



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 November 2014  
EMA/HMPC/166767/2014  
Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on European Union herbal monograph (EMA/HMPC/320930/2012) and European Union herbal list entry (EMA/HMPC/166767/2014) on *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum

Table 1: Organisations and/or individuals that commented on the draft European Union herbal monograph on *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum as released for public consultation on 28 August 2013 until 15 December 2013.

	Organisations and/or individuals
1	Association of the European Self-Medication Industry (AESGP)
2	Australian Tea Tree Industry (ATTIA Ltd)



Table 2: Comments

**General comments to draft document**

Interested party	Comment and Rationale	Outcome
AESGP	<p>AESGP in principle welcomes the development of the above-mentioned Community monograph which, by providing harmonised assessment criteria for tea tree oil-containing products, should facilitate mutual recognition in Europe.</p> <p>AESGP received the enclosed comments principally from an Australian based tea tree oil producer and the Australian Tea Tree Industry Association (ATTIA). ATTIA is the Australian national industry representative body for Australian Tea Tree Oil producers and manufacturers. It is recognised by the Australian Federal Government as the industry representative body with which it co- funds research into the safety and efficacy of tea tree oil.</p> <p>Australia is the main producer and exporter of tea tree oil in the world. Nearly 30% of the Australian crop of tea tree oil is exported annually to the European Union. From 1 January until 30 September 2013, a total of 102,532kg of Oil of <i>Melaleuca alternifolia</i> (pure Australian Tea Tree Oil) has been exported from Australia to Europe, according to Harmonised Code.</p>	
ATTIA Ltd.	<p>ATTIA Ltd. is the Australian national industry representative body for Australian Tea Tree Oil producers and manufacturers. ATTIA Ltd is recognised by the Australian Federal Government as the industry representative body and co-funds research into the safety and efficacy of tea tree oil with ATTIA.</p> <p>ATTIA Ltd claims standing as an interested party on the basis that</p> <ul style="list-style-type: none"> <li>• It filed a submission to the EMEA in 2009 in response to a call for submissions providing evidence of traditional and well established uses of tea tree oil for the purposes of preparing a draft Monograph.</li> <li>• almost 30% of the Australian crop of tea tree oil is exported annually to the European Union. In the year to 30<sup>th</sup> September 2013, a total of 102,532kg of Oil of <i>Melaleuca</i></li> </ul>	

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	<p><i>alternifolia</i> (pure Australian Tea Tree Oil) has been identified by Harmonised Code as being exported from Australia to Europe.</p> <p>Attachments 1 – 3 are provided as supporting documentation for comments below.</p>	
AESGP	<p>“The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.”</p> <p>We would like to present additional evidence of traditional use in Europe and Australia of the pure (undiluted) tea tree oil and additional proof of safety.</p>	
ATTIA Ltd.	<p>The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.</p> <p>ATTIA presents additional evidence of traditional use in the EU since at least 1993 and argues that the interests of consumer safety are best served by acknowledging this well understood usage of 100% oil and implementing it in the Community List Entry where the quality of the essential oil and the posology are controlled and regulated.</p>	
ATTIA Ltd.	<p>ATTIA Ltd provides additional evidence of traditional usage in Australia since the 1930’s and of the safe usage of 100% essential oil in the Australian marketplace where tea tree oil has been regulated by the Therapeutics Goods Administration since its creation in 1989 and prior to that (since the 1930’s) on a State by State basis. (see attached)</p>	

## SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
Monograph-Title:	ATTIA Ltd.	Insert “ <i>Melaleuca alternifolia</i> ”	Inserted

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Monograph- Keywords	AESGP	Misspelling: "Mela <u>l</u> eucae aetheroleum" (not 'Mela <u>e</u> ucae aetheroleum')	Amended
List entry- European Pharmacopoeia monograph reference	AESGP ATTIA Ltd.	Misspellings: - "Te <u>a</u> Tree Oil" (not 'Tee tree oil') - "Mela <u>l</u> eucae aetheroleum" (not 'Mela <u>e</u> ucae aetheroleum')	Amended
4.2 Posology and method of administration	AESGP	<p>Indications 1 to 3 refer to diluted preparations of the oil. The following posologies for the use of undiluted oil in indications 1 to 3 should be added, as follows:</p> <p>Indication 1) Adolescents, adults and elderly: <b><u>Undiluted essential oil: apply 1-2 drops to the site by cotton swab, 1-3 times daily.</u></b></p> <p>Indication 2) Adolescents, adults and elderly: <b><u>Dab the boil with undiluted tea tree oil. Repeat 2-3 times a day</u></b></p> <p>Indication 3) Adolescents, adults and elderly: <b><u>Undiluted essential oil:</u></b> - <b><u>5-10 drops of undiluted tea tree oil in a bowl of warm water; soak feet for 5-10 minutes a day.</u></b> - <b><u>Apply undiluted tee tree oil to the affected areas. Continue to apply 2-3 times daily until the condition has cleared up.</u></b></p> <p>Traditional use in Europe and in Australia as evidenced in reference materials supports</p>	Endorsed with changes in wording, see monograph.

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		<p>the use of 100% oil as indicated in the treatment of small superficial wounds and insect bites, of small boils (furuncles and mild acne) and of mild athlete's foot.</p> <p>A minimal application via a cotton swab provides the patient with good control over dosing and application and has a good tolerance and safety record (as shown below by the extensive use and pharmacovigilance data in Australia).</p> <p>The use of the undiluted oil is also referred to in the assessment report and we hence wonder why this use of the undiluted oil is not reflected in the Community Monograph and in the Community List Entry.</p> <p>Community monographs on other essential oils refer to posology of the undiluted oils. We wonder why this is not the case for tea tree oil. We assume this may be motivated by safety considerations and for this reason would like to present the following arguments:</p> <p>Tea Tree Oil has been a regulated substance in Australia as an herbal (Complementary) Medicine since 1988. It is also regulated by State Poisons regulations since the 1970's. Since 1987 when regulation of tea tree oil under the <u>national</u> SUSMP (Poisons &amp; Drugs control) commenced, the Therapeutic Goods Administration of Australia has recorded 23 adverse events for tea tree oil products. (There are currently 203 tea tree oil products Listed on the ARTG). Adverse events are reported at less than 1 incident per year.</p> <p>Of the 23 incidents reported –</p> <ul style="list-style-type: none"> <li>• 6 are of identified 100% oil products;</li> <li>• 7 are completely unidentified as to manufacturer or concentration but Melaleuca Oil is 'suspected'.</li> <li>• The remaining 10 complaints related to formulated product of less than 100% concentration.</li> </ul> <p>Exact figures are not available, but industry estimates that in the time period 1987 – 2013, approximately 25 million units of bottled 100% tea tree oil have been sold in Australia (communication per manufacturers). Current Australian consumption is approximately 2.6 million units per annum of 100% oil sold as 10ml, 15ml, 25ml and</p>	

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		<p>50ml bottles.</p> <p>Usage in Australia of 100% oil is evidenced by:</p> <ul style="list-style-type: none"> <li>• Spreadsheet of products Listed on the Australian Register of Therapeutic Goods nominating 'Melaleuca Oil' in the active ingredients (203 products). Attached spreadsheet. <ul style="list-style-type: none"> <li>○ Worksheets within the Spreadsheet segregate products by <ul style="list-style-type: none"> <li>▪ 100% oil in a bottle</li> <li>▪ 100% oil by named Active Ingredient</li> <li>▪ 100% oil by Approval Area</li> </ul> </li> </ul> </li> <li>• TGA Public Summaries for 38 current products on the Australian Register of Therapeutic Goods of 100% oil. <ul style="list-style-type: none"> <li>○ Public Summaries list indications, dosage form &amp; route of administration.</li> <li>○ Sampling of labels with dosage and instructions for use</li> </ul> </li> <li>• TGA Ingredient Summaries defining 'Melaleuca Oil' and '<i>Melaleuca alternifolia</i>'</li> <li>• Documentary evidence of historical Australian uses of 100% tea tree oil</li> </ul> <p>The extremely low incidence of adverse events recorded in Australia in a regulated environment is a reflection of the high quality of Pure Australian Tea Tree Oil. The medicinal product status would ensure compliance with the Ph. Eur. monograph and hence high quality and safe use of the product.</p> <p><b>References</b></p> <ol style="list-style-type: none"> <li>1. Lawless J. Tea Tree Oil. 1994</li> <li>2. Drury S. Tea Tree Oil a Medicine Kit in a Bottle. 1991</li> <li>3. TAOASIS letter regarding sales of bottles of 100% tea tree oil since 1993. 3 million units. <ol style="list-style-type: none"> <li>a. TAOASIS label</li> </ol> </li> <li>4. James L. A random controlled trial to compare the effects of two home treatments: <i>Melaleuca alternifolia</i> (tea tree) oil and Salicylic acid on the resolution rates of <i>verrucae pedis</i> (history of use – see page 30</li> </ol>	

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		<p><a href="http://www.teatreewonders.com/support-files/leisajames-warts-teatree.pdf">http://www.teatreewonders.com/support-files/leisajames-warts-teatree.pdf</a>)</p> <p>5. WHO monographs on selected medicinal plants – volume 2 <a href="http://apps.who.int/medicinedocs/en/d/Js4927e/17.html">http://apps.who.int/medicinedocs/en/d/Js4927e/17.html</a></p> <p>6. Carson C.F <i>et al.</i> <i>Melaleuca alternifolia</i> (Tea Tree) Oil: a Review of Antimicrobial and Other Medicinal Properties. Clin. Microbio. Rev. Journal, 2006 19:50-62 <a href="http://cmr.asm.org/content/19/1/50.full#ref-121">http://cmr.asm.org/content/19/1/50.full#ref-121</a></p> <p>7. Australian Government – Rural Industries Research and Development Corporation (RIRDC). The effectiveness and safety of Australian tea tree oil. August 2007 <a href="https://rirdc.infoservices.com.au/items/07-143">https://rirdc.infoservices.com.au/items/07-143</a></p> <p>8. Williamson E. Tea tree oil. Potter’s Herbal Cyclopedia 2003; 427-8</p> <p>9. Newalan Ltd Website</p>	
4.2 Posology and method of administration Duration of use Indications	ATTIA Ltd.	<p><u>Indication 1)</u> <i>Liquid preparations containing 0.5% to 10% of essential oil to be applied on the affected area 1-3 times daily.</i> <i>If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</i> We request a <b>change</b> to the posology to state :</p> <p><u>Indication 1)</u> Adolescents, adults and elderly: <b>Undiluted essential oil: apply 1-2 drops to the site by cotton swab, 1-3 times daily. If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</b> Indications 2 and 3 refer to diluted preparations of the oil. The following posologies for the use of undiluted oil in indications 2 and 3 should be <b>added</b>, as follows:</p>	<p>Endorsed with changes in wording, see monograph.</p> <p>Endorsed with changes in wording, see monograph.</p> <p>Duration of use: Not endorsed. For self medication it is considered that if small superficial wounds or insect bites persist after 1 week a doctor or a qualified healthcare practitioner should be consulted, in order to</p>

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		<p><u>Indication 2)</u> Adolescents, adults and elderly <b>Dab the boil with undiluted tea tree oil. Repeat 2-3 times a day.</b></p> <p><u>Indication 3)</u> Adolescents, adults and elderly <b>Undiluted essential oil:</b></p> <ul style="list-style-type: none"> <li>• <b>5-10 drops of undiluted tea tree oil in a bowl of warm water; soak feet for 5-10 minutes a day.</b></li> <li>• <b>Apply undiluted tea tree oil to the affected areas. Continue to apply 2-3 times daily until the condition has cleared up.</b></li> </ul> <p>Additional evidence of Traditional use of 100% oil in Europe is provided [Attachment 1– Europe]:</p> <p><u>Books</u> Lawless, J. , 1994 UK; German edition 1996; Drury, S., 1991 UK, French edition 1995;</p> <p><u>Magazines</u> German Magazines 1995 &amp; 1997, attached;</p> <p><u>Websites</u> Hobbythek website, 1998 attached) ;</p> <p><u>Web &amp; Newspapers</u> Thursday Plantation current product information (UK) &amp; Australian news article 1986 and 1990 evidencing product sales in UK, Sweden and Holland.</p>	<p>verify whether a serious condition is occurring.</p> <p>Endorsed with changes in wording, see monograph. Endorsed.</p> <p>Endorsed with changes in wording, see monograph.</p>

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		<p><u>Letter</u> TAOASIS letter regarding sales of bottles of 100% tea tree oil since 1993 (3 million units) with no adverse effects recorded.</p> <p>Summary: <b>Lawless:</b> 1994 &amp; 1996 Athlete's foot, boils, cuts &amp; wounds, Paronychia, insect bites, burns <b>Drury,</b> 1991 &amp; 1997: Tinea, Boils, cuts &amp; abrasions, paronychia, insect bites, burns <b>Fit &amp; Healthy Life Magazine,</b> 1995 (German): Skin problems, Wounds, Insect Bites <b>Natural Medicine Magazine,</b> 1997 (German): Skin problems, Wounds, Insect Bites <b>Hobbythek</b> 1998 (German): Pimples &amp; Boils, Wounds, Onychitis/onychomycosis, insect bites</p> <p><b>Thursday Plantation Tea Tree Oil,</b> 1988 onward Pimples, cuts, insect bites, burns Clinical references [Attachment 5]</p> <p>Tea Tree Oil (<i>Melaleuca alternifolia</i>) to treat wounds with <i>Staphylococcus aureus</i>: Product development, clinical protocol and feasibility. Halcon, L et al. Int. J. Clinical Aromatherapy, 2010 Vol 1 Uncontrolled, open-label, pilot study of tea tree (<i>Melaleuca alternifolia</i>) oil solution in the decolonisation of methicillin-resistant <i>Staphylococcus aureus</i> positive wounds and its influence on wound healing. Edmondson, M et al. Int Wound J 2011; 8:375–384 The Effect of Tea Tree Oil (<i>Melaleuca alternifolia</i>) on Wound Healing Using a Dressing Model. Chin &amp; Cordell, J. Alternative &amp; Complementary Medicine, Vol . 18, 2013</p>	

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		<p>In Australia evidence is provided [Attachments 2 &amp; 3] for the use of 100% oil as indicated, for the treatment of small superficial wounds and insect bites, of small boils (furuncles and mild acne) and mild athlete's foot.</p> <p>A minimal application via a cotton swab provides the consumer with more control over dosing and application with the opportunity for adverse reactions limited by usage time ie one-two weeks. Further, this method of application and dosing for these indications is supported by a high level of safety as evidenced by pharmacovigilance data (supplied) from Australia.</p> <p>Exact figures are not available, but industry estimates that in the time period 1987 – 2013, approximately 25 million units of bottled 100% tea tree oil have been sold in Australia (communication per manufacturers). Current Australian consumption is approximately 2.6million units per annum of 100% oil sold as 10ml, 15ml, 25ml &amp; 50ml bottles.</p> <p>Usage in Australia of 100% oil is evidenced by:</p> <ul style="list-style-type: none"> <li>• Spreadsheet of products Listed on the Australian Register of Therapeutic Goods nominating 'Melaleuca Oil' in the active ingredients (203 products). [Attachment 2 - spreadsheet.] <ul style="list-style-type: none"> <li>○ Worksheets within the Spreadsheet segregate products by <ul style="list-style-type: none"> <li>▪ 100% oil in a bottle</li> <li>▪ 100% oil by named Active Ingredient</li> <li>▪ 100% oil by Approval Area</li> </ul> </li> </ul> </li> <li>• TGA Public Summaries for 38 current products on the Australian Register of Therapeutic Goods of 100% oil. [Attachment 2] <ul style="list-style-type: none"> <li>○ Public Summaries list indications, dosage form &amp; route of administration.</li> <li>○ Sampling of labels with dosage and instructions for use are attached.</li> </ul> </li> <li>• TGA Ingredient Summaries defining 'Melaleuca Oil' and '<i>Melaleuca alternifolia</i>' [Attachment 2]</li> </ul>	

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		<ul style="list-style-type: none"> <li>• Documentary evidence of <u>historical</u> Australian uses of 100% tea tree oil [Attachment 3]:               <ul style="list-style-type: none"> <li>○ 1936 'Ti-trol' 100% concentration for painting boils and pimples, paryonchia, ringworm, tinea. Inhalant. Internally for colitis. Root canal treatment.</li> <li>○ 1980 – brochure distributed at farmer markets, advertising tea tree oil and uses</li> <li>○ 1980's – history of establishment of Thursday Plantation Tea Tree Oil</li> <li>○ 1980's various newspaper and magazine articles on tea tree oil and its uses</li> <li>○ 1975-1983 history of Sunspirit Aromatherapy and booklet with uses of tea tree oil</li> </ul> </li> </ul> <p>ATTIA Ltd believes that requiring the consumer to dilute the oil via labelling instructions (per draft Monograph) increases the opportunity for error by the consumer and consequent failure or harm from or by the product. A minimal application via a cotton swab provides the consumer with more control over dosing and application limiting the possibilities of adverse outcomes.</p> <p>The extremely low incidence of adverse events recorded in Australia in a regulated environment is a reflection of the high quality of Pure Australian Tea Tree Oil. Regulating the use of 100% oil as a Traditional Herbal Medicine as above will ensure raw material tea tree oil (from whatever source) that is compliant with the Ph. Eur. Monograph, increasing safety for European consumers and minimise the sale of unregulated and potentially very harmful product to European consumers and protect the standards of Traditional Herbal Medicines generally.</p>	
4.4 Special Warnings and precautions for use	ATTIA Ltd.	<p><i>Indication 1) Not to be used on burn wounds</i></p> <p>The Assessment report relies on a Short Communication (a letter) by Foagali <i>et al.</i> 1997 as the basis for this recommendation. The Short Communication described in vitro data derived from a non-optimal method (well diffusion method). The authors did not look at in vitro or in vivo cytotoxicity. There is no relationship between the antimicrobial data described in the paper and the suggested contra-indication. Indicators from other</p>	Endorsed. The warning has been deleted.

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		<p>studies on wound healing suggest that TTO does not delay healing in vivo and is not cytotoxic. (Halcon et al., 2010; Edmondson et al., 2011; Chin &amp; Cordwell, 2013). [Attachment 5]</p> <p>Mild, analgesic effects of tea tree oil are well documented and accepted in Indication 1 with respect to insect bites. We would suggest that use on minor burns could be <u>excluded</u> from this contra-indication.</p> <p><b>New wording:</b>  <b>May only be used on mild, superficial burns. If fever or signs of exacerbating skin infection are observed, a doctor or a qualified health care practitioner should be consulted.</b></p> <p>Additional evidence of Traditional use of 100% oil in Europe is provided [Attachment 1 – Europe]:</p> <p><u>Books</u> Lawless, J. , 1994 UK; German edition 1996;  Drury, S., 1991 UK, French edition 1995;</p> <p><u>Magazines</u> German Magazines 1995 &amp; 1997, attached;</p> <p><u>Websites</u> Hobbythek website, 1998 attached) ;</p> <p><u>Web &amp; Newspapers</u>  Thursday Plantation current product information (UK) &amp; Australian news article 1986 and 1990 evidencing product sales in UK, Sweden and Holland.</p> <p><u>Letter</u>  TAOASIS letter regarding sales of bottles of 100% tea tree oil since 1993 (3 million units) with no adverse effects recorded.</p> <p>Summary:  <b>Lawless:</b> 1994 &amp; 1996  Athlete’s foot, boils, cuts &amp; wounds, Paronychia, insect bites, burns</p>	

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		<p><b>Drury</b>, 1991 &amp; 1997: Tinea, Boils, cuts &amp; abrasions, paronychia, insect bites, burns</p> <p><b>Fit &amp; Healthy Life</b> Magazine, 1995 (German): Skin problems, Wounds, Insect Bites</p> <p><b>Natural Medicine</b> Magazine, 1997 (German): Skin problems, Wounds, Insect Bites</p> <p><b>Hobbythek</b> 1998 (German): Pimples &amp; Boils, Wounds, Onychitis/onychomycosis, insect bites</p> <p><b>Thursday Plantation Tea Tree Oil</b>, 1988 onward Pimples, cuts, insect bites, burns</p> <p>In Australia evidence is provided (multiple documents attached) for the use of 100% oil as indicated, for the treatment of small superficial wounds and insect bites, of small boils (furuncles and mild acne) and mild athlete's foot.</p> <p>A minimal application via a cotton swab provides the consumer with more control over dosing and application with the opportunity for adverse reactions limited by usage time ie one- two weeks. Further, this method of application and dosing for these indications is supported by a high level of safety as evidenced by pharmacovigilance data (supplied) from Australia.</p> <p>Tea Tree Oil has been a regulated substance in Australia as an herbal (Complementary) Medicine since 1988. It is also regulated by State Poisons regulations since the 1970's. Tea Tree Oil has been a regulated substance in Australia as an herbal (Complementary) Medicine since 1988. It is also regulated by State Poisons regulations since the 1970's.</p> <p>Since 1987 when regulation of tea tree oil under the <u>national</u> SUSMP (Poisons &amp; Drugs control) commenced, the Therapeutic Goods Administration of Australia has recorded 23 adverse events for tea tree oil products . (There are currently 203 tea tree oil products Listed on the ARTG).Adverse events are reported at less than 1 incident per year.</p>	

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		<p>Of the 23 incidents reported –</p> <ul style="list-style-type: none"> <li>• 6 are of identified 100% oil products;</li> <li>• 7 are completely unidentified as to manufacturer or concentration but Melaleuca Oil is 'suspected'.</li> <li>• The remaining 10 complaints related to formulated product of less than 100% concentration.</li> </ul> <p>In 1995 the Australian Medicines Evaluation Committee reviewed tea tree oil , evaluating the 100% oil for topical use. The claim approved at the time was "mild antiseptic for minor cuts, abrasions, bites and stings and minor burns". In 1999 the Complementary Medicines Evaluation Committee (successor to the MEC) resolved at its December meeting , <i>"that in future, registration applications for uncompounded Melaleuca alternifolia oil products, intended for topical use and with low level claims of a first aid nature, can be approved by the TGA without ...prior consideration...by the CMEC."</i></p> <p>Usage in Australia of 100% oil is evidenced by:</p> <ul style="list-style-type: none"> <li>• Spreadsheet of products Listed on the Australian Register of Therapeutic Goods nominating 'Melaleuca Oil' in the active ingredients (203 products). [Attachment 2 - spreadsheet.] <ul style="list-style-type: none"> <li>○ Worksheets within the Spreadsheet segregate products by <ul style="list-style-type: none"> <li>▪ 100% oil in a bottle</li> <li>▪ 100% oil by named Active Ingredient</li> <li>▪ 100% oil by Approval Area</li> </ul> </li> </ul> </li> <li>• TGA Public Summaries for 38 current products on the Australian Register of Therapeutic Goods of 100% oil. [Attached] <ul style="list-style-type: none"> <li>○ Public Summaries list indications, dosage form &amp; route of administration.</li> <li>○ Sampling of labels with dosage and instructions for use are attached.</li> </ul> </li> </ul>	

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