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Research Paper

To - Whom it May Concern

Subject - TGA registered/approved Squalene endorsed as 'Made in Australia'

Investigation regarding the labelling and marketing of 'Australian Made' Squalene reveals further evidence that the Complimentary Medicines (CM) situation is a real mess.

Available evidence suggest this bizarre state of affairs is facilitated by the ignorance, inaction and/or co-operation of those within the Australian Competition and Consumer Commission (ACCC), the Australian Made Campaign Ltd (AMCL) and Australia's Therapeutic Goods Administration (TGA). As the evidence becomes becomes increasingly public, it is likely there will greatly diminished trust in the eyes of the Australian and international consumers. This should be of deep concern to all.

Investigations undertaken into its part of Australia's Therapeutic Goods Administration (TGA) in the deception of the consuming public, in Australia and overseas, regarding the retail sale of Squalene by TGA registered entities in Australia and overseas are quite revealing. It can be seen that the TGA has in place an online registration, self-certification and approval process (for a fee) for CM products such as Squalene.

As an example, attached are a few *public summaries* freely available from the internet of products having the banner product name of 'Squalene' as registered, regulated and approved for retail sale by the TGA.

In total, the TGA's Australian Register of Therapeutic Goods shows 148 products registered for sale under the banner name 'squalene' or having the word 'squalene' feature prominently in the name of the product. Registration fees are received by the TGA. Please see this list here.

Although marketed/sold to Australian and international consumers as 'Squalene', there are numerous examples of registered product formulations showing only 10% squalene and as little as 8% squalene. And because no one at TGA, ACCC or AMCL is checking or regulating this disturbing situation, it is unknown by these parties whether there is truly any squalene whatsoever in the mix...? Regrettably, the big loser in all this mess is the naïve and trusting consumer. It is deeply troubling that the TGA allows a registered product that may contain as little as 8% squalene (if at all) to be called 'Squalene' or Squalene Plus'?

Most of the scrutinised TGA *public summaries* registered for Squalene products were for 1000mg capsules, which is standard capsule size in Australia. However there were a number

of odd size capsules, indicating that the relevant squalene capsules may have come from overseas, either retail-ready in labelled bottles or in bulk then bottled and labelled here. It was observed in all cases that this imported Squalene (likely contained in imported gelatine) is contained in packaging and supported by advertising as 'Made in Australia'. The Squalene in these capsules may be from India, China, Portugal or elsewhere. Given that Ocean Oils sells no Squalene in Australia, it is absolutely certain that none of this counterfeit 'Australian' and 'Australian Made' Squalene is actually of Australian origin.

In reality, for a substance to be known as Squalene it must have a defined product specification with numerous identifying unique characteristics and defined minimum purity etc; otherwise it is not Squalene but just another adulterated mixture of ingredients. The same scientific principle applies to countless other substances that we all use such as steel, tin, copper, polyethylene, alcohol, methanol, plywood etc. All have a minimum defined specification in order to be known as that particular substance with the characteristics and qualities that define that substance.

The user buys the substance and it follows he/she trusts that the substance is what it claims to be and will do what it is believed to do. In their regulation of Squalene, the TGA has entirely neglected this simple principle. Despite repeated inquiries, the TGA is able to furnish no benchmark specification for Squalene. So how can the TGA certify and regulate a product for which it has no quality, purity or other specific parameters? Product purity, quality and origin is also conveniently overlooked and/or masked by the other interested parties in the CM food chain in order to facilitate the trade and generate regulatory and endorsement fees.

These imported fake 'Australian' Squalene products are presented in store and online to the Australian and international consumer as 'Australian' in every facet of their being. This strategy is cleverly undertaken by the widespread promotion of the 'Made in Australia' logo and endorsement, the TGA registration plus the liberal use of iconic Australian images (e.g. Australian flag, Opera House, Sydney Harbour Bridge, Kangaroos, Emus etc. etc.) Product brands such as Australia Antarctic Sea squalene , Native Australian squalene, South Pole Ocean King squalene, Oz squalene, Tas squalene, Tasman squalene, Tasmania squalene, Tasmanian squalene, Australian By Nature Squalene etc. etc.

Study of the available widespread evidence clearly shows this is clearly intentional misleading and deceptive conduct by numerous unscrupulous players in the CM sector.

Australian and international consumers that are being duped, intentionally misled and possibly put at risk. In all cases, they are definitely not getting the product they believe they are purchasing.

Author –
Richard Saul
Ocean Oils Pty Ltd

Public Summary

Summary for ARTG Entry: 121018 5 in 1 SQUALENE

ARTG entry for	Medicine Listed
Sponsor	Star Combo Australia Pty Ltd
Postal Address	PO Box 70, RYDALMERE, NSW, 2116 Australia
ARTG Start Date	2/08/2005
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27). This condition does not apply to powdered or dried leaf.

Products

1. 5 in 1 SQUALENE

Product Type Single Medicine Product **Effective date** 2/08/2005

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

May assist in maintaining peripheral circulation and promoting general health.

Aids digestion and may be used to assist in the distribution and assimilation of fats in the digestive system.

Specific Indications

Helps maintain healthy skin.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. COMPONENT ONE

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

d-alpha-Tocopherol	**4.03 mg**

Public Summary

Fish oil - natural	**650 mg**
Ginkgo biloba	**50 mg**
Equivalent: Ginkgo biloba (Dry)	2.5 g
Lecithin	**200 mg**
Squalene	**100 mg**

Public Summary

Summary for ARTG Entry: 121029 V Mores Tas SQUALENE 1000mg

ARTG entry for	Medicine Listed
Sponsor	Health Sharing Group Pty Ltd
Postal Address	7-9 Amax Avenue, GIRRAWEEN, NSW, 2145 Australia
ARTG Start Date	2/08/2005
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

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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

1. V Mores Tas SQUALENE 1000mg

Product Type Single Medicine Product **Effective date** 11/08/2011

Warnings

No Warnings included on Record

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Squalene is an antioxidant and promote general health. Assists in the maintenance of healthy skin and hair

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Squalene	**1 g**

Public Summary

Summary for ARTG Entry: 146593 Jo Jo Squalene 9-in-1

ARTG entry for	Medicine Listed
Sponsor	Jo Jo International Pty Ltd
Postal Address	2/3 Pat Devlins Close, CHIPPING NORTON, NSW, 2170 Australia
ARTG Start Date	24/10/2007
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

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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

1. Jo Jo Squalene 9-in-1

Product Type Single Medicine Product **Effective date** 17/11/2008

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

Specific Indications

Jo Jo Squalene 9-in-1 is a rich source of omega-3 fatty acids that help maintain health especially in individuals with low status or low dietary intake of this particular fatty acids.

Pure natural goodness dietary supplement.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Cod-liver oil	**100 mg**
d-alpha-Tocopherol	**4 mg**
Evening Primrose Oil	**50 mg**
Fish oil - natural	**200 mg**
Lecithin	**5 mg**

Linseed Oil	**100 mg**
Olive Oil	**100 mg**
Shark-liver oil	**100 mg**
Squalene	**100 mg**

Public Summary

Summary for ARTG Entry: 128967 BLUE WATER WEALTHY HEALTH SQUALENE 1000mg

ARTG entry for	Medicine Listed
Sponsor	Universal Pharmaceuticals Pty Ltd
Postal Address	PO Box 223, AUBURN, NSW, 1835 Australia
ARTG Start Date	23/06/2006
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

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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

1. BLUE WATER WEALTHY HEALTH SQUALENE 1000mg

Product Type Single Medicine Product **Effective date** 7/08/2015

Warnings

No Warnings included on Record

Standard Indications

Aids, assists or helps in the maintenance of general well-being

Specific Indications

SQUALENE IS EXTRACTED FROM DEEP SEA SHARKS OBTAINED FROM THE ANTARCTIC SEA AROUND AUSTRALIA.
SQUALENE HAS BEEN FOUND TO PLAY AN IMPORTANT ROLE IN THE MAINTENANCE OF HEALTHY SKIN.
SQUALENE ALSO FUNCTIONS AS AN ANTIOXIDANT.
DDT - NEGATIVE, PCB - NEGATIVE

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Squalene	**1000 mg**

Public Summary

Public Summary

Public Summary

Summary for ARTG Entry: 162011 Native Australian Squalene 1000mg

ARTG entry for	Medicine Listed
Sponsor	Australian By Nature Pty Ltd
Postal Address	PO Box 476, COLLAROY, NSW, 2097 Australia
ARTG Start Date	26/05/2009
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

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The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

1. Native Australian Squalene 1000mg

Product Type Single Medicine Product **Effective date** 22/06/2010

Warnings

No Warnings included on Record

Standard Indications

Specific Indications

Dietary supplement. Squalene is the oil extracted from the livers of Deep Sea Sharks. It helps facilitate the delivery of oxygen throughout the body. Supports the immune system. May help maintain a healthy immune system. Helps maintain wellbeing.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Squalene	**1 g**

Public Summary

Summary for ARTG Entry: 158246 Squalene Complex 1000

ARTG entry for	Medicine Listed
Sponsor	Atherton International Pty Ltd
Postal Address	59 Kirby Street, RYDALMERE, NSW, 2116 Australia
ARTG Start Date	24/12/2008
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

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The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

1. Squalene Complex 1000

Product Type Single Medicine Product **Effective date** 24/12/2008

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

May assist peripheral circulation.

May assist blood circulation.

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Rich in natural essential fatty acids Omega-3, Omega-6, Omega-9, and Gamma-Linolenic Acid (GLA).
Contains natural vitamin D and vitamin A.
Assists in the maintenance of healthy skin and hair.
Functions as a strong anti-oxidant.
Helps maintain healthy heart and cardiovascular system.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form Capsule, soft

Route of Administration

Public Summary

Oral

Visual Identification

Active Ingredients	
Cod-liver oil	**20 mg**
Evening Primrose Oil	**25 mg**
Fish oil - natural	**100 mg**
Linseed Oil	**733.85 mg**
Retinol	**240 microgram**
Shark-liver oil	**20 mg**
Squalene	**100 mg**

Public Summary

Summary for ARTG Entry: 72121 SOUTHPOLE OCEANKING DEEP OCEAN SHARK SQUALENE 1000MG

ARTG entry for	Medicine Listed
Sponsor	Australian Antarctic Ocean Bio-Technology Pty Ltd
Postal Address	81 Norcal Road, Nunawading, VIC, 3131 Australia
ARTG Start Date	30/11/1999
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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'.

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The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

1. SOUTHPOLE OCEANKING DEEP OCEAN SHARK SQUALENE 1000MG

Product Type Single Medicine Product **Effective date** 5/05/2009

Warnings

No Warnings included on Record

Standard Indications

Specific Indications

Squalene is derived from Deep Ocean Shark Liver Oil. It has been found to play a key role in maintaining health. Assists in the maintenance of skin and hair.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Squalene	**1 g**

Public Summary

Summary for ARTG Entry: 226638 Squalene Shark Liver Oil

ARTG entry for	Medicine Listed
Sponsor	Australian Antarctic Ocean Bio-Technology Pty Ltd
Postal Address	81 Norcal Road, Nunawading, VIC, 3131 Australia
ARTG Start Date	7/08/2014
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

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The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

1. Squalene Shark Liver Oil

Product Type Single Medicine Product **Effective date** 7/08/2014

Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

No Specific Indications included on Record

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Shark-liver oil	**950 mg**
Squalene	**50 mg**

Public Summary

Public Summary

Public Summary

Summary for ARTG Entry: 201145 Natural Source Bio-Squalene 6 in 1 Capsules

ARTG entry for	Medicine Listed
Sponsor	Natralab Australia Pty Ltd
Postal Address	5 Minna Close, BELROSE, NSW, 2085 Australia
ARTG Start Date	18/09/2012
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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'.

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Products

1. Natural Source Bio-Squalene 6 in 1 Capsules

Product Type Single Medicine Product **Effective date** 18/09/2012

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

Aids, assists or helps in the maintenance of general well-being

Specific Indications

Provides important, healthy fats and oils. Provides healthy fats and oils that support the health and function of the entire body.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Cod-liver oil	**100 mg**
d-alpha-Tocopherol	**5 mg**
Evening Primrose Oil	**25 mg**
Fish oil - natural	**130 mg**
Lecithin	**50 mg**

Squalene	**500 mg**

Public Summary

Summary for ARTG Entry: 205747 Rebirth Life Platinum Squalene Complex

ARTG entry for	Medicine Listed
Sponsor	Lanopearl Pty Ltd
Postal Address	19-23 Sydenham Road, MARRICKVILLE, NSW, 2204 Australia
ARTG Start Date	7/02/2013
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

1. Rebirth Life Platinum Squalene Complex

Product Type Single Medicine Product **Effective date** 7/02/2013

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Squalene is extracted from deep sea sharks obtained from the most pollution free Antartic Sea around Australia. It functions as a strong antioxidant. It aids , assists or helps in the maintainence or improvement of general well being. Squalene has been found to play a key role in maintaining health. It may assist in the maintenance of healthy skin & hair.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Cod-liver oil	**100 mg**
d-alpha-Tocopherol	**4 IU**
Evening Primrose Oil	**50 mg**
Fish oil - natural	**200 mg**

Lecithin	**5 mg**
Linseed Oil	**100 mg**
Olive Oil	**100 mg**
Shark-liver oil	**100 mg**
Squalene	**100 mg**

Public Summary

Summary for ARTG Entry: 77832 OZ Squalene Plus Vitamin E

ARTG entry for	Medicine Listed
Sponsor	Jo Jo International Pty Ltd
Postal Address	2/3 Pat Devlins Close, CHIPPING NORTON, NSW, 2170 Australia
ARTG Start Date	2/03/2001
Product category	Medicine
Status	Active
Approval area	Listed Medicines

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

1. OZ Squalene Plus Vitamin E

Product Type Single Medicine Product **Effective date** 20/04/2009

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

For the symptomatic relief of dry skin.

Specific Indications

Squalene is a natural poly-unsaturated marine lipid purified from deep -sea shark liver oil. Squalene is a free radical scavenger, free radicals may be generated b y lifestyle factors such as excess dietary fats, cigarette smoke, alco hol consumption, pollutants and stress. Helps maintain normal healthy cholesterol levels. May be used for the relief of minor skin complaints. May also aids in repair of skin tissue. Helps the skin get the nutrients it needs, and gives it a more beautiful complexion. Squalene is a natural poly-unsaturated marine lipid.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

d-alpha-Tocopherol	**3.5 mg**
Squalene	**1 g**

Public Summary

Public Summary