



Cellulose, Microcrystalline and Carboxymethylcellulose Sodium, Coprocessed

1 Nonproprietary Names

BP: Dispersible Cellulose

PhEur: Microcrystalline Cellulose and Carmellose Sodium

USP–NF: Microcrystalline Cellulose and Carboxymethylcellulose Sodium

2 Synonyms

Avicel CL-611; *Avicel RC-591*; *Avicel RC/CL*; cellulose microcrystallinum et carmellosum natricum; colloidal cellulose; *Vivapur MCG 591 PCG*; *Vivapur MCG 611 PCG*.

3 Chemical Name and CAS Registry Number

See Section 8.

4 Empirical Formula and Molecular Weight

See Section 8.

5 Structural Formula

See Section 8.

6 Functional Category

Dispersing agent; emulsion stabilizing agent; suspending agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Coprocessed microcrystalline cellulose and carboxymethylcellulose sodium is used to produce thixotropic gels suitable as suspending vehicles in pharmaceutical and cosmetic formulations. The sodium carboxymethylcellulose aids dispersion and serves as a protective colloid.

Concentrations of less than 1% solids produce fluid dispersions, while concentrations of more than 1.2% solids produce thixotropic gels. However, *Avicel Cl 611* needs a concentration slightly higher than 1.2% for thixotropy. Colloidal *Avicel* is compatible with many other hydrocolloids such as alginate, carrageenans, carbomer, guar gum, pectin and the cellulose ether polymers. When properly dispersed, it imparts emulsion stability, opacity, and suspension to a variety of products, and is used in nasal sprays, topical sprays and lotions, oral suspensions,⁽¹⁾ emulsions, creams⁽²⁾ and gels.

8 Description

Coprocessed microcrystalline cellulose and carboxymethylcellulose sodium occurs as a white or off-white odorless and tasteless hygroscopic powder. It has a composition, on a dry basis, of 82–89% microcrystalline cellulose and 11–18% sodium carboxymethylcellulose, medium viscosity. It is a water-dispersible anionic hydrocolloid.

9 Pharmacopeial Specifications

See Table I. See also Section 18.

Table I: Pharmacopeial specifications for coprocessed microcrystalline cellulose and carboxymethylcellulose sodium.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
pH	6.0–8.0	6.0–8.0
Solubility	+	–
Loss on drying	≤8.0%	≤8.0%
Sulfated ash	≤7.4%	–
Residue on ignition	–	≤5.0%
Apparent viscosity of nominal value	60–140%	60–140%
Heavy metals	–	≤10 µg/g
Assay (dried basis)	75–125%	75–125%

10 Typical Properties

Acidity/alkalinity pH 6–8 for a 1.2% w/v aqueous dispersion.

Density (bulk) 0.6 g/cm³

Microbial content Total aerobic microbial count ≤100 cfu/g for *Avicel RC/CL* (*Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Salmonella* species absent); total yeast and mold count ≤20 cfu/g for *Avicel RC/CL*.

Moisture content Not more than 6.0% w/w

Particle size distribution

Avicel CL-611: ≤0.1% retained on a #60 mesh and ≤50% retained on a #325 mesh;

Avicel RC-591: ≤0.1% retained on a #60 mesh and ≤45% retained on a #325 mesh;

Vivapur MCG 591 PCG: ≤5% retained on a #30 mesh and ≤50% retained on a #60 mesh;

Vivapur MCG 611 PCG: ≤5% retained on a #30 mesh and ≤50% retained on a #60 mesh.

Sodium content 940 mg/100 mg of *Avicel RC-591* and 1000 mg/100 mg of *Avicel CL-611*; or 0.94% w/w for *Avicel RC 591* and 1.0% w/w for *Avicel CL 611*.

Solubility Practically insoluble in dilute acids and organic solvents. Partially soluble in dilute alkali and water (carboxymethylcellulose sodium fraction).

Viscosity (dynamic)

39–91 mPa s (39–91 cP) for *Avicel RC-591/Vivapur MCG 591 PCG* (1.2% w/v aqueous dispersion);

50–118 mPa s (50–118 cP) for *Avicel CL-611/Vivapur MCG 611 PCG* (2.4% w/v aqueous dispersion).

11 Stability and Storage Conditions

Coprocessed microcrystalline cellulose and carboxymethylcellulose sodium is hygroscopic and should not be exposed to moisture. It is stable over a pH range of 4–11. Store in a cool, dry place. Avoid exposure to excessive heat.

Changes in temperature have little effect on the viscosity of *Avicel RC-591* and *Avicel CL-611* dispersions. This is beneficial in maintaining long-term stability. *Avicel* dispersions can be sterilized. However, there is a minimal change in the viscoelastic properties of the gel. Suspensions prepared with Colloidal *Avicel* show little to no viscosity changes after exposure to accelerated temperatures, prolonged (over 5 years) storage at room temperature at 5°C (refrigeration), or after freeze-thaw shock and stress testing.