

**REVIVE HAND SANITIZER - PROTECT- 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.*

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**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. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according 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

## Package Label - Principal Display Panel

30 ml NDC: 78266-001-01

**REVIVE**

**Hand Sanitizer**

**Protect**

Eliminates 99.9% of germs  
100% Pure Therapeutic  
Grade Essential Oil  
Pre-Diluted Spray

30mL

Made with ♥  
Bottled in the USA  
San Francisco, California  
www.revive-eo.com  
#GOREVIVE

Drug Facts	
<b>Active ingredient(s)</b> Isopropyl alcohol 75% v/v	<b>Purpose</b> Antiseptic
<b>Use(s)</b> Hand purifier to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP, Orange Peel, Clove Fruit, Cinnamon Leaf, Cinnamon Bark, Cassia Leaf/Twig, Eucalyptus Leaf and Rosemary Leaf	

## REVIVE HAND SANITIZER - PROTECT

isopropyl alcohol hand sanitizer spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78266-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	21.1 mL in 30 mL

**Inactive Ingredients**

Ingredient Name	Strength
CITRUS SINENSIS FRUIT OIL (UNII: WV48LBL15Q)	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: 059QF0K00R)	6.6 mL in 30 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78266-001-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/28/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/28/2020	

**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(78266-001)

Revised: 7/2020

TKS Co-Pack Manufacturing