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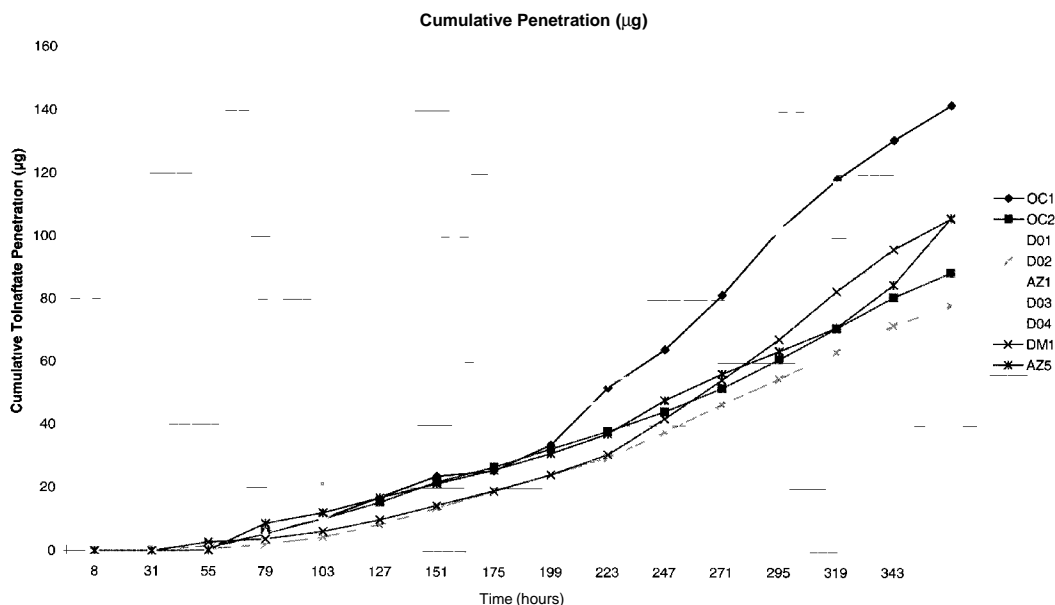
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(54) Title: TOPICAL NAIL FORMULATION



(57) Abstract: The present invention relates to a topical nail formulation comprising at least one active agent (e.g., tolnaftate) and at least one nail penetration enhancer selected from the group consisting of a fatty acid, an azone derivative, and mixtures thereof. The invention also relates to the use of said topical nail formulation for the treatment of nail disorders such as onychomycosis. The invention further provides a method of enhancing the nail flux of an active agent by using a topical nail formulation containing the said penetration enhancer.

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# INTERNATIONAL SEARCH REPORT

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<b>A CLASSIFICATION OF SUBJECT MATTER</b> <b>IPC: A61K 47/22 (2006.01) , A61K 31/27 (2006.01) , A61K 47/12 (2006.01) , A61K 47/20 (2006.01) , A61K9/70 (2006.01) , A61P 17/06 (2006.01) , A61P 31/10 (2006.01)</b> According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) <b>IPC: A61K 47/22 (2006.01), A61K 31/27 (2006.01), A61K 47/12 (2006.01), A61K 47/20 (2006.01), A61K 5/70 (2006.01), A61P 17/06 (2006.01), A61P 31/10 (2006.01)</b> Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used) Delphion (keywords = penetration enhancer, permeation enhancer, nail, fatty acid, azone), STN CAPlus (keywords), Canadian Patent Database (IPC)		
<b>C DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	US 6,585,963 (Quan et al ) 1 July 2003 (Of-07-2003) entire document	1-42, 55-59
X	US 2004/0258739 (Susilo) 23 December 2004 (23-12-2004) paragraphs 0016-00t9, 0037-0040, 0075; claims	36, 38-42
X	US 6,846,837 (Maibach et al.) 25 January 2005 (25-01-2005) entire document	1-4, 6-19, 21-42, 55-59
A	CA 2,278,328 (Samour et al.) 9 August 1999 (09-08-1999) entire document	1-59
A	CA2,035,263 (van den Hoven et al ) 31 July 1991 (31-07-1991) entire document	1-59
A	Journal Eur. Acad. Dermatol. Venereol., 1995, vol. 4 (suppl. 1), pp. S17-S21 entire document	1-59
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family	
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search	Date of mailing of the international search report	
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Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No : 001-819-953-2476	Authorized officer  Tung Sm 819- 934-6735	

Box No. $\pi$	Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)
<p>This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons</p> <p>1    <input checked="" type="checkbox"/> Claim Nos      55-59  because they relate to subject matter not required to be searched by this Authority, namely</p> <p>Claims 55-59 are directed to methods for treatment of the human or animal body by surgery or therapy which the International Search Authority are not required to search. Regardless, this Authority has carried out a search based on the alleged effects or purposes/uses of the product defined in claims 55-59</p> <p>2    <input type="checkbox"/> Claim Nos  because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically</p> <p>3    <input type="checkbox"/> Claim Nos  because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6 4(a)</p>	
Box No. III	Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
<p>This International Searching Authority found multiple inventions in this international application, as follows</p> <p>1    <input type="checkbox"/> As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims</p> <p>2    <input type="checkbox"/> As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees</p> <p>3    <input type="checkbox"/> As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos</p> <p>4    <input type="checkbox"/> No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claim Nos</p> <p><b>Remark on Protest</b>    <input type="checkbox"/> The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee</p> <p>   <input type="checkbox"/> The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation</p> <p>   <input type="checkbox"/> No protest accompanied the payment of additional search fees</p>	

INTERNATIONAL SEARCH REPORT  
Information on patent family members

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PC17CA2007/000323

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
US6585963	01-07-2003	CA2443563 A 1	24-10-2002
		CN1514712 A	21-07-2004
		EP1383464 A 1	28-01-2004
		JP2004529923T T	30-09-2004
		WO02083084 A 1	24-10-2002
US2004258739	23-12-2004	BR0212290 A	14-09-2004
		CA2459400 A 1	13-03-2003
		CN1599601 A	23-03-2005
		CZ20040316 A3	13-10-2004
		EP1423101 A 1	02-06-2004
		IL160551 D D0	25-07-2004
		JP2005501884T T	20-01-2005
		MXPA04002082 A	07-06-2004
		NO20040935 A	04-06-2004
		NZ531405 A	25-11-2005
		PL367514 A 1	21-02-2005
		RU2004106778 A	20-04-2005
		WO03020249 A 1	13-03-2003
		ZA200401449 A	10-03-2005
US6846837	25-01-2005	AU2003247617 A 1	06-01-2004
		EP1 558228 A 1	03-08-2005
		WO2004000291 A 1	31-12-2003
CA2278328	09-08-1999	AT238751T T	15-05-2003
		BR9904780 A	08-03-2000
		DE69907341D D1	05-06-2003
		DE69907341T T2	22-01-2004
		DK983037T T3	01-09-2003
		EP0983037 A 1	08-03-2000
		ES2198893T T3	01-02-2004
		JP2001523273T T	20-11-2001
		PT983037T T	30-09-2003
		US6224887 B1	01-05-2001
		WO9939680 A 1	12-08-1999
CA2035263	31-07-1991	AU639975B B2	12-08-1993
		AU7003291 A	01-08-1991
		EP0440298 A 1	07-08-1991
		FI910413 A	31-07-1991
		HU56717 A2	28-10-1991
		IE910317 A 1	31-07-1991
		IL97012D D0	29-03-1992
		NO910340 A	31-07-1991
		NZ236929 A	23-12-1993
		PT96592 A	29-11-1991
		ZA9 100684 A	30-10-1991