

Product Technical Dossier

Product	Vitamin B6 (Pyridoxine HCl)
CCL Product Code	P2211

Specification Details

	Specification
Identification	Positive
Assay (on dry basis)	Pyridoxine HCl 99.0 - 101.0%
Appearance	Fine Free Flowing Powder
Colour	White/Off-White
Aroma	Characteristic
Flavour	Characteristic
Loss on Drying	Max 0.5%
Ash	Max 0.1%
Chloride	16.9 - 17.6%
pH	2.4 - 3.0
Impurity B	Max 0.15%
Unspecified Impurity	Max 0.10%
Total Impurity	Max 0.2%

Microbiological Limits

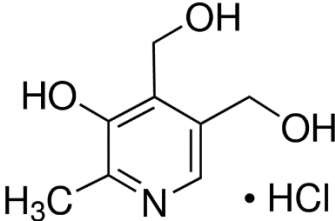
Total Viable Count	Max 1,000cfu/g
Yeasts & Moulds	Max 100cfu/g
E. Coli	Negative/1g
Salmonella	Negative/25g
Staphylococcus Aureus	Negative/25g

Heavy Metal Limits

Total Heavy Metals	Max 20ppm
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Additional Technical Information

Raw Material Full Chemical Name	(5-Hydroxy-6-methylpyridine-3, 4-diy) dimethanol hydrochloride
The material is Food Grade	Yes
Solvent used	Ethanol
Residual Solvent/Ethanol	Max 0.5%
Country of Manufacture	China
Melting Point	205 °C – 209 °C
Solubility in Alcohol	Slightly Soluble
Solubility in Water	0.1 g/mL 20°C (Freely Soluble)
Average Molecular weight	205.64
Molecular Formula	C ₈ H ₁₁ NO ₃ .HCl
Molecular Structure (image)	
CAS Number	58-56-0
EC/EINECS Number	200-386-2
Shelf Life from Date of Manufacture	Min 3 Years (Batch specific)
Pharmacopeia Standard Used	BP, EP, USP, FCC
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
Vitamin B6 (Pyridoxine Hydrochloride)	Active ingredient	100%	4-methyl-5-ethoxyoxazole, n-propyl dioxepin

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 excelsis), 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
Mollusks 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	Used in another production line

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	Ethanol is used as solvent. Residual solvent max 0.5%
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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Compliance 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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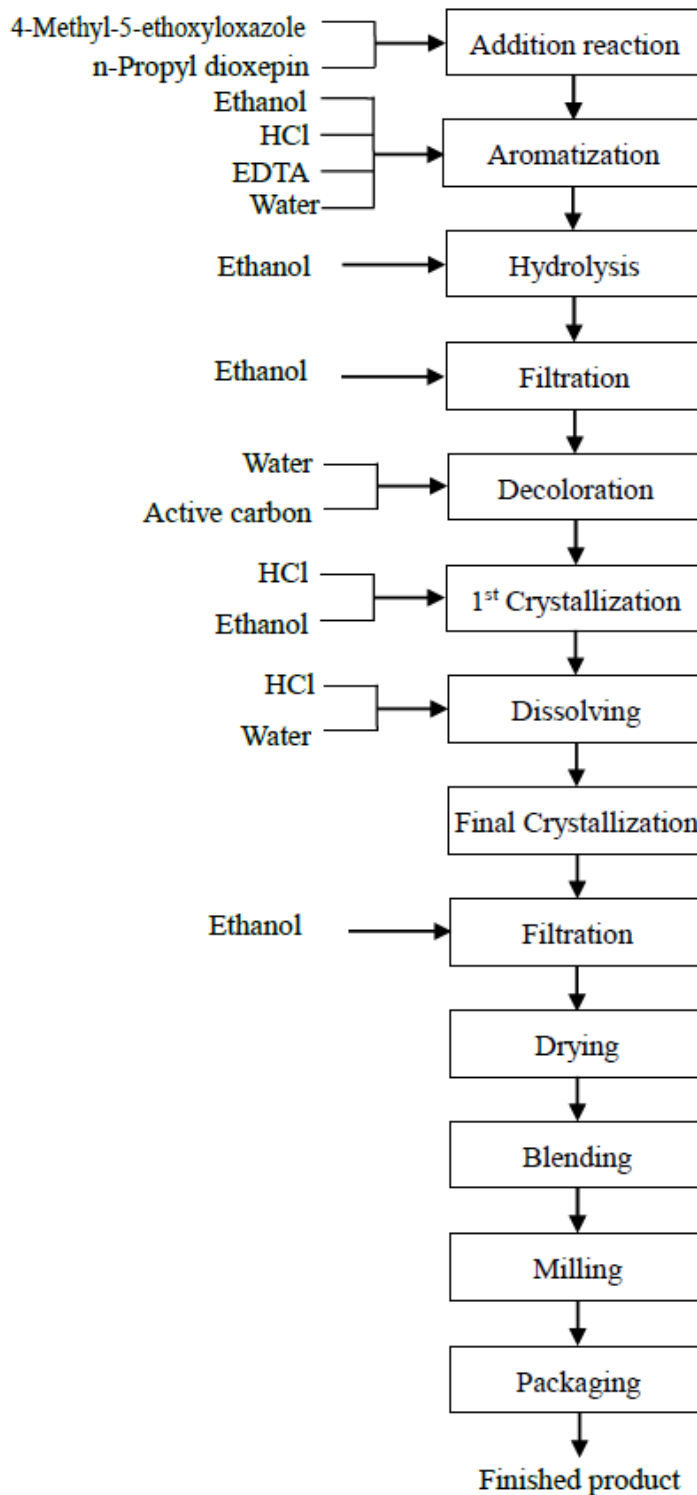
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Product Flow Chart



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	Shelf Life updated to Minimum 3 Years from 3 Years	No
3	<ul style="list-style-type: none"> - Solvent Used (95% Ethanol) has been added to clarify the production process and Food Intolerance Information has been updated accordingly - Molecular Formula has been amended from (C8H11NO6.HCl) to (C8H11NO3.HCl) to correct a clerical error - Pharmacopeia Standards Used has been changed from BP2009, USP30, EP6.0 to BP, EP, USP and FCC due to the supplier updating their specification - The Footer and Header have been updated 	Yes
4	<ul style="list-style-type: none"> Added vegetarian and vegan suitability statement. Assay (on dry basis) amended from min 99.0 to 98.0% Chemical full name, density values, molecular structure, EC/EINECS Number and Identification Method added. Sulphur Dioxide listed on manufacturer's site (allergen table). Complies with French Arrêté 26 September 2016. 	Yes
5	Bulk density changed from 0.48-0.6 to 0.48-0.9 g/ml and tapped density removed.	Yes
6	The Organic Volatile Impurities parameter was removed. The Solvents limit and the microbiology limits were edited	Yes
7	<ul style="list-style-type: none"> Changed Particle Size: 40-90 Mesh and percentage passed through from 99% to 90%. New MSDS added. General reformat. 	Yes
8	<ul style="list-style-type: none"> Updated Production flow chart, assay from 98.0 – 101.0% to 98.0 – 101.0% Pyridoxine HCl, 81.45% - 83.09% Pyridoxine. Added Staphylococcus Aureus Negative/25g specification and nutritional information. Added FEMAS status. General reformat. 	Yes

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9	Amended Pyridoxine value in product name and removed specification as this is for information only. Removed mention of FEMAS, if needed, please refer to our certified product list on our website	Yes
10	Vitamin B6 content amended from '80.6250mg - 83.0930mg (per 100g)' to '80,6250mg-83,0930mg per 100g'. Sieve analysis changed from '90% pass 40-90 mesh' to 'approx 90% pass 80 mesh'.	Yes
11	Amended Vitamin B6 content from '80,6250mg – 83,0930mg (per 100g)' to 'dry basis: min 80.625% & as is basis: min 80.22%', Sieve Analysis from 'approx. 90% pass 80 mesh' to 'approx. 80% pass 60 mesh' and Assay from '98.0 - 101.0%' to '98-102%'. Removed Total Heavy Metals specification.	Yes
12	Removed Nutritional Information	Yes
13	Added additional technical information	Yes
14	Updated the Assay from 98.0 - 102.0% to 99-101%	Yes
15	Removed sieve & bulk density from specifications. Replaced specific heavy metal limits with total heavy metals specification as per EP.	Yes

Document Approval

Originator	Approver
 Anne Stevens Quality Assurance Technician <small>04/06/2024 16:27</small>	 Ash Bayne Senior Quality Specialist <small>04/06/2024 16:51</small>

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