WONVIA INDIVIDUALLY WRAPPED ANTIBACTERIAL HAND WIPES 70% ALCOHOL- alcohol cloth
KAPLAN DISTRIBUTION 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.

Active Ingredient(s)

Ethyl Alcohol 58%

Isopropyl Alcohol 12%

Alkyl Dimethyl Benzyl Ammonium Chloride 0.2%

Purpose: Antimicrobial

Purpose

Antimicrobial, Hand Wipes

Use

Single-use hand wipes to help reduce bacteria on the skin. 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 and/or redness develop. 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

- Wet hands thoroughly with product and allow to dry.
- Discard wipes in a trash receptacle after use. Do not flush.
- Children under 6 years of age should be supervised when using this product.

Other information

- Store between 15-30C (59-86F) at room temperature.
- Avoid freezing and excessive heat above 40C (104F)
- Flammable keep away from fire.

Inactive ingredients

Softener 1.5%

Resolvent 28.19%

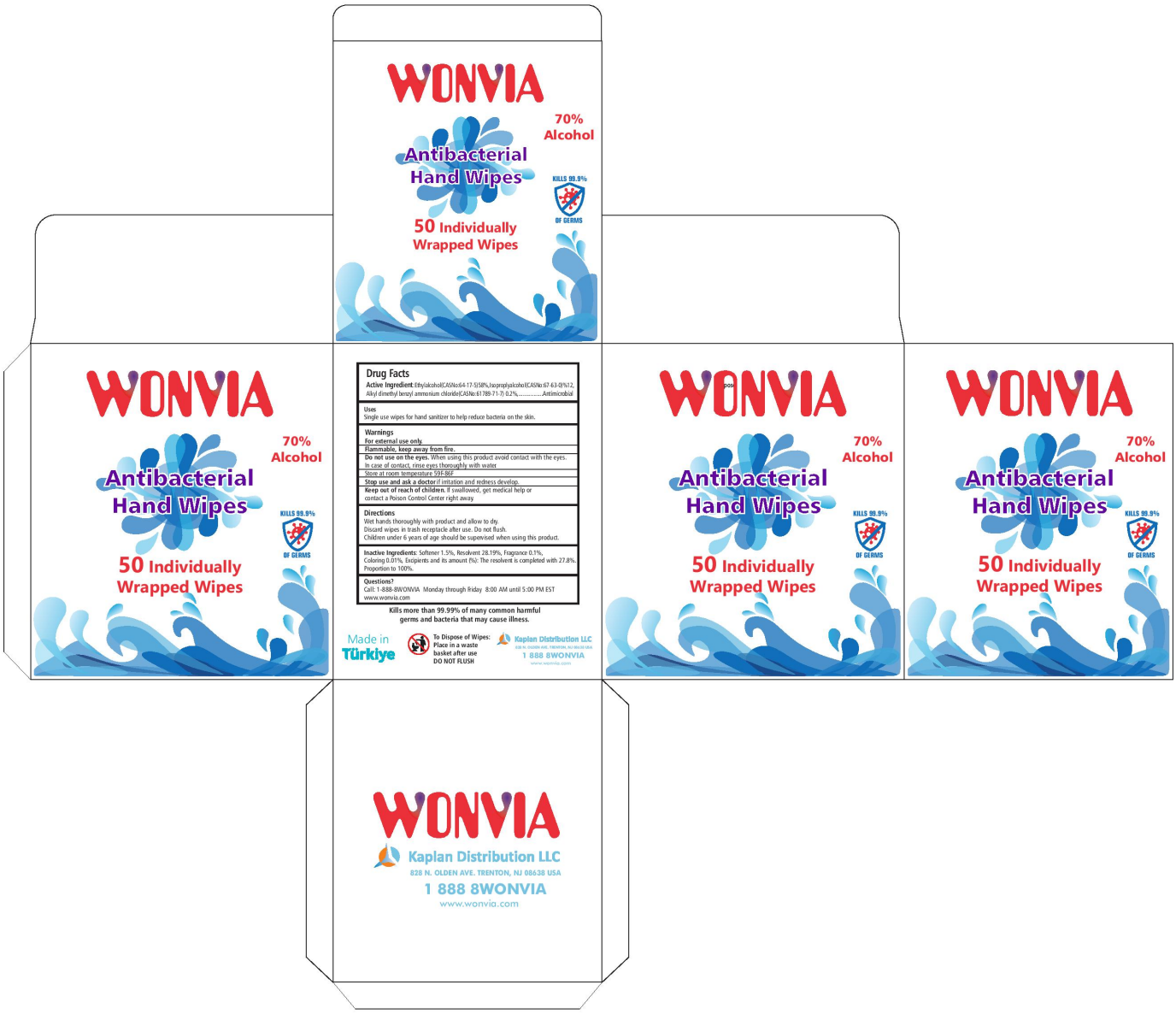
Fragrance 0.1%

Coloring 0.01%

Excipients and its amount (%): The resolvent is completed 27.8%

Proportion to 100%

Package Label - Principal Display Panel



50 individually wrapped hand wipes= NDC: 78876-713-50

WONVIA INDIVIDUALLY WRAPPED ANTIBACTERIAL HAND WIPES 70% ALCOHOL

alcohol cloth

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78876-713
Route of Administration	TOPICAL		

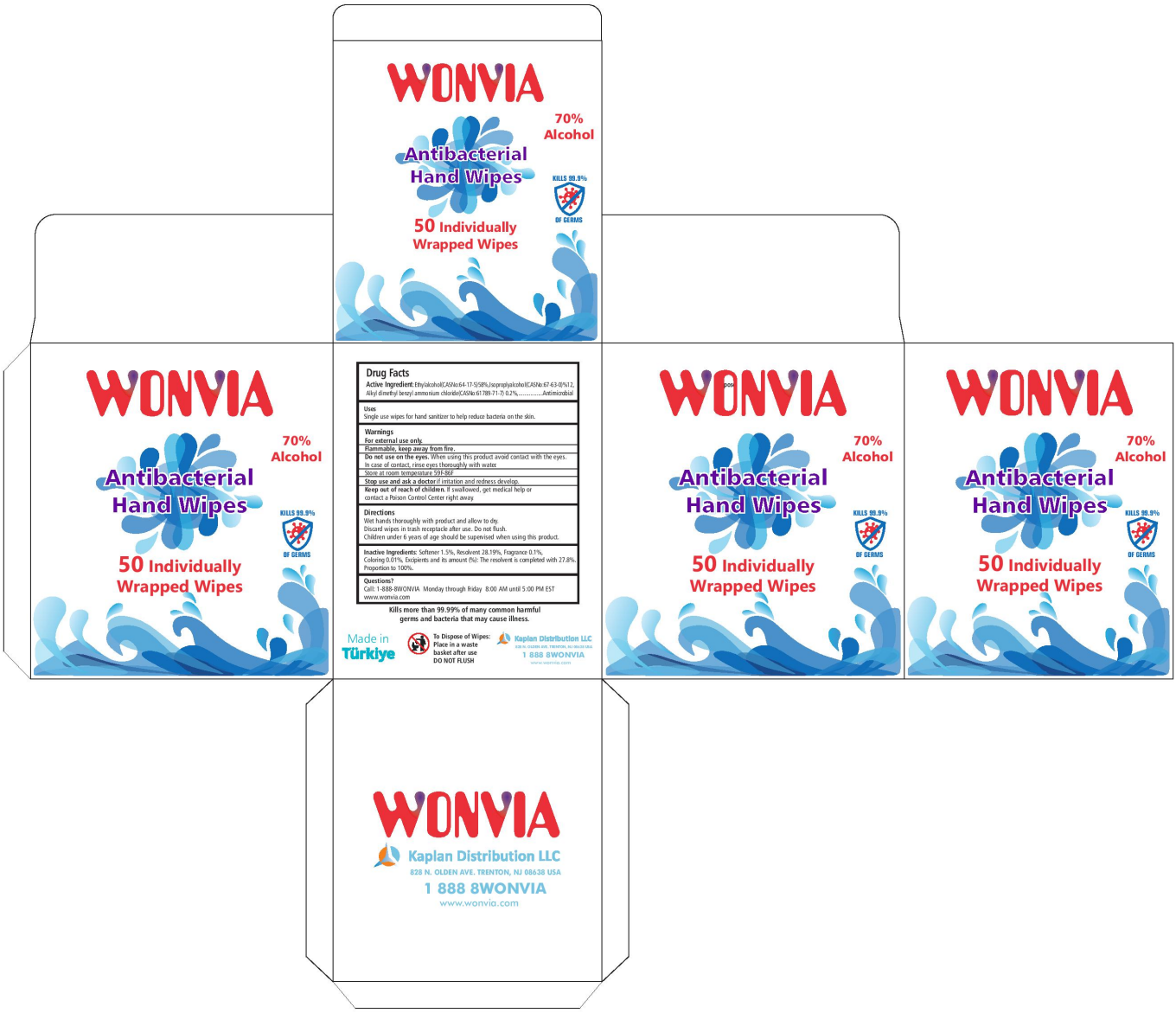
Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	58 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.2 g in 100 g

ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	12 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:78876-713-50	50 g in 1 BOX; Type 0: Not a Combination Product	08/31/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/31/2020	

Labeler - KAPLAN DISTRIBUTION LLC (117548994)

Registrant - KAPLAN DISTRIBUTION LLC (117548994)

Establishment

Name	Address	ID/FEI	Business Operations
KAPLAN DISTRIBUTION LLC		117548994	relabel(78876-713)

Establishment

Name	Address	ID/FEI	Business Operations

RKS GROUP YAPI KIMYASALLARI SANAYI VE TICARET LIMITED SIRKETI		520136931	manufacture(78876-713)