MY LITTLE PONY HAND SANITIZER MLP 202- alcohol gel Gold Orient International Limited

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.

My Little Pony(MLP 202)Hand Sanitizer

Active ingredient

Alcohol Denat.62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water is not available.

Warnings

For external use only.

Flammable, keep away from fire and flames.

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

irritation and redness develop

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

wet hands thoroughly with product and allow to dry without wiping.

Other information

- Store at 68 to 77F (20-25C)
- Do not store above 110F (43C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536.

Inactive ingredients

Water,

Glycerin,

Acrylates/C10-30 Alkyl Acrylate Crosspolymer,

Fragrance,

Polysorbate 20,

Sodium Hydroxide,

Red 33,

Yellow 5

Label

HAND SANITIZER











MY LITTLE PONY HAND SANITIZER MLP 202

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51522-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				

]	Packaging			
#	# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51522-021- 01	1 in 1 POUCH	07/16/2020	
1	L	89 mL in 1 BOTTLE, PLASTIC; 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	07/16/2020			

Labeler - Gold Orient International Limited (679905914)

Establishment				
Name	Address	ID/FEI	Business Operations	
Gold Orient International Limited		679905914	manufacture(51522-021)	

Revised: 7/2020 Gold Orient International Limited