

29 October 2001

4735 '01 NOV -9 AIO :19



**Thursdays
Plantation**

Health from Nature

**Thursdays Plantation
Laboratories Limited**
ABN 17 002 833 141

Food and Drug Administration
5630 Fishers Lane r. 1061
Rockville, MD 20852
U S A

Dear Sir/Madam,

Re.: Thursdays Plantation Laboratories Ltd.
Thursdays Plantation 100% Pure Tea Tree Oil Antiseptic
Size: 1.69 fl oz (50 ml)

We would like to request exemption from your requirement of 21CFR201.66 based on the following circumstances presented. It is impracticable due to:

1. The label size is too small to fit bar lines and all the wording in the font size required.

Please find enclosed our proposed label artwork for this product.

Should you have any questions and need more information, please contact our regulatory consultant, Mrs Norma Daliva-Banks at 559-346-0233, California, USA.

Your kind consideration of this matter and immediate action are greatly appreciated.

Thanking you.

Yours sincerely

Robert Riedl
Technical Manager
Regulatory Affairs

98N-0337

APP32



097467064102

100%  Pure

**Thursday
Plantation**

Tea Tree Oil*
Antiseptic

1.69 fl oz (50ml)

*Oil of Melaleuca Alternifolia

Guaranteed Activity: minimum 36% Terpinen-4-ol

LUS032

Australian Made Product No. 6410 NDC 59165 641 50

Drug Facts

Active Ingredient

Tea Tree Oil 100%

Purpose

Antiseptic

Use Treats minor cuts, minor burns, scrapes, abrasions, insect bites and stings.

Warnings For external use only • if condition worsens or does not improve within 7 days, consult a doctor • avoid contact with eyes, mouth, ears or other sensitive areas of the body • do not exceed recommended dosage unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • apply externally to the affected area • children under 12 years of age: consult a doctor.

Other Information • packaged in glass amber bottle for maximum potency, purity and activity • store at room temperature.

Thursday Plantation Laboratories Ltd.
Ballina, Australia. www.thursdayplantation.com

Distributed in the USA by:
Natural Organics, Inc. Melville, NY 11747



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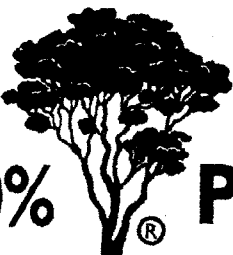
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Purpose
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Not tested on animals

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Not Tested on Animals



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 Ballina N
 2478 Austr
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 Facsimile (02) 6686 7
 International Fax: +61 2 668
 email: teatree@thursdaysplantation.com
 www.thursdaysplantation.com

Customs Douane CN 22 (02) (0001)
 May be opened officially.
 Peut être ouvert d'office.

See instructions on the back
 Detailed description of contents
 Désignation détaillée du contenu

SENDER'S DECLARATION POST
 I certify that this article **DOES NOT** contain any **DANGEROUS** or **PROHIBITED GOODS**, e.g. explosives, flammables, corrosives, aerobols etc.

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 • A false declaration is a criminal offence

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Value Valeur SA
 Net weight Poids net 100

Thursdays Plantation
 Health from Plants

Thursdays Plantation Laboratories Limited
 PACIFIC HIGHWAY BALLINA N.S.W. 2478
 PHONE (02) 6686 7273
 FAX (02) 6686 7485

TO: FOOD AND DRUG ADMINISTRATION

STREET 5630 FISHERS LANE r. 1061

CITY ROCKVILLE, MD 20852

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 THE ESSENCE OF EXCELLENCE