



**Thursdays
Plantation**

Health from Nature

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

7 3 1 4 '01 NOV 13 P5:45

1 November 2001

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 Tea Tree Ointment and Vitamin E
Size: 1.76 oz (50 g)

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

cc. Norma Daliva-Banks

AIN-0398

LET1



Quality
Endorsed
Company



**Thursdays
Plantation**
The Original

**Tea Tree[®]
Ointment
and Vitamin E**

Net Wt. 1.76 oz (50g) Net

Active Ingredients: Tea Tree Oil (Melaleuca
Alternifolia) 50mg, Vitamin E 1000IU

097467064454

Product No. 6445 LUST34

Drug Facts
Active Ingredient (per gram): Tea Tree (Melaleuca Alternifolia) Oil 50mg **Purpose** Antiseptic
Uses protects cuts, abrasions, gravel rash, cracked dry skin, chapped lips and other minor wounds against
 invasion by infection. **Warnings for external use only. When using this product avoid contact with eyes.**
 If contact occurs, rinse thoroughly with water. **Stop and ask a doctor** • in case of deep puncture wounds
 or serious burns • if redness, irritation or pain persists or increases or if infection occurs. **Keep out of reach**
 of children. If swallowed, get medical help or contact a poison control center right away. **Directions** spread
 gently over infected skin area two or three times per day. **Other Information** store at room temperature.
Inactive Ingredients Paraffin, Coconut, Alcohol, Sodium Lauryl Sulfate, Tocopheryl Acetate (Vitamin E).
 Thursdays Plantation Laboratories Ltd. Belina Australia www.thursdaysplantation.com **Australian Made**
 Distributed in the USA by: Natural Organics Inc. Melville NY 11747

100%


Thursdays Plantation
The Original

**Tea Tree[®]
 Ointment
 and Vitamin E**

Net Wt. 1.76 oz (50g) Net

Available in the following Alternative
 Commodity Accounts: 1-800-745-4444
 1-800-745-4444

097467064454
 Product No. 6445 LUS134

Drug Facts
Active Ingredient (per gram): Tea Tree (Melaleuca Alternifolia) Oil 50mg **Purpose** Antiseptic
Uses protects cuts, abrasions, gravel rash, cracked dry skin, chapped lips and other minor wounds against
 invasion by infection. **Warnings for external use only. When using this product avoid contact with eyes.**
If contact occurs, rinse thoroughly with water. Stop and ask a doctor. • In case of deep puncture wounds
 or serious burns • if redness, irritation or pain persists or increases or if infection occurs. **Keep out of reach
 of children.** If swallowed, get medical help or contact a poison control center **right away. Directions** spread
 gently over infected skin area two or three times per day. **Other information** store at room temperature.
Inactive Ingredients Paraffin, Cetearyl Alcohol, Sodium Lauryl Sulfate, Tocopheryl Acetate (Vitamin E).
 Thursdays Plantation Laboratories Ltd, Ballina Australia www.thursdaysplantation.com **Australian Made**
 Distributed in the USA by: Natural Organics Inc, Melville NY 11747

170%

ENLARGED LABEL

NDC 66141 6445 5



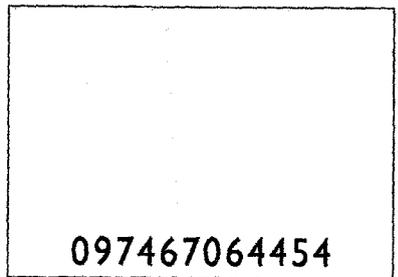
Thursday
Plantation

The Original

Tea Tree* Ointment and Vitamin E

Net Wt 1.76 oz (50g) Net

* Australian Oil Melaleuca Alternifolia
Guaranteed Activity - Tea Tree Oil active
contains minimum 36% Terpinen-4-ol



097467064454

Product No. 6445

LUS134

Drug Facts

Active Ingredient (per gram): Tea Tree (Melaleuca Alternifolia) Oil 50mg **Purpose** Antiseptic
Uses protects cuts, abrasions, gravel rash, cracked dry skin, chapped lips and other minor wounds against invasion by infection. **Warnings for external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop and ask a doctor** • in case of deep puncture wounds or serious burns • if redness, irritation or pain persists or increases or if infection occurs. **Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away. **Directions** spread gently over infected skin area two or three times per day. **Other Information** store at room temperature. **Inactive Ingredients** Paraffin, Ceatearyl Alcohol, Sodium Lauryl Sulfate, Tocopheryl Acetate (Vitamin E). Thursday Plantation Laboratories Ltd. Ballina Australia www.thursdayplantation.com **Australian Made**
Distributed in the USA by: Natural Organics Inc. Melville NY 11747



th frdants

day itation
atorlimited
CN 002141

acific lay
NSW Australia

one: (06 7273
nile (06 7485
al Fax: 2 6686 7485
e@thunantion.com
nursdaytion.com

POSTAGE
PAID
AUSTRALIA

HFA-305

Food and Drug Administration
5630 Fishers Lane r. 1061
Rockville, MD 20852
USA

20851#0001

