

Food Additive for Foods with Health Claims

## Magnesium Stearate

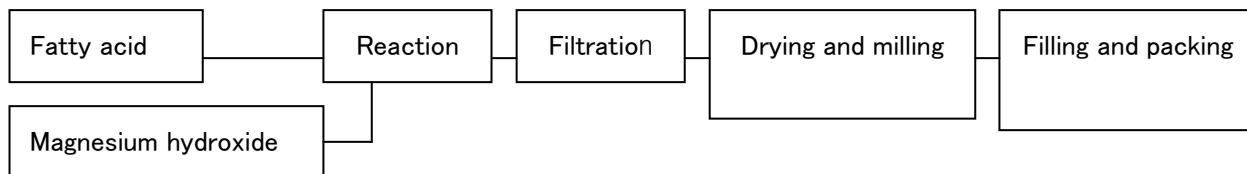
Magnesium stearate, consisting mainly of magnesium stearate and palmitate, is an example of a palm fatty acid product that is used to confer the properties of lubricity or fluidity on “capsules and tablets of foods with health claims.” In particular, magnesium stearate shows a highly favorable lubricity at a low dose when compared with conventional products such as sucrose fatty acid esters.

This product is based on our custom technologies, which have been developed as a result of our extensive experience in the manufacturing and distribution of pharmaceutical and industrial magnesium stearate. They ensure that we can meet a wide spectrum of customer requirements.

<Standard Ingredients>

Ingredients		Standards
Content	Magnesium	4.0–5.0%
Validation		Passed
Purity test	Acid or Alkali	Passed
	Chloride (Cl)	<0.10%
	Sulfate (SO <sub>4</sub> )	<1.0%
	Heavy metal (Pb)	<20 μg/g
	Ratio of stearate and palmitate	Ratio of stearate/total ratio of stearate with palmitate = >40%/>90%
Loss on drying		<6.0%

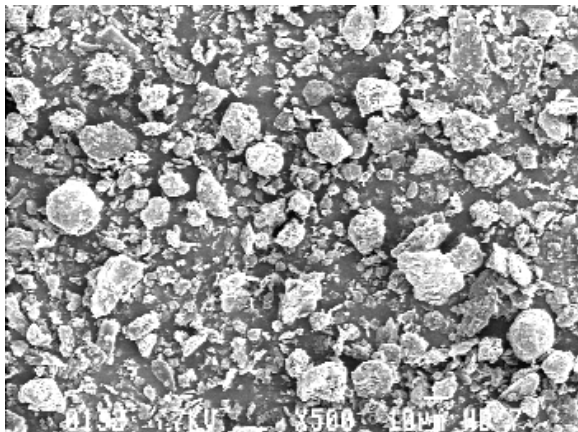
<Manufacture>



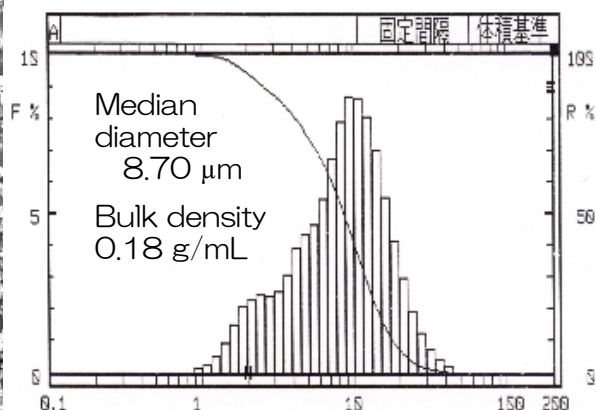
Direct reaction that does not result in any by-produced impurities

<Packaging> A 10-kg polyethylene-lined paper bag

<Particle description>



Electron micrograph



Particle size distribution

<Safety>

Acceptable daily intake (ADI) Not specified

[Source: the FAO/WHO Joint Expert Committee on Food Additives (JECFA)]

(1) Single dose toxicity study

LD<sub>50</sub> in rats Male: >7500 mg/kg, Female: >6000 mg/kg

(2) 90-day repeated dose toxicity study

No observed adverse effect level (NOAEL) in rats 2500 mg/kg body weight/day

(3) Mutagenicity study

Microbial backward mutation test Negative

Chromosomal aberration test Negative

In Japan, this substance has been used as a pharmaceutical additive. Also, in the US, the FDA designated it as GRAS (Substances Generally Recognized as Safe) and in Europe it was designated as a food additive without a specified limited concentration.

<Instructions>

Mix this substance into a powder material at a dose of approximately 0.1–2.0%.

<Example>

Tableting: The powder was mixed according to the following prescription, which was to be tableted using a direct compression method.

Tableting machine: Rotary tableting machine (HT-9.15 mm  $\phi$  x 3 kN, Hata Iron Works)

Study methods (1) Intact tablet rate: the proportion of intact tablets (yield)

(2) Hardness: Mean measurements of hardness of 10 tablets using a Monsanto durometer

(3) Disintegration time: Time for a tablet to disintegrate according to the Japanese Pharmacopoeia 14th edition

Example Prescription

Composition	Mixing ratio (%)
Glucose	74.9–74.0
Corn starch	15
Ascorbate	10
Magnesium stearate	0.1–1.0

Results

	Loading (%)	Magnesium stearate	Sucrose fatty acid ester
Fluidity	0.1	◎	○
	0.5	◎	○
	1.0	◎	◎
Intact tablet rate (%)	0.1	93	64
	0.5	93	77
	1.0	78	78
Hardness (kg)	0.1	7.1	7.2
	0.5	7.1	7.5
	1.0	6.7	7.5
Disintegration time (sec.)	0.1	24	31
	0.5	49	35
	1.0	111	60

As shown above, a mixed powder with a high fluidity can be provided at a low dose of this substance and tablets with an intact surface can be easily prepared without capping, sticking, or binding during tableting.