

TYCHE HAND SANITIZER- ethyl alcohol gel
Proxima 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.

[Proxima Inc.] 500 ml : 74359-0562



TYCHE HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74359-0562
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	310 mL in 500 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74359-0562-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/31/2020	

Labeler - Proxima Inc. (929495414)**Establishment**

Name	Address	ID/FEI	Business Operations
PL COSMETIC		688393375	manufacture(74359-0562)

Revised: 4/2020

Proxima Inc.