SODIUM STEARYL FUMARATE (SSF) is a tablet lubricant for use in traditional and orally disintegrating tablets (ODT), effervescent formulas, or in formulas where the active is incompatible with Magnesium Stearate. SSF is an inert, hydrophilic to provide tablets of adequate stability, hardness, content uniformity, disintegration and dissolution rate. SSF is used as a lubricant in capsule and tablet formulations at 0.25%-2% w/w concentrations.

**PHYSICAL PROPERTIES OF SSF**

- Fine, white powder
- Hydrophilic
- High melting point (220-240°C)

**THE PERFECT LUBRICANT**

Magnesium Stearate is incompatible with many APIs, mainly because of the electrophilic character of the Mg²⁺ ion and the basic reaction of the material itself. Magnesium Stearate shows higher voltage and retention times than SSF. Low electric charge and retention improve lubricant dispersion during blending. As a result, SSF, due to its low voltage and retention, can be considered a superior lubricant with improved lubricant uniformity.

SSF is an excellent lubricant for effervescent formulations because it is more hydrophilic and exhibits a lower residue in solution. SSF also has a smaller impact on dissolution.

**SSF and Mgst have a similar lubrication effect**

<table>
<thead>
<tr>
<th>Ejection Forces [N]</th>
<th>Sodium Stearyl Fumarate</th>
<th>Magnesium Stearate</th>
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</thead>
<tbody>
<tr>
<td>500</td>
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</tbody>
</table>

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**US FDA APPROVAL**

**(EP/USP-NF/JPE)**

**US DMF & CEP**
**SSF VS. MgST**
Compatibility studies comparing SSF to MgSt showed that SSF was superior with respect to impact on tablet hardness, ejection forces, friability and disintegration.

**Effect on Dissolution rate**

![Dissolution Rate Graph](image1)

**Effect on disintegration time**

![Disintegration Time Graph](image2)

**SSF HAS SUPERIOR PERFORMANCE WHEN COMPARED TO MAGNESIUM STEARATE:**

- Higher tablet hardness
- Lower ejection forces
- Less impact on disintegration times
- Less sensitive to blending time
- Semi-soluble so lower residue when in solution or effervescent
- Especially effective in ODT Tablets
- Faster formulation development and scale-up
- High degree of API compatibility
- No adverse effect on bioavailability

**USE OF SODIUM STEARYL FUMARATE**

- to improve drug stability
- to avoid metallic taste of Magnesium Stearate
- for Organic Salts
- for Carbonyl-Carboxylgroup APIs
- for Sulfogroup APIs
- for high-speed direct compression