



December 2016

## CAB-O-SIL® M5F AND EH-5F FUMED SILICA FOR FOOD APPLICATIONS

### Food Grade Statement

#### European Regulatory Requirements

CAB-O-SIL® M-5F and EH-5F Fumed Silica are high purity silicon dioxide products. Silicon dioxide (E551) is a permitted food additive in the EU per listing in Annex II –Part B of the Regulation (EC) No 1333/2008.

Authorized food categories and conditions of use of E551 are described in Annex II - Part E of the Regulation (EC) No 1333/2008 and summarized here below:

Categories of foods	Max. level (mg/kg)	Restrictions/exceptions
All (0)	q.s.	Only foods in tablet and coated tablet form, excluding foods listed in table 1 Part-A of Annex II.
	10 000	Only foods in dried powdered form (foods dried during production process and mixture thereof), excluding foods listed in table 1 Part A of Annex II.
Ripened cheese (01.7.2), cheese products (01.7.6)	10 000	Only sliced or grated cheese hard and semi-hard cheese
Processed cheese (01.7.5)	10 000	
Dairy analogues (01.8)	10 000	Only sliced or grated cheese analogues and processed cheese analogues; beverage whiteners
Other fat and oil emulsions (incl. spreads) and liquid emulsions (02.2.2); vegetable oil pan spray (02.3)	30 000	Only tin greasing products
Other confectionary including breath freshening microsweets (05.2); chewing gum (05.3); decorations, coatings, and fillings (except fruit-based filling in 04.2.4) (05.4)	q.s.	Surface treatment only
Sugars and syrups(11.1)	q.s.	Only foods in tablet and coated tablet form
	10 000	Only dried powdered foods
Table-top sweeteners in powder (11.4.2) and tablet (11.4.3) form	10 000	In powder
	q.s.	In tablets
Salt (12.1.1)	10 000	
Salt Substitutes ( 12.1.2)	20 000	
Seasonings and condiments (12.2.2)	30 000	Only seasonings

Processed cereal-based foods and baby foods for infants and young children (13.1.3)	2 000	Only dry cereals
Food supplements supplied <ul style="list-style-type: none"> <li>◆ in solid form(17.1),</li> <li>◆ in liquid form (17.2)</li> <li>◆ In a syrup-type or chewable form (17.3)</li> </ul>	q.s.	

q.s. – quantum satis

According to Annex III of the Regulation (EC) No 1333/2008, silicon dioxide is also permitted as an additive (including the carrier functionality) for use in food additives, food enzymes, food flavourings, and nutrients:

Categories of food additives	Maximum level (mg/kg)	Function*
Emulsifiers and colours	q.s.	Carrier
Dry powdered colour preparations	50 000	Additive other than carrier
Dry powdered preparations of emulsifiers		
Dry powdered preparations of polyols	10 000	
E 508 Potassium chloride and E 412 guar gum preparations		
E 1209 polyvinyl alcohol-polyethylene glycol-graft-co-polymer	5000	
Dry powdered extracts of rosemary (E 392)	30 000	
Dry powder preparations	<ul style="list-style-type: none"> <li>◆ 50 000 in enzymes preparation</li> <li>◆ q.s.in final food including beverages</li> </ul>	Additive including carrier in food enzymes
All flavourings	50 000	Additive including carrier in food flavourings
Dry powdered preparations of all nutrients (except for infants and young children)	50 000	Additive including carrier in food nutrients
Potassium chloride preparations used in salt substitutes	10 000	
Foods for infants and young children – dried powdered preparations	10 000	

\*no food additives are authorized for their function as colour, sweetener or flavour enhancer.



### United States Regulatory Requirements

Silicon dioxide (INS 551) is a permitted food additive (anti caking agent) in the US per listing in 21 CFR 172.480. In addition, CAB-O-SIL M-5F and EH-5F fumed silica are produced according to current Good Manufacturing Practices (cGMP). Cabot's Rheinfelden, Germany manufacturing site is a registered food facility in the US and meets the Hazard Analysis and Preventive Control (HARPC) requirements of the Food Safety Modernization Act (FSMA) regulation.

### Purity Information

CAB-O-SIL® M-5F and EH-5F fumed silica products, manufactured at our Rheinfelden facility, are routinely tested and comply with the E551 purity criteria listed in Commission Regulation (EU) N° 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and Council. This testing allows Cabot to claim compliance with the "silicon dioxide" monograph (INS 551) of Food Chemical Codex (FCC) 10th edition and Joint FAO/WHO Expert Committee on Food Additives.

Monographs endpoints	E 551	FCC 10th - INS 551
Assay	≥99%	
LOI	≤2.5%	≤2%
LOD	≤2.5%	
Soluble ionisable salts (as Na <sub>2</sub> SO <sub>4</sub> )	≤5%	not applicable
Pb	≤5ppm	
As	≤3ppm	not required
Hg	≤1ppm	not required

In addition, to the best of our knowledge, CAB-O-SIL® M-5F and EH-5F fumed silica products do not contain:

- ◆ Any genetically modified organism (GMO) products or materials, nor do they come into contact with any GMO product or material during our manufacture and handling processes;
- ◆ Any product of animal origin, nor do they contain any animal product associated with Bovine Spongiform Encephalopathy (BSE) or Creutzfeldt-Jakobs Disease (CJD). The regulated chemicals that typically are associated with the development of BSE or CJD are not involved in our production and handling processes;
- ◆ Any food allergens regulated by US FDA (Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)) and listed in Annex II of Regulation (EU) No 1169/2011 on the provision of food information to consumers (formerly in annex IIIa of the EU Directive 2000/13/EC) and amends. Specifically, Cabot's CAB-O-SIL® M-5F and EH-5F fumed silica products do not contain allergenic proteins derived from crustacean shellfish (e.g., crab, crayfish, lobster, shrimp, etc.), fish, egg, milk, peanuts, soy, cereals containing gluten including wheat, tree nuts (e.g., almonds, Brazil nuts, cashews, hazelnuts/filberts, macadamia nuts, pecans, pine nuts, pistachios, walnuts, etc.) and also celery, mustard, sesame seeds, sulfur dioxide and sulphites, lupin and products thereof.
- ◆ Intentionally added sugars (lactose, glucose, etc.), gluten, alcohol, latex, enzymes, colorants, pigments, flavors, preservatives, hormones, antibiotics, stabilizers and antioxidants;



- ◆ Mycotoxins including aflatoxin. Those substances are the main contaminants of plant origin material (e.g., grains, cereals, nuts, oilseeds, and spices) and Cabot does not use any plant origin material as raw material in our high temperature manufacturing process. Therefore such mycotoxins are not expected to be present in our CAB-O-SIL® M-5F and EH-5F Fumed Silica products.
- ◆ Melamine: Cabot Corporation does not analyze CAB-O-SIL® M-5F and EH-5F Fumed Silica products for the presence of melamine. However, based on our knowledge of the production and handling processes, Cabot does not expect melamine to be present in CAB-O-SIL® M-5F and EH-5F Fumed Silica products above trace levels.

### Packaging Information

CAB-O-SIL® M-5F and EH-5F fumed silica packaging materials are suitable for food contact applications. To the best of our knowledge, our paper bags and plastics FIBC's comply with:

- ◆ Regulation (EC) No 1935/2004 of the European Parliament and the Council on materials and articles intended to come into contact with food,
- ◆ Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food,
- ◆ European Parliament and Council Directive 94/62/EC and latest amends on packaging and packaging waste and US CONEG requirements.

In addition,

**For paper bags** (multi wall kraft paper bags):

- ◆ The paper part complies with German BfR Recommendation XXXVI and 21 CFR 176.180
- ◆ The plastic used in the middle layer complies with Regulation (EC) 10/2011 and 21 CFR 177.1520. The overall migration values are below the 10 mg/dm<sup>2</sup> migration limit stated in Regulation (EC) No 10/2011.
- ◆ The printing inks comply with EuPIA guidelines and 21 CFR 178.3297
- ◆ Our paper bags are sealed with a mix of corn and potato starch glue; we cannot exclude a potential contact of silica material with the glue.

**For FIBCs:**

- ◆ The plastic used complies with Regulation (EC) 10/2011 and 21 CFR 177.1520. The overall migration values are below the 10 mg/dm<sup>2</sup> migration limit stated in Regulation (EC) No 10/2011.
- ◆ The printing inks comply with EuPIA guidelines and 21 CFR 178.3297

Buyer assumes full responsibility for testing and determination of suitability of a Product for Buyer's intended application or use according to the applicable food requirements.



This information is being provided as of the date hereof. Please visit [cabotcorp.com/certifications](https://cabotcorp.com/certifications) for any updates to this information.

The CAB-O-SIL name is a registered trademark of Cabot Corporation.

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