Food Additive

Calcium Stearate

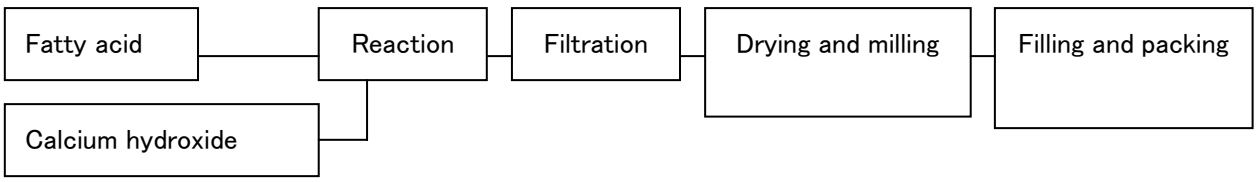
Calcium stearate, consisting mainly of calcium stearate and palmitate, is a palm fatty acid distillate that is used to confer the properties of lubricity or fluidity on powder products, preventing them from consolidating. It also facilitates emulsification as well as making preparations more viscous. In particular, calcium stearate results in a highly favorable lubricity at a low dose when compared with conventional products such as sucrose fatty acid esters.

This product is based on custom technologies that have been cultivated as a result of our extensive experience in the manufacturing and distribution of pharmaceutical and industrial calcium stearate; they ensure that we can meet a wide spectrum of customer requirements.

<Standard Ingredients>

Ingredients		Standards
Content	Calcium	6.4–7.1%
Validation		Passed
Purity test	Heavy metal (Pb)	<10 μg/g
	Arsenic (As_2O_3)	<4.0 μg/g
	Free fatty acids (or stearate)	<3.0 %
	Loss on drying	<4.0 %

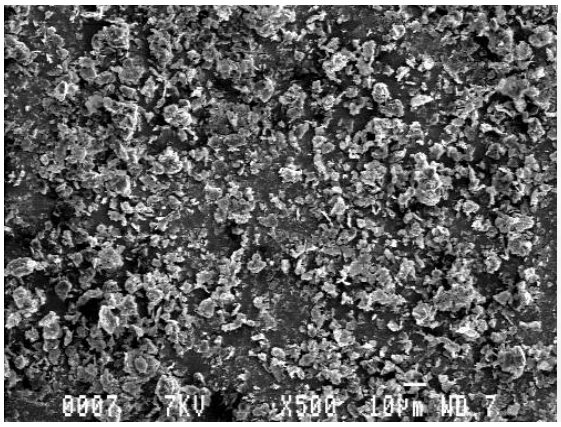
<Manufacture>

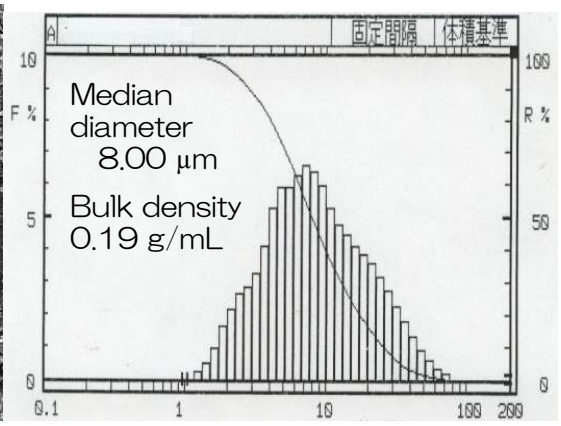


Direct reaction that does not result in any by-produced impurities

<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_{50} in rats and mice >10 g/kg bw

(2) 9-month repeated dose toxicity study

No observed adverse effect level (NOAEL) in rats 1 g/kg bw

(3) Mutagenicity study

Although no report or results are included here, tests of a related chemical, magnesium stearate, provided the following results.

Microbial backward mutation test Negative

Chromosomal aberration test Negative

(4) Carcinogenicity

No findings (Pathology in the 9-month repeated dose toxicity study showed no change associated with this substance)

(5) Reproduction and development toxicity

No findings

In Japan, this substance has long 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-9.8 mmϕ 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 Monsant durometer

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

Example Prescription

Composition	Mixing ratio (%)
D-sorbitol (containing 1.0% water)	89.0–89.9
Corn starch	5
Vitamin C	5
Calcium stearate	0.1–1.0

Results

	Loading (%)	Calcium stearate	Sucrose fatty acid ester
Fluidity	0.1	◎	△
	0.5	◎	○
	1.0	◎	◎
Intact tablet rate (%)	0.1	65	45
	0.5	90	75
	1.0	95	81
Hardness (kg)	0.1	13.6	13.4
	0.5	13.3	13.5
	1.0	12.4	13.4
Disintegration time (sec.)	0.1	192	193
	0.5	230	195
	1.0	472	221

As shown above, even when saccharides with a high hygroscopicity were used, 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.