HAND SANITIZER- ethyl alcohol spray
Skaffles Group Limited Liability Company

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.

77720-018 hand sanitizer Spray 71% Ethyl Alcohol

Active Ingredient

Ethyl Alcohol 71%

Purpose

Antiseptic

USE

Hand sanitizing to help reduce bacteria on the skin. Recommended for repeated use.

Warning

For external use only./ Para uso externo uinicamente.
Do not use / No utilice o lf you are allergic to any of the ingredients. o In the eyes;if contact occurs, rinse thoroughly with water.i Si es alergico a alguno de losingredientes.· Si entra en contacto con los ojos,enjuague por completo con agua.Discontinue use ifiritation and redness develop. lf condition persists for morethan 72 hours consult a doctor./Suspenda el uso si se presenta irritacion yenrojecimiento.Consulte a un medico si la condicion persiste por mas de 72 horas.Keep out of reach of children. If swallowed, get medical help or contact aPoison Control Center right away./ Mantengase fuera del alcance de los niios.Sise ingiere, obtenga atencion medica o pongase en contacto de inmediato conun Centro de control de envenenamientos.

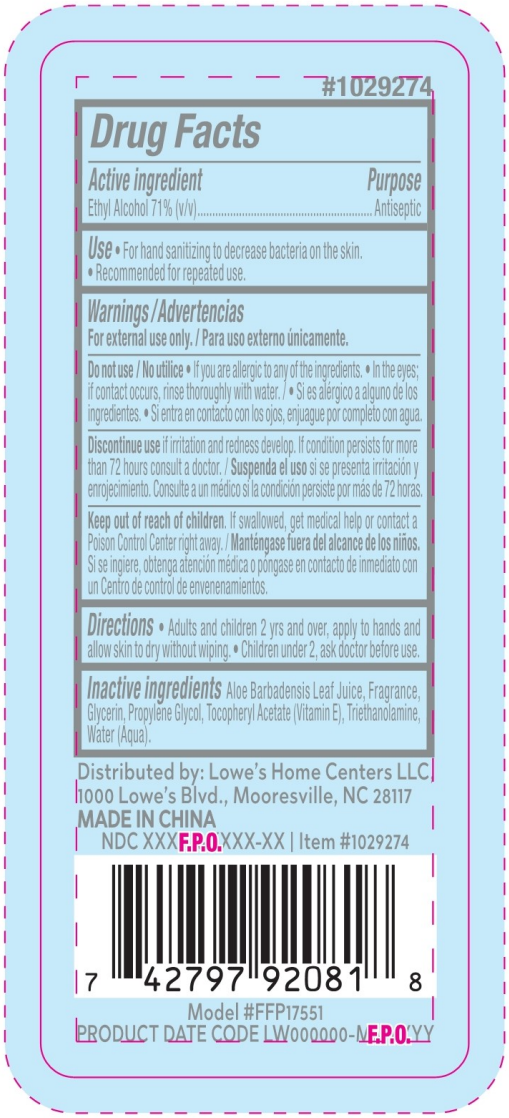
Keep out of reach of children. If swallowed, get medical
help or contact a Poison Control Center right away.

Directions

Adtults and children 2 yrs and over, apply to hands and allow skin to dry without wiping. Children under 2, ask doctor before use.

Inactive ingredients

Aloe Barbadensis Leaf Juice, Fragrance, Glycerin, Propylene Glycol, TocopheryI Acetate (Vitamin E), Triethanolamine, Water(Aqua).



HAND SANITIZER

ethyl alcohol spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77720-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	71 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77720-018-01	30 in 1 CARTON	12/30/2020	
1		237 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/30/2020	

Labeler - Skaffles Group Limited Liability Company (831115642)

Establishment

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	manufacture(77720-018)

Revised: 12/2020 Skaffles Group Limited Liability Company