MOISTURIZING HAND SANITIZER- hand sanitizer gel
American Chemical LLC

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.

Moisturizing Hand Sanitizer

Active Ingredient(s)

Alcohol 70% w/w. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin that could cause disease.

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

- On children less than 2 months of age
- On open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.

Directions

- Place a small amount in your palms and rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Do not store above 104° F (40° C)

Inactive ingredients

Water, Glycerin, Hydroxypropyl Cellulose, Cetyl Lactate, Natural Fragrance

Package Label - Principal Display Panel

MOISTURIZING HAND SANITIZER

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80375-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
CETYL LACTATE (UNII: A7EVH2RK4O)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80375-001-01	3260.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2020	
2	NDC:80375-	861362 g in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not	07/07/2020	

2	001-02	a Combination Product	07/07/2020	
3	NDC:80375-001-03	293.7 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2020	
4	NDC:80375-001-04	391.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2020	
5	NDC:80375-001-05	97.85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2020	
6	NDC:80375-001-06	24.43 g in 1 BOTTLE; Type 0: Not a Combination Product	09/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/07/2020	

Labeler - American Chemical LLC (117076305)

Establishment

Name	Address	ID/FEI	Business Operations
American Chemical LLC		117076305	manufacture(80375-001) , label(80375-001) , pack(80375-001)

Revised: 9/2020 American Chemical LLC