

Product Technical Dossier

Product	Methyl Cobalamin Hydrate (B12)
CCL Product Code	P13175

Specification Details

	Specification	
Identification (UV) UV-VIS spectrum pH2 UV-VIS spectrum pH7 Identification2 (Chemistry)	Conforms to Standard Conforms to Standard Positive	
Assay (HPLC)	98.0%-101.0% on dry basis	
Appearance	Hygroscopic Crystalline Powder	
Colour	Red to Dark Red	
Aroma	Characteristic	
Flavour	Characteristic	

Loss on Drying	Max 12%	
Related Substances (HPLC)	Max 2%	
Acetone	<0.5%	
Clarity & Colour of solution	The solution is clear and red in colour	
Individual Impurities (HPLC)	Max 0.5%	

Microbiological Limits

Total Viable Count	Max 1,000cfu/g
Yeasts & Moulds	Max 300cfu/g
E. Coli	Negative
Salmonella	Negative
Staphylococcus aureus	Negative

Heavy Metal Limits

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

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates







+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Registered in England No: 3590758 VAT No:GB711 6598 32 Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

Product Code: P13175 Version: 6 Page 1 of 8



Additional Technical Information

Raw Material Full Botanical / Chemical Name	Co a – [a – (5,6-Dimethyl-1H-benzoimidazol-l-yl)]- Co β – methylcobamide
The material is Food Grade	Yes
Solvent used	Acetone and Ethanol
Country of Origin	China
Country of Manufacture	China
Average Molecular weight	1344.38
Molecular Formula	C63H91C0N13O14P
CAS Number	13422-55-4
EC/EINECS Number	236-535-3
Shelf Life from Date of Manufacture	Min 2 Years
Pharmacopeia standard used	JP
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
Mecobalamin	-	100%	Cyanocobalamin (obtained via fermentation from Pseudomonas dentrificans Ensifer adhaerens), Trimethylsulfoxonium iodide and Sodium Borohydride

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.

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates



Registered in England No: 3590758





Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Product Code: P13175 Version: 6 Page 2 of 8



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, barleygrass)	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	Yes	No

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	No
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	Yes, Solvent Used
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

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates



Registered in England No: 3590758





Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Product Code: P13175 Version: 6 Page 3 of 8



Bovine Products or Derivatives (which may include growth/yield hormones, antibiotics etc.)

No
No
No
N/A

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates







+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Registered in England No: 3590758

VAT No:GB711 6598 3

Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

Product Code: P13175 Version: 6 Page 4 of 8



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

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates and the following properties of the following propertie







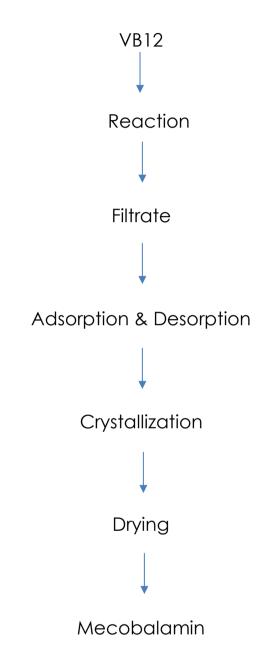
+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Registered in England No: 3590758 VAT No:GB711 6598 32 Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

Product Code: P13175 Version: 6 Page 5 of 8



Product Flow Chart



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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates



Registered in England No: 3590758





Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

 $\textbf{+44 (0) 1353667258} \hspace{0.1cm}|\hspace{0.1cm} www.cambridgecommodities.com \hspace{0.1cm}|\hspace{0.1cm} enquiries@cambridgecommodities.com$

Product Code: P13175 Version: 6 Page 6 of 8



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	Removed Bulk and Tapped Density.	No
3	Updated format.	No
4	Specified that the material is pharmaceutical grade.	Yes
5	Removed solubility in water and alcohol, Enterobacteriaceae. Updated the TVC to 1,000cfu/g General Reformat Added strain used Added Trimethylsulfoxonium iodide and Sodium Borohydride to the starting materials statement. Amended the base source/start material The TD has also undergone a General Reformat	Yes
	Removed (96.904 - 98.882% COBALAMIN) from the product name and total content Added Additional Supplementary Technical Information Changed assay from Min 98.0% to 98.0%-101.0% on dry basis, related substances from Max 0.5% to Max 2.0%, Changed Maize/Corn and any Derivatives in Additives table as Product contains "No", Listed on site "Yes" and "No" for risk of cross-contamination & Sulphur Dioxide and Sulphites (E220, E228) at levels > 10mg/kg or 10mg/litre in Allergens table from product contains "No", Listed on site "Yes" and "No" for risk of contamination Updated product flowchart	Yes

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates







+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Product Code: P13175 Version: 6 Page 7 of 8



Document Approval

	Originator	Approver	
Mel Lee	Mel Lee	Dealling August	Cecilia Anzani
× 27/05/2022 12:51	Quality Administrator		Senior Quality Specialist

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

For a full range of our accreditations visit www.cambridgecommodities.com/quality-accreditations/certificates



Registered in England No: 3590758





Registered Office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6

+44 (0) 1353667258 | www.cambridgecommodities.com | enquiries@cambridgecommodities.com

Product Code: P13175 Version: 6 Page 8 of 8