

## **Product Technical Dossier**

Product	L- Carnitine
CCL Product Code	P0313

## Specification Details

	Specification	
Identification	Positive	
Assay	97.0% - 103.0%	
Appearance	Free Flowing Crystalline Powder	
Colour	White to off White	
Aroma	Characteristic	
Flavour	Characteristic	
Loss on Drying	Max 4%	
Residue on Ignition	Max 0.5%	
Chloride	Max 0.4%	
Sodium	Max 0.1%	
Potassium	Max 0.2%	
рН	5.5 - 9.5	
Specific Rotation	-29.0° – 32.0°	
Residue Acetone	NMT 1000ppm	
Residue Ethanol	NMT 5000ppm	

## Microbiological Limits

Total Viable Count Max 1,000cfu/g		
Yeasts & Moulds	Max 100cfu/g	
E. Coli	Negative/g	
Salmonella	Negative/25g	

## Heavy Metal Limits

Total Heavy metals	Max 10ppm		
Lead (Pb)	Max 3ppm		
Cadmium (Cd)	Max 1ppm		
Mercury (Hg)	Max 0.1ppm		
Arsenic (As)	Max 1ppm		

Product Code: P0313 Version: 7 Page 1 of 6

Committed to meeting quality standards. BRC Food Safety . FEMAS . FSMA . Informed Manufacturer. Soil Association Organic . Halal . Kosher .









#### Additional Technical Information

Raw Material Full Botanical / Chemical Name	L- Carnitine Base	
The material is Food Grade	Yes	
Country of Origin	China	
Country of Manufacture	China	
Solubility in Alcohol	Soluble in warm ethanol (96%)	
Solubility in Water	Very soluble	
Average Molecular weight	161.2	
Molecular Formula	C <sub>7</sub> H <sub>15</sub> NO <sub>3</sub>	
CAS Number	541-15-1	
EC/EINECS Number	208-768-0	
Shelf Life from Date of Manufacture	Min 2 years	
Pharmacopeia Standard Used	USP	
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 fron moisture and direct sunlight.	

#### Composition Origin, Function and Percentages

Ingredients	Function	% composition	Source
L-Carnitine Base	-	100%	Synthetic (D-Chloroepoxy propane and Trimethylamine Hydrochloride)

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: P0313 Version: 7 Page 2 of 6

Committed to meeting quality standards. BRC Food Safety . FEMAS . FSMA . Informed Manufacturer. Soil Association Organic . Halal . Kosher .









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	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	Max 5,000ppm
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: P0313 Version: 7 Page 3 of 6

Committed to meeting quality standards. BRC Food Safety . FEMAS . FSMA . Informed Manufacturer. Soil Association Organic . Halal . Kosher .









#### 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 Ionising 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: P0313 Version: 7 Page 4 of 6

Committed to meeting quality standards. BRC Food Safety . FEMAS . FSMA . Informed Manufacturer. Soil Association Organic . Halal . Kosher .









## **Product Flow Chart**



Product Code: P0313 Version: 7 Page 5 of 6

Committed to meeting quality standards. BRC Food Safety . FEMAS . FSMA . Informed Manufacturer. Soil Association Organic . Halal . Kosher .









# 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
	The following has been updated, due to the supplier updating their specification:  - Cyanamid has been removed  - Arsenic (As) has been updated from Max 2ppm to Max 1ppm  - Lead (Pb), Cadmium (Cd) and Mercury (Hg) have been added	Yes
3	Changed residual acetone from 0.1% to 0.5%	Yes
	Added microbiological specifications. Changed 'residue acetone' specification to 'residual solvents'.	Yes
5	Added FEMAS status	Yes
	Added production flow chart, Residue Acetone NMT 1000ppm and Residue Ethanol NMT 5000ppm information. Amended Loss on Drying from Max 4% to Max 0.5% and Removed Residual Solvents Max 0.5% information. General reformat.	Yes
	Loss on Drying Changed from Max 0.5% to Max 4%. Removed Staphylococcus Aureus specification.	Yes

## **Document Approval**

Originator		App	prover
Hen Feethern	Alan Feetham QC Technician	Ash Bean 24/11/2021 13:49	Ash Bean  Quality Specialist

24/11/2021 12:31

Product Code: P0313 Version: 7 Page 6 of 6

Committed to meeting quality standards. BRC Food Safety . FEMAS . FSMA . Informed Manufacturer. Soil Association Organic . Halal . Kosher .





