



HUBER ENGINEERED MATERIALS

J. M. Huber Corporation

PRODUCT DOSSIER

HuberCal[®]
FG, USP, and ELITE grades



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SIGNATURE PAGE

The information presented has been reviewed and approved by J.M. Huber Global Regulatory Affairs and Quality Management. It is intended to address or meet all current regulatory and quality requirements for registration, external, or internal documentation needs and is authorized and approved by the signatories below for distribution.

Product: HuberCal® FG, USP, and ELITE grades
Date of Last Revision 30 October 2017

Global Regulatory Affairs

Name Chinyere Ubani **Signature** *Chinyere Ubani*

Title Regulatory Affairs Specialist **Date** 30 October 2017

Quality Management

Name Josh Winkel **Signature** *Josh Winkel*

Title Senior Technology and Quality Manager **Date** 30 October 2017

NOTE: The information provided in this document is neither a specification nor guarantee of future or past shipments. To the best of our knowledge, the information contained herein is accurate. However, no liability whatsoever is assumed for the accuracy or completeness of the information contained herein. Final determination of suitability of any materials is the sole responsibility of the user.

Part I - PRODUCT INFORMATION

1. PRODUCT INFORMATION

PRODUCT NAME: HuberCal[®] FG
HuberCal[®] USP
HuberCal[®] ELITE grades

PRODUCT DESCRIPTION:

Chemical Name:	Calcium carbonate, CAS 471-34-1
Appearance :	White to off-white powder
Color:	White to off-white
Odor:	Odorless
Taste:	Tasteless

DOCUMENT SCOPE: Product, Regulatory and Quality information

INTENDED USES: Dietary Supplement Ingredients,
Active Pharmaceutical Ingredients,
Food fortification, and Cosmetics

PRODUCT FORM: Powder

2. MANUFACTURING INFORMATION

NAME AND ADDRESS OF MANUFACTURER:

J.M. Huber Micropowders, Inc.
3150 Gardner Expressway
Quincy, IL 62305
Telephone: 217-231-0220
Fax: 217-224-7607

NAME AND ADDRESS OF SUPPLIER:

J.M. Huber Corporation
3100 Cumberland Blvd., Suite 600
Atlanta, GA 30339
Telephone: 1-678-247-7300
Email: hubermaterials@huber.com

CURRENT GOOD MANUFACTURING PRACTICES (cGMP) COMPLIANCE: Food grade products manufactured and sold by J.M. Huber Corporation, and are produced in compliance with the current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food as defined in the United States Code of Federal Regulations, Title 21, Part 110. Excipient and API products are manufactured under cGMPs, as defined in ICH Q7.

STERILIZATION OR FUMIGATION METHODS: This product or its components have not been subjected to irradiation, ethylene oxide or any other method of post processing sterilization.

METAL CATALYST: No metal catalysts or metal reagents are used in the manufacture of the HuberCal[®] FG, USP, and ELITE grade products or in the production of the major constituent, HuberCal[®] calcium carbonate powder. Therefore, the products comply with the requirements of:

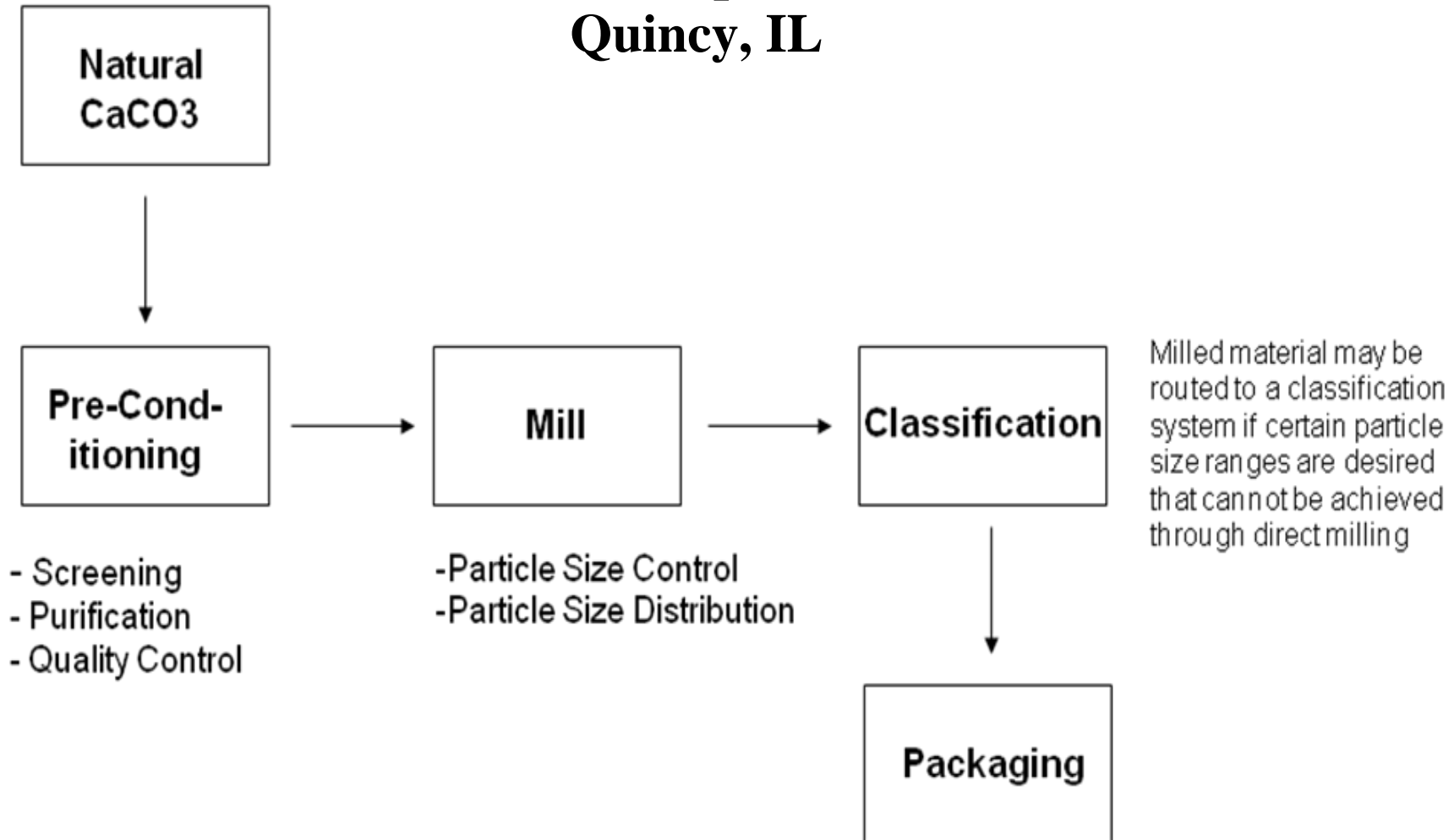
- EMA/CHMP/SWP/4446/2000 (Guideline on the specification limits for residues of metal catalysts or metal reagents)

- European Pharmacopeia Chapter 5.20 (Metal catalyst or metal reagent residues)

QUALITY SYSTEMS (HACCP, ISO): HuberCal® products are produced at production facilities with quality systems which meet cGMP requirements for food, and Active Pharmaceutical Ingredients. The HuberCal® production facility has a HACCP system and is audited against the FSSC 22000 standard and inspected by the Food and Drug Administration (FDA).

DESCRIPTION OF MANUFACTURING PROCESS:

Powder Operation Quincy, IL



3. PHYSICAL AND CHEMICAL INFORMATION

COMMON OR USUAL NAME	SYNONYM	BASIS OF ORIGIN	CAS NUMBER	PERCENT
Calcium carbonate	Limestone	Mineral	471-34-1	approx 95

PRODUCT SPECIFICATION:

See attached product specification sheet

4. LABELLING INFORMATION

Nutritional Facts

[For food uses]

PROXIMATES PER 100 grams	US	EU
Total Calories	0	0
Protein, grams	0	0
Energy (kj)	0	0
Total Carbohydrate, grams	0	0
Dietary Fiber, grams	0	0
Soluble Fiber or Gums, grams	0	0
Total Sugars, grams	0	0
Added Sugar, grams	0	---
Other Carbohydrate, grams	0	0
Total Fat, grams	0	0
Saturated Fat, grams	0	0
Polyunsaturated Fat, grams	0	0
Monounsaturated Fat, grams	0	0
Trans Fatty Acid, grams	0	0
Cholesterol, mg	0	0
Vitamins	0	0
Calcium (Ca), mg	39890	39890
Iron (Fe), mg	4	4
Magnesium (Mg), mg	133	133
Sodium (Na), mg	29	29
Salt (Sodium (Na) x2.5), mg	---	73
Potassium (K), mg	16	16
Vitamin D, mg	0	---

This product is not a significant source of any nutrients that are not shown above, or are shown as "0" (zero).
Moisture and Ash are not permitted labeling values but are given for our customers' information.

The above values are calculated from data from analysis and should be considered "typical" and not a specification. Caloric values are calculated, using the general factors of 4, 4, and 9 kcal per gram of protein, carbohydrate and fat, respectively. Nutrients known to be present in nutritionally insignificant levels are reported as ZERO.

US: The US values are in accordance with 21 CFR 101.9, issued by the Food & Drug Administration on January 6, 1993, implementing provisions of the Nutrition Labeling and Education Act of 1990 and to the Revision of the Nutrition and Supplement Facts Labels Final Rule issued on May 20, 2016 (FDA-2004-N-0258). Carbohydrate is calculated by subtraction of the sum of protein, fat, moisture and ash, from 100 grams. In regard to the use of the above values in calculating nutritional profiles for food products using this ingredient, users are cautioned that the FDA has expressed reservations on the validity of such calculations (See the FEDERAL REGISTER of January 6, 1993 (58 FR 2163 - 2165). At the present time the convention in the US for calculating carbohydrate content and subsequent energy value is to treat all polysaccharides as carbohydrates, with energy value of 4 kcal/g.

EU: The EU values are in conformance with EU Regulation 1169/2011 (including EC Directive 2008/100). The energy values are calculated using the conversion factors of 4, 4, 9, and 2 kcal per gram of protein, carbohydrate, fat and fiber, respectively. The energy value may be express as kcal/ g and kJ/g. (To convert kcal to kJ, multiply by 4.19.)

The information contained herein is, to the best knowledge of JM Huber, true and accurate, but all recommendations or suggestions are made without guarantee, since we can neither anticipate nor control the different conditions under which this information and our products are used. Therefore, JM Huber does not warrant the application of this information to particular situations. It is JM Huber's policy, however, to assist our customers and to help in the solution of particular problems that may arise in connection with applications of JM Huber products.

5. REGULATORY INFORMATION

REGULATORY STATUS:

For **HuberCal® FG grade** products, the ingredients comply with the following:

- Calcium carbonate is tested to meet the purity criteria in the current *Food Chemicals Codex (FCC)* for Calcium Carbonate.

For **HuberCal® USP grade** products, the ingredients comply with the following:

- Calcium carbonate is tested to meet the purity criteria in the current *Food Chemicals Codex (FCC)* for Calcium Carbonate, *United States Pharmacopeia (USP)*, the purity criteria in the current EC Directives (E170) for Calcium Carbonate, and the purity criteria in the current *European Pharmacopeia*.

For **HuberCal® ELITE grade** products, the ingredients comply with the following:

- Calcium carbonate is tested to meet the purity criteria in the current *Food Chemicals Codex (FCC)* for Calcium Carbonate, *United States Pharmacopeia (USP)*, the purity criteria in the current EC Directives (E170) for Calcium Carbonate, and the purity criteria in the current *European Pharmacopeia*.

EU REGULATIONS ON HAZARDOUS SUBSTANCES STATUS: HuberCal® FG, USP and ELITE grades does not meet the definition of hazardous as defined in EU directive 1999/45/EC and regulation 1272/2008.

REACH/SVHC: J.M. Huber's **HuberCal® FG, USP and ELITE grade** products are intended for use in food, dietary supplements and pharmaceutical applications, which are exempt from registration, evaluation and authorization (including Substances of Very High Concern) under Regulation (EC) No. 1097/2006 (REACH)

BSE/TSE INFORMATION: J.M. Huber's **HuberCal® FG, USP, and ELITE grade** products do not contain, nor are they derived from specified risk material as defined in the FDA Interim Final Rule (Prohibiting the Use of Certain Cattle Materials that May Carry the Risk of BSE in Human Foods and Cosmetics. Docket Number 2004N-0081 July 14, 2004) and Regulation (EC) 999/2001 and its amendments. J.M. Huber's **HuberCal® FG, USP, ELITE grade** products contain no animal by-products of specified risk material, additives, preservatives, or colors. No products of bovine origin are used in the manufacture of **HuberCal® FG, USP and ELITE grade**; therefore there is no source for BSE (bovine spongiform encephalopathy) or TSE (transmissible spongiform encephalopathy) materials or to contaminate our products.

ALLERGENS: J.M. Huber Regulatory Affairs has, as part of our ongoing regulatory review of changing requirements in the global marketplace, reviewed the labeling of our food grade products in accordance with:

- The Food Allergen Labeling and Consumer Protection Act (FALCPA), in effect January 1, 2006, require clear labeling of food containing the eight (8) allergen classes: Peanuts, Soybeans, Milk, Eggs, Fish, Crustacea, Tree Nuts, and Wheat.
- EU Directive 1169/2011 as amended requires the labeling of foods containing allergenic

substances: Cereals containing gluten, Crustaceans, Eggs, Fish, Peanuts, Soybeans, Milk and dairy products (including lactose), Nuts, Celery, Mustard, Sesame seeds, Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter, Lupin, Molluscs.

J.M. Huber's **HuberCal® FG, USP, and ELITE grade** products do not contain allergens from the above lists. See below for more detailed information.

Allergenic foods and derivatives	2. Material supplied contains	3.The material supplied is produced:		4. Cross-contact with the material supplied
		On the same equipment with:	In the same factory with:	
Peanut or its derivatives, e.g., Peanut - pieces, protein, oil, butter, flour, and mandelona nuts etc. Peanut may also be known as ground nut.	No	No	No	No
Crustaceans and products thereof (including crab, crayfish, lobster, prawn and shrimp)	No	No	No	No
Fish or its derivatives, (fish protein, extracts, etc.)	No	No	No	No
Eggs or its derivatives, (frozen yolk, egg white powder, egg protein isolates, etc.)	No	No	No	No
Tree Nuts (almonds, Brazil nuts, cashews, coconut, hazelnuts (filberts), macadamia nuts, pecans, pine nuts, pistachios and walnuts or their derivatives, e.g., nut butters and oils etc.	No	No	No	No
Milk and products thereof (inc. lactose)	No	No	No	No
Soybeans and products thereof (lecithin, oil, tofu and protein isolates etc.)	No	No	No	No
Cereals containing gluten and products thereof	No	No	No	No
Sulphur dioxide and sulphites	No	Not applicable	Not applicable	Not applicable
Celery and products thereof	No	No	No	No
Sesame seeds and	No	No	No	No

products thereof				
Mustard and products thereof	No	No	No	No
Lupin and products thereof	No	No	No	No
Molluscs and products thereof	No	No	No	No
Fungi/Fungi products	No	No	No	No
Fruit	No	No	No	No
SENSITIVITIES /OTHER INFORMATION FOR LABELING PURPOSES				
Animal and Animal By Products	No	No	No	No
Antioxidants	No	No	No	No
Artificial Colors (Tartrazine FD&C Yellow #5), Preservatives, Flavorings	No	No	No	No
Aspartame	No	No	No	No
Barley, Rye, Oats and their hybrid strains, Spelt, Kamut, Triticale	No	No	No	No
Bee pollen	No	No	No	No
Buckwheat	No	No	No	No
Caffeine	No	No	No	No
Carmine/cochineal	No	No	No	No
Chocolate	No	No	No	No
Corn (Maize) or its derivatives	No	No	No	No
Gluten	No	No	No	No
Fruit (Orange, Apple, Peaches, etc.)	No	No	No	No
Stone fruits (Prunus dulcis, sin.: Prunus amygdalus, Amygdalus communis L.).	No	No	No	No
Hydrolyzed Vegetable or Plant Protein (HVP/HPP)	No	No	No	No
MSG	No	No	No	No
Natural Latex	No	No	No	No
Phenylalanine	No	No	No	No
Propolis	No	No	No	No
Royal jelly	No	No	No	No
Seeds (Poppy, Sunflower)	No	No	No	No
Spices, Spice extracts, Herbs	No	No	No	No
Tocopherols	No	No	No	No
Wheat or its derivatives, e.g., flour, starches and	No	No	No	No

brans etc.				
Yeast	No	No	No	No

J.M. Huber's calcium carbonate products also have the following allergen information according to the ALBA databank:

Cow's milk protein	-	Chicken	-	Sesame	-
Lactose	-	Fish	-	Sesame oil	-
Chicken's egg	-	Shellfish and crustaceans	-	Glutamate	-
Soy protein	-	Maize	-	Sulfite	-
Soy lecithin	-	Cocoa	-	Lupine	-
Gluten	-	Legumes/pulses	-	Coriander	-
Wheat	-	Nuts	-	Celery	-
Rye	-	Nut oil	-	Carrot	-
Beef	-	Peanuts	-	Mustard	-
Pork	-	Peanut Oil	-		

+ present - absent ? unknown

[For cosmetic uses]

J.M. Huber's calcium carbonate products do not contain any substances likely to cause allergic reaction as cited in Regulation (EC) 1223/2009 as amended.

GLUTEN: No products from wheat, rye, barley, malt, oats, spelt, triticale and their derivatives are used in the manufacture, manufacturing process and raw materials used to produce JM Huber's **HuberCal[®] FG, USP, and ELITE grade** products.

PRESERVATIVES, FLAVORS, AFLATOXINES: This product contains no preservatives, flavors or aflatoxines.

KOSHER: Kosher certified.

HALAL: Halal certified

VEGETARIANS: Suitable.

VEGAN: Suitable.

ORGANIC STATUS:

[For food uses]

Calcium carbonate is listed as an allowable ingredient in products labeled as organic, per the following:

- United State's guidelines established by the National Organic Standards Board¹, 2;
- European Communities of Council Regulation (EC) 834/2007 and Commission Regulation (EC) 889/2008³, 4.
- Agriculture and Agri-Foods Canada by the guidelines established by Canada General Standards Board CAN/CGSB 32.311-2006, Section 6.4.15, in force 2008.
- Internationally by the guidelines established by the Codex Alimentarius Commission⁶;

¹ Calcium carbonate [7 CFR 205.605(a), per 7 CFR 205.105 (c)(e)(f)(g)]

² The USDA National Organic Program allows food additives as listed on the National List and as approved by US FDA unless otherwise annotated. Polypropylene glycol is used as a processing aid, not used as an ingredient, and is essential to the manufacturing process of calcium carbonate and falls under the definition of US FDA under 21 CFR 101.100 Food; exemptions from labeling (c).

³ Repealing Regulation (EEC) No. 2092/91

⁴ Calcium carbonate shall not be used for coloring or calcium enrichment of products (E170).

⁵ Calcium carbonate, for milk products. Prohibited as a coloring or anti-caking agent.

⁶ Calcium carbonate, as a food additive; Calcium carbonate as a mineral for livestock and bee products in milk products. Not as coloring agent; Calcium carbonate as a processing aid. (INS 170).

Products manufactured in a manner consistent with the provisions of the above referenced citations and the intended end-use can be produced using the ingredient calcium carbonate without excluding the organic claim on the label.

- It is not required to certify calcium carbonate as organic per the EU and US organic laws.
- Calcium carbonate food additive is defined in the EU directives & Food Chemicals Codex
- J.M. Huber manufactures calcium carbonate to the compendial and regulatory requirements of the market (EU & US) and the end use (food additive).

No sewage sludge, ionizing radiation, synthetic solvents, carrier systems, and artificial preservatives are used in the production of calcium carbonate. The product does not require any GMO label in the US, EU, or Canada.

ANIMAL TESTING: J.M. Huber does not conduct testing for any other purposes than worker, environment or consumer safety. J.M. Huber Regulatory Affairs, in accordance with guidance from the US FDA, OSHA, EU, and other international regulatory agencies, may be required to perform tests to assess the safety and regulatory compliance of our products. These tests are performed in accordance with US and international test standards. If animal testing is required, it is conducted in accordance with these test standards. An OECD approved alternative to animal testing will be evaluated.

In accordance with and pursuant to Article 11, 2. (e) of Regulation (EC) 1223/2009 on cosmetic products, the most recent safety assessment based on animal testing using **calcium carbonate test articles** analogous to the J.M. Huber's commercial product was conducted prior to 1986.

NATURAL STATUS: US FDA and EU do not have a regulatory definition of "natural" that applies to regulated food additive products. Canada has labeling guidelines on "natural" foods (Canadian 2003 Guide to Food Labeling and Advertising – Chapter 4, Section 4.7). We leave to your own good judgment and your own legal counsel, the decision regarding the use of the term "natural" in your advertising or labeling for those products.

GMO STATUS: J.M. Huber's **HuberCal® FG, USP, and ELITE grade** products comply with all appropriate U.S. standards and specifications, including the general U.S. regulations governing food ingredients. These products are not considered "bioengineered foods" as defined by the Food and Drug Administration's proposed rule governing such foods.

J.M. Huber's **HuberCal® FG, USP, and ELITE grade** products are manufactured using raw materials which have not been genetically modified as defined in Directive 2001/18/EC as amended. These products are outside the scope of Regulations (EC) 1829/2003 as amended and 1830/2003 as amended concerning traceability of raw materials and labeling. More specifically, these products are manufactured using non-GMO substances and GMO labeling is not required.

Furthermore, J.M. Huber's manufacturing facilities employ strict manufacturing standards that comply with all relevant requirements in the United States and the European Union for food products.

RESIDUAL SOLVENTS/ORGANIC VOLATILE IMPURITIES (OVI): This product contains no

Class I, Class II or Class III USP or CPMP/ICH/283/95 guidance residual solvents. It does contain less than 0.2% of the residual solvent propylene glycol which is used as a processing aid.

PROPOSITION 65: J.M. Huber's **HuberCal® FG, USP, and ELITE grade** products sold to you, either within or for sale or distribution within the state of California This product is in compliance with California's Proposition 65.

WORLD ANTI-DOPING AGENCY'S PROHIBITED SUBSTANCE LIST (WADA):

The ingredients in the **HuberCal® FG, USP, and ELITE grade** products do not appear in the listing of banned substances, nor do any listed ingredients used in the raw materials, processing, or packing of this product.

FACILITY REGISTRATION - BIOTERRORISM ACT

Registration Number	Facility Name	Facility Address
18872866406	J. M.Huber Micropowder Inc.	3150 Gardner Expressway, Quincy, IL 62305

OTHER INFORMATION: Based on process and raw material knowledge, calcium carbonate is not expected to contain any of the substances listed below:

- Aflatoxines
- Alkyl phenols and their ethoxylates
- Aromatic amines
- Aromatic hydrocarbons
- Asbestos
- AZO compounds
- BHT
- Bisphenol A
- Dioxin
- Endocrine disruptors
- Epoxy derivatives (BADGE, BFDGE, NOGE)
- Flavors
- Formaldehyde
- Furans
- Halogens and their compounds
- Melamine
- Natural rubber latex (NRL)
- Nitrates
- Nonyl phenol
- Organotin
- Pesticide Residues
- Phthlates
- Polybrominated compounds
- Polychlorinated compounds
- Polycyclic aromatic compounds
- Preservatives
- Tris nonyl phenyl phosphate

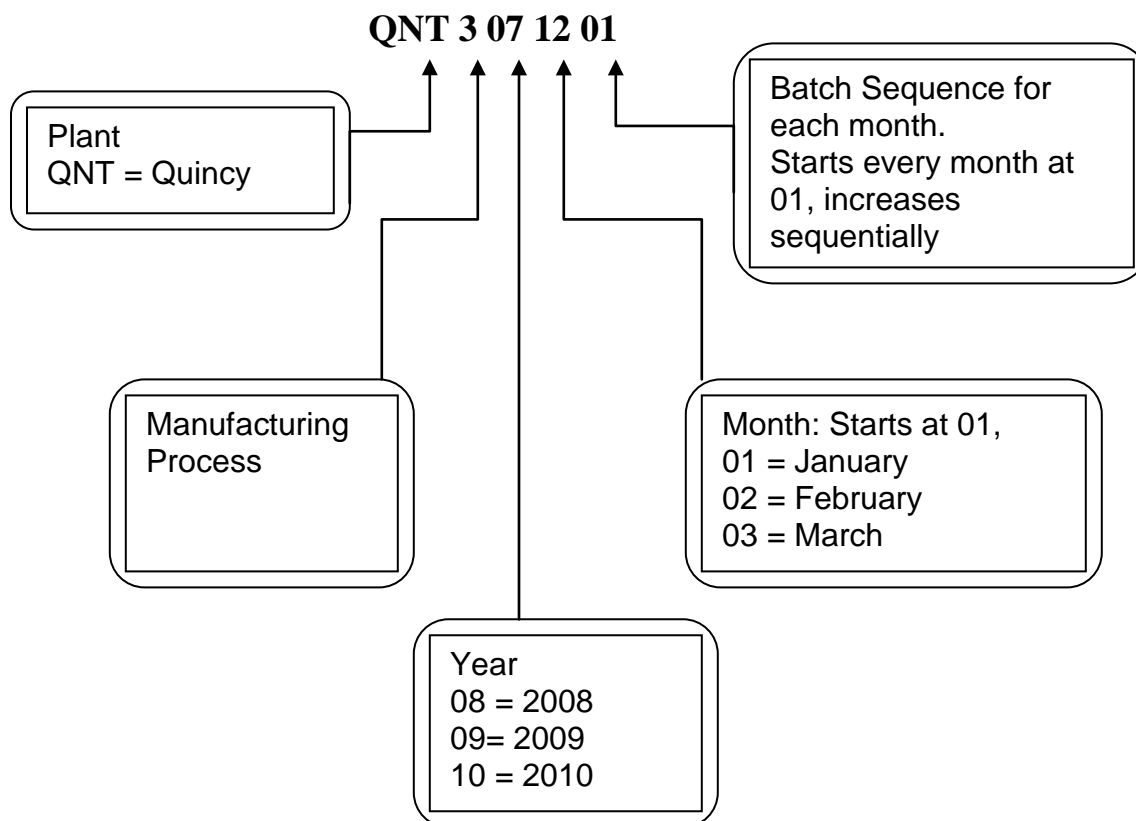
FDA CONTINUING GUARANTEE: Available upon request.

6. MISCELLANEOUS PRODUCT INFORMATION

SDS: SDS's are available on the internet at <http://msds.hubermaterials.com/> or upon request.

BATCH DEFINITION: A batch is defined as 18000-20000kgs.

BATCH / LOT NUMBERING SYSTEM:



RECOMMENDED STORAGE CONDITIONS: The product should be stored in unopened containers and in cool, dry conditions. If stored properly, with assurance that no contamination has taken place, the product should be retested after 3 years from the date of manufacture and prior to use to ensure compliance with specification..

TRANSPORTATION INFORMATION: Product is not regulated by the US DOT, IATA, IMDG or ADR. For more information see Safety Data Sheet (section 14).

PACKAGE SIZE OFFERINGS AND/OR TYPES: 50 lb paper bags or custom bulk bags

RECYCLED PACKAGING MATERIALS: None Used

COUNTRY OF ORIGIN (COO)/HARMONIZED TARIFF SYSTEM (HTS): Country of origin statements and Harmonized Tariff System (HTS) are available upon request by material number.

CHEMICAL/PHYSICAL/MICROBIOLOGICAL ANALYSIS: All grades of Calcium carbonate are subject to review for compliance with product release specifications. All finished product will be evaluated per J.M. Huber's HuberCal® Release Procedure.

All lots of each grade of the drug substance are tested for microbiological quality in accordance with the USP and EP Microbial Limit Tests. A clean specimen from each lot is collected using rubber gloves, a sterile tongue depressor, and sterile sample bags. This specimen is sent to an outside microbiology lab for microorganism analysis.

From each lot of each grade of drug substance, the first, last and every even-numbered pallet or sack is sampled. A composite sample is made by combining and mixing equal amounts of product from the first, last and every even-numbered pallet or sack. The composite sample is split and one-half is sent to the Huber Analytical Laboratory for FCC, USP or EP monograph compliance testing and the remaining one-half is sent to the Huber Quincy Quality Control Laboratory for physical property testing.

Drug substance not meeting finished product specifications will not be reprocessed. This material is diverted to non-food, non-drug industrial applications

7. REVISIONS

8. CONTACT INFORMATION

J.M. Huber Corporation
3100 Cumberland Blvd., Suite 600
Atlanta, Georgia 30339
Main Phone: (678) 247-7300
Email: hubermaterials@huber.com

FOR CHEMICAL EMERGENCY, SPILL LEAK, FIRE, EXPOSURE, OR ACCIDENT:
Call CHEMTREC - Day or Night - 1-800-424-9300. Toll free in the continental U.S., Hawaii, Puerto Rico, Canada, Alaska, or Virgin Islands. For calls originating elsewhere. 1-703-527-3887 (collect calls accepted).

Part II - SITE QUALITY INFORMATION

1. SITE OVERVIEW: Quincy, IL

SITE NAME: J.M. Huber Micropowders, Inc.

ADDRESS: 3150 Gardner Expressway
Quincy, IL 62305

CORPORATE OWNERSHIP: J.M. Huber Corporation

GENERAL SITE INFORMATION: The J.M. Huber Micropowders, Inc Quincy facility is located at 3150 Gardner Expressway, Adams County Illinois, 110 miles north of St. Louis, Missouri. The Micropowders facility occupies approximately 39 acres of the 900 acre J.M Huber Quincy site.

UNION BACKGROUND: The facility is a non-union site.

TYPE(S) OF INGREDIENT(S) PRODUCED/SUPPLIED BY THE SITE AND THEIR INTENDED APPLICATIONS

J.M. Huber Micropowders, Inc produces processed nutritional ingredients for the dietary supplement market and active pharmaceutical ingredients for the pharmaceutical industry.

SITE ACTIVITIES CONDUCTED: Granulation, Milling, Packaging, Testing

2. QUALITY COMPLIANCE

J.M. Huber Micropowders, Inc has a Quality Management System in place. The facility is routinely audited by third parties for ISO compliance and Food Safety Management compliance.

3. GMP COMPLIANCE

Please see Site Information Package.

4. ADDITIONAL INFORMATION

No additional information.

5. REVISIONS

6. CONTACT INFORMATION

Quality Contact: Josh Winkel
Title: Senior Technology and Quality Manager
Address: 3150 Gardner Expressway, Quincy, IL 62305
Telephone: (217) 231-0335
Fax: (217) 224-7607
E-Mail: josh.winkel@huber.com

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