

Product Technical Dossier

Product	Microcrystalline Cellulose (MCC) 101 Bulk Dried	
CCL Product Code	P17752	

Specification Details

	Specification		
Identification (EP/E460(i))	A. The infra-red absorption spectrum of sample is concordant with the reference spectrum of microcrystalline cellulose standard. B. The substance becomes violet-blue with iodinated Zinc Chloride Solution. C. The degree of Polymerization should not be more than 350.		
Assay (EP/E460(i))	Min 97% (On dried basis)		
Appearance	Fine or granular, slightly hygroscopic powder		
Colour	White to off-white		
Aroma	Characteristic		
Flavour	Characteristic		
Sieve Analysis % passed	<1.0% (+ 60 mesh) < 30.0% (+200 mesh)		
Loss on Drying	<7.0%		
Ash	<0.50%		
Bulk Density	0.28-0.34g/cc		
рН	5.0-7.5		

Microbiological Limits

Total Viable Count	Max 1,000cfu/g	
Yeasts & Moulds	ulds Max 100cfu/g	
E. coli	Absent/1g	
Salmonella	Absent/10g	

Heavy Metal Limits (Periodically tested)

Total Heavy metals	Max 10ppm
Lead (Pb)	Max 2ppm
Cadmium (Cd)	Max 1ppm
Mercury (Hg)	Max 0.1ppm
Arsenic (As)	Max 1ppm

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Additional Technical Information

Raw Material Full Botanical / Chemical Name	Microcrystalline cellulose
Plant Part Used	Fibrous plant material
The material is Food Grade	Yes
Country of Origin	USA, Canada, South Africa, Switzerland
Country of Manufacture	India
Solubility in Alcohol	Practically insoluble
Solubility in Water	Insoluble
Average Molecular weight	About 36,000
Molecular Formula	(C ₆ H ₁₀ O₅)n
CAS Number	9004-34-6
Shelf Life from Date of Manufacture	Min 5 years
Pharmacopeia Standard Used	EP/E460(i)
Suitable for Vegetarians?	Yes
Suitable for Vegans?	Yes
Storage Conditions	This material is to be stored in a tightly sealed bag/container and to be kept in a cool place away from moisture and direct sunlight.

Composition Origin, Function and Percentages

Ingredients	Function	%	Source
Microcrystalline cellulose (E460 i)	n/a	100%	Plants

Please note that surveillance testing may mean that not all the parameters stated on this specification are tested for every batch.

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The allergen information is supplied by the manufacturer, we have not tested for each individual allergen to ensure they are not present. The information given is based on a documented risk assessment and is accurate to the best of our knowledge. If you intend to make a voluntary "free from" claim on your pack, additional testing may need to be carried out. For technical and labelling guidance, you should always speak to the competent authority for the market or member state in which the final products are placed.

Allergens and Food Intolerances

Allergens	Product Contains YES/NO	Handled at Manufacture site YES/NO	Please see risk rating A to F listed below
Peanuts and Peanut Derivatives (including possible cross contamination)	NO	NO	F
Nut and Nut Derivatives Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)	NO	NO	F
Sesame Seeds and Sesame Seed Derivatives	NO	NO	F
Milk and Milk Derivatives (including lactose)	NO	NO	F
Egg and Egg Derivatives	NO	NO	F
Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten (wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass)	NO	NO	F
Soya and Soya Derivatives	NO	NO	F
Lupin and Lupin Derivatives	NO	NO	F
Mustard and Mustard Derivatives	NO	NO	F
Celery or Celery Derivatives (including Celeriac)	NO	NO	F
Fish and Fish Derivatives	NO	NO	F
Molluscs and their Derivatives	NO	NO	F
Crustaceans and their Derivatives	NO	NO	F
Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre	NO	NO	F

- A Risk of contact at source during harvesting and may contain traces
- B Raw material handled on same line as other allergenic materials and may contain traces
- C Raw material handled on same line as other allergenic materials however formal control programme in place to minimise cross contact risk
- D Exempt from labelling according to EU regulations
- E Not handled on the same line
- ${\sf F}$ Not handled at manufacture site and therefore no risk of cross contamination

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Additives / Contaminants / Dietary Requirements / Intolerances	Product Contains YES/NO	Handled at Manufacture site YES/NO	Please see risk rating A to E listed below
Additives / E Numbers	YES	YES	Material is (E460 i)
Antioxidants	NO	NO	F
Ethylene Oxide	NO	NO	F
Gelatine	NO	NO	F
Flavourings (Artificial / Nature Identical / Natural / Smoked)	NO	NO	F
Maize / Corn and any Derivatives	NO	NO	F
Legumes / Pulses	NO	NO	F
Rice and Rice Derivatives	NO	NO	F
Added Salt	NO	NO	F
Added Sugar / artificial or natural sweeteners	NO	NO	F
Aspartame	NO	NO	F
BHA / BHT (E320 / E321)	NO	NO	F
Caffeine	NO	NO	F
Colours (Artificial / Nature Identical / Natural / Smoked)	NO	NO	F
Dextrose	NO	NO	F
Other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds)	NO	NO	F
Fruits (Kiwi fruit, orange, banana, apple, peach)	NO	NO	F
Polyols (sugar alcohols)	NO	NO	F
Grapefruit	NO	NO	F
Sorbic Acid (E200, E203)	NO	NO	F
Any other Preservatives	NO	NO	F
Ethanol	NO	NO	F
Honey	NO	NO	F
Lactose	NO	NO	F
Yeast and Yeast Derivatives	NO	NO	F
All Animal Products (Beef, Pork, Poultry or other) and Derivatives (which may include growth/yield hormones, antibiotics etc.)	NO	NO	F
Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)	NO	NO	F
Matsutake mushroom and Derivatives	NO	NO	F
Yam and Derivatives	NO	NO	F
Buckwheat and Derivatives	NO	NO	F
Palm Oil and Derivatives	NO	NO	F
Coconut and Derivatives	NO	NO	F

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Compliance Statements

Confirmation of BSE / TSE Status This product complies with all relevant current UK and EU Legislative requirements in regard to Transmissible Spongiform Encephalopathies (TSE) and Bovine Spongiform Encephalopathy (BSE) for human food, and so is free of TSE/BSE.	Yes
Confirmation of GM Status This product is not manufactured from GM raw materials and is therefore not subject to labelling under current regulations.	Yes
Confirmation of Non-Irradiation Status This product, whole or in part, has not been subjected to Ionising Radiation as per European Directives.	Yes
Confirmation of IOC Product Status This product, whole or in part, has not come into contact with any product which is banned by the IOC (International Olympics Committee) and/or WADA.	Yes
Confirmation of Animal Testing Status This product has not been tested on animals in any part of its manufacture in accordance with current regulations.	Yes
Confirmation of Pesticides Status This product complies with the EU max residue limits (MRLs) on pesticides.	Yes
Confirmation of Nanomaterial Status This product does not contain nanomaterials as per relevant EU regulations.	Yes
Confirmation of Food Grade Packaging The packaging used in this product conforms to EU regulations and subsequent amendments on food grade packaging	Yes
Confirmation of Pyrrolizidine Alkaloids (PA) status This product complies with the PA limit set by the EU regulations	Yes
This product complies with Commission Regulation (EC) No 2023/915 wherever applicable	Yes

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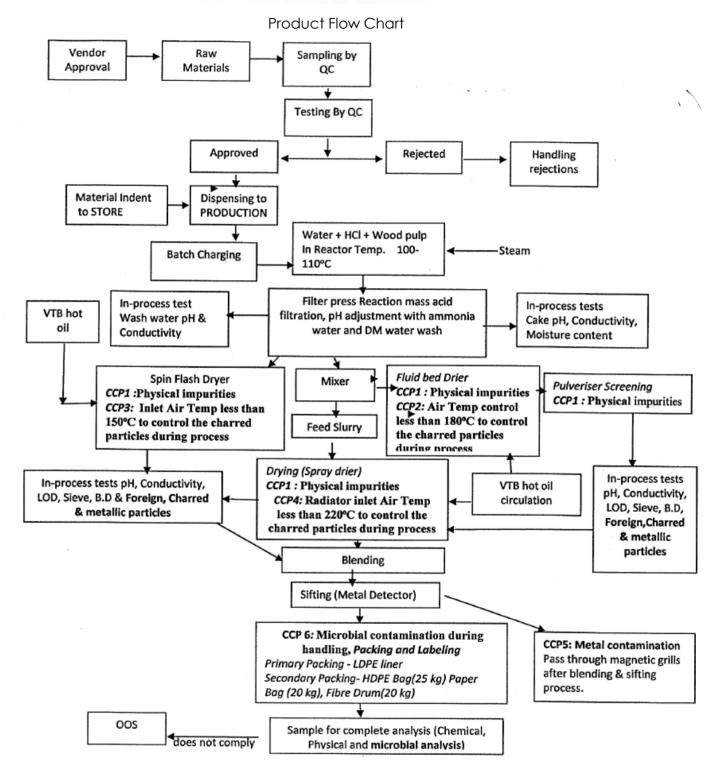
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Material Safety Data Sheet

To download this product's material safety data sheet, please click <u>here</u> and search for the Cambridge Commodities product code. If there is no MSDS available, please follow the onscreen instructions to request one.

The Information provided in this document is subject to change and the batch specific certificate of analysis should always be referenced.

To be used as per local legislation.

Change History

Version	Change	Customer Notification required Yes / No
1	First Issue	N/A
2	Changed Mercury limit from "Max 1ppm" to "Max 0.1ppm" & Arsenic from "Max 3ppm" to "Max 1ppm"	Yes

Document Approval

Originator		Approver	
nAAA	Mel Lee	< >0.	C White
× el Kel × 24/08/2023 14:50	Quality Administrator	C White 25/08/2023 07:32	Senior Quality Specialist

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