



Kerry
158 State Highway 320
Norwich, NY 13815 USA
Tel: +1 800 833 8308
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Product Data Sheet

Product Information

Product Name SheffCel 65HD

Synonyms: Hypromellose, Hydroxypropyl methyl cellulose

Chemical name: Cellulose, 2-hydroxypropyl methyl ether

USP Chemistry: Type 2906

E# 464

CAS# 9004-65-3

Application SheffCel 65HD is used as a tablet/granule binder and as a thickening agent.

Product List

Product Name	Labelled Viscosity	Viscosity Range	Methoxy Content	Hydroxypropoxy Content
SheffCel 65HD50	50 mPa*s	40 - 60 mPa*s	27.0 – 30.0%	4.0% - 7.5%
SheffCel 65HD4000	4000 mPa*s	3000 – 5600 mPa*s	27.0 – 30.0%	7.0 – 12.0%

Manufacturing, Packaging, & Storage Information

Manufacturing Site Zhoucun Plant
Shandong
China

Packaging Product is 25kg net packaged in a polyethylene liner within a fiber drum.

Storage Keep container tightly closed. Avoid excessive heat. Protect from moisture. Do not freeze.

Shelf Life Minimum shelf life of 36 months is expected for unopened containers.





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Quality Control Specifications

Physical and Chemical Specifications

Analysis	Specification	Method
Identification (A)	Conforms	Current USP, Ph. Eur., JP
Identification (B)	Conforms	Current USP, Ph. Eur., JP
Identification (C)	Conforms	Current USP, Ph. Eur., JP
Identification (D)	Conforms	Current USP, Ph. Eur., JP
Identification (E)	Conforms	Current USP, Ph. Eur., JP
Viscosity (2% in water)	Conforms	Current USP, Ph. Eur., JP
pH (2% in water)	5.0 – 8.0	Current USP, Ph. Eur., JP
Heavy Metals	NMT 20 ppm	Current USP, Ph. Eur., JP
Loss on Drying	NMT 5.0%	Current USP, Ph. Eur., JP
Ash, Sulfated	NMT 1.5%	Current USP, Ph. Eur., JP.
Appearance, Opalescence	Conforms	Current Ph. Eur.
Appearance, Solution	Conforms	Current Ph. Eur.
Assay – Hydroxypropoxy groups (%)	4.0% - 7.5%	Current USP, Ph. Eur., JP
Assay – Methoxy groups (%)	27.0 – 30.0	Current USP, Ph. Eur., JP

Microbiological Specifications

Total Aerobic Microbial Count	1000 max	USP/10g, CFU/g
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Regulatory Compliance

SheffCel 65HD complies with the following monographs: USP, Ph. Eur., JP





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Regulatory Information

California Proposition 65 Information

SheffCel 65HD does not contain any known carcinogens, mutagens and/or reproductive toxins that are currently identified by California Proposition 65, The Safe Drinking Water and Toxic Enforcement Act of 1986.

Certificate of Origin

No animal-derived components are used in the manufacture of this product. The product is manufactured in Shandong, China.

Genetically Modified Organisms (GMO) Information

Kerry does not consider **SheffCel 65HD** to be free from genetically modified organisms (GMO). However, Kerry does not perform PCR Analysis for the demonstration of GMO status of the materials.

Latex Information

Latex is not used as a raw material component or as a material of construction of any equipment utilized to manufacture the Kerry products.

Residual Solvent Information (formerly OVI) Information

SheffCel 65HD fully complies with the current USP/NF General chapter <467> Residual Solvents, the ICH Guideline Q3C on Residual Solvents, and the European Pharmacopeia Chapter 5.4 on Residual Solvents. No solvents are used in the manufacture of **SheffCel 65HD**.

TSE/BSE Information

The product does not present a TSE/BSE risk based on the Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents Via Human and Veterinary Medicinal Products (EMEA/410/01 Rev. 3). No animal derived components are used in the manufacture of this product.





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Allergen Information

Ingredients listed below are based on the current allergen legislation in the European Union and the United States of America.

Ingredient	Present
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	-
Crustaceans and products thereof	-
Eggs and products thereof	-
Fish and products thereof	-
Peanuts and products thereof	-
Soybeans and products thereof	-
Milk and products thereof (including lactose)	-
Nuts i.e. Almond (<i>Amygdalus communis L.</i>), Hazelnut (<i>Corylus avellana</i>), Walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan nut (<i>Carya illinoensis (Wangenh.) K. Koch</i>), Brazil nut (<i>Bertholletia excelsa</i>), Pistachio nut (<i>Pistacia vera</i>), Macadamia nut and Queensland nut (<i>Macadamia ternifolia</i>) and products thereof	-
Celery and products thereof	-
Mustard and products thereof	-
Sesame seeds and products thereof	-
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as SO ₂	-
Lupin and products thereof	-
Molluscs and products thereof	-

+ = Present as an ingredient as defined in Annex IIIa.

- = Not present as an ingredient.

Additional Information

Requests for additional technical and/or regulatory information about this product can be requested by visiting our website at www.SheffieldBioScience.com or by contacting your local Kerry representative.

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Supersedes: New

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