

A close-up photograph of a person's hand holding two white, round pills. In the background, a glass of water with lemon slices is visible, suggesting a medical or health-related context.

SheffCoat™ CG

The Clear Choice for Coating and Regulatory Professionals Worldwide

SheffCoat™ CG is an immediate release film coating designed for regulatory acceptance in most major pharmaceutical and dietary supplement markets.

Ingredient Compliance

The ingredients in SheffCoat™ CG have been chosen for their compliance, availability, cost and functionality in film coating.

Product	Ingredients	E#	CAS#
SheffCoat™ CG (Product Code: 30679653)	Hydroxypropylmethyl cellulose / hypromellose (USP, FCC, EP, JP)	E464	9004-65-3
	Glycerol (USP, FCC, EP)	E422	56-81-5

SheffCoat™ CG is:

- California Proposition 65 compliant and does not contain any known carcinogens, mutagens, or reproductive toxins.
- Non-GMO (validated)
- Kosher and Halal certified.
- Composed entirely of ingredients derived from plant based material
- Allergen free
- Residual solvent free
- Manufactured in a FDA Registered Drug Establishment #1310124, located in Norwich, NY, which utilizes CFR sections
- 210/211 and USP/NF <1078> as guidelines and complies with IPEC's PQG GMP guidelines.
- Recommend whenever a strong, clear coating with good adhesion and elasticity is needed

SheffCoat™ CG

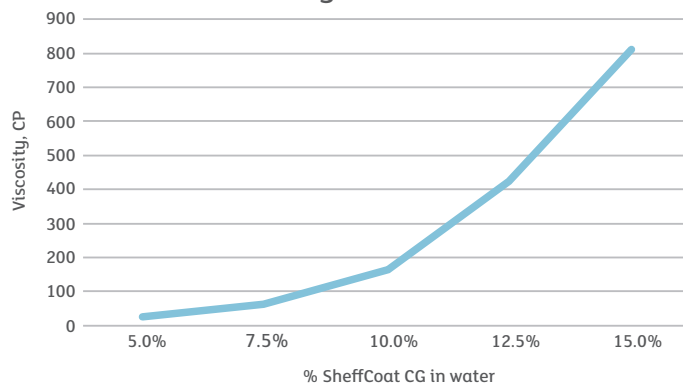
Packaging, shelf life and storage

SheffCoat™ CG is supplied in 20 kg net fibreboard cartons with polyethylene liners. This product has a 24 month re-evaluation date. It is recommended that the package be protected from heat and freezing temperatures and moisture.

Ease of application

SheffCoat™ CG is designed for application in aqueous solutions of 8-12% solids or in hydroalcoholic systems for moisture sensitive applications.

Viscosity of SheffCoat CG



Process Parameters	12" Pan (conventional)	12" Lab Unit	15" Lab Unit	24" Pan	48" Pan	60"Pan
Pan Load (kg)	1.0	1.0	3.0	15.0	140	325
SheffCoat™ (kg)	Multiply pan charge x theoretical weight gain x (1+ overage) Note: overage written as a decimal rather than %					
Water (kg) (18% dispersion)	Multiply kg of SheffCoat x by 9.00 for a 10% dispersion					
Inlet Temperature (°C)	60 - 65	60 - 65	60 - 65	60 - 65	60 - 65	60 - 65
Inlet Temperature (°F)	140 - 149	140 - 149	140 - 149	140 - 149	140 - 149	140 - 149
Tablet Bed Temperature (°C)	40 - 45	40 - 45	40 - 45	40 - 45	40 - 45	40 - 45
Tablet Bed Temperature (°F)	104 - 113	104 - 113	104 - 113	104 - 113	104 - 113	104 - 113
Number of Spray Guns	1	1	1	1-2	2-4	4-6
Spray Rate Total (g/min)	4-8	4-8	12 - 20	40-65	250-400	500-700
Atomizing Air Pressure (bar)/(psi)	1.4 bar (20 psi)	1.4 bar (20 psi)	1.4 bar (20 psi)	1.7 – 2.1 Bar (25 – 30 psi)	2.1 - 2.8 bar (30 - 40 psi)	2.1 - 2.8 bar (30 - 40 psi)
Pattern (fan width) Pressure (bar)/(psi)	1.4 bar (20 psi)	1.4 bar (20 psi)	1.4 bar (20 psi)	1.7 – 2.1 Bar (25 – 30 psi)	2.1 - 2.8 bar (30 - 40 psi)	2.1 - 2.8 bar (30 - 40 psi)
Pan Speed (rpm)	20 - 25	16-22	14-18	10-14	8-10	4-6
Drying Airflow (ft3/min) (approximate)	45-55	35-55	150-170	250-300	1500-1750	3500-4000
Drying Airflow (m3/hour) (approximate)	75-95	60-95	250-290	425-500	2550-3000	6000-6800



SheffCoat™ CG

Compliance Status in Key Pharmaceutical and Dietary Supplement Markets

	Hypromellose	Glycerin
United States	Permitted use under 21CFR 172.874 Listed in the FDA IIG for pharmaceutical products* * (536.8 mg, oral tablet, 1/16/2016)	Permitted for use under 21CFR182.1320. Listed in the FDA IIG for pharmaceutical products* *(16 mg ,oral tablet, 1/16/2016).
Canada	permitted Drug and Health Product by Health Canada by inclusion on Natural Health products Ingredients Database	permitted Drug and Health Product by Health Canada by inclusion on Natural Health products Ingredients Database
Brasil	Permitted by Resolução RDC N° 64, de 28 de Dezembro de 2012 And Resolução de Directoria Colegiada – RDC n. 45, de 03 de novembro de 2010	Permitted by Resolução RDC N° 64, de 28 de Dezembro de 2012 And Resolução de Directoria Colegiada – RDC n. 45, de 03 de novembro de 2010
Mexico	Approved for Use under Good Manufacturing Practices per ACUERDO por el que se determinan los aditivos y coadyuvantes en alimentos, bebidas y suplementos alimenticios, su uso y disposiciones sanitarias. ANEXO II - SIN: 464	Approved for Use under Good Manufacturing Practices per ACUERDO por el que se determinan los aditivos y coadyuvantes en alimentos, bebidas y suplementos alimenticios, su uso y disposiciones sanitarias. ANEXO II – SIN: 422
Japan	Listed as permitted; #312 on Table 1, article 10 of the Food Sanitation Act, May be used <i>quantum satis</i>	Listed as permitted; #115 on Table 1, article 10 of the Food Sanitation Act, May be used <i>quantum satis</i>
China	Food additive Standard GB 2760-2014, Table A.2 May be used <i>quantum satis</i>	Food additive Standard GB 2760-2014, Table A.2 May be used <i>quantum satis</i>
Korea	Korea Food Additive Code Maximum Limits: no	Korea Food Additive Code Maximum Limits: no
EU countries	EC regulation EC no 1333/2008, Annex II May be used <i>quantum satis</i>	EC regulation EC no 1333/2008, Annex II May be used <i>quantum satis</i>
Turkey	Turkish Food Codex Ingredients Regulation 5996. Permitted under Article 17.	Turkish Food Codex Ingredients Regulation 5996. Permitted under Article 17.
Australia / New Zealand	Permitted by Food Standards Australia New Zealand (FSANZ). Listed as permitted number 464.	Permitted by Food Standards Australia New Zealand (FSANZ). Listed as permitted number 422.

*contact Kerry for current regulatory statements