TRU AND GEN 75% ALCOHOL WET WIPES- alcohol cloth TRU & GEN

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.

TRU & GEN ALCOHOL WET WIPES

Active Ingredient

ALCOHOL ---- 75%

Purpose:

Antibacterial

Inactive Ingredients

Water, Sodium benzoate, PEG-60 Hydrogenated Castor Oil, Lavandual Angustifolia (Lavender) Oil, Butylene Glycol, Aloe Vera Leaf Extract, Chamomila Recutita (Matricaria) Flower Extract

Directions for Use

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.

Warnings:

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

When using this product:

Keep out of eyes, ears, and mouth.

In case of contact with eyes, rinse eyes thoroughly with water.

Uses:

Hand Sterilization to help reduce bacteria that potentially can cause disease.

Keep Out of Reach of Children:

If swallowed, get medical help or contact a Poison Control Center right way.

Other Information:

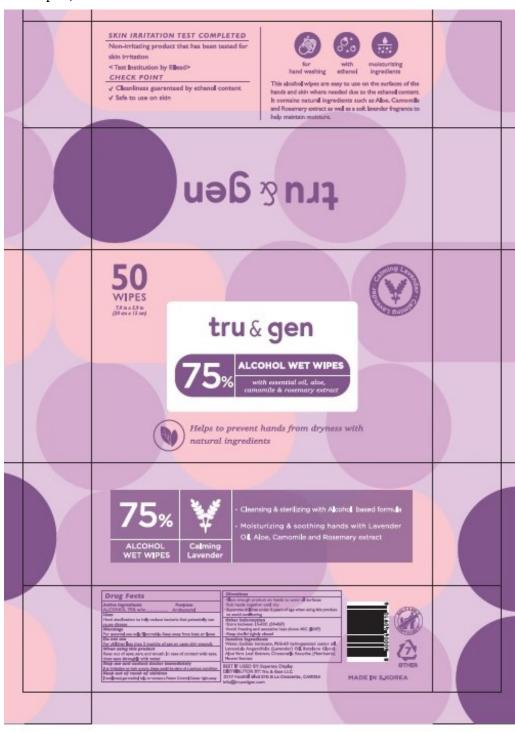
Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C (104F)

Keep the lid tightly closed

50 Wipes PDP, NDC: 80500-001-01

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TRU AND GEN 75% ALCOHOL WET WIPES

alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80500-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75		

Inactive Ingredients			
Ingredient Name	Strength		
MATRICARIA CHAMOMILLA (UNII: G0 R4UBI2ZZ)			
LAVENDER OIL (UNII: ZBP1YXW0H8)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
WATER (UNII: 059QF0KO0R)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)			
ROSEMARY (UNII: IJ67X351P9)			

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:80500-001-01	50 in 1 PACKET; Type 0: Not a Combination Product	09/10/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/10/2020		

Labeler - TRU & GEN (117625864)

Registrant - TRU & GEN (117625864)

Establishment			
Name	Address	ID/FEI	Business Operations
TRU & GEN LLC		117625864	pack(80500-001), label(80500-001)

Establishment				
Name	Address	ID/FEI	Business Operations	
DONGBANG COSMETICS CO., LTD		694452564	manufacture (80500-001)	

Revised: 9/2020 TRU & GEN