SOFTCIDE-ES- softcide-es liquid Erie Scientific, LLC

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.

SoftCIDE-ES

Chloroxylenol 0.3% w/w

Water, Tall Oil Acid, Potassium Hydroxide, Sodium Lauryl Sulfate, Coconut Acid, Cocamide DIPA, Phenoxyethanol, Tetrasodium EDTA, Sodium Sulfate, Sodium Laureth Sulfate, Aloe Barbadensis Leaf, Tocopheryl Acetate (Vitamin E Acetate), Iodopropynyl Butylcarbamate, Fragrance, Red 33, Yellow 5

Wet skin and apply a sufficient amount on hands and forearms. Scrub well and rinse thoroughly after washing.

Handwash to help reduce bacteria that can potentially cause disease.

Handwash to help reduce bacteria that can potentially cause disease.

Avoid contact with the eyes. If contact occurs, flush eyes with water.

Discontinue use and consult a health practitioner if irritation develops. If swallowed seek medical help or contact Posion Control immediately. Keep out of reach of children.

Keep out of reach of children. If swallowed, seek medical help or contact Poison Control immediately.

Avoid contact with eyes. If contact occurs, flush eyes with water.

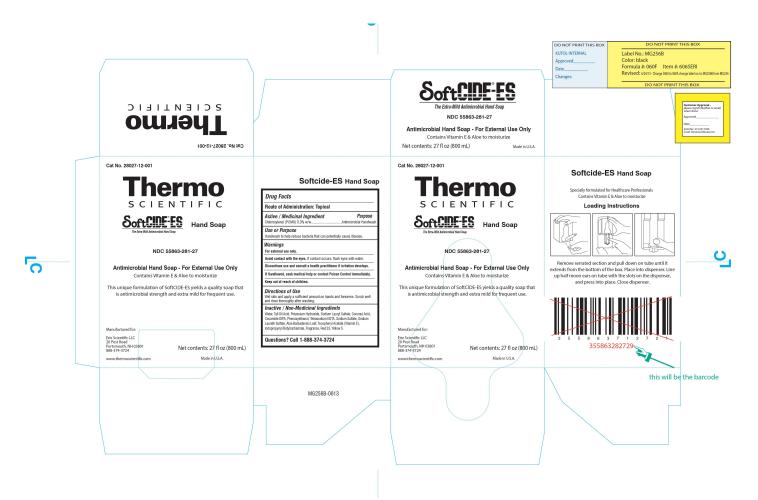
For external use only.

Avoid contact with the eyes. If contact occurs, flush eyes with water.

Discontinue use and consult a health practitioner if irritation develops.

If swallowed seek medical help or contact Posion Control immediately.

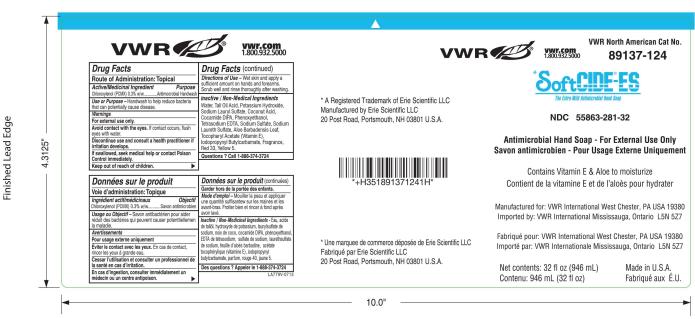
Keep out of reach of children.



55863-281-27-ERI.jpg







55863-281-32-VWR.jpg



DO NOT PRINT THIS BOX

Formula #: 060F Item #: 6042VWR Revised: 7/23/13 - Change £060 to 060F, change label no. to LA779V from CS2051 add label no.

Antiseptic Hand Soap - For External Use Only

Savon Antiseptique - Pour Usage Externe Uniqueme

Net contents: 27 fl oz (800 mL) Contenu: 800 ml (27 fl oz)

Do Not Print Until Further Notice ****7/23/13 - *** Updated for Shawn's approval only -



Label No.: LA779V Color: PMS 298 and black

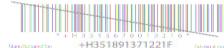
89137-12



NDC 55869-281-27

Antiseptic Hand Soap - For External Use Only Savon Antiseptique - Pour Usage Externe Uniquemer

Contains Vitamin E & Aloe to moisturize Contient de la vitamine E et de l'aloès pour hydrater



Made in U.S.A. Fabriqué aux É. U. Net contents: 27 fl oz (800 mL) Contenu: 800 ml (27 fl oz)

DO NOT PRINT THIS BOX

KUTOL INTERNAL

Approved

Changes:

221-76160 WWR North American Cat No.

WWW.E8 0 2 2 5 1.800.932.5000

VWR North 89137-122

Loading Instructions / Chargement des instructions



Remove serrated section and pull down on tube until it extends from the bottom of the box. Place into dispenser, Line up half moon ears on tube with the slots on the

Retirer la section dentelée et tirer le tube vers le bas jusqu'à ce qu'il dépasse la bas de la boîte. Placer dans le avec les fentes du distributeur et bien encliqueter en

WANTER OF THE PROPERTY OF THE 89137-122 Route of Administration: Topical Active / Medicinal Ingredient Chloroxylenol (PCMX) 0.3% w/w..... Use or Purpose Handwash to help reduce bacteria that can potentially cause disease For external use only. Discontinue use and consult a health practitioner if irritation develops lf Swallowed, seek medical help or contact Poison Control immediately. Directions of Use Wet skin and apply a sufficient amount on hands and forearms. Scrub well and risse thoroughly after washing.

Inactive / Non-Wedicinal Ingredients Questions? Call 1-888-374-3724

MG256C-0713

55863-281-27-VWR.jpg

SOFTCIDE-ES

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55863-281	
Route of Administration	Topical			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLOROXYLENOL (UNII: 0 F32U78 V2Q) (CHLOROXYLENOL - UNII: 0 F32U78 V2Q)	CHLOROXYLENOL	12.604 g in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
EDETATE SO DIUM (UNII: MP1J8420LU)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
TALL OIL (UNII: 1GX6Z36A79)			
COCONUT ACID (UNII: 40 U37 V50 5D)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
COCO DIISOPROPANOLAMIDE (UNII: S485AM948Q)			
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)			
SODIUM SULFATE (UNII: 0 YPR65R21J)			
SODIUM LAURETH SULFATE (UNII: BPV390 UAP0)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
.ALPHATO COPHERO L ACETATE, DL- (UNII: WR1WPI7EW8)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55863-281-27	800 mL in 1 BAG		
2	NDC:55863-281-32	946 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	06/13/2013		

Labeler - Erie Scientific, LLC (361605223)

Registrant - Kutol Products Company, Inc. (004236139)

Establishment

Name	Address	ID/FEI	Business Operations
Kutol Products Company, Inc.		004236139	manufacture(55863-281), pack(55863-281), analysis(55863-281)

Revised: 7/2013 Erie Scientific, LLC