SAFEWAY - ethyl alcohol liquid SAFEWAY INC

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.

DRUG FACTS

ACTIVE INGREDIENT

ETHYL ALCOHOL 65%

PURPOSE

ANTISEPTIC

USES

TO HELP REDUCE BACTERIA ON THE SKIN. RECOMMENDED FOR REPEATED USE

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES WITH WATER.

STOP USING AND ASK A DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS

KEEP OUT OF REACH OF CHILDREN.

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY

DIRECTIONS

WET HANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY. SUPERVISE CHILDREN IN THE USE OF THIS PRODUCT.

QUESTIONS / COMMENTS

1-888-723-3929

OTHER INFORMATION

STORE BELOW 110 F (43 C)

INACTIVE INGREDIENTS

WATER (AQUA), ISOPROPYL ALCOHOL, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL, FRAGRANCE (PARFUM), PROPYLENE GLYCOL, ISOPROPYL MYRISTATE,

ALOE BARBADENSIS LEAF JUICE, TOCOPHERYL ACETATE, BLUE 1 (CI 42090), YELLOW 5 (CI 19140).

LABEL COPY





SAFEWAY

ethyl alcohol liquid

Product	Inform	ation
Promine		

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:21130-255

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) ALCOHOL 65 mL in 100 mL

Inactive Ingredients

Ingredient Name

WATER (UNII: 059QF0KO0R)

ISOPROPYL ALCOHOL (UNII: ND2M416302)

GLYCERIN (UNII: PDC6A3C0OX)

CARBOMER 934 (UNII: Z135WT9208)

AMINOMETHYLPROPANOL (UNII: LU49E6626Q)

PROPANEDIOL (UNII: 5965N8W85T)

ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-255-08	236 mL in 1 BOTTLE, PUMP		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	12/13/2011		

Labeler - SAFEWAY INC (009137209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment					
Name	Address	ID/FEI	Business Operations		
APOLLO HEALTH AND BEAUTY CARE		20 19 0 12 0 9	manufacture		

Revised: 12/2011 SAFEWAY INC