Product Technical Dossier

Product	Levagen®
CCL Product Code	P11786

Specification Details

	Specification
Identification (FTIR, HPLC)	Positive
Assay (On Anhydrous Basis)	Min 99%
Appearance	Crystalline Powder
Colour	White
Aroma	Characteristic
Flavour	Characteristic

Particle size	d(0.9): Less than 60 µm
Loss on Drying	Max 0.5%
Ash	Max 0.1% w/w
Bulk Density	Min 0.2 g/cc
Tapped Density	Min 0.3 g/cc
pH	6.0-7.0
Impurities/Residual Solvents	Isopropanol Max 1,000 ppm

Related compounds (By HPLC)

Palmitic acid	Max 0.5% w/w (LOQ:0.2%)
N-(2-idrossietil)-octadecanamide (SEA)	Max 0.2% w/w (LOQ:0.02%)
N-(2-idrossietil)-tetradecanamide(MEA)	Max 0.2% w/w (LOQ:0.04%)
Single maximum impurity	Max 0.1% w/w
Total impurities	Max 1% w/w

Microbiological Limits

Total Viable Count	Max 1,000cfu/g
Yeasts & Moulds	Max 100cfu/g
E. Coli	Negative/10g
Salmonella	Negative/10g

Heavy Metal Limits

Total Heavy metals	Max 10 ppm
Lead (Pb)	Max 0.5 ppm
Cadmium (Cd)	Max 0.5 ppm
Mercury (Hg)	Max 0.1 ppm
Arsenic (As)	Max 0.5 ppm

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Additional Technical Information

Raw Material Full Botanical / Chemical Name	Palmitic Acid Mono Ethanolamide
Part Used	Palm kernel oil
The material is Food Grade	Yes
Solvent used	Isopropanol
Country of Origin	Malaysia
Country of Manufacture	India
Melting Point	98°C to 102°C
Solubility in Alcohol	Soluble
Solubility in Water	Practically insoluble
Average Molecular weight	299.499 g/mol
Molecular Formula	$C_{18}H_{37}NO_2$
CAS Number	544-31-0
EC/EINECS Number	208-867-9
Shelf Life from Date of Manufacture	Min 2 Years
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.

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 *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
grape fruit	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

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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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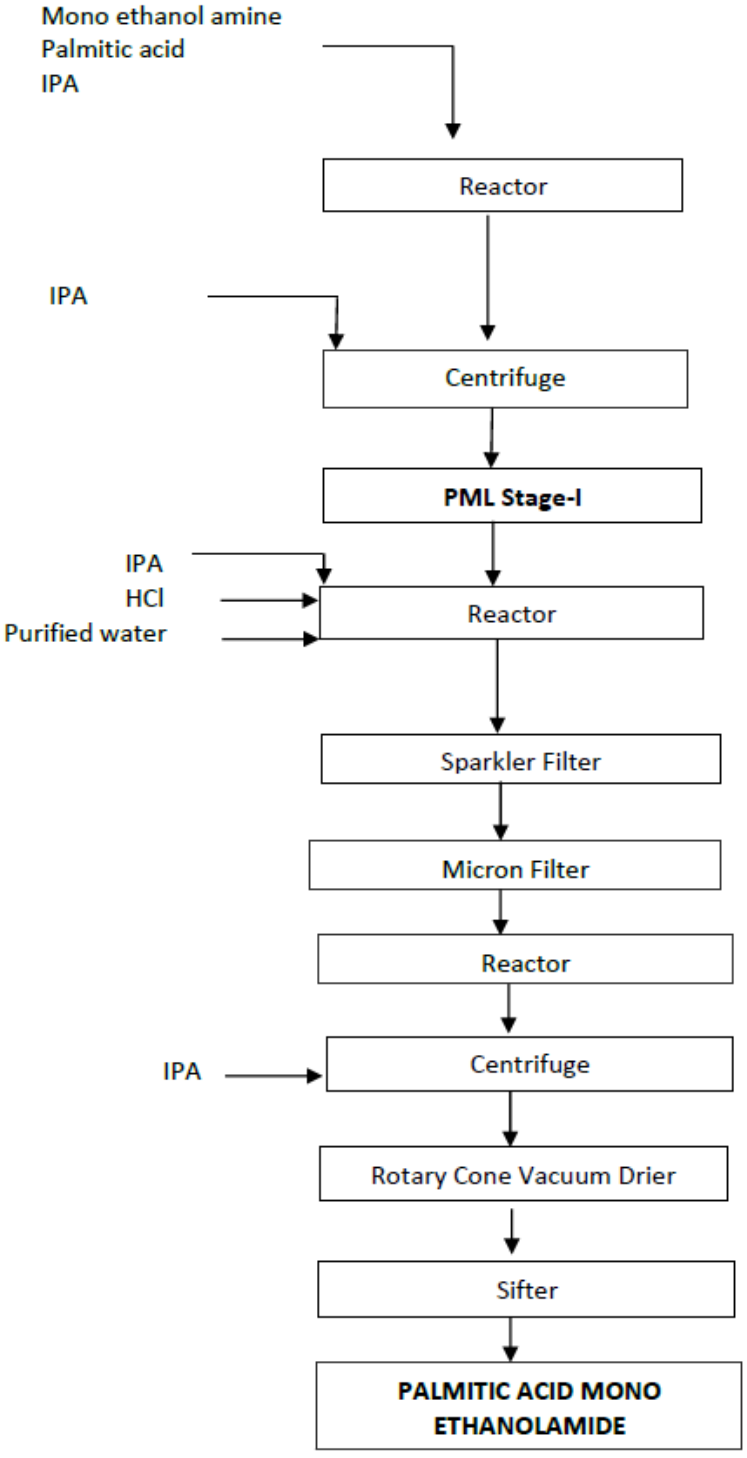
Product Flow Chart



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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	Added ® to name to signify this is a branded product and amended the raw product from palmitic acid to Palmitic Acid Mono Ethanolamide.	Yes
3	Amended the Mercury specification from max 3ppm to 1ppm to match supplier's specification	Yes
4	Changes: • Mercury from max 1ppm to max 0.1ppm • Particle size from less than 50 µm to less than 60 µm • Melting point from 98.5°C to 98°C to 102°C • Total impurities from max 2% to max1%	Yes

Document Approval

Originator		Approver	
Chloe Binns x 22/02/2021 09:26	Chloe Binns Quality Apprentice	Cecilia Anzani x 22/02/2021 10:41	Cecilia Anzani Senior Quality Specialist

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