



**Mallinckrodt**  
Pharmaceuticals

# Measurably Superior Stearates





## Over a Century of Production and Progress

In 1908, Mallinckrodt Pharmaceuticals first began producing zinc stearates, and by 1923, other stearates were added to our product line. Today, we sell a broad portfolio of high quality pharmaceutical stearates worldwide. Our production is based in the United States, operating from GMP manufacturing sites located in Saint Louis, MO and Greenville, IL.

We consider our clients to be partners in producing quality healthcare and food products, and focus on providing strong technical support. Our skilled technical and regulatory team is available to help you during all phases of your development and production process. We provide extensive analytic capabilities, including:

- Scanning electron microscopy
- Gas chromatography
- Infrared spectroscopy
- Microbiology
- Thermogravimetric analysis
- Differential scanning calorimetry

We are determined to protect human and environmental health globally. That's why we use responsibly sourced raw materials, and rigorously comply with environmental regulations concerning clean air, water, and waste management.



## Consistent High Quality is Our Greatest Asset

Mallinckrodt uses high purity raw materials and a precipitation process that yields unique “platelet-like” particles, resulting in highly controlled physical properties, including:

- Particle size distribution
- Specific surface area
- Morphology
- Minimal lot-to-lot variability

## Efficient

Products containing Mallinckrodt stearates require less stearate as raw materials and enable an exact, known amount of stearate to be added to a formulation or a batch of product.

## Meets the Best Standards

We follow Good Manufacturing Practices for Active Pharmaceutical Ingredients for production of our stearates. Our stearates meet the worldwide compendia of Food Chemical Codex (FCC); National Formulary (NF); European Pharmacopeia (EP); British Pharmacopeia (BP); Japanese Pharmacopeia (JP) and Chinese Pharmacopeia (CHP). Our portfolio of stearates includes Kosher-certified for Passover products and products that meet Halal requirements.

## Responsible



For our palm based products, we use fatty acids derived from Roundtable on Sustainable Palm Oil (RSPO) Mass Balance palm oil, helping to protect fragile eco-systems and endangered species while guarding unique environments from deforestation and forest fires.



**How Important Can 1% Be?**  
*Very important* if it affects the  
other 99% of your tablet.

## Magnesium Stearate: A True *Monohydrate*

Unlike many competitors' products, Mallinckrodt's magnesium stearates are true monohydrate compounds. Customers who use Mallinckrodt's magnesium stearate, including some of the largest global blockbuster medicines, experience a high success rate in **avoiding**:

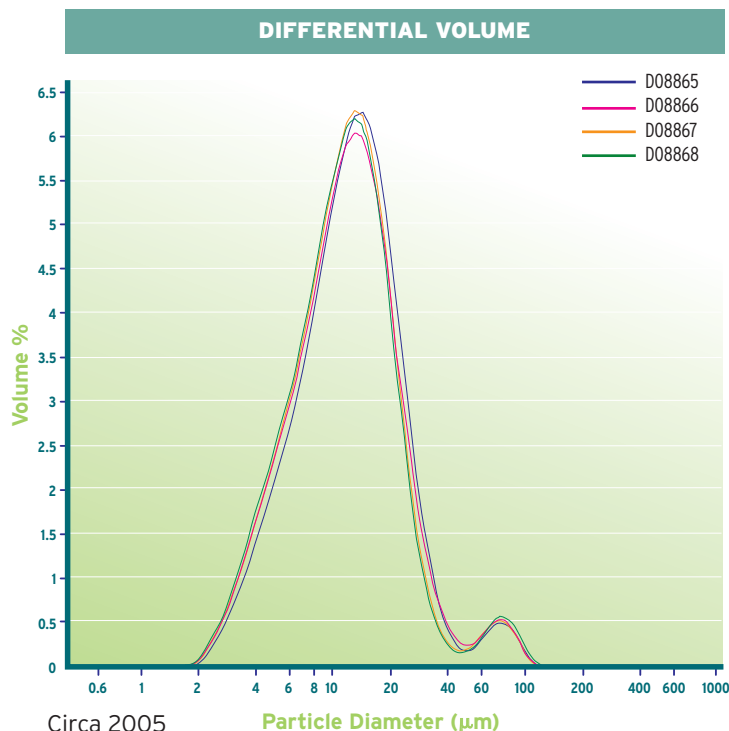


## Measurably Better

Our manufacturing process controls result in high purity, high quality, and measurable results. Repeated studies show that our line of magnesium stearates surpasses the leading competitors' products in particle size consistency.

### Our stearates provide:

- Powder Flowability
- Blend Uniformity
- Tableting Ease
- Tablet Quality



vs.



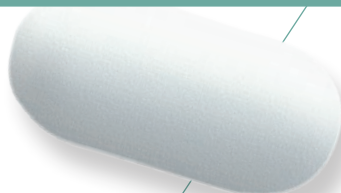


## Mallinckrodt Stearates Meet Key Pharmaceutical Application Specifications

PRODUCT	SOURCE	SPECIFICATIONS
Magnesium Stearate NF Veg 1726	Soy	NF/EP/BP/JP/FCC
Magnesium Stearate HyQual 2257	Palm	NF/EP/BP/JP/ChP/FCC
Magnesium Stearate HyQual 5712	Palm	NF/EP/BP/JP/ChP
Stear-O-Wet 8577	Palm	Magnesium Stearate NF/EP/BP/JP/ChP/FCC Sodium Lauryl Sulfate NF
Aluminum Monostearate Hyqual 2263	Palm	NF
Calcium Stearate HyQual 2248	Palm	NF/FCC
Calcium Stearate HyQual 2249	Palm	NF

- Magnesium Stearate NF Veg 1726 is suitable for formulations with a larger particle size
- Magnesium Stearate HyQual 2257 is our most frequently used product for pharmaceutical applications, while Magnesium Stearate HyQual 5712, our second most frequently used product, provides a slightly smaller particle size
- The spray-dried mixture of magnesium stearates and sodium lauryl sulfate in Stear-O-Wet 8577 improves the disintegration and dissolution of drug substances in tablets; RSPO Certification still in process
- Aluminum Monostearate Hyqual 2263 promotes gelling in oil-based preparations, including suppositories, injections and topicals
- Calcium Stearate HyQual 2249 comes in a fine powder, offering a smaller particle size option

***All pharmaceutical grade products are Kosher for Passover (except 1726 and Stear-O-Wet which are not Kosher) and Halal-certified (except 1726).***



## Mallinckrodt Offers a Top Line of Food Grade and Nutraceutical Stearates

PRODUCT	SOURCE	SPECIFICATIONS
Magnesium Stearate Nutraceutical 4024	Palm	NF
Magnesium Stearate Food Grade 3508	Palm	FCC
Calcium Stearate Food Grade 5853	Palm	FCC

*All food grade and nutraceutical products are Kosher for Passover and Halal-certified.*



## Protecting Human and Environmental Health

We are committed to meeting all government agency and surrounding community environmental permits and regulations.

### Air

- Air permit July 19, 2017
- 34,379 total leak detection and repair (LDAR)
- More than 31,000 LDAR inspections in 2018

### Water

- MSD user permit December 22, 2017
- 21 discharge points
- 8 special discharge permits in 2018
- 166 water samples in 2018

### Waste

- 817 active waste streams in 2018
- 41 waste samples in 2018
- 187 shipments in 2018
- 153 soil roll-offs shipped in 2018



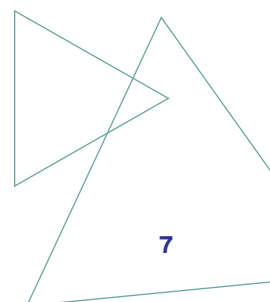
## Dedicated to Environmental Health & Safety (EHS) and Sustainability

### At Our Saint Louis Manufacturing Site We Enhanced:

- Utilization of our Near Miss and Hazard Observation Program to increase employee awareness and lead to improvements
- Lean tools utilization to drive systematic improvements relating to EHS

### Earned:

- Missouri Water Environmental Association (MWEA) Award for Excellence in wastewater compliance
- 2016 and 2017 Mallinckrodt EHS Excellence awards
- Recognition by local businesses and agencies for maintaining decades of community outreach and facilitating a quarterly Community Advisory Panel (CAP)





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