

Product Technical Dossier

Product	D-Biotin Pure
CCL Product Code	P0207

Specification Details

Identification	Specification
Biotin (assay on a dry basis)	Positive
Appearance	98.5-101.0%
Colour	Crystalline powder
Aroma	White/off-white
Flavour	Characteristic
Sieve Analysis % passed	Min 95% pass 100 mesh
Loss on Drying	Max 1%
Sulphated Ash	Max 0.1%
Bulk Density	0.4-0.8 g/ml
Specific Optical Rotation	+89.0° to +93.0°
Residual Solvents	Toluene Max 890ppm Tetrahydrofuran Max 720ppm Ethanol Max 5,000 ppm Residual solvents comply with EP
Impurities (HPLC)	Individual impurity Max 1.0% Total Impurities Max 2.0%

Microbiological Limits

Total Viable Count	Max 1,000cfu/g
Yeasts & Moulds	Max 10cfu/g
E. Coli	Negative/25g
Salmonella	Negative/25g

Heavy Metal Limits

Lead (Pb)	Max 3ppm
Cadmium (Cd)	Max 1ppm
Mercury (Hg)	Max 0.1ppm
Arsenic (As)	Max 1ppm

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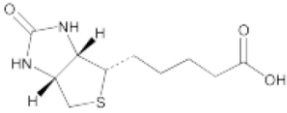
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Additional Technical Information

Raw Material Full Botanical / Chemical Name	D-Biotin
The material is Food Grade	Yes
Solvent Used	THF, toluene & Ethanol
Country of Origin	China
Country of Manufacture	China
Solubility in Alcohol	Very slightly soluble
Solubility in Water	Very slightly soluble
Melting Point	229-232°C
Average Molecular weight	244.3
Molecular Formula	C ₁₀ H ₁₆ N ₂ O ₃ S
Molecular Structure	
CAS Number	58-85-5
EC/EINECS Number	200-399-3
Shelf Life from Date of Manufacture	Min 2 years
Pharmacopeia Standard Used	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	Function	% Composition	Source
D-Biotin	n/a	100%	Chemical Synthesis

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 as Solvent
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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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

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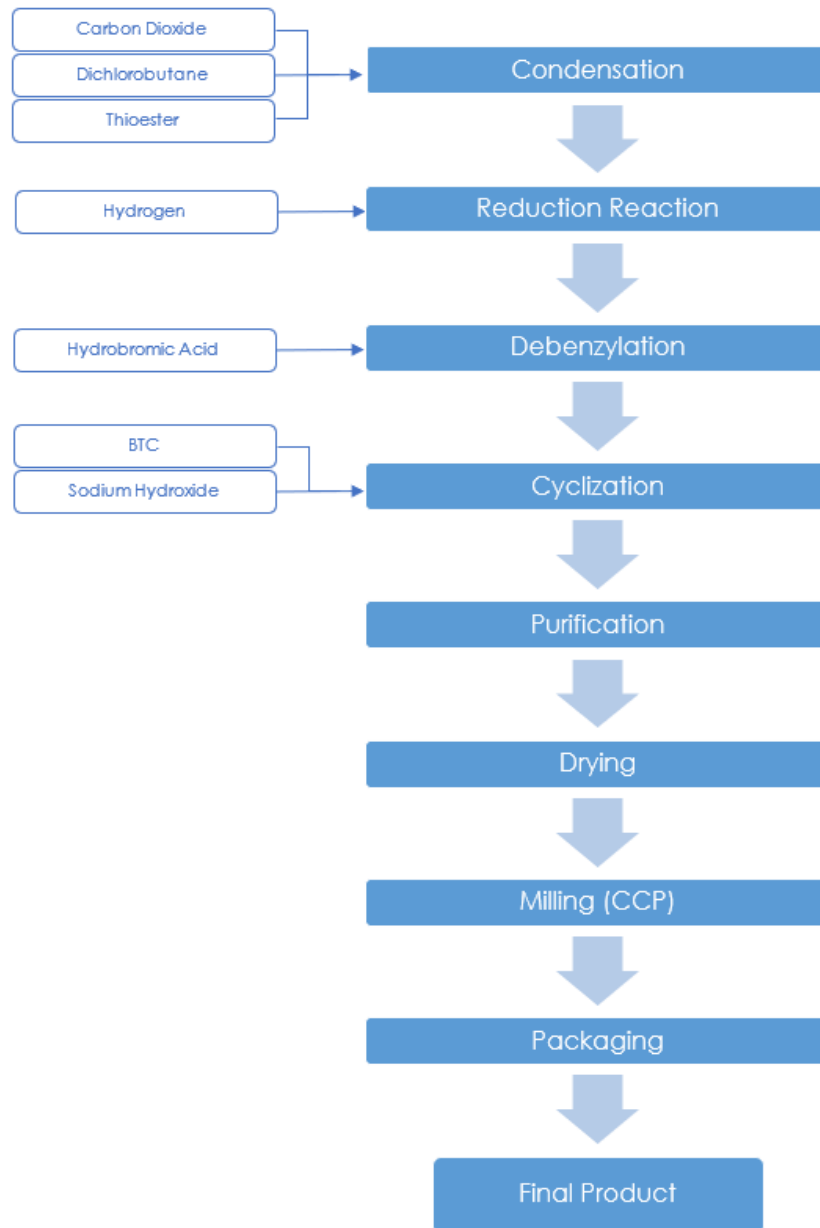
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Product Flow Chart



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	Format updated.	No
3	Updated Assay to 98.5 – 101.0% Updated Loss on Drying to Max 1% Added Sulphated Ash Max 0.1% The above changes were made so our specification conforms to EP Added Vegan and Vegetarian Status	Yes
4	Changed mesh size from 300 to 100. Changed bulk density from about 0.35g/cm ³ to 0.4-0.8g/cm ³ . Removed specification for tapped density. General reformat.	Yes
5	Changed sieve analysis from 100% pass 100 mesh to 95% pass 100 Mesh, Flow chart update and General td reformat	Yes
6	Confirmed ethanol is used as a solvent. Removed pH and total heavy metals specifications. Added supplementary technical information. Updated production flowchart.	Yes
7	Updated 'Assay' to 'Biotin (assay on a dry basis)' with no change to the product.	Yes

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8	Added Additional Supplementary Technical Information Updated Residual Solvents from "Ethanol - Max 5,000ppm" to Toluene Max 890ppm Tetrahydrofuran Max 720ppm Ethanol Max 5,000 ppm Residual solvents comply with EP	Yes
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Document Approval

Originator	Approver
 <small>16/08/2022 13:31</small> Mel Lee Quality Administrator	 <small>16/08/2022 14:57</small> C White Senior Quality Specialist

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