

DERMAPROT TRICLOTREX-B- triclosan liquid
SAPI-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 disinfected 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 frotarlas.

INGREDIENTES: Alcohol, agua, glicerina, extracto de hojas de aloe barbadensis, polysorbato 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, +/-CI 19140, +/- CI 42090.

**Use profesional
Professional use**



7 702376 291077

Manufactured by SPAI-SUNS Pharmaceutical International Cosmetics
Natl. Sanit. NSC2004CO13905
For American SPAI-SUNS USA Corp. MIAMI, FL (305)2066008
Distribuido por: All-Time Spai-suns Ecuatoriana/ Tulcan- Ecuador
Made in Bogotá Colombia / Phone: 4279090
www.spai-suns.com / ventas@spai-suns.com
Lots No.

DERMAPROT TRICLOTREX-B

triclosan liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66854-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.3 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIPYRITHIONE (UNII: 9L87N86R9A)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics			
Color	green	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66854-004-01	500 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333E	08/30/2012	

Labeler - SAPI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS (880172184)

Establishment			
Name	Address	ID/FEI	Business Operations
SPAI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS		880172184	manufacture(66854-004) , analysis(66854-004) , label(66854-004) , pack(66854-004)

Revised: 8/2012

SAPI-SONS PHARMACEUTICAL INTERNATIONAL COSMETICS