HYDRAGEN PRO BARRIER HAND SANITIZER- alcohol liquid ADVANCED SKIN TECHNOLOGY, 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.

HydraGen® Pro Barrier Hand Sanitizer with Hyaluronic Acid

Drug Facts

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antispetic

Uses

- Hand Sanitizer to help reduce bacteria that potentially cause disease.
- For use when soap and water are not available.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

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.

Do Not Use

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

Directions

- Place enough product in your palm to thoroughly cover your hands.
- Rub hands briskly until they are fully dry.

Other Information

- Store between 15-30°C (59-86°F).
- Avoid freezing and excessive heat above 40°C (104°F).

Inactive Ingredients

Water, hydrolized jojoba esters, glycerin, PEG-10 dimethicone, sodium hyaluronate.

HydraGen Pro Barrier Hand Sanitizer with hyaluronic acid 5.7 fl. oz /168 ml



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alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52205-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)			
WATER (UNII: 059QF0KO0R)			
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:52205-004- 01	168 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/18/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/18/2020	

Labeler - ADVANCED SKIN TECHNOLOGY, LLC (130977940)

Establishment			
Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(52205-004)

Revised: 6/2020 ADVANCED SKIN TECHNOLOGY, LLC