

Product Technical Dossier

| | |
|------------------|--------------------------|
| Product | Croscarmellose Sodium EP |
| CCL Product Code | P15486 |

Specification Details

| | |
|------------------------------|------------------------------------|
| | Specification |
| Identification | Meets Requirements |
| Appearance | Free Flowing Powder |
| Colour | White |
| Aroma | Characteristic |
| Flavour | Characteristic |
| Sieve Analysis % passed | Min 90% Pass 200 Mesh (74 Microns) |
| Loss on Drying | Max 10% |
| Sulphated Ash | 14.0-28.0% |
| pH | 5.0-7.0 |
| Impurities/Residual Solvents | Ethanol, max 0.5% |
| Na-chloride & Na-glycolate | Max 0.50% |
| Degree of Substitution | 0.60-0.85 |
| Water Soluble Substances | Max 10% |
| Settling volume | 10-30ml |

Microbiological Limits

| | |
|--------------------|----------------|
| Total Viable Count | Max 1,000cfu/g |
| Yeasts & Moulds | Max 100cfu/g |
| E. Coli | Absent |
| Salmonella | Absent |

Heavy Metal Limits

| | |
|--------------------|------------|
| Total Heavy Metals | Max 10ppm |
| Lead (Pb) | Max 0.5ppm |
| Cadmium (Cd) | Max 0.5ppm |
| Mercury (Hg) | Max 3ppm |
| Arsenic (As) | Max 1.5ppm |

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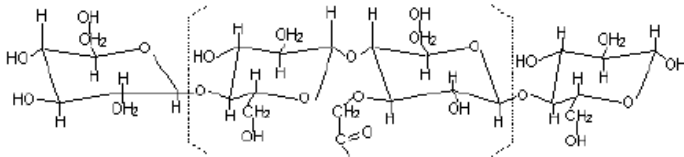
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Additional Technical Information

| | |
|---|--|
| Raw Material Full Botanical / Chemical Name | Croscarmellose Sodium |
| The material is Food Grade | Suitable for use in food, material is Pharma grade |
| Country of Origin | China |
| Country of Manufacture | China |
| Solubility in Water | Soluble |
| Average Molecular weight | 160.22 |
| Molecular Structure |  |
| CAS Number | 74811-65-7 |
| EC/EINECS Number | 39123100 |
| Shelf Life from Date of Manufacture | Min 2 Years |
| Pharmacopeia Standard Used | USP, EP |
| 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 | % composition | Source |
|-----------------------|---------------|-----------|
| Croscarmellose Sodium | 100% | Wood Pulp |

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

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.

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| Allergens | Product Contains YES/NO | Listed Item on Site at Manufacturer YES/NO | Where applicable, is there risk of cross-contamination? YES/NO or N/A |
|---|-------------------------|--|---|
| Peanuts and Peanut Derivatives (including possible cross contamination) | NO | NO | N/A |
| Nut and Nut Derivatives <i>Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoensis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)</i> | NO | NO | N/A |
| Sesame Seeds and Sesame Seed Derivatives | NO | NO | N/A |
| Milk and Milk Derivatives (including lactose) | NO | NO | N/A |
| Egg and Egg Derivatives | NO | NO | N/A |
| Cereals and Derivatives containing OR POTENTIALLY CONTAMINATED WITH Gluten <i>(wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barleygrass)</i> | NO | NO | N/A |
| Soya and Soya Derivatives | NO | NO | N/A |
| Lupin and Lupin Derivatives | NO | NO | N/A |
| Mustard and Mustard Derivatives | NO | NO | N/A |
| Celery or Celery Derivatives (including Celeriac) | NO | NO | N/A |
| Fish and Fish Derivatives | NO | NO | N/A |
| Molluscs and their Derivatives | NO | NO | N/A |
| Crustaceans and their Derivatives | NO | NO | N/A |
| Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre | NO | NO | N/A |

| Additives / Contaminants / Dietary Requirements / Intolerances | Product Contains YES/NO | Listed Item on Site at Manufacturer YES/NO | Where applicable, is there risk of cross-contamination? YES/NO or N/A |
|--|-------------------------|--|---|
| Additives / E Numbers | NO | NO | N/A |
| Antioxidants | NO | NO | N/A |
| Ethylene Oxide | NO | NO | N/A |
| Gelatine | NO | NO | N/A |
| Flavourings (Artificial / Nature Identical / Natural / Smoked) | NO | NO | N/A |
| Maize / Corn and any Derivatives | NO | NO | N/A |
| Legumes / Pulses | NO | NO | N/A |
| Rice and Rice Derivatives | NO | NO | N/A |
| Added Salt | NO | NO | N/A |
| Added Sugar / artificial or natural sweeteners | NO | NO | N/A |
| Aspartame | NO | NO | N/A |
| BHA / BHT (E320 / E321) | NO | NO | N/A |
| Caffeine | NO | NO | N/A |
| Colours (Artificial / Nature Identical / Natural / Smoked) | NO | NO | N/A |
| Dextrose | NO | NO | N/A |
| other Seeds and Seed Derivatives (Poppy Seeds, Cotton Seeds, Sunflower Seeds) | NO | NO | N/A |
| Kiwi fruit | NO | NO | N/A |
| Polyols (sugar alcohols) | NO | NO | N/A |
| Grapefruit | NO | NO | N/A |
| Sorbic Acid (E200, E203) | NO | NO | N/A |
| Any other Preservatives | NO | NO | N/A |
| Ethanol | YES | YES | Used during processing |
| Honey | NO | NO | N/A |
| Lactose | NO | NO | N/A |
| Yeast and Yeast Derivatives | NO | NO | N/A |
| All Animal Products (Beef, Pork, Poultry or other) and Derivatives (which may include growth/yield hormones, antibiotics etc.) | NO | NO | N/A |
| Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.) | NO | NO | N/A |

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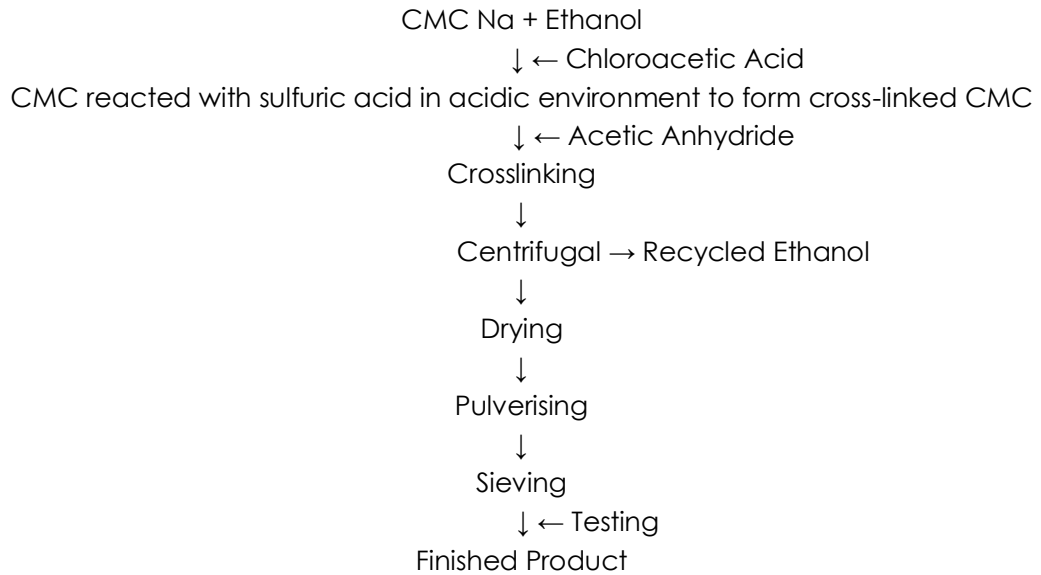
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Statements

| | |
|---|-----|
| <p>Confirmation of BSE / TSE Status This is to certify that 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.</p> | Yes |
| <p>This is also to certify that, during the course of their manufacture, the above-mentioned product did not come into contact with any materials, which could be derived from TSE/BSE risk materials.</p> | Yes |
| <p>Confirmation of GM Status This is to certify that this product is not manufactured from GM raw materials and is therefore not subject to labelling under current regulations.</p> | Yes |
| <p>Confirmation of Non-Irradiation Status This is to certify that this product, whole or in part, has not been subjected to Ionising Radiation as per European Directives.</p> | Yes |
| <p>Confirmation of Nandrolone Status This is to certify that this product, whole or in part, has not come into contact with Nandrolone or any of its precursors in any way.</p> | Yes |
| <p>Confirmation of IOC Product Status This is to certify that this product, whole or in part, has not come into contact with any product/s, which is banned by the IOC (International Olympics Committee) and or WADA.</p> | Yes |
| <p>Confirmation of Animal Testing Status This is to certify that all the products sold by Cambridge Commodities have not been tested on animals in any part of its manufacture in accordance with current regulations.</p> | Yes |
| <p>Confirmation of Pesticides Status This is to certify that the above-mentioned product complies with the EU max residue limits (MRLs) on pesticides.</p> | Yes |
| <p>Confirmation of Nanoparticles Status This is to certify that unless otherwise stated, the above-mentioned product is free of nanoparticles. Commission Recommendation, defines as follows: "Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm".</p> | Yes |
| <p>Packaging Status We hereby certify that the packaging used in the above-mentioned material conforms to EU regulations and subsequent amendments on food grade packaging</p> | Yes |
| <p>Confirmation of PAH status This is to certify that the above-mentioned product complies with the max PAH limits set by the EU regulations</p> | Yes |



Product Flow Chart



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Material Safety Data Sheet

To download this product's material safety data sheet, please click [here](#) and search for the Cambridge Commodities product code. If there is no MSDS available, please follow the on-screen 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 | Amended food grade status to show the product is suitable for use in food and is pharma grade | Yes |

Document Approval

| Originator | Approver |
|---|--|
|  <small>x 31/10/2022 09:42</small> Mel Lee Quality Administrator |  <small>x 31/10/2022 11:53</small> Ash Bean Quality Specialist |

