MY LITTLE PONY HAND SANITIZER- alcohol denat. 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 100) Hand Sanitizer

Active Ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Use

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

Warnings

When using this product

- do not get into eyes.
- if contact occurs, rinse eyes thorouly 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 77°F (20°~25°C)
- Do not store above 110°F (43°C)
- 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, Yellow 5, Blue 1.

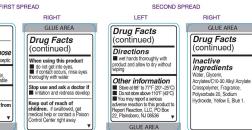
Label



FRONT







MY LITTLE PONY HAND SANITIZER

alcohol denat. gel

Product Information	Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51522-040	
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		
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)			
WATER (UNII: 059QF0KO0R)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GLYCERIN (UNII: PDC6A3C0OX)			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:51522-040- 01	1 in 1 POUCH	07/24/2020		
1	30 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	07/24/2020		

Labeler - Gold Orient International Limited (679905914)

Establishment			
Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-040)

Revised: 7/2020 Gold Orient International Limited