REVIVE HAND SANITIZER - PROTECT- alcohol spray REVIVE HAND SANITIZER - IMMUNITY BOOST- alcohol spray REVIVE HAND SANITIZER - LAVENDER- isopropyl alcohol hand sanitizer spray TKS Co-Pack Manufacturing

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.

Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Ethyl Alcohol (75%, v/v) in an aqueous solution denatured to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Essential oil as fragrance (5.0% v/v)

Active Ingredient(s)

Isopropyl Alcohol 75% 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)

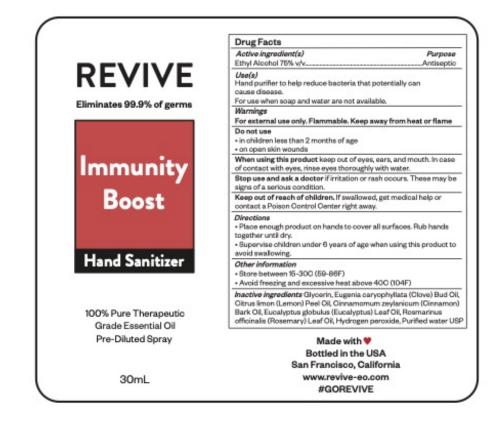
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP, essential oil

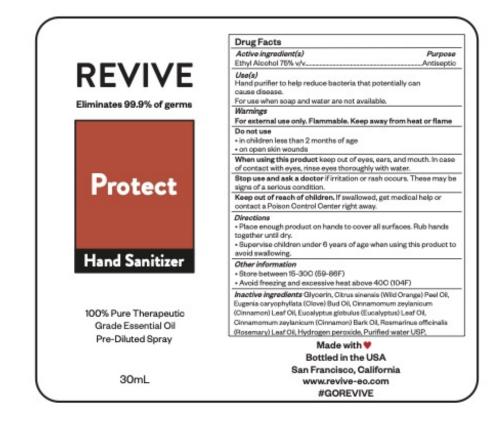
Package Label - Principal Display Panel



30 mL NDC: 78266-005-01



30 mL NDC: 78266-004-01



30 mL NDC: 78266-006-01

REVIVE HAND SANITI alcohol spray	ZER - PROTECT					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code	(Source)	NDO	C:78266-009	
Route of Administration						
Active Ingredient/Active Mo	iety					
Ingredient Name Basis of Strengt			h	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL			ALCOHOL		22.5 mL in 30 mL	
Inactive Ingredients						
	Ingredient Name				Strength	
CINNAMON BARK OIL (UNII: XE54U569EC)				0.53	5 mL in 30 mL	
CLOVE OIL (UNII: 578389D6D0)				0.322 mL in 30 mL		
GLYCERIN (UNII: PDC6A3C0OX)				0.62	3 mL in 30 mL	
HYDROGEN PERO XIDE (UNII: BBX060AN9V)					mL in 30 mL	
WATER (UNII: 059QF0KO0R)					5.219 mL in 30 mL	
CITRUS SINENSIS FRUIT OIL (UNII: WV48LBL15Q)					7 mL in 30 mL	

EUCALYPTUS OIL (UNII: 2R04ONI662)	
ROSMARINUS OFFICINALIS FLOWERING TOP OIL (UNII: OXN0D3N28L)	

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:78266-009- 01	- 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combina Product	ation 12/23/2020				
Marketing I	nformation					
Marketing In Marketing Cates		ation Marketing Start Date	Marketing End Dat			

alcohol spray						
Product Inform	ation					
Product T ype		(Source)	NDC:78266-007			
Route of Administration TOPICAL						
Active Ingredie	nt/Active Moi	ety				
	Ingred	lient Name		Basis of Strength	ngth Strength	
ALCOHOL (UNII: 3K	9958V90M) (ALC	COHOL - UNII:3K9958V90M)		ALCOHOL	22.5 mL in 30 mL	
		Ingredient Name			Strength	
Inactive Ingredi	ents	T 1				
CINNAMON BARK OIL (UNII: XE54U569EC)					0.322 mL in 30 mL	
					.322 mL in 30 mL	
					.623 mL in 30 mL	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V) 0.05 mL in					.05 mL in 30 mL	
WATER (UNII: 059QF0KO0R)					5.217 mL in 30 mL	
CITRUS LIMON SEED OIL (UNII: T78Z8273XO)				0	0.322 mL in 30 mL	
EUCALYPTUS OIL (UNII: 2R04ONI662)				0	0.322 mL in 30 mL	
ROSMARINUS OFF	CINALIS FLOWI	E RING TOP OIL (UNII: OXN0D)3N28L)	0	.322 mL in 30 mL	
Packaging						
# Item Code		Package Description		Marketing Start Date	Marketing End Date	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	12/23/2020			

sopropyl alcohol h	and sanitizer s	pray				
Product Inform	ation					
Product T ype		HUMAN OTC DRUG	(Source)	vce) NDC:78266-008		
Route of Administ	ration	TOPICAL				
Active Ingredie	nt/Active Mo	iety				
Ingredient Name					Strength	Strength
ALCOHOL (UNII: 3k	(AL	COHOL - UNII:3K9958V90M)		ALCOHOL		22.5 mL in 30 mL
Inactive Ingred	ients					
Ingredient Name				Strength		
LAVENDER OIL (UNII: ZBP1YXW0H8)				1.6 mL in 30 mL		
GLYCERIN (UNII: PDC6A3C0OX)				0.62 mL in 30 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				0.05 mL in 30 mL		
WATER (UNII: 059Q	F0KO0R)				5.2 mL in 3	0 mL
Packaging						
# Item Code		Package Description		Marketing Start Date		Marketing End Date
NDC:78266-008- 01 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product			natio n	12/23/2020		
01						
01						
Marketing In		tion Number or Monograph C		Marketing S		Marketing End Dat

Labeler - TKS Co-Pack Manufacturing (117172434)

Registrant - TKS Co-Pack Manufacturing (117172434)

Establishment					
Name	Address	ID/FEI	Business Operations		
TKS Co-Pack Manufacturing		117172434	manufacture(78266-007, 78266-008, 78266-009)		

Revised: 12/2020