



FINISHED PRODUCT SPECIFICATION

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|---|--|---|---|
| Product MONOLAURIN | Issue No. 4.0 | Supersedes Issue No.3 dtd 09/17/2012 | Page Number Page 1 of 2 |
| Prepared by CHAYADEVI Junior Executive | Approved by Dr.S Natarajan Executive Vice President | Effective date December 22, 2015 | Review date December 21, 2018 |

| | |
|-----------------------------|---|
| Product code | 1350 |
| Category | Intended for Cosmeceutical application |
| Botanical/Scientific name | Cocos nucifera |
| CAS No | Glyceryl laurate: 142-18-7 |
| Plant part | Coconut endosperm (coconut oil) |
| Preparation type | High vacuum distillation and esterification |
| Solvent used in manufacture | Methanol, Ethyl acetate and Hexane |
| Final extract ratio | 25:1 to 30: 1 |
| Standardization | Monolaurin |
| Excipient used | None |

| Parameters | Limit | Reference |
|-------------------------------|---|--------------------------|
| PHYSICAL | | |
| Description | Off white powder* | Visual |
| Identification | To comply by GC | SLL/STP-M-015 |
| Solubility | Soluble in alcohol, chloroform and insoluble in water | USP |
| Loss on drying | Not more than 5.0% w/w (dried at 40°C, under vacuum) | USP <731> |
| Ash Content | Not more than 2.0% w/w | USP <561> |
| Tapped bulk density | Between 0.30g/ml and 0.60g/ml | USP <616> |
| Loose bulk density | Between 0.20g/ml and 0.45g/ml | USP <616> |
| CHEMICAL | | |
| Assay | | |
| -Content of Monolaurin by GC | Not less than 90.0% w/w on dry basis | SLL/STP-M-015 |
| OTHERS | | |
| Total heavy metals | Not more than 20ppm (µg/g) | USP <231> Method II |
| Lead | Not more than 3ppm (µg/g) | ICP-OES, SLL/STP-H-006** |
| Arsenic | Not more than 1ppm (µg/g) | ICP-OES, SLL/STP-H-006** |
| Cadmium | Not more than 1ppm (µg/g) | ICP-OES, SLL/STP-H-006** |
| Mercury | Not more than 0.1ppm (µg/g) | ICP-OES, SLL/STP-H-006** |
| Residual solvents | To comply as per USP | USP <467> |
| Residual pesticides | To comply as per USP | USP <561> |
| MICROBIAL | | |
| Total aerobic microbial count | Not more than 5000cfu/g | USP <61> |
| Total yeasts and molds count | Not more than 100cfu/g | USP <61> |
| Escherichia coli | Negative/10g | USP <62> |
| Salmonella | Negative/10g | USP <62> |



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| Parameters | Limit | Reference |
|------------------------|-------------------|----------------------------------|
| Staphylococcus aureus | Negative/10g | USP <62> |
| Pseudomonas aeruginosa | Negative/10g | USP <62> |
| Coliforms | Less than 10cfu/g | BAM 2001, 8th Edition, Chapter 4 |

ADDITIONAL INFORMATION

| | |
|-------------------------------------|--|
| Sanitizing Treatment | Non-irradiated and not treated with ETO |
| Certification status (Kosher/Halal) | Halal certified |
| Genetic Modification Status | GMO free |
| BSE/TSE status | BSE / TSE free |
| Country of origin | India |
| Cultivated or wild crafted | Cultivated |
| Storage condition | Store at room temperature |
| Shelf Life | 2 Year(s) |
| Manufactured by | Sami Labs Limited 19/1,19/2 I Main, II Phase,Peenya Industrial Area,Bangalore - 560058, Karnataka, India |

*Since it is a herbal product, there is likely to be minor color variation because of the geographical and seasonal variations of the raw material.

*Natural products can be hygroscopic and may agglomerate sometimes. It is suggested to sift the product before use.

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****In-House developed and validated methods**

NAP:Not Applicable

NAV:Not Available