

## **Product Technical Dossier**

Product	Hydroxyproline (L-)
CCL Product Code	P0804

## Specification Details

	Specification	
Identification	Positive	
Assay	98.5% to 101.0%	
Appearance	Crystals/Crystalline Powder	
Colour	White/Off White	
Aroma	Characteristic	
Flavour	Characteristic	
Loss on Drying	Max 0.20%	
Ash	Max 0.1%	
Bulk Density	0.7g/ml~0.9g/ml (**)	
Tapped Density	0.8g/ml~1.0g/ml (**)	
рН	5.0-6.5	
Chloride (CI)	Max 0.020%	
Sulphate (SO <sub>4</sub> )	Max 0.020%	
Ammonium (NH <sub>4</sub> )	Max 0.020%	
Other Amino Acids	Conforms	
Specific Rotation	-74.0° to -77.0°	
State of Solution	Min 95%	

(\*\*) Not tested for every batch.

## Microbiological Limits

Total Viable Count	Max 1000cfu/g	
Yeasts & Moulds	Max 100cfu/g	
E. Coli	Negative/10g	
Salmonella Negative/25g		

## Heavy Metal Limits

Lead (Pb)	Max 3ppm	
Cadmium (Cd)	Max 1ppm	
Mercury (Hg)	Max 0.1ppm	
Arsenic (As)	Max 1ppm	
Iron (Fe)	Max 10ppm	

Product Code: P0804 Version: 3 Page 1 of 6

























#### Additional Technical Information

Raw Material Full Chemical Name	L-Hydroxy Proline
The material is Food Grade	Yes
Solubility in Alcohol	Soluble
Solubility in Water	Soluble
Solvent Used	Pure Water
Country of Origin	China
Country of Manufacture	China
Average Molecular weight	131.13g/mol
Molecular Formula	C <sub>5</sub> H <sub>9</sub> NO <sub>3</sub>
CAS Number	51-35-4
EC/EINECS Number	200-091-9
Shelf Life from Date of Manufacture	Min 2 Years
Pharmacopeia Standard Used	AJI92
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
Hydroxyproline (L-)	-	100%	Glucose started from corn

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.

Product Code: P0804 Version: 3 Page 2 of 6

























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 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	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 (wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass)	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	Yes	Glucose as start material
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	No	No	N/A
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

Product Code: P0804 Version: 3 Page 3 of 6

























#### Statements

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.	Yes
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.	Yes
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.	Yes
Confirmation of Non-Irradiation Status  This is to certify that this product, whole or in part, has not been subjected to lonising Radiation as per European Directives.	Yes
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.	Yes
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.	Yes
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.	Yes
Confirmation of Pesticides Status  This is to certify that the above-mentioned product complies with the EU max residue limits (MRLs) on pesticides.	Yes
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".	Yes
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	Yes
Confirmation of PAH status This is to certify that the above-mentioned product complies with the max PAH limits set by the EU regulations	Yes

Product Code: P0804 Version: 3 Page 4 of 6

























**Product Flow Chart** 

# Freezing tube Primary slant Subsidiary slant Suspension Seeding tank inoculation Fermentation Liquid Membrane Filtration ↓ Ion Exchange Ion Exchange – Purified liquid Ammonia Water Stripping $\downarrow$ Stripping Liquid Concentrated Liquid First Crude Product ↓ Add Activated Carbon Discoloured Liquid Concentrate Liquid Second Crude Product ↓ Add Activated Carbon Discoloured Liquid 1 Concentrated Liquid ↓ Centrifugal Crystallization Hydroxyproline (L-)

Product Code: P0804 Version: 3 Page 5 of 6

























## 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
	Base Source updated: Glucose now sourced from corn. Updated heavy metals, added microbial specifications, updated allergen and additive tables, updated flow chart, MSDS and format of TD Removed; Fermentation media used, compound ingredients and Pharmacopoeia. MSDS removed- now available on request.	Yes
3	Amended the following:  • Bulk Density from 0.6602g/ml to 0.7g/ml~0.9g/ml  • Tapped Density from 0.8687g/ml to 0.8g/ml~1.0g/ml  • E. Coli from <10cfu/g to Negative/10g  Added Pharmacopeia Standard used, solvents used and solubility information.  Updated additives and allergens tables.  General reformat.	Yes

## **Document Approval**

0	riginator		Approver
M. Sosnin	Malgorzata Sosnin QC Team Leader	Julia Otto	Julia Otto Quality Specialist
× 26/09/2019 10:53 - DocsVault		26/09/2019 11:06 - DocsVault	

Product Code: P0804 Version: 3 Page 6 of 6





















