

Product Technical Dossier

Product	Soybean Extract $\geq 45\%$ Beta Sitosterols
CCL Product Code	P02053

Specification Details

Identification (HPTLC)	Specification
Beta-Sitosterols (HPLC)	Positive
Appearance	Min 45%
Colour	Fine Powder
Aroma	White/off White
Flavour	Characteristic
Sieve Analysis % passed	100% Pass 80 Mesh
Loss on Drying (5g/105°/5hrs)	Max 5%
Ash (2g/525°C/5hrs)	Max 5%
Bulk Density	40~60g/100mL
Sulphate	Max 0.5%
Phytosterol	Min 90%

Microbiological Limits

Total Viable Count	Max 1,000cfu/g
Yeasts & Moulds	Max 50cfu/g
E. Coli	Negative
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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FDA number: 16806073982

+44 (0) 1353 667258 | www.c-c-l.com | info@c-c-l.com

Registered in England No: 3590758 VAT No: GB 711 6598 32

Registered office: 203 Lancaster Way Business Park, Ely, Cambridgeshire, CB6 3NX, UK.

Additional Technical Information

Raw Material Full Botanical Name	Glycine max (Linn.) Merr.
Part Used	Beans
The material is Food Grade	Yes
Ratio of Material	50:1
Solvent used	Water/ Alcohol 30/70
Country of Origin	China
Country of Manufacture	China
Solubility in Alcohol	Partly soluble
Solubility in Water	Partly soluble
Shelf Life from Date of Manufacture	Min 2 Years
Pharmacopeia Standard Used	CP
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
Soybean Extract	-	100%	Glycine max (Linn.) Merr.

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 (wheat, wheatgrass, faro, freekeh, spelt, kamut, rye, oats, barley, barley grass)	No	No	N/A
Soya and Soya Derivatives	Yes	Yes	Product originates from Soy Bean
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	Ethanol used in extraction
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

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

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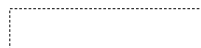
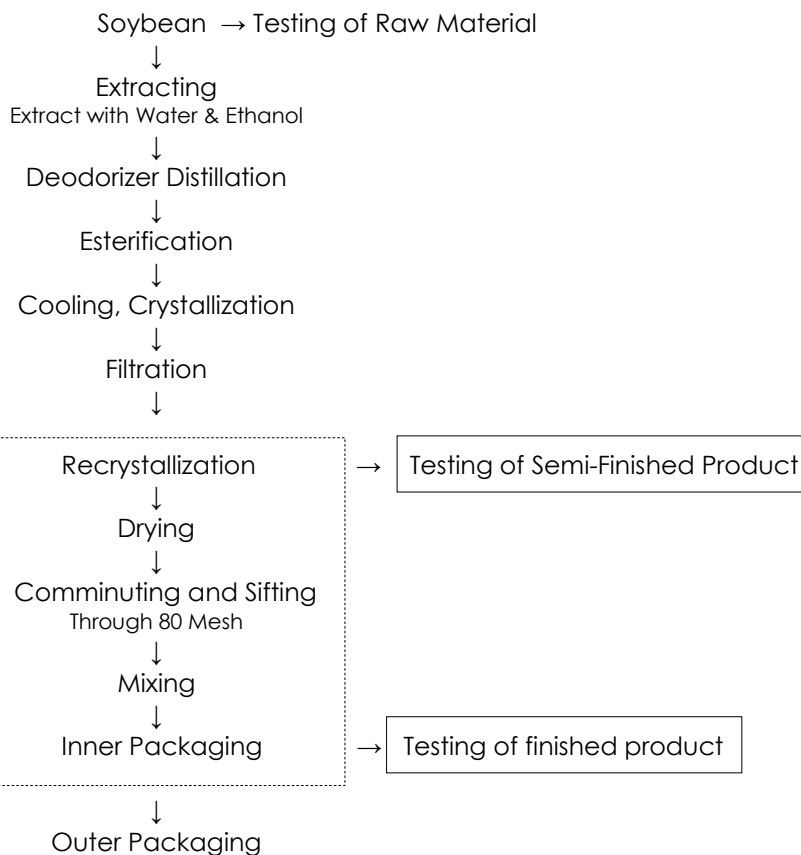
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Product Flow Chart



Clean area



Critical control point

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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, Lead Specification updated to Max 3ppm to conform with COMMISSION REGULATION (EC) No 1881/2006 - 3.1.18 Food supplements (39) 3,0	Yes
3	The following has been amended: <ul style="list-style-type: none"> Header up dated Particle Size has changed from 80 mesh to 30 mesh Percentage Pass Through has changed from 100% to 80% Format Updated	Yes
4	The following parameters were removed; assay, CAS-number, molecular formula, average molecular weight, sulphate, phosphate organics, pesticide residues, Heavy metals, P. aeruginosa, S. aureus and chlorate. The following parameters were updated: Identification, solubility in alcohol, particle size, percentage passed through, shelf life, allergen table, additive table, flow chart and MSDS. Lastly the format was updated, these changes are due to a change in supplier.	Yes
5	Amended Sieve Analysis % passed from 80% pass 80 mesh to 100% Pass 80 Mesh, Arsenic max 2ppm to Max 1ppm and production flow chart. Added the following: <ul style="list-style-type: none"> Bulk Density 40~60g/100mL Sulphate Max 0.5% Phytosterol Max 90% Beta-Sitosterols Min 45% Stigmasterol Max 20% Campesterol Max 20% Brassicasterol Max 20% General reformat.	Yes

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6	Changed: <ul style="list-style-type: none"> Name from 'Beta Sitosterol 45%' to 'Soybean Extract ≥45% Beta Sitosterols' Identification method from HPLC to HPTLC 	Yes
7	Amended: Phytosterol, Stigmasterol and Campesterol from max to min Removed grain from solvents Changed Brassicasterol from max 20 to min 2%	Yes
8	Removed Stigmasterol, Campesterol & Brassicasterol specifications	Yes

Document Approval

Originator		Approver	
 <small>X</small> 13/07/2020 15:26	Ash Bean	 <small>X</small> 13/07/2020 16:00	Cecilia Anzani
	Quality Specialist		Senior Quality Specialist

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