Excipients in Dietary Supplements

As part of our focus on quality, we verify safety of both our ingredients and the carriers and binders, known as excipients, used to form tablets or run our equipment. Excipients are substances that are minimally active and added for manufacturing purposes.

Chances are you’ve read articles that claim excipients like magnesium stearate or calcium stearate can be bad for your health. Based on our investigation, however, those articles aren’t thoroughly researched.

At Standard Process, our research and development department employs a board-certified toxicologist and scientists with nutrition and manufacturing expertise. We reviewed the concerns regarding magnesium stearate and calcium stearate thoroughly and found some interesting things.

Claim: Magnesium stearate impairs your immune response. The study most often cited as proof of this statement does not present any evidence that magnesium stearate suppresses the immune system. The paper discusses a technique used to prevent rejection of transplanted organs. In this paper, the scientists demonstrate that by growing mouse T cells in amounts of stearic acid (not the same as magnesium stearate) unattainable by normal consumption, immune response could be suppressed. There is no way to relate this finding to the human consumption of supplements that contain magnesium or calcium stearate.

Claim: Excipients decrease bioavailability of active ingredients in supplements. The most cited paper for this claim is an article published in 1985. This paper examined a compound called cropovidone that is used to help drugs disintegrate. Cropovidone was found to prevent the target drug from dissolving, and magnesium stearate was added to the undissolved drug to determine its effect on dissolution. The study was not designed to determine if magnesium stearate interfered with the dissolution of the drug. The magnesium stearate was added 25 minutes after the researchers combined the drug and cropovidone, which is significantly different from how magnesium stearate is used in supplements. Additionally, the authors of the paper only recorded 25 minutes of data. The normal transit time of the gut is far longer than that, suggesting that their findings are not applicable to human consumption. Also, water was used to dissolve the drug in question, so this test is not comparable to what happens in either the gut or stomach environments.

   - This experiment used stearic acid (not magnesium stearate) on mouse cell cultures.
   - Actual mice could not be used because feeding this level of stearic acid is not possible.
   - Metabolism of stearic acid into oleic acid prevents stearic acid from accumulating in plasma membranes beyond 10 percent.
   - There was no effect on T cells until stearic acid in the cell membrane reached 15 percent.

Background

The calcium stearate used by Standard Process is made by combining calcium and a fatty acid found in vegetable oils called stearic acid. These nutrients are commonly found in our food and are easily used by the body. While calcium stearate does help our tableting machines run faster, the main reason we use it is to improve the quality of our tablets. Tablets can stick in the machine, so the stearate helps ensure tablets are defect-free and the proper weight.

A typical Standard Process tablet contains, at most, about 0.01 grams of calcium stearate, a level considered very safe by the scientific and regulatory community.

Although a safe upper level for magnesium stearate consumption has not been set, one rat study reported that up to 2.5 grams/kilograms/day of magnesium stearate is safe for consumption.3

At that level, a 110-pound person could consume up to 4.4 ounces of stearate per day. Even with the stearates found in food (5-8 grams per day), that person could consume almost 26 pounds of supplements a day before exceeding the safe level.

Standard Process has researched excipients used in our industry and found calcium stearate and magnesium stearate to be safe and effective in ensuring formulas are well mixed and tablets meet hardness requirements.

If you have questions about stearates, please contact the Standard Process quality control department.