

**Bulk Pharmaceutical Actives****Directly Compressible Ibuprofen U.S.P. / E.P.****Typical Properties and Applications**

| Grade | DCI - 63[®] Product code 3823 | DCI - 90[®] Product code 3825 |
|-----------------------------|---|---|
| Appearance | White to off-white granular powder | |
| Active Ingredients % | 63% | 90% |
| Excipients % | 37% | 10% |

Particle size analysis (ROTAP)**Typical Cumulative % Retained**

| | | |
|---|--|---|
| <ul style="list-style-type: none"> • US Std #20 mesh (850μ) • US Std #60 mesh (250μ) • US Std #100 mesh (150μ) • US Std #200 mesh (75μ) | 7% max. 20% min. 40% min. 65% min. | 5% max. 25% min. 60% min. 80% min. |
| Bulk density (g/ml) | 0.44 - 0.64 | 0.40 - 0.59 |
| Packaging | 50kg fibre drum | 50kg fibre drum |
| Other | Contains lubricants Completely formulated | No lubricants Additional formulation needed |
| Application | Developed for 200mg tablets | Developed for 200-800mg tablets, also for formulations with other actives. |

- **Continuous quality testing and monitoring**
- **High purity and consistent particle size**
- **Fully validated process**
- **Full compliance to current GMP**
- **Country of Origin – U.S.A**

The information printed herein is derived from our own laboratories and other sources and is believed to be accurate. However, it may be modified by later findings and should be used with this understanding. Nothing herein shall be construed as a recommendation to use any product in violation of any patent rights. The user shall have sole responsibility for determination of whether this product is suitable for any particular purpose. Prior to use, refer to the Material Safety Data Sheet for assistance in determining safe handling, storage and use procedures.

Pharmaceuticals Operating Group Office for Europe, Middle East, Africa and Asian Sub-Continent
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Bulk Pharmaceutical Actives Medicinal Narcotic Product List

| Code | Product | US DMF | EDMF | COS | DEA Schedule | Unit |
|------|--|--------|------|-----|--------------|-------|
| 3993 | Amphetamine Aspartate | Yes | No | | II | kg |
| 4942 | Amphetamine Sulphate | Yes | No | | II | kg |
| 1535 | Codeine USP Small Crystals | Yes | No | | II | kg |
| 1548 | Codeine Phosphate USP Powder (EP) | Yes | Yes | Yes | II | kg |
| 1550 | Codeine Phosphate USP Special | Yes | No | | II | kg |
| 1561 | Codeine Phosphate USP Coarse crystals | Yes | No | Yes | II | kg |
| 2901 | Dextroamphetamine Saccharate | Yes | No | | II | kg |
| 1950 | Dextroamphetamine Sulphate | Yes | No | | II | kg |
| 1578 | Dihydrocodeine Bitartrate (Parzone) | Yes | IP | | II | kg |
| 1568 | Dihydrocodeine Tartrate BP | Yes | IP | | II | kg |
| 1592 | Diphenoxylate Hydrochloride USP | Yes | No | | II | kg |
| 1593 | Diphenoxylate Hydrochloride with 1% Atropine Sulfate | Yes | No | | V | kg |
| 0129 | Fentanyl Alkaloid (EP) | Yes | Yes | IP | II | g |
| 5527 | Fentanyl Alkaloid Powder (EP) | Yes | Yes | IP | II | g |
| 1130 | Fentanyl Citrate USP Special (EP) | Yes | Yes | | II | g |
| 1582 | Hydrocodone Bitartrate USP Crystals | Yes | Yes | | II | kg |
| 3245 | Hydromorphone Hydrochloride USP | Yes | No | | II | g |
| 0735 | Levorphanol Tartrate USP | Yes | No | | II | g |
| 1585 | Meperidine HCl USP | Yes | No | | II | kg |
| 1571 | Methylphenidate Hydrochloride USP | Yes | Yes | | II | kg |
| 7654 | Methylphenidate Base | Yes | No | | II | kg |
| 7689 | Morphine Alkaloid | Yes | Yes | | II | kg |
| 1521 | Morphine Sulphate USP (Special) (EP) | Yes | Yes | | II | kg |
| 3310 | Nalbuphine Hydrochloride (Low Beta Epimer) | Yes | Yes | | NR | kg |
| 1492 | Naloxone Hydrochloride USP Dihydrate Standard (EP) | Yes | Yes | | NR | kg |
| 4605 | Naltrexone Base | Yes | Yes | | NR | kg |
| 3940 | Naltrexone Base Anhydrous | Yes | Yes | | NR | kg |
| 1479 | Naltrexone Hydrochloride (EP) | Yes | Yes | IP | NR | kg |
| 6040 | Noscapine USP Small Crystals (EP) | Yes | Yes | | NR | kg |
| 6150 | Noscapine Hydrochloride Purified (EP) | Yes | Yes | | NR | kg |
| 1676 | Opium Powder USP | No | No | | II | kg |
| 4311 | Opium Tincture 2% | No | No | | II | litre |
| 8865 | Oxycodone Hydrochloride USP (D) | Yes | Yes | | II | kg |
| 6464 | Oxycodone Terephthalate USP | Yes | No | | II | kg |
| 0881 | Oxymorphone Hydrochloride | Yes | No | | II | kg |
| 1273 | Propoxyphene Hydrochloride USP Powder | Yes | No | | II | kg |
| 1283 | Propoxyphene Napsylate USP | Yes | No | | II | kg |
| 0310 | Sufentanil Base (EP) | Yes | Yes | | II | g |
| 0672 | Sufentanil Citrate USP (EP) | Yes | Yes | | II | g |

NR: Not regulated under the Controlled Substance Act

IP: In progress

Pharmaceuticals Operating Group Office for Europe, Middle East, Africa and Asian Sub-Continent:

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PARACETAMOL DIRECT COMPRESSION GRADES (Paracetamol Ph.EUR. / Acetaminophen, U.S.P.)

Chemical Specifications

| COMPAP | COMPAP L | COMPAP COARSE L | COMPAP CPM | COMPAP WSE | COMPAP PVP3 | DC (PGS) 273N | DC (PVP) 284N | DC 272N |
|-------------------|-------------------|-----------------------|------------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| 0090 50KG ● | 0093 50KG ■ | 0114 50KG ■ | 0117 50KG ▲ | 2907 50KG ▲ | 3930 50KG ● | 4255 50KG ● | 3973 50KG ● | 4377 50KG ● |
| ● DRY BLEND | ■ DRUM TO HOPPER | ▲ SPECIAL FORMULATION | ■ SUITABLE FOR COMBINATION TABLETS | | | | | |

GRADE:
PRODUCT CODE:
CONTAINER:
PACKAGING TYPE:

SPECIFICATION

Appearance
Assay % as C₈H₉NO₂
Water
Loss on drying
Residue on Ignition
Heavy Metals
Total Viable Count
Yeast and Mold
E. Coli Type 1
Staphylococcus Aureus
Pseudomonas Aeruginosa
Salmonella Sp.

LIMITATION

| White free-flowing granular powder | White free-flowing granular powder | White free-flowing granular powder | White free-flowing granular powder | White free-flowing granular powder | White free-flowing granular powder | White to pale cream free-flowing powder | White to pale cream free-flowing powder | White to pale cream free-flowing powder |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|---|---|---|
| 87.5-92.5 ≤1.5% | 87.5-92.5 ≤2.5% | 87.5-92.5 ≤1.5% | 87.5-92.5 ≤0.45% | 92.5-97.5 ≤0.1% | 95.5-98.5 ≤1.0% | 93.0-96.0 ≤0.85% | 94.5-97.5 | 94.5-97.5 |
| ≤0.14% | ≤0.2% | ≤0.14% | ≤0.14% | ≤10 p.p.m | ≤20 p.p.m. | ≤10 p.p.m. | ≤10 p.p.m. | ≤10 p.p.m. |
| ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g | ≤1000 organisms/g |
| Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative |
| Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative |
| Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative |
| Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative | Negative |
| ● Organisms absent from a 10gm. sample | | | | | | | | |

TYPICAL BULK
DENSITY (g/ml)

PARACETAMOL /
ACETAMINOPHEN
% CONTENT

| | | | | | | | |
|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| 0.44-0.51 | 0.49-0.70 | 0.46-0.50 | 0.48-0.57 | 0.50-0.56 | 0.48-0.52 | 0.48-0.52 | 0.48-0.52 |
| 90 | 90 | 90 | 95 | 97 | 95 | 96 | 96 |

Note: All paracetamol used for these products complies with the United States Pharmacopoeia (USP) and the European Pharmacopoeia (Ph.EUR).

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Date of issue: 02/10/97

M ALLINCKRODT
CHEMICAL

Product Composition
Direct Compression
Paracetamol (Ph.EUR) / Acetaminophen (USP)

| Grade | Composition |
|-----------------------------|--|
| Compap | Paracetamol Pregelatinized Starch |
| Compap L | Paracetamol Pregelatinized Starch Povidone Crospovidone Stearic Acid |
| Compap Coarse L | Paracetamol Pregelatinized Starch Povidone Stearic Acid |
| Compap CPM | Paracetamol Chlorpheniramine Maleate Pregelatinized Starch Povidone Stearic Acid |
| Compap WSE | Paracetamol Povidone Maltodextrin |
| Compap PVP3 | Paracetamol Povidone |
| Paracetamol, Taste - Masked | Paracetamol Ethylcellulose |
| DC 272 | Paracetamol Gelatin |
| DC 273 | Paracetamol Pregelatinized Starch Povidone |
| DC 284 | Paracetamol Povidone |

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Date of Issue: 05/03/98

 **MALLINCKRODT
CHEMICAL**

PARACETAMOL POWDER GRADES
(100% Paracetamol Ph.EUR./Acetaminophen, U.S.P.)

Physical Characteristics

| MICRONISED | FINE POWDER | SEMI-FINE POWDER | POWDER | DENSE POWDER | GRANULAR | SPECIAL GRANULAR |
|---|----------------|---------------------------------------|--|--|---|------------------|
| 0422 50KG ● | 7845 50KG ● | 0084 0896 100KG 600KG ● | 6088-0048 50KG-100KG ● | 5542 - 5543 50KG - 100KG ● | 6135 - 0057 50KG - 100KG ● | 1617 100KG ● |
| LEVERPAK DRUM INCORPORATING METAL CHURN AND LEVERLOCK | | 'BIG BAG' PACKING TECHNOLOGY (IBC) | 100% FIBRE DRUM WITH NO METAL OR PLASTIC PARTS (CYLINDRICAL) | 100% FIBRE DRUM WITH NO METAL OR PLASTIC PARTS (CYLINDRICAL) | 100% FIBRE DRUM WITH NO METAL OR PLASTIC PARTS ('ROCON' TYPE FOR OPTIMUM PALLETISATION) | |

TYPICAL PARTICLE SIZE DISTRIBUTION ANALYSIS (CUMULATIVE % RETAINED).

| MESH | MICRON | | SPEC | | TYPICAL | | SPEC | | TYPICAL | | SPEC | | TYPICAL | |
|------|--------|---------|------|---------|---------|---------|------|---------|---------|---------|------|---------|---------|---------|
| | SPEC | TYPICAL | SPEC | TYPICAL | SPEC | TYPICAL | SPEC | TYPICAL | SPEC | TYPICAL | SPEC | TYPICAL | SPEC | TYPICAL |
| >10 | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| >16 | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| >18 | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| >20 | - | - | - | - | - | 0.1 | - | - | 0 | - | ≤0.1 | - | - | - |
| >40 | - | 0 | - | 0 | ≤1 | 0.6 | - | - | 5 | - | 39 | 0.1 | - | 0 |
| >60 | 0 | 0.3 | - | ≤2 | 1 | 4 | - | - | 35 | - | 86 | - | - | 0.1 |
| >80 | - | 1 | - | 3 | - | 10 | - | - | 46 | - | 93 | - | - | 80 |
| >100 | ≤1 | 0.1 | - | 5 | - | 11 | - | - | 50 | - | 94 | - | - | 98 |
| >140 | - | - | - | ≤12 | - | 10-25 | - | - | - | - | - | - | - | 100 |
| >200 | 0.1 | - | 9 | 17 | - | 32 | - | - | 75 | - | 97 | - | - | - |
| >325 | 0.4 | - | 21 | 34 | - | 47 | - | - | 88 | - | 98 | - | - | - |
| >400 | 1 | 10-30 | 23 | 37 | 30-45 | 56 | - | - | 90 | - | 99 | - | - | - |
| >500 | 38 | - | 38 | 52 | - | 65 | - | - | 93 | - | - | - | - | - |
| >635 | 67 | - | 50 | 68 | - | 84 | - | - | 98 | - | - | - | - | - |

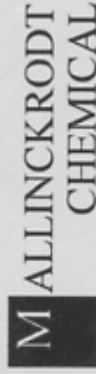
| TYPICAL BULK DENSITY g/ml | 0.24 | 0.26 | 0.31 | 0.41 | 0.90 | 0.89 | 0.83 |
|---------------------------|------|------|------|------|------|------|------|
|---------------------------|------|------|------|------|------|------|------|

| SUGGESTED APPLICATION | SUPPOSITORIES | LIQUID PRODUCTS GRANULATION | GRANULATION FOR TABLETS | GRANULATION FOR TABLETS | CAPSULES / SACHETS | TABLETS / SACHETS | ENCAPSULATION |
|-----------------------|---------------|-----------------------------|-------------------------|-------------------------|--------------------|-------------------|---------------|
|-----------------------|---------------|-----------------------------|-------------------------|-------------------------|--------------------|-------------------|---------------|

Note: All grades are tested for compliance with the United States Pharmacopoeia (USP) and the European Pharmacopoeia (Ph. EUR.)

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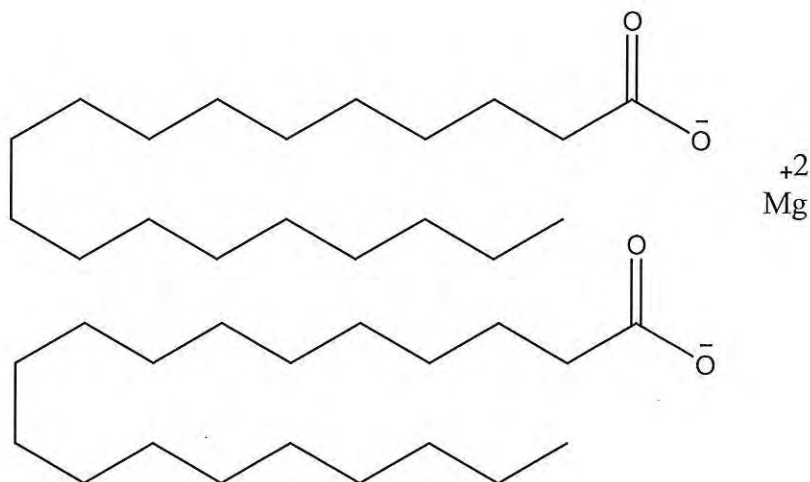
Date of Issue: 01/11/95



Magnesium Stearate NF Kosher Passover HyQual[®]

Technical Package, January 2020

**Magnesium Stearate NF Kosher Passover HyQual[®],
Code 5712**





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Pharmaceuticals

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Camille Pokorny

Sales Support Representative
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Properties

Generic Names

Magnesium Stearate

Chemical Name

- a) Octadecanoic Acid Magnesium Salt
- b) Stearic Acid Magnesium Salt

Chemical Abstract Services (CAS) Registry Number

557-04-0

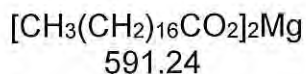
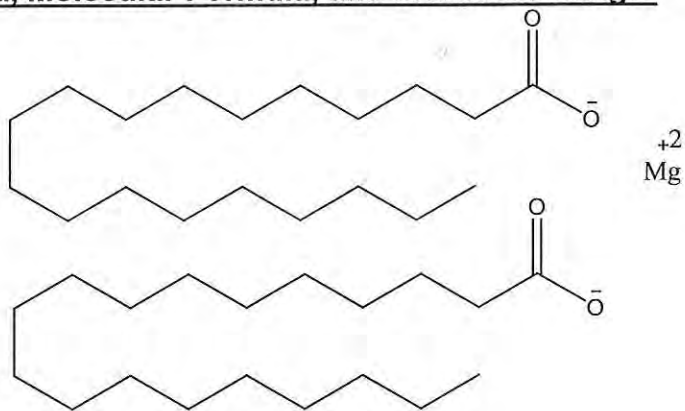
SpecGx LLC Code Number

5712

Physical Description

Fine, white powder

Structural Formula, Molecular Formula, and Molecular Weight



Solubility

Insoluble in water, ether
Soluble in hot alcohol

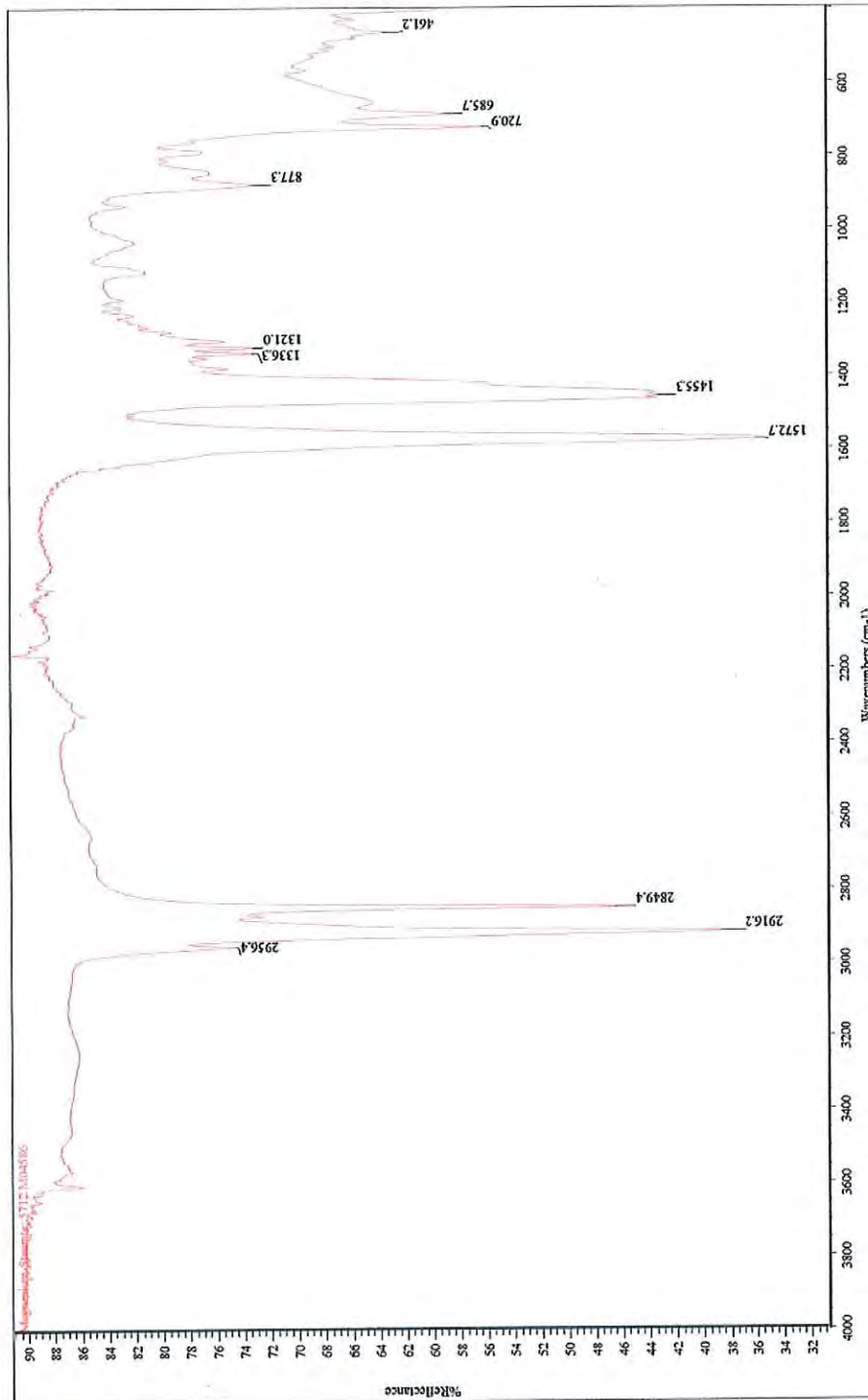
Odor

Slightly characteristic, fatty odor

Specific Gravity

1.03

Infrared Spectrum



Davidson 8/14/09
MS 8/4/09

Collection time: Mon Jul 27 15:02:46 2009 (GMT-07)
 Magnesium Stearate; 5712 M04586
 IR #46133 CAR #10718 Prep: ATR/diamond From: Ball
 Center for Analytical Research, Covidien

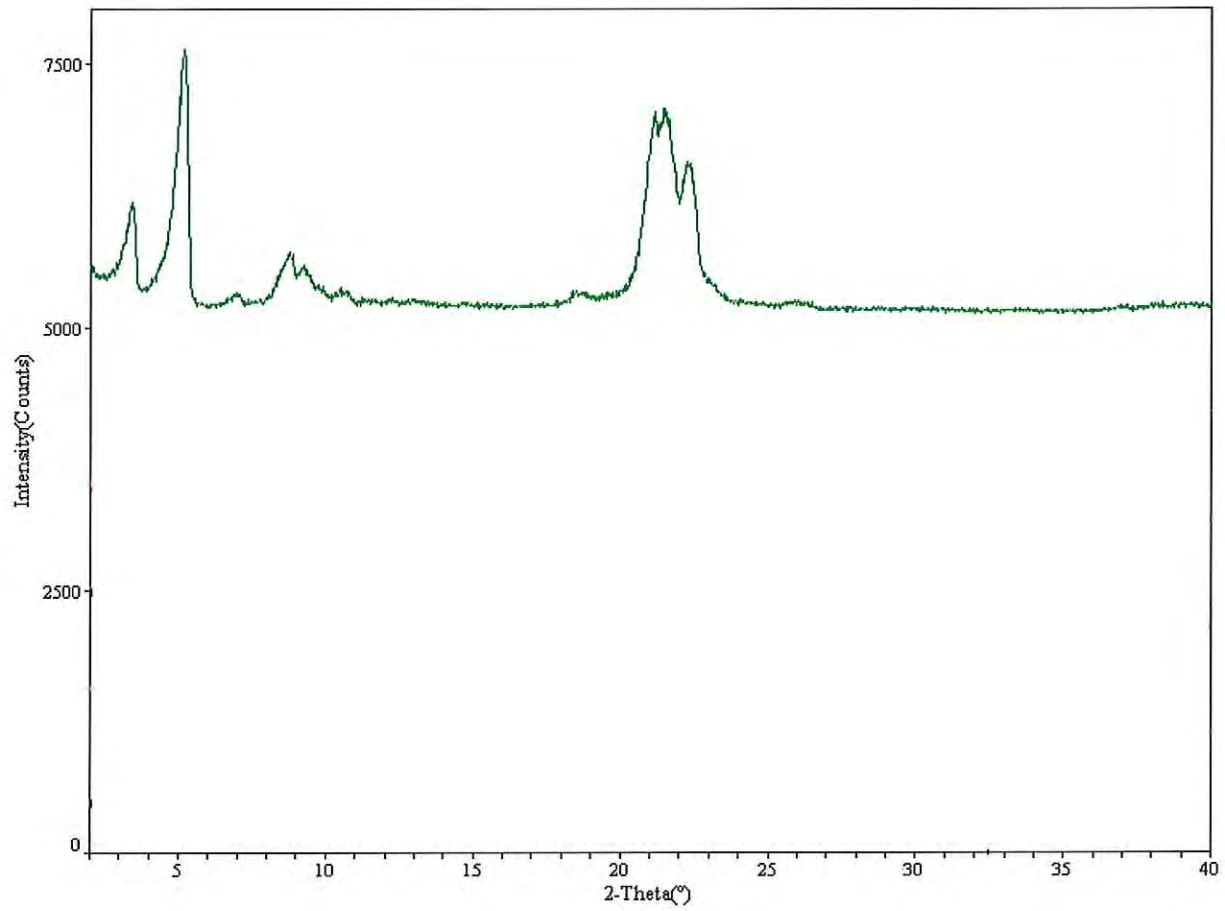
Number of sample scans: 64
 Number of background scans: 64
 Resolution: 4.000
 Sample gain: 5.0
 Mirror velocity: 0.6329
 Aperture: 100.00

Scanning Electron Microscope (SEM) pictograph

Image 10718-G3, Sample Code 5712 Lot M04586 (10718-G3.tif)



X-Ray Diffraction (XRD) pattern



Particle Size Distribution

The particle size of Magnesium Stearate code 5712 is controlled per the product specification found in the Specifications and Methods Manual for code 5712. This manual is found in the specifications portion of this package.

The results of three (3) typical production lots are listed below.

| <u>SpecGx LLC Samples</u> | <u>D10(microns)</u> | <u>D50 (microns)</u> | <u>D90 (microns)</u> | <u>Mean (microns)</u> |
|----------------------------------|----------------------------|-----------------------------|-----------------------------|------------------------------|
| 5712 L09626 | 3.98 | 9.14 | 21.64 | 11.59 |
| 5712 L09463 | 4.34 | 10.11 | 25.63 | 13.36 |
| 5712 L09464 | 4.74 | 10.95 | 23.68 | 13.12 |

Purity/Impurity Profile

The purity/impurity profile for Magnesium Stearate Code 5712 is controlled by product release specifications. The impurities are as follows: chloride (0.025% max.), sulfate (0.5% max.), lead (10.0 ppm max.), cadmium (3.0 ppm max.), nickel (5.0 ppm max.), and heavy metals (20 ppm max.). No class I, II, III or other organic solvents are used in the production of Magnesium Stearate, code 5712.

Stability

Samples from one lot per year of Magnesium Stearate are stored at H2 conditions, 25°C (+/- 2°C) / 60% RH (+/- 5%) and are tested initially and at 3, 6, 9, 12, 18, 24, 36, 48, and 60 months. The data from these studies do not indicate chemical or physical instability of Magnesium Stearate under the conditions of the tests, thus, a 5 year retest date has been established for Magnesium Stearate Code 5712.

Forced Degradation

Magnesium Stearate Code 5712 is very stable under normal storage conditions. This product is shown to dehydrate when heated above 60°C and to decompose at temperatures above 275°C.

Specifications

Attached is the specification for Magnesium Stearate, Code 5712.

Specifications and Methods Manual

| | |
|------------------------------|--|
| Page 1 of 2 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSOVER HYQUAL® |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Bulk Drug |

MEETS NATIONAL FORMULARY (NF) SPECIFICATIONS

MEETS EUROPEAN/BRITISH PHARMACOPEIA (EP/BP) SPECIFICATIONS

MEETS CHINESE PHARMACOPEIA (ChP) SPECIFICATIONS

MEETS JAPANESE PHARMACOPEIA (JP) SPECIFICATIONS

MEETS MB (Mass Balance) RSPO CERTIFICATION. Member Number: 4-1048-18-000-00. Certificate Number:
BMT-RSPO-001149

THIS PRODUCT IS MANUFACTURED WITH NO ANIMAL
DERIVED RAW MATERIALS

NO CLASS I, II, III OR OTHER ORGANIC SOLVENTS ARE USED IN
THE MANUFACTURING PROCESS. MEETS USP <467> RESIDUAL
SOLVENT OPTION 1 GUIDELINES.

SAFETY PRECAUTIONS

- Use appropriate laboratory safety procedures. Consult your supervisor and the appropriate SDS (Safety Data Sheet).
- WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR. Store in a tightly closed container. Avoid dust cloud in presence of an ignition source. Maintain adequate ventilation.

TEST AND SPECIFICATION LIMITS

| | |
|--|----------------------------|
| Appearance | Fine, white powder |
| Identification (Magnesium) (NF/EP/BP/JP/ChP) | Meets requirements |
| Identification (Major Peak) (NF/EP/BP/JP/ChP) | Peak retentions match |
| Microbial Limits (NF/EP/BP/JP/ChP) | |
| Total Aerobic Count | 1000 cfu/g max |
| Total Mold And Yeast | 100 cfu/g max |
| Salmonella | Negative |
| E. Coli | Negative |
| Acidity Or Alkalinity (NF/EP/BP/JP/ChP) | Meets requirements |
| Loss On Drying (NF/EP/BP/JP) | 4.0% max |
| Loss on Drying (ChP) | 5.0% max |
| Specific Surface Area (NF<846>Method II) (EP<2.9.26>Method II) | 6.0-12.0 m ² /g |

Specifications and Methods Manual

| | |
|---------------------------|--|
| Page 2 of 2 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSOVER HYQUAL® |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Bulk Drug |

| | |
|--|-------------------|
| Limit Of Chloride (NF/EP/BP/JP) | 0.025% max |
| Limit of Chloride (ChP) | 0.10% |
| Limit Of Sulfate (NF/EP/BP/JP) | 0.5% max |
| Limit of Sulfate (ChP) | 0.6% max |
| Iron (ChP) | 0.01% max |
| Lead (NF/EP/BP) (VR#622) | 10.0 ppm max |
| Cadmium (NF/EP/BP) | 3.0 ppm max |
| Nickel (NF/EP/BP) | 5.0 ppm max |
| Residual Solvents (USP<467>Method IV) | Certified free |
| Relative Content Of Stearic Acid And Palmitic Acid (NF/JP/ChP) | |
| Fatty Acid Composition (EP/BP) | |
| Stearic Acid | 40.0% min |
| Stearic Acid And Palmitic Acid | 90.0% min |
| Assay (Mg) (Dried Basis) (NF/EP/BP/JP/ChP) | 4.0-5.0% |
| Heavy Metals (JP) | 20 ppm max |
| Heavy Metals (ChP) | 0.0015% max |
| Sieve Test Us Standard No. 325 | 99.5% min through |
| Apparent Density | 0.07-0.17 g/cc |
| Tapped Density | 0.18-0.33 g/cc |
| Particle Size 90th Percentile | 35 µm max |
| Particle Size 50th Percentile | 6.0-14.0 µm |
| Acid Value | 195-210 |

Specifications and Methods Manual

| | |
|---------------------------|--|
| Page 1 of 5 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSEVER HYQUAL® |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Bulk Drug |

MEETS NATIONAL FORMULARY (NF) SPECIFICATIONS

MEETS EUROPEAN/BRITISH PHARMACOPEIA (EP/BP) SPECIFICATIONS

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BMT-RSPO-001149

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- Use appropriate laboratory safety procedures. Consult your supervisor and the appropriate SDS (Safety Data Sheet).
- **WARNING! MAY FORM COMBUSTIBLE DUST CONCENTRATIONS IN AIR.** Store in a tightly closed container. Avoid dust cloud in presence of an ignition source. Maintain adequate ventilation.

APPEARANCE

Fine, white powder

This test is stability indicating.

Place a small amount of sample on glassine paper. Spread evenly using a spatula and observe over a white background under good lighting. The sample should be a fine, white powder with no contamination, foreign matter, or dirt present.

IDENTIFICATION (Magnesium) (NF/EP/BP /JP/ChP)

Meets requirements

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/FCC)"

IDENTIFICATION (Major Peak) (NF/EP/BP/ JP/ChP)

Peak retentions match

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

Specifications and Methods Manual

| | |
|------------------------------------|--|
| Page 2 of 5 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSOVER HYQUAL® |
| SITE RESPONSIBLE: St. Louis | |
| INTENDED USE: Bulk Drug | |

MICROBIAL LIMITS (NF/EP/BP/JP/ChP)

| | |
|----------------------|----------------|
| TOTAL AEROBIC COUNT | 1000 cfu/g max |
| TOTAL MOLD AND YEAST | 100 cfu/g max |
| SALMONELLA | Negative |
| E. COLI | Negative |

This test is stability indicating.

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

ACIDITY OR ALKALINITY (NF/EP/BP/JP/ChP) Meets requirements

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

LOSS ON DRYING (NF/EP/BP/JP) 4.0% max

This test is stability indicating

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

LOSS ON DRYING (ChP) 5.0% max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

SPECIFIC SURFACE AREA (NF<846>Method II) (EP<2.9.26>Method II) 6.0-12.0 m²/g

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

LIMIT OF CHLORIDE (NF/EP/BP/JP) 0.025% max

LIMIT OF CHLORIDE (ChP) 0.10%

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

LIMIT OF SULFATE (NF/EP/BP/JP) 0.5% max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

LIMIT OF SULFATE (ChP) 0.6% max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

IRON (ChP) 0.01% max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

Specifications and Methods Manual

| | |
|---------------------------|--|
| Page 3 of 5 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSOVER HYQUAL® |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Bulk Drug |

LEAD (NF/EP/BP) (VR#622) 10.0 ppm max

CADMIUM (NF/EP/BP) 3.0 ppm max

NICKEL (NF/EP/BP) 5.0 ppm max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

RESIDUAL SOLVENTS (USP<467>Method IV) Certified free

This product is certified free of Residual Solvents. Record as "Certified free".

RELATIVE CONTENT OF STEARIC ACID AND PALMITIC ACID (NF/JP/ChP)

FATTY ACID COMPOSITION (EP/BP)

STEARIC ACID 40.0% min

STEARIC ACID AND PALMITIC ACID 90.0% min

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

ASSAY (Mg) (dried basis) (NF/EP/BP/JP/ChP) 4.0-5.0%

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

HEAVY METALS (JP) 20 ppm max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

HEAVY METALS (ChP) 0.0015% max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

SIEVE TEST US STANDARD NO. 325 99.5% min through

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)".

APPARENT DENSITY 0.07-0.17 g/cc

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)".

Specifications and Methods Manual

| | |
|---------------------------|--|
| Page 4 of 5 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSOVER HYQUAL® |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Bulk Drug |

TAPPED DENSITY 0.18-0.33 g/cc

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)".

PARTICLE SIZE 90th Percentile 35 µm max

PARTICLE SIZE 50th Percentile 6.0-14.0 µm

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)".

ACID VALUE 195-210

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)".

FREE FATTY ACID (run on request only) 2.0% Max.

This test is stability indicating.

Reagents:

Acetone

0.1 N Sodium Hydroxide – Prepare and standardize according to USP.

Phenolphthalein Test Solution:

Dissolve 1 gram of phenolphthalein in 100 mL of alcohol.

Sample Solution:

Transfer about 2.0 grams of sample, accurately weighed using an analytical balance, to a dry 125-mL Erlenmeyer flask. Add 50 mL of acetone and swirl to mix. Fit an air-cooled reflux condenser onto the neck of the flask and boil the mixture on a steam bath for 10 minutes. Cool the solution to room temperature. Filter the mixture through two (2) layers of Whatman No. 42 filter paper and wash the flask, residue, and filter with 50 mL of acetone. Add 5 mL of water to the filtrate.

Sample Analysis:

Add a few drops of phenolphthalein TS to the Sample Solution and titrate with 0.1 N sodium hydroxide. Perform a blank determination on 100 mL of acetone and 5 mL water.

Specifications and Methods Manual

| | |
|---------------------------|--|
| Page 5 of 5 | Mallinckrodt Pharmaceuticals |
| Formula Wt. or Atomic Wt. | CODE: 5712 FORMULA: ITEM: MAGNESIUM STEARATE NF KOSHER PASSOVER HYQUAL® |
| SITE RESPONSIBLE: | St. Louis |
| INTENDED USE: | Bulk Drug |

Calculation:

Calculate the free fatty acid result from the following equation:

$$\% \text{ Free Fatty Acid} = \frac{(V_{\text{sample}} - V_{\text{blank}}) \times (\text{BF}) \times (0.02845) \times 100\%}{(\text{Sample Weight, g})}$$

where: V_{sample} = titration of sample
 V_{blank} = titration of blank
 BF = bottle factor of sodium hydroxide (bottle factor = actual normality/0.1 N)

SUBDIVISION

Perform the following tests on the Subdivision sample.

BULK DISPOSITION CHECK

To pass test

The disposition of the parent lot should be carried forward to this subdivided lot.

APPEARANCE

Fine, white powder

Place a small amount of sample on glassine paper. Spread evenly using a spatula and observe over a white background under good lighting. The sample should be a fine, white powder with no contamination, foreign matter, or dirt present.

IDENTIFICATION (Magnesium) (NF/EP/BP/JP/ChP)

Meets requirements

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

MICROBIAL LIMITS (NF/EP/BP/JP)

| | |
|----------------------|----------------|
| TOTAL AEROBIC COUNT | 1000 cfu/g max |
| TOTAL MOLD AND YEAST | 100 cfu/g max |
| SALMONELLA | Negative |
| E. COLI | Negative |

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

LOSS ON DRYING (NF/EP/BP/JP)

4.0% max

Determine according to SM-208 "Analysis of Magnesium Stearate (NF/EP/BP/JP/ChP/FCC)"

SDS

Attached is the SDS for Magnesium Stearate, Code 5712.

1. Identification

| | | | |
|---|--|---------------------------------|--|
| Product identifier | MAGNESIUM STEARATE | | |
| CAS # | 557-04-0 | | |
| Other means of identification | | | |
| SDS number | M0230 | | |
| Synonyms | STEARIC ACID, MAGNESIUM SALT * Octadecanoic acid, magnesium salt | | |
| Recommended use | Laboratory reagent or process chemical. | | |
| Recommended restrictions | None known. | | |
| Manufacturer/Importer/Supplier/Distributor information | | | |
| Manufacturer | | | |
| Company name | SpecGx LLC | | |
| Address | 385 Marshall Ave Webster Groves MO, 63119 | | |
| E-mail | Not available. | | |
| Customer Service | Customer Service | 1-800-895-9048 (USA and Canada) | |
| | Customer Service | +1-314-654-2000 (Worldwide) | |
| 24 Hour Emergency | CHEMTREC | 1-800-424-9300 (USA and Canada) | |
| Item code | 1277, 1726, 1729, 2254, 2255, 2256, 2257, 2279, 3508, 4024, 5705, 5712, 5716, 5774, 5777, 6504, 7205, 7807 | | |

2. Hazard(s) identification

| | |
|-----------------------|------------------|
| Physical hazards | Not classified. |
| Health hazards | Not classified. |
| Environmental hazards | Not classified. |
| OSHA defined hazards | Combustible dust |

*Hazards not stated here are "Not classified", "Not applicable" or "Classification not possible".

Labeling

| | |
|---|---|
| Contains | MAGNESIUM STEARATE |
| Label elements | |
| Hazard symbol | None. |
| Signal word | Warning |
| Hazard statement | May form combustible dust concentrations in air. |
| Precautionary statement | |
| Prevention | Observe good industrial hygiene practices. |
| Response | Wash hands after handling. |
| Storage | Store away from incompatible materials. |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Hazard(s) not otherwise classified (HNOC) | May form combustible dust concentrations in air. Dust accumulation from this product may present an explosion hazard in the presence of an ignition source. |
| Supplemental information | None. |

3. Composition/information on ingredients**Substances**

| Chemical name | Common name and synonyms | CAS number | % |
|--------------------|---|------------|--------|
| MAGNESIUM STEARATE | STEARIC ACID, MAGNESIUM SALT Octadecanoic acid, magnesium salt | 557-04-0 | <= 100 |

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Call a POISON CENTER or doctor/physician if you feel unwell.

Skin contact Remove contaminated clothing. Wash off with soap and water. Wash clothing separately before reuse. Get medical attention if irritation develops and persists.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Rinse mouth thoroughly. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

Most important symptoms/effects, acute and delayed Dusts may irritate the respiratory tract, skin and eyes.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen.

General information Call a POISON CENTER or doctor/physician if you feel unwell. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Flammable properties Dust may form explosive mixture with air.

Suitable extinguishing media Water spray. Alcohol foam. Dry chemical powder. Carbon dioxide (CO₂). Addition of water or foam to the fire may cause frothing.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical Melted fatty acid can give "grease" type fire. Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed such as: Carbon oxides. May include oxides of Magnesium.

Special protective equipment and precautions for firefighters Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

Fire-fighting equipment/instructions In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Specific methods In the event of fire and/or explosion do not breathe fumes. Cool containers exposed to flames with water until well after the fire is out.

General fire hazards Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust from the spilled material. Wear a dust mask if dust is generated above exposure limits. Ventilate closed spaces before entering them.

Methods and materials for containment and cleaning up ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions No special environmental precautions required.

7. Handling and storage

| | |
|---|---|
| Precautions for safe handling | DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Minimize dust generation and accumulation. Keep formation of airborne dusts to a minimum. Dust may form explosive mixture with air. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges. Static electricity and formation of sparks must be prevented. All equipment used when handling the product must be grounded. Ground and bond containers when transferring material. Use non-sparking tools and explosion-proof equipment. Avoid breathing dust. Avoid contact with skin and eyes. When using, do not eat, drink or smoke. Wash thoroughly after handling. Handle and open container with care. |
| Conditions for safe storage, including any incompatibilities | For storage condition, see finished product label. Keep container tightly closed. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat and sources of ignition. This material can accumulate static charge which may cause spark and become an ignition source. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Use care in handling/storage. |

8. Exposure controls/personal protection

Occupational exposure limits

U.S. - OSHA

| Material | Type | Value | Form |
|--------------------------------------|------|----------|--|
| MAGNESIUM STEARATE (CAS 557-04-0) | PEL | 5 mg/m3 | Respirable fraction for nuisance dusts |
| | | 15 mg/m3 | Total dust |

ACGIH

| Material | Type | Value |
|--------------------------------------|------|----------|
| MAGNESIUM STEARATE (CAS 557-04-0) | TWA | 10 mg/m3 |

US. ACGIH Threshold Limit Values

| Material | Type | Value |
|--------------------------------------|------|----------|
| MAGNESIUM STEARATE (CAS 557-04-0) | TWA | 10 mg/m3 |

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection Use tight fitting goggles if dust is generated. Provide eyewash station and safety shower.

Skin protection

Hand protection

Wear protective gloves. Gloves of nitrile rubber, PVA or Viton are recommended.

Other

Wear suitable protective clothing.

Respiratory protection

Wear respirator with dust filter. If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using, do not eat, drink or smoke. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Wash hands after handling and before eating. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

| | |
|-----------------------|---------|
| Appearance | Powder. |
| Physical state | Solid. |
| Form | Powder. |

| | |
|---|---|
| Color | White or Yellow. |
| Odor | Slight. |
| Odor threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | 248 - 266 °F (120 - 130 °C) |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not available. |
| Evaporation rate | Not applicable. |
| Flammability (solid, gas) | Not available. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |
| Vapor pressure | < 0.0000001 kPa at 25 °C |
| Vapor density | Not available. |
| Relative density | 1.028 g/cm ³ |
| Solubility(ies) | |
| Solubility (water) | Insoluble in water. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Bulk density | 0.3 g/ml |
| Moisture | 3.5 % |
| Molecular formula | C ₁₈ H ₃₆ O ₂ .1/2Mg |
| Molecular weight | 591.27 g/mol |
| Specific gravity | 1.03 |
| Dust Electrostatic Properties | |
| Minimum Ignition Energy (Cloud) | 3 - 10 mJ |
| Dust Explosion Properties | |
| dP/dT | 955 bar/s |
| Kst | 259 bar.m/s |
| Limiting Oxygen Concentration | 12 - 13 % |
| Minimum Explosible Concentration | 20 - 30 g/m ³ |
| Minimum Ignition Temperature-Cloud | 824 - 860 °F (440 - 460 °C) |
| Minimum Ignition Temperature-Layer | 716 - 734 °F (380 - 390 °C) |
| Moisture | 1 % |
| Particle Size | 8 µm |
| Pmax | 8.8 bar |

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

| | |
|---|--|
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |
| Conditions to avoid | Avoid dust formation. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Heat, flames and sparks. Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. Acids. |
| Hazardous decomposition products | Carbon monoxide. May include oxides of magnesium. |

11. Toxicological information

Information on likely routes of exposure

| | |
|---------------------|---|
| Inhalation | Inhalation of dusts may cause respiratory irritation. Coughing. Difficulty in breathing. Prolonged inhalation may be harmful. |
| Skin contact | May cause skin irritation. |
| Eye contact | Dust or powder may irritate eye tissue. |
| Ingestion | May cause discomfort if swallowed. However, ingestion is not likely to be a primary route of occupational exposure. |

Symptoms related to the physical, chemical and toxicological characteristics Dust or powder may irritate eye tissue. Inhalation of dusts may cause respiratory irritation. Coughing. Difficulty in breathing.

Information on toxicological effects

| | |
|--|--|
| Acute toxicity | Dusts may irritate the respiratory tract, skin and eyes. |
| Skin corrosion/irritation | May cause skin irritation. |
| Serious eye damage/eye irritation | Dust or powder may irritate eye tissue. |

Respiratory or skin sensitization

| | |
|----------------------------------|---|
| Respiratory sensitization | Due to lack of data the classification is not possible. |
| Skin sensitization | Not a skin sensitizer. |

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

MAGNESIUM STEARATE (CAS 557-04-0) A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not available.

| | |
|---|--|
| Reproductive toxicity | This product is not expected to cause reproductive or developmental effects. |
| Specific target organ toxicity - single exposure | Due to lack of data the classification is not possible. |
| Specific target organ toxicity - repeated exposure | Due to lack of data the classification is not possible. |
| Aspiration hazard | Not an aspiration hazard. |
| Chronic effects | Lung edema. Pneumonitis (inflammation of lung tissue). Cyanosis. |
| Further information | Prolonged or repeated inhalation may cause: Pneumonitis (inflammation of lung tissue). Cyanosis (blue tissue condition, nails, lips, and/or skin). Inhalation of powder/dust may cause lung edema. |

12. Ecological information

| | |
|--------------------------------------|---|
| Ecotoxicity | This product has no known eco-toxicological effects. |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulative potential | Not established. |
| Mobility in soil | Not available. |
| Other adverse effects | An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. |

13. Disposal considerations

| | |
|--|--|
| Disposal instructions | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations. |
| Hazardous waste code | Waste codes should be assigned by the user based on the application for which the product was used. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Waste from residues / unused products | Dispose of in accordance with local regulations. |
| Contaminated packaging | Offer rinsed packaging material to local recycling facilities. Empty containers should be taken to an approved waste handling site for recycling or disposal. |

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
All components are on the U.S. EPA TSCA Inventory List.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Total food additive
Direct food additive
GRAS food additive

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | Yes |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | Yes |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | Yes |
| Korea | Existing Chemicals List (ECL) | Yes |
| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | Yes |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | Yes |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

| | |
|------------------------------|---|
| Issue date | 03-19-2015 |
| Revision date | 12-01-2017 |
| Version # | 06 |
| Further information | Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. |
| List of abbreviations | CAS: Chemical Abstract Service. |
| References | ACGIH EPA: AQUIRE database NLM: Hazardous Substances Data Base US. IARC Monographs on Occupational Exposures to Chemical Agents HSDB® - Hazardous Substances Data Bank IARC Monographs. Overall Evaluation of Carcinogenicity National Toxicology Program (NTP) Report on Carcinogens ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices |
| Disclaimer | SpecGx LLC provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. SpecGx LLC MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, SpecGx LLC WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION. |

Revision information

Hazard(s) identification: Hazard(s) not otherwise classified (HNOC)
Other information, including date of preparation or last revision: Disclaimer

Allergens

Attached is SpecGx LLC's Allergens statement, Code 5712.



Thursday, January 09, 2020

**Allergen Statement - Magnesium Stearate NF Kosher Passover HyQual®,
Code 5712**

To Whom It May Concern:

Please be assured that SpecGx LLC's manufactured all lots of Magnesium Stearate, code 5712, are not produced with any of the allergens normally listed by the FDA as common allergens or any of their derivatives. These include the following:

Crustacean shellfish (and products thereof), egg (and products thereof), fish (and products thereof), gluten (wheat/rye/barley), milk (and products thereof), tree nuts/coconut/peanut (and products thereof), Soy/Soybeans (and products thereof)

In addition, our products do not contain additives, including the following common allergens/materials/additives. These are not introduced into our product during manufacturing:

Alcohols (Synthetic/Grain), Animal products (including Porcine), Antibiotics, Apples, Artificial Colors and/or Flavors, Aspartame, Beans, Beets, Benzoate, Caffeine or derivatives thereof, Canola Oil, Carrot, Casein, Cauliflower, Celery (and products thereof), Cereals containing gluten (and products thereof), Cereals Used For Making Alcoholic Distillates Including Ethyl Alcohol or Agricultural Origin, CFC (Chlorofluorocarbon), Cobalt, Colophony, Coloring Agents, Corn/Maize and products thereof, Corn Starch, Cottonseed, Dairy (Milk Derivatives), DEHP, Diethylene Glycol, Diluents, Dried Fruit, Dyes, Eggplant, Flax, Fleshy fish, Flavoring/Sweetener (including nut flavor), Fluorescent Agents or Substances, Fruit, Galactose, Gelatin, Glucose Syrups based on Barley, Glutamate, Glycerin, Glycol, Honey, Hormones, Hydrolyzed plant protein, Hydroxybenzoic Acid Esters, Guaiaac Gum, Iodine, Kamut or their hybridized strains, Lactalbumin, Lactose, Latex or latex contaminants, Lemon/Citrus, Lentils, Lupin, Mercury, Molluscs (and products thereof), MSG, Mustard (and products thereof), Nitrites/Nitrates, Nitrofurazone, Oats, Odor, Olive Oil, Parabens, Parsley, Parthenolide, Peach, Peas, Penicillin, Phenylalanine, Phthalates, Pineapple, Plasticizers, Pollen, Polyethylene Glycol, Pine Resin, Porcine, Potassium Salts, Potato, Preservatives, Potassium Salts, Propolis, Propylene, PVC, Rice, Royal Jelly, Saccharin, Salicylates, Seeds (other than sesame), Seed Oils, Sesame (or products thereof), Sesame Seeds, Sodium Salts, Sorbates, Sorbitol, Spelt, Starch/Carbohydrate/Sugar (including sucralose, sucrose, sugar alcohols, fructose, invert sugar, glucose, maltose), Sulfa/Sulfonamides, Sulfites, Sulphur, Sulphur Dioxide, Sunflower, Talc, Tomato, Tartrazine, Wheat Based Glucose Syrups including Dextrose, Wheat Based Maltodextrins, Whey, Xanthan Gum, Yeast, Zinc

Please note that no carbohydrates, aflatoxins and/or mycotoxins have been detected in our Magnesium Stearate.

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

Digitally signed by Darija Hadziselimovic
DN: cn=Darija Hadziselimovic, o=Mallinckrodt
Pharmaceuticals, ou=Regulatory Affairs,
email=darija.hadziselimovic@mnk.com, c=US
Reason: I attest to the accuracy and integrity of this
document
Date: 2020.01.09 13:29:42 -06'00'

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BSE/TSE

Magnesium Stearate, Code 5712, is a non-bovine product. Attached is SpecGx LLC's BSE/TSE statement.



Thursday, January 09, 2020

BSE/TSE Statement - Magnesium Stearate NF Kosher Passover HyQual®, Code 5712

To Whom It May Concern:

Please be assured our manufactured lots of Magnesium Stearate, code 5712, do not contain, nor are they manufactured with any raw material containing bovine or other animal related products. In addition, this product does not come into contact with any equipment or vessel which could transfer animal related impurities to the product. These Stearates are derived from edible vegetable sources. The fatty acid used in production, Fatty Acid Food Grade Kosher, is derived from palm and produced from the fruit of *Elaeis guineensis*.

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

A handwritten signature in blue ink that reads "DHadziselimovic".

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Elemental Impurities

Attached is SpecGx LLC's Elemental Impurities statement, Code 5712.



Thursday, January 09, 2020

Elemental Impurities/Catalysts - Magnesium Stearate NF Kosher Passover HyQual®, Code 5712

To whom it may concern:

As a supplier of Active Pharmaceutical Ingredients (API) and excipients, SpecGx LLC recognizes the need to provide information to customers with respect to elemental impurities which may be present and expected levels of these impurities. Using a validated method, we have evaluated elemental impurities that may be present in the above product using standards published in USP General Chapter <232>, *Elemental Impurities – Limits*, General Chapter <233> *Elemental Impurities-Procedures* and the ICH Q3D Guideline for Elemental Impurities. Results from four representative, full-scale batches are given in Table 1. As shown in the table, the results for all of the elements tested, except Nickel, were below the limit of quantification (LOQ) for the method.

Table 1: Result Summary for Four Batches

| Element | LOQ (ppm) | Amount Found (ppm) |
|-----------------|-----------|--------------------|
| As | 0.2 | <0.2 |
| Cd | 0.05 | <0.05 |
| Co | 0.5 | <0.5 |
| Hg | 0.4 | <0.4 |
| Mo | 2.0 | <2.0 |
| Pb | 0.3 | <0.3 |
| Se | 2.0 | <2.0 |
| V | 1.0 | <1.0 |
| Ni ¹ | 0.5 | 0.7, 0.6, 0.8, 0.7 |

1. Nickel results are significantly below compendial (NF/EP) requirements

Our Magnesium Stearate is not manufactured with any metal catalysts or metal reagents, and fully complies with EP Chapter 5.20 - Metal Catalyst or Metal Reagent Residues. As per the NF and EP monographs, we currently test for Cadmium (3 ppm), Nickel (5 ppm) and Lead (10 ppm) using a validated ICP-MS method. In addition, we meet the JP <1.07> and ChP (Appendix VIII, Method 2) requirement for heavy metals.

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GMO

Attached is SpecGx LLC's Genetically Modified Organisms (GMO) statement, Code 5712.



Thursday, January 09, 2020

GMO Statement - Magnesium Stearate NF Kosher Passover HyQual®, Code 5712

To Whom It May Concern:

Please be assured our manufactured lots of Magnesium Stearate, code 5712, do not contain, nor are they manufactured with any raw materials containing Genetically Modified Organisms.

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

A handwritten signature in blue ink that reads "DHadziselimovic".

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Manufacturing Site/GMP

Attached is SpecGx LLC's Manufacturing Site/Good Manufacturing Practices (GMP) statement, Code 5712.



Monday, January 13, 2020

cGMP/ Manufacturing Site Statement - Magnesium Stearate NF Kosher Passover HyQual®, code 5712

To Whom It May Concern:

We hereby declare that Magnesium Stearate, Code 5712, is manufactured at our St. Louis facility. Please be assured that this facility adheres to cGMP requirements. Our manufacturing address is:

SpecGx LLC
 3600 North Second Street
 St. Louis, Missouri 63147

We certify that the methods used in, and facilities and controls used for the manufacture, laboratory testing, holding and distribution of material produced at this plant are in compliance with the Guidance for Industry: Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. In addition, we are compliant with 21 CFR parts 210 and 211. The St. Louis facility's Dun and Bradstreet (DUNS) number is 16-320-5300. Our FDA registration number is 19-40521. The last three dates of FDA inspections are listed below.

- June 2014 - We received no 483s.
- November 2016 – One 483 issued for a laboratory chart recorder
- September 2019 – Four item 483 issued (2 items on documentation deviation and scope, 1 item on data integrity gap and 1 item on our finished dosage product per NDA- FAR requirements/ not applicable on the APIs)

SpecGx LLC (Establishment Identifier 1940521) site is currently registered with the FDA. The following image was taken from the FDA website on October 2019, using the following link:

<https://www.accessdata.fda.gov/scripts/cder/drfs/default.cfm>

The screenshot shows the FDA website's 'Drug Establishments Current Registration Site'. A search for 'SpecGx LLC' has been performed, resulting in a table of five entries. The table columns are Firm Name, FDA Establishment Identifier, DUNS, Business Operations, Address, and Expiration Date.

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|------------|------------------------------|-----------|--|--|-----------------|
| SpecGx LLC | 300275005 | 80768054 | ANALYSIS, MANUFACTURE | 311 & 315 Marshall Ave, Wichee Grove, Missouri (MO) 63115 United States (USA) | 12/31/2020 |
| SpecGx LLC | 1021325 | 00722294 | ANALYSIS, API MANUFACTURE | 6801 Capital Blvd, Raleigh, North Carolina (NC) 27616 United States (USA) | 12/31/2020 |
| SpecGx LLC | 131725 | 56741231 | ANALYSIS, MANUFACTURE, RELABEL, REPACK | 172 Railroad Avenue P.O. Box P, Hickory, New York (NY) 13768 United States (USA) | 12/31/2020 |
| SpecGx LLC | 1416578 | 70275046 | ANALYSIS, API MANUFACTURE | 100 Louis Labor Dr., Greenville, Illinois (IL) 62243 United States (USA) | 12/31/2020 |
| SpecGx LLC | 1940521 | 163205300 | ANALYSIS, API MANUFACTURE, MANUFACTURE | 3600 N 2nd Street, St. Louis, Missouri (MO) 63147 United States (USA) | 12/31/2020 |



SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

A handwritten signature in blue ink that reads "DHadziselimovic".

Digitally signed by Darija Hadziselimovic
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Pharmaceuticals, ou=Regulatory Affairs,
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Melamine

Attached is SpecGx LLC's Melamine statement, Code 5712.



Thursday, January 09, 2020

Melamine Statement - Magnesium Stearate NF Kosher Passover HyQual®, Code 5712

To Whom It May Concern:

We have assessed the above mentioned Magnesium Stearate, its manufacturing process, and raw materials to conclude the following:

“The subject component, Magnesium Stearate NF Kosher Passover HyQual®, Code 5712, is not listed as an at risk component per FDA Guidance for Industry ‘Pharmaceutical Components at Risk for Melamine Contamination.’ Further, the ingredients used in the manufacture of the Magnesium Stearate component do not rely on Nitrogen content assays for ID, strength or purity or have nitrogen contents of >2.5%. Therefore, Magnesium Stearate NF Kosher Passover HyQual®, Code 5712, is not at risk for contamination by Melamine.”

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

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Process Flow

Attached is SpecGx LLC's Process Flow for Code 5712.



Thursday, January 09, 2020

**Process Flow - Magnesium Stearate NF Kosher Passover HyQual®,
Code 5712**

To Whom It May Concern:

Our Magnesium Stearate, code 5712, is a pharmaceutical grade product. It is filed with the FDA with a DMF number of #20585.

Magnesium Stearate is processed on equipment that also processes other stearates. We have a validated clean out process to ensure there is no contamination. We expect to see no dioxins in this product. Our Magnesium Stearate is not irradiated or processed using any irradiated raw materials. During our manufacturing process, a vegetable source Fatty Acid (a mixture of Stearic and Palmitic) reacts with Sodium Hydroxide, forming soluble Sodium Stearate which will be referred to as "Soap Solution". A Magnesium Sulfate solution is added to the Soap Solution and insoluble Magnesium Stearate (monohydrate form) is precipitated. The excess Mg^{2+} is precipitated as Magnesium Hydroxide. A brief flow chart can be found attached. We do not expect contaminants in our product. We also have foreign matter controls built into our process. Our Magnesium Stearate goes through a sifter prior to packaging. In addition, there are 3 magnets and one hump magnet that are checked on a weekly process to aid in controlling foreign material.

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

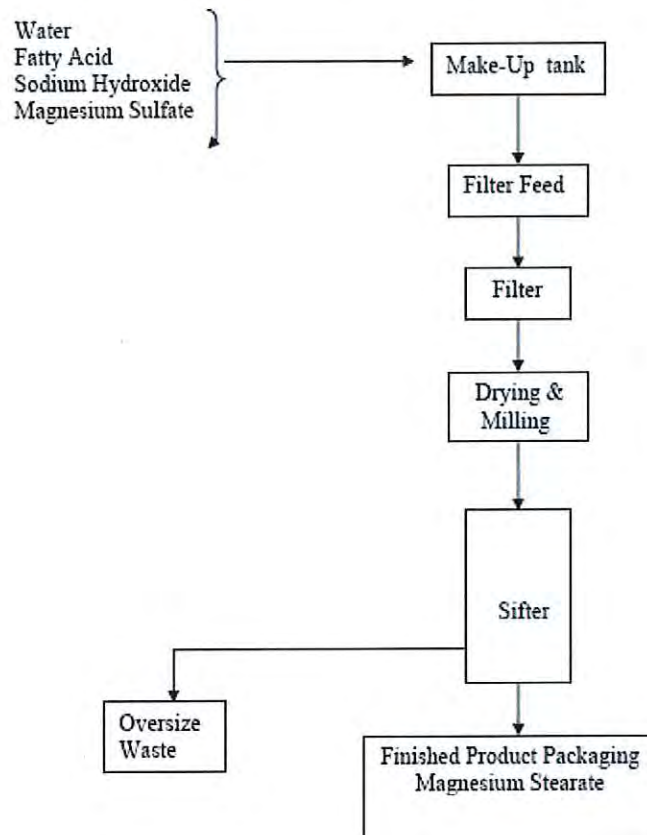
A handwritten signature in blue ink that reads "DHadziselimovic".

Digitally signed by Darija Hadziselimovic
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Magnesium Stearate Brief Flow Chart
Mallinckrodt Pharmaceuticals

Brief Outline Flow Chart and Description



Residual Solvents

Attached is SpecGx LLC's Residual Solvents statement, Code 5712.



Thursday, January 09, 2020

**Residual Solvents Statement – Magnesium Stearate NF Kosher Passover HyQual®,
Code 5712**

To Whom It May Concern:

Please be assured that no Class I, II, III residual solvents or any other organic solvents, as defined by the ICH/USP, are used during the manufacturing process of Magnesium Stearate, code 5712.

We have assurance, based on knowledge of the manufacturing process and controlled handling and storage, that there is no potential for Organic Volatile Impurities/Residual Solvents to be present in the Magnesium Stearate manufactured in St. Louis, MO. And, if tested, these products would comply with the standards listed in the current USP <467> and with ICH Q3 – Impurities: Residual Solvent guidelines. Mallinckrodt will continue to evaluate this characteristic in our Magnesium Stearate products.

1. There are no ICH/USP Class I Solvents used.
2. There are no ICH/USP Class II Solvents used.
3. There are no ICH/USP Class III Solvents used.
4. There are no other organic solvents, as defined by the ICH/USP, used.

SpecGx LLC is dedicated to providing the highest quality products and services to our customers. If you should have any additional questions, please do not hesitate to contact your customer service representative.

Sincerely,

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T: 314.654.0353
darija.hadziselimovic@mnk.com | www.mallinckrodt.com

Kosher Certification

Attached is SpecGx LLC's Kosher Certification for Code 5712.



Chicago Rabbinical Council

2701 West Howard Street
 Chicago, IL 60645-1303
 Ph: 773.465.3900 Fax: 773.465.6929
www.crcweb.org/kosherletters
 Rabbi Sholem Fishbane, Kashruth Administrator

ת"ד כ"ט



November 22, 2019

Total # of Products on Certificate: 9

KASHRUTH CERTIFICATION

This is to certify that the following products, produced by:

SpecGx LLC, 3600 N. 2nd St., P. O. Box 5840, St. Louis, MO 63147

are under the Kashruth certification of the cRc (Chicago Rabbinical Council).

| Grouping | Codes | Product Name | Status | Certifying Requirement | UKD-ID |
|----------|-------|--|--------|------------------------|-----------|
| 1 | 4024 | * Magnesium Stearate NF Nutraceutical | Pareve | cRc Logo Required | CC2140629 |
| 2 | 2248 | * Calcium Stearate NF Powder Kosher Passover | Pareve | cRc Logo Required | CC2109460 |
| 3 | 2249 | * Calcium Stearate NF (Fine Powder) Kosher Passover | Pareve | cRc Logo Required | CC2123701 |
| 4 | 2257 | * Magnesium Stearate NF/EP/JP (Powder) Kosher Passover | Pareve | cRc Logo Required | CC2123698 |
| 5 | 2263 | * Aluminum Monostearate NF Powder Vegetable Grade | Pareve | cRc Logo Required | CC2123703 |
| 6 | 3508 | * Magnesium Stearate Kosher Passover Food Grade | Pareve | cRc Logo Required | CC2126294 |
| 7 | 5712 | * Magnesium Stearate NF Kosher Passover | Pareve | cRc Logo Required | CC2123699 |
| 8 | 5716 | * Magnesium Stearate NF Kosher Passover Food Grade | Pareve | cRc Logo Required | CC2123839 |
| 9 | 5853 | * Calcium Stearate Kosher Passover Food Grade | Pareve | cRc Logo Required | CC2123702 |

* = *Kosher for Passover.*

Note: The UKD is an identification number assigned by the cRc for global tracking.

Expiration Date: 12/31/2020.

For up-to-date certification information please visit www.crcweb.org

cRc ID:#267

Sholem Fishbane
 Rabbi Sholem Fishbane
 Kashruth Administrator