus, the use of this article as the basis for claims that magnesium stearate lowers nutrient bioavailability is invalid.

Indeed, in papers that use magnesium stearate as the target of investigation, tablet dissolution times were not consistent with actual bioavailability of the active ingredient:

- In researching sulfadiazine bioavailability with different mixing methods using rabbits, the authors report that "large differences were found in the in vitro dissolution studies, but only minimal differences existed in vivo."[3]
- Furosemide tablets containing different amounts of magnesium stearate showed varying levels of bioavailability, with the tablet containing more (2.0%) "rendering the drug 25% more bioavailable than the formulation containing 0.5%."[4]

However, the story is more complicated. Another paper found that relative to no magnesium stearate, 0.5 percent magnesium stearate did reduce availability of the target molecule, sulphadiazine.[5] Also, magnesium stearate reacts to active ingredients differently, as do other excipients. For example, in the case of prednisone, magnesium stearate is preferred over talc, but magnesium stearate cannot be used in the making of ampicillin tablets.[6]

Despite this complexity, it’s important to remember that magnesium stearate is used at range of 0.25–1 percent weight-per-weight of a tablet or fractions of a gram for drugs and supplements. One recent article on the problems with magnesium stearate used as a reference a document called a material safety data sheet (MSDS) that characterizes a substance used in manufacturing (there’s even one for water). MSDS

documents are used by companies to guide handling of substances in production-scale amounts; in the case of magnesium stearate, this means *barrel-size quantities*, not tablet-sized.

This is a vital distinction because dose is key when determining harmful effects of any material. Using MSDS sheets to promote the supposed harm of a chemical would be equivalent to requiring each of us to remove all jewelry, complete a sanitary scrub and wear a hair net to make a cup of tea. While taking those actions and using tools like the MSDS make sense in a factory setting, they are excessive and unnecessary when applied elsewhere.

So, what does a clinician say to patients who want to know if magnesium stearate is harmful? Significant scientific agreement based on strong evidence suggests that magnesium stearate is safe for consumption, does not impact T cells, and does not meaningfully affect bioavailability of the bioactive ingredients in animal or human models.

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