DYPER HAND SANITIZER- alcohol gel DYPER 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.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

Warnings

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

Do not use

- in 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. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

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

Inactive ingredients

acrylates copolymer, fragrance, glycerin, trolamine, water USP.

Package Label - Principal Display Panel

500 mL NDC: 80405-001-01



Germs are everywhere! They can get onto hands and items we touch during daily activities and make us sick. Cleaning hands at key times with soap and water or hand sanitizer is one of the most important steps you can take to avoid getting sick and spreading germs to those around you.

Do **NOT** use hand sanitizer if your hands are visibly dirty or greasy. Wash your hands with soap and water instead.

Always supervise young children when they use hand sanitizer to prevent swallowing alcohol, especially in schools and childcare facilities. This sanitizer is not recommended for infants.

Apply, Put enough product on hands to cover all surfaces. Use the included cap or pump for accurate dispensing.
 Rub hands together, until hands feel dry. This should take around 20 seconds. Allways securely close the bottle when finished.

Note: Do not rinse or wipe off the hand sanitizer before it's dry; it may not work as well against germs.



Drug Facts

Active ingredient Ethyl Alcohol 70.0% v/v Purpose

Uses • for handwashing to decrease bacteria on the skin • recommended for repeated use

Warnings

For external use only.

Flammable, keep away from heat and flame.

Do not use in the eyes. In case of contact, rinse eyes

thoroughly with water.

Store use and ask a doctor if irritation and redness

Store use and ask a doctor if initiation and rediness develop and persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • wet hands with product • brisklyrun hands together until dry • supervise children under 6 years

Other information

store at 68° to 77° F • may discolor certain fabrics

Inactive ingredients Water, Glycerol Acrylates Copolymer, Triethanolamine, Fragrance

DISTRIBUTED BY DYPER INC. 688 W 1ST ST, SUITE 6, TEMPE, AZ 85281, USA

Strength

DYPER HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80405-001(NDC:80211-001)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (UNII: 3K9958V90M) ALCOHOL 70 mL in 100 mL

Inactive Ingredients

Ingredient Name

FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)

CARBOMER 1342 (UNII: 809Y72KV36)

GLYCERIN (UNII: PDC6A3C0OX)
TROLAMINE (UNII: 9O3K93S3TK)

WATER (UNII: 059QF0KO0R)

Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:80405-001- 01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/03/2020					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	09/03/2020					

Labeler - DYPER INC. (061417570)

Registrant - DYPER INC. (061417570)

Establishment							
Name	Address	ID/FEI	Business Operations				
DYPER INC.		061417570	relabel(80405-001)				

Establishment							
Name	Address	ID/FEI	Business Operations				
Distribuidora Provenza S.A. de C.V.		8 1246 18 12	manufacture (80405-001)				

Revised: 12/2020 DYPER INC.