DERMAPROT TRICLOTREX-B- triclos an liquid SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DERMAPROT TRICLOTREX-B

This product is an antibacterial liquid which produces a synergistic effect between the Triclosan is the active ingredient with a volatile carrier such as alcohol.

This product is designed to produce an antibacterial effect both in the hands and utensils commonly used as combs and scissors in the facial aesthetics

This product must be keep out of reach of children

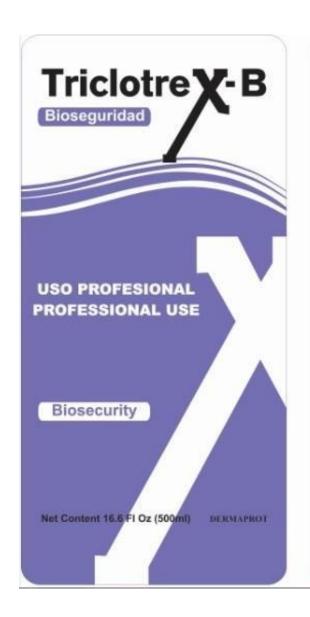
This product is for topical application as well as being used in beauty salons utensils that need to be desinfected before being used.

If this product to contact with eyes rinse immediately with water and consult a physician.

Spray an hands before rubbing them.

The active ingredient is in a volatile carrier of alcohol, Aloe Vera extract and glycerin to help form a protective glove on the skin and objects that are using this product.

IMAGE OF THE LABEL



Triclotrex-B

Bioseguridad / Biosecurity

TRICLOTREX-B: Contiene triclosan, extracto de aloe y glicerina que forma un guante protector contra bacterias para sus manos.

USOS: Antibacterial para las manos antes de ejecutar cualquier trabajo en estética facial, corporal y peluquería.

MODO DE EMPLEO: Atomizar sobre las manos y frotarias.

INGREDIENTES: Alcohol, agua, glicerina, extracto de hojas de aloe barbadensis, polisorbato 20, fragancia, triclosan, metil parabeno sodico, diazolidinil urea, dispiritiona, acido citrico, +/-CI 19140, +/-CI 42090.

TRICLOTREX-B: Contains Triclosan, Aloe extract and glycerin all of which form an antibacterial protection glove on your hands.

RECOMMENDED USE:Anti-bacterial for hands, before performing any task related to the trade on facial aesthetics, body and hairdresser.

DIRECTIONS: Spray on hands before rubbing them.

INGREDIENTS: Alcohol, water, glycerin, aloe barbadensis leaf extract, polysorbate 20, fragrance, triclosan, sodium methylparaben, citric acid, diazolidinyl urea, Bispyrithione, +/-Cl 19140, +-/ Cl 42090.





All TO 23 7 0 12 7

Manufactured by SPAL SONS Phermacoulical International Commetics
Netf. Sant. NSC2004CO13905

For American SPAL-SONS USA Corp. MIAAM, Ft (305)2066008

Distributed per: All-Time Spal-aons Equationanal Tutors-Equation
Made in Bogota Colombia / Pherm: 4279090

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Lote No.

DERMAPROT TRICLOTREX-B

triclosan liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66854-013

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength | |
|-----------------|-------------------|---------------|--|
| | mn.c | 0 0 7 4 400 7 | |

TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)

TRICLOSAN

0.3 mL in 100 mL

Inactive Ingredients

| indente ingredients | | |
|-----------------------------|----------|--|
| Ingredient Name | Strength | |
| ALCOHOL (UNII: 3K9958V90M) | | |
| WATER (UNII: 059QF0KO0R) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |

| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
|---|--|
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| METHYLPARABEN SO DIUM (UNII: CR6 K9 C2NHK) | |
| CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP) | |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) | |
| DIPYRITHIO NE (UNII: 9L87N86R9A) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| D&C BLUE NO. 4 (UNII: 0KSY80VYS3) | |
| | |

| Product Characteristics | | | |
|-------------------------|---------------|--------------|--|
| Color | green (GREEN) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | ackaging | | | |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:66854-013-01 | 500 mL in 1 JAR | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part333E | 05/31/2012 | | |
| | | | | |

Labeler - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Registrant - SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

| Establishment | | | | |
|--|---------|-----------|------------------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS | | 880172184 | analysis, label, manufacture, pack | |

Revised: 5/2012 SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS