

**Australian Government** 

## **Department of Health and Aged Care**

Therapeutic Goods Administration

**Public Summary** 

| Summary for ARTG Entry: | 405873                       | Vital Vegan Omega-3       |
|-------------------------|------------------------------|---------------------------|
| ARTG entry for          | Medicine Listed              |                           |
| Sponsor                 | Martin & Pleasan             | nce Pty Ltd               |
| Postal Address          | PO Box 2007, SO<br>Australia | OUTH MELBOURNE, VIC, 3205 |
| ARTG Start Date         | 7/03/2023                    |                           |
| Product Category        | Medicine                     |                           |
| Status                  | Active                       |                           |
| Approval Area           | Listed Medicines             | S                         |
| Conditions              |                              |                           |

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

## Products

| Product Type   | Single Medicine Product                          | Effective Date                       | 10/03/2023                              |  |
|--|--|--------------------------------------|---|--|
| Permitted Indication   | ons  |                                      |   |  |
| Maintain/support he  | ealthy eye function                              |                                      |   |  |
| Maintain/support ey  | ve health  |                                      |   |  |
| Maintain/support ge  | eneral health and wellbeing                      |                                      |   |  |
| Helps in the mainte  | nance of healthy blood lipids/blood fats         |                                      |   |  |
| Maintain/support ca  | rdiovascular system health                       |                                      |   |  |
| Helps maintain/sup   | port healthy heart function                      |                                      |   |  |
| Maintain/support he  | ealthy cardiovascular system function            |                                      |   |  |
| Maintain/support co  | gnitive function/mental function                 |                                      |   |  |
| Maintain/support ge  | eneral mental wellbeing                          |                                      |   |  |
| Maintain/support br  | ain function                                     |                                      |   |  |
| Maintain/support he  | ealthy pregnancy                                 |                                      |   |  |
| Indication Require   | ements   |                                      |   |  |
| Product presentation   | on must not imply or refer to vision correction, | faults or serious eye disease e.g.   | macular degeneration.                   |  |
| Product presentation   | on must not imply or refer to serious cardiovas  | cular conditions.                    |   |  |
| Label statement: A   | dvise your doctor of any medicine you take du    | rring pregnancy, particularly in you | ur first trimester.                     |  |
| Product presentation   | on must not imply or refer to mental illnesses,  | disorders or conditions.             |   |  |
| Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides. |  |                                      |   |  |
| Standard Indicatio   | ns   |                                      |   |  |
| No Standard Indica   | tions included on Record                         |                                      |   |  |
| Specific Indication  | IS   |                                      |   |  |
| No Specific Indicati   | ons included on Record                           |                                      |   |  |
| Warnings   |  |                                      |   |  |
| No Warnings includ   | led on Record                                    |                                      |   |  |
| Additional Produc  | t information                                    |                                      |   |  |
|  |  |                                      |   |  |
| Page 1 of 2<br>This is not an A  | ARTG Certificate document.                       |                                      | Produced at 02.01.2024 at 04:10:16 AEDT |  |

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## Department of Health and Aged Care

Therapeutic Goods Administration

| Pack Size Poison Schedule     Components     1. Formulation 1     Dosage Form Capsule, soft   Route of Administration Oral   Visual Identification   Oral        DHA/EPA rich Schizochytrum atgal oil   Guivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp.   265 mg   Equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp.   255 mg   equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp.   265 mg   equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp.   255 mg   equivalent: docosahexa-ica cid (DHA)-rich oil derived from microalgae Schizochytrium sp.   255 mg   inited (low-alpha type)-to-to-to-to-to-to-to-to-to-to-to-to-to-   | Pack Size/Poison informatio  | n                     |            |
|--|--|-----------------------|------------|
| 1. Formulation 1         Dosage Form       Capsule, soft         Route of Administration       Oral         Visual Identification       Oral         Active Ingredients       818.295 mg         DHA/EPA rich Schizochytrium algal oil       818.295 mg         Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.       255 mg         Equivalent: eicosapentaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.       255 mg         Chter Ingredients (Excipients)       127.5 mg         ascorbyl palmitate       giycerol         mixed (low-alpha type) tocopherols concentrate       Schizochytrium sp.         modified food starch       Univeroli         purified water       Rosemary Oil         sorbiol       Sunflower Oil  | Pack Size  | Poison Schedule       |            |
| Dosage Form       Capsule, soft         Route of Administration       Oral         Visual Identification       Active Ingredients         DHA/EPA rich Schizochytrum algal oil       818.295 mg         Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.       255 mg         Equivalent: eicosapentaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.       255 mg         Equivalent: eicosapentaenoic acid       127.5 mg         Other Ingredients (Excipients)       state | Components   |                       |            |
| Route of Administration       Oral         Visual Identification          Active Ingredients       818.295 mg         DHA/EPA rich Schizochytrium algal oil       818.295 mg         Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.       255 mg         Equivalent: eicosapentaenoic acid       127.5 mg         Other Ingredients (Excipients)       327.5 mg         ascorbyl palmitate       glycerol         mixed (low-alpha type) tocopherols concentrate   | 1. Formulation 1   |                       |            |
| Visual Identification Active Ingredients DHA/EPA rich Schizochytrium algal oil Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp. Equivalent: eicosapentaenoic acid Equivalent: eicosapentaenoic acid Cother Ingredients (Excipients) Cother Ingredients (Excipients) Scorbyl palmitate glycerol mixed (low-alpha type) tocopherols concentrate modified food starch purified water Rosemary Oil sorbitol Sunflower Oil  | Dosage Form  | Capsule, soft         |            |
| Active Ingredients       818.295 mg         DHA/EPA rich Schizochytrium algal oil       818.295 mg         Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.       255 mg         Equivalent: eicosapentaenoic acid       127.5 mg         Other Ingredients (Excipients)       327.5 mg         ascorbyl palmitate       glycerol         mixed (low-alpha type) tocopherols concentrate       "Hondified food starch"         purified water       Rosemary Oil         sorbitol       Sunflower Oil  | Route of Administration  | Oral                  |            |
| DHA/EPA rich Schizochytrium algal oil818.295 mgEquivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.255 mgEquivalent: eicosapentaenoic acid127.5 mgOther Ingredients (Excipients)ascorbyl palmitateglycerolscorbyl polmerols concentratemodified food starchscorbyl food starchpurified waterRosemary OilRosemary OilsorbitolSunflower OilSunflower Oil   | Visual Identification  |                       |            |
| Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.255 mgEquivalent: eicosapentaenoic acid127.5 mgOther Ingredients (Excipients)127.5 mgascorbyl palmitate<br>glycerol<br>mixed (low-alpha type) tocopherols concentrate<br>modified food starch<br>purified water  | Active Ingredients   |                       |            |
| Equivalent: eicosapentaenoic acid 127.5 mg   Other Ingredients (Excipients) ascorbyl palmitate   ascorbyl palmitate glycerol   mixed (low-alpha type) tocopherols concentrate  | DHA/EPA rich Schizochytr   | rium algal oil        | 818.295 mg |
| Other Ingredients (Excipients)<br>ascorbyl palmitate<br>glycerol<br>mixed (low-alpha type) tocopherols concentrate<br>modified food starch<br>purified water<br>Rosemary Oil<br>sorbitol<br>Sunflower Oil  | Equivalent: docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytriur |                       | 255 mg     |
| ascorbyl palmitate<br>glycerol<br>mixed (low-alpha type) tocopherols concentrate<br>modified food starch<br>purified water<br>Rosemary Oil<br>sorbitol<br>Sunflower Oil  | Equivalent: eicosapentaer  | noic acid             | 127.5 mg   |
| glycerol<br>mixed (low-alpha type) tocopherols concentrate<br>modified food starch<br>purified water<br>Rosemary Oil<br>sorbitol<br>Sunflower Oil  | Other Ingredients (Excipie   | ents)                 |            |
| mixed (low-alpha type) tocopherols concentrate<br>modified food starch<br>purified water<br>Rosemary Oil<br>sorbitol<br>Sunflower Oil  | ascorbyl palmitate   |                       |            |
| modified food starch<br>purified water<br>Rosemary Oil<br>sorbitol<br>Sunflower Oil  | glycerol   |                       |            |
| purified water<br>Rosemary Oil<br>sorbitol<br>Sunflower Oil  | mixed (low-alpha type) too   | copherols concentrate |            |
| Rosemary Oil<br>sorbitol<br>Sunflower Oil  |  |                       |            |
| sorbitol<br>Sunflower Oil  |  |                       |            |
| Sunflower Oil  | -  |                       |            |
|  |  |                       |            |
| vaniiin  |  |                       |            |
|  | vaniiiin   |                       |            |

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