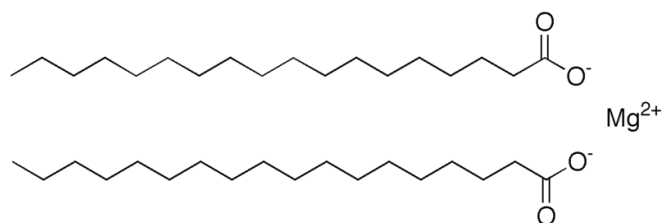


MAGNESIUM STEARATE

Magnesium stearate is a widely used excipient in drugs and herbal remedies. It has been used for many years without any safety concern. However, I have been investigating how magnesium stearate is made and I have come to the conclusion that it is better to avoid it. As a result, all the *Three Treasures* and *Women's Treasure* remedies are now made without magnesium stearate and the only excipient used in their manufacture is potato starch.

Magnesium stearate, also called *octadecanoic acid*, is a white powder which becomes solid at room temperature. It has the chemical formula $\text{Mg}(\text{C}_{18}\text{H}_{35}\text{O}_2)_2$. It is a magnesium salt of stearic acid. It is a salt containing two equivalents of stearate (the anion of stearic acid) and one magnesium cation (Mg^{2+}).

Magnesium stearate is widely used as a diluent in the manufacture of medical tablets, capsules and powders. The substance has lubricating properties, preventing ingredients from sticking to manufacturing equipment during the compression of powders into solid tablets; magnesium stearate is the most commonly used lubricant for tablets and it is widely used in the manufacture of herbal remedies and other supplement. Magnesium stearate is also used to bind sugar in hard candies like mints, and is a common ingredient in baby formulas.



Manufacture of Magnesium Stearate

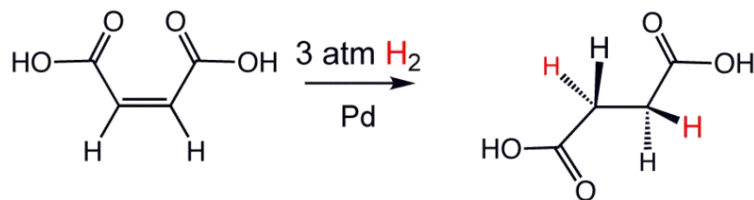
Magnesium stearate is usually manufactured from vegetable oils. Stearates can be produced by hydrogenation although some supplement manufacturers claim that they use magnesium stearate derived from non-hydrogenated, non-GM palm oil.

The commonly used sources of magnesium stearate are palm oil and cottonseed oil after hydrogenation. Hydrogenated oils are a common source of magnesium stearate in tablets. Hydrogenation creates a hydrogenated partially saturated fat.

Hydrogenation

Hydrogenation - to treat with hydrogen - is a chemical reaction between molecular hydrogen (H_2) and another compound or element, usually in the presence of a catalyst. The process is commonly employed to reduce or saturate organic compounds. Hydrogenation

typically constitutes the addition of pairs of hydrogen atoms to a molecule, generally an alkene. Hydrogenation of unsaturated fats produces saturated fats and, in some cases, trans fats.



Production of hydrogenated fats increased steadily until the 1960s, as processed vegetable fats replaced animal fats in the US and other western countries. At first, the argument was a financial one due to lower costs; advocates also said that the unsaturated trans fats of margarine were healthier than the saturated fats of butter. This view has now been completely reversed.

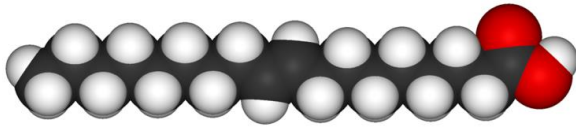
Trans-fats

Trans fat is the common name for unsaturated fat with *trans*-isomer (E-isomer) fatty acid(s). Because the term refers to the configuration of a double carbon-carbon bond, trans fats are sometimes monounsaturated or polyunsaturated, but never saturated. Trans fats do exist in nature but also occur during the processing of polyunsaturated fatty acids in food production.

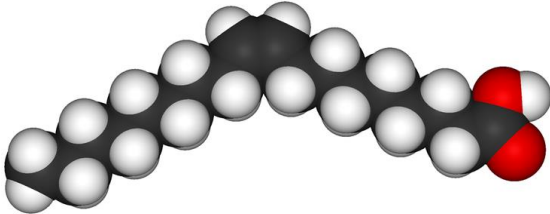
The consumption of trans fats increases the risk of coronary heart disease by raising levels of LDL cholesterol and lowering levels of "good" HDL cholesterol. There is an ongoing debate about a possible differentiation between trans fats of natural origin and trans fats of vegetable origin but so far no scientific consensus has been found.

In most naturally occurring unsaturated fatty acids, the hydrogen atoms are on the same side of the double bonds of the carbon chain (*cis* configuration — from the Latin, meaning "on the same side"). However, partial hydrogenation reconfigures most of the double bonds that do not become chemically saturated, twisting them so that the hydrogen atoms end up on different sides of the chain. This type of configuration is called *trans*, from the Latin, meaning "across".

The same molecule, containing the same number of atoms, with a double bond in the same location, can be either a *trans* or a *cis* fatty acid depending on the configuration of the double bond. For example, oleic acid and elaidic acid are both unsaturated fatty acids with the chemical formula C₁₈H₃₄O₂.^[39] They both have a double bond located midway along the carbon chain. It is the configuration of this bond that sets them apart. The configuration has implications for the physical-chemical properties of the molecule. The *trans* configuration is straighter, while the *cis* configuration is noticeably kinked as can be seen from the three-dimensional representation shown above.



Elaidic acid (trans fat)



Oleic acid (cis fat)

The National Academy of Sciences (NAS) advises the United States and Canadian governments on nutritional science for use in public policy and product labeling programs. Their 2002 *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*¹ contains their findings and recommendations regarding consumption of trans fat.

The NAS reached the conclusion that "*trans fatty acids are not essential and provide no known benefit to human health*", whether of animal or plant origin. They also concluded that, while both saturated and trans fats increase levels of LDL cholesterol (so-called bad cholesterol), trans fats also lower levels of HDL cholesterol (good cholesterol); thus increasing the risk of coronary heart disease. Because of these facts and concerns, the NAS has concluded there is no safe level of trans fat consumption.

Safety

In 1979, the FDA's Subcommittee on GRAS (generally recognized as safe) Substances (SCOGS) reported, "*There is no evidence in the available information on ... 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.*"

However, some research has shown that stearic acid suppresses T cells—your natural killer cells—which are a key component of your immune system¹. According to that study, stearic acid causes the collapse of cell membrane integrity—an effect that was found to be time and dose dependent—which, ultimately, can destroy cell function. See <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1384169/>

Another issue that has been raised in relation to magnesium stearate is the fact that the stearate is commonly sourced from hydrogenated oils such as cottonseed oil. This crop is oftentimes genetically engineered, but even when it's not, cottonseed oil tends to have very high levels of pesticide residues.

Other contamination can also occur during the manufacturing process of the magnesium stearate. According to a December 2011 report by the World Health Organization (WHO), several batches of magnesium stearate by a particular manufacturer were found to contain various levels of harmful contaminants such as calcium hydroxide, Bisphenol-A and Irganox 1010.

During the March 2010 session of the Codex Committee on Food Additives (CCFA), it was recommended that "magnesium salts of fatty acids" (ie magnesium stearate) be deleted from the Codex, as it has no known use in food. The following year, at the March 2011 CCFA session, the International Alliance of Dietary Supplement Associations (IADSA) submitted a request to reinstate magnesium stearate as a food additive. It was subsequently reinstated under INS number 470(iii).

However, it must be said that there are many voices in defence of magnesium stearate. They affirm that Stearic acid is unique among all saturated fatty acids because it does not raise **LDL cholesterol** levels. They say that 10% - 12% of cocoa is fatty acids of stearic acid, one of the richest sources of stearic acid in the food supply. It is easy to get 5 grams of stearic acid (5,000 mg) by eating a bar of chocolate. By comparison, a dietary supplement capsule product typically contains between 1% - 2% stearic acid or 10 mg - 20 mg of stearic acid per capsule, or 1000 mg to 2000 mg per bottle (20% - 40% of a chocolate bar for the entire bottle). See http://www.wellnessresources.com/health/articles/the_facts_on_magnesium_stearate/

Legislation and regulation

Canada

In Canada, Health Canada has required that food labels list the amount of trans fat in the nutrition facts section for most foods. Products with less than 0.2 grams of trans fat per serving may be labeled as free of trans fats. In June 2007, the federal government announced its intention to regulate trans fats to the June 2006 standard unless the food industry voluntarily complied with these limits within two years. Effective September 30, 2009, British Columbia became the first province in Canada to mandate the June 2006 recommendation in provincially regulated food services establishments.

United Kingdom

In January 2007, the British Retail Consortium announced that major UK retailers intended to cease adding trans fatty acids to their own products by the end of 2007. On 13 December 2007, the Food Standards Agency issued news releases stating that voluntary measures to reduce trans fats in food had already resulted in safe levels of consumer intake. Rejecting an outright ban, the Health Secretary Andrew Lansley launched on 15 March 2012 a voluntary pledge to remove artificial trans fats by the end of the year.

USA

On July 11, 2003, the Food and Drug Administration (FDA) issued a regulation requiring manufacturers to list trans fat on the Nutrition Facts panel of foods and some dietary supplements. The new labeling rule became mandatory across the board, even for companies that petitioned for extensions, on January 1, 2008. However, unlike in many other countries, trans fat levels of less than 0.5 grams per serving can be listed as 0 grams trans fat on the food label.

The state of California and some US cities are acting to reduce consumption of trans fats. In May 2005, Tiburon, California, became the first American city wherein all restaurants voluntarily cook with trans fat-free oils.

The following countries have implemented a total ban on trans fats:

Austria

Denmark

Iceland

Sweden

Switzerland