

NEUTREVO ALCOHOL WET WIPES- alcohol, hydrogen peroxide cloth SCK ZETA DIS TICARET

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.

NEUTREVO ALCOHOL WET WIPES

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol .
- c. Hydrogen peroxide (0.125% v/v).
- d. Triethanolamine
- e. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antibacterial

Hydrogen Peroxide 0.125 v/v Purpose: Antibacterial

Purpose

Antibacterial - Antiseptic

Use

Alcohol wet wipe to help reduce bacteria on the skin.

Warnings

For external use only. Before using certainly read the label and the instructions. Avoid direct contact with eyes. Flammable liquid and vapour. Keep away from heat , hot surfaces, sparks, open-ames and other ignition sources. No smoking. Keep container tightly closed. Use only non-sparking tools. Store in a well ventilated place. Keep cool

Do not use

- on open skin wounds

When using this product Keep out of reach of children, food and animal feeds. Do not eat, dirnk and smoking. Follow use instructions to prevent risks on human and environmental health.If contact the skin: This product is produced to contact the skin. Wash the excess with water. In case of redness, swelling,

itching or burning occurs, get medical help. In case of eye contact: wash the eyes with the clean water at least 15 minutes with the eyes cover open. If swallowed shake the mouth with water. Do not induce vomiting. Immediately apply to the doctor and show him the label of the product.

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.

Directions

- Use wipes as much as needed, used by wiping the hands, between the fingers, all internal and external surfaces and under the nails. Do not rinse after use.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 30C (86F)

Inactive ingredients

glycerin, triethanolamin, water

Package Label - Principal Display Panel

Drug facts	Purpose
Active ingredient	Antibacterial
Ethyl Alcohol (62.0%)	
Hydrogen peroxide (0.125%)	Antibacterial
Use:	Alcohol wet wipes to help reduce bacteria on the skin.
Warnings	
For external use only	Before using, carefully read the label and the instructions. Avoid direct contact with eyes. Flammable liquid and vapour. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Use only non-splintering tools. Store in well ventilated place. Keep cool.
Do not use	On open skin wounds
Shelf life	Shou use and date a doctor's prescription or rash occurs. There may be signs of a serious condition.
When using this product	Keep away from children, food and animal feeds. Do not eat, drink, or smoke. Follow use instructions to prevent risks to human and environmental health. If contact the skin, this product is produced to contact the skin. Wash the excess with water. In case of redness, swelling, itching or burning occurs, get medical help. In case of eye contact, Wash the eyes with the clean water at least 15 minutes with the eyes over open.
Keep out of reach of children.	If swallowed, get medical help or contact a poison control center right away.
Directions	Use wipes as much as needed, used by wiping the hands, between the fingers, all internal and external surfaces, and under the nails. Do not use after use. Supervise children under 6 years of age when using this product to avoid swallowing.
Other informations	Store below 30°C (86°F).
Inactive ingredients	Aqua, Glycerin, Methanolanime

Hygienic Protection For Skin

BACTERIA
 Pseudomonas Aeruginosa ✓
 Staphylococcus Aureus ✓
 Enterococcus Hirae ✓

Saf Dokunus
 Pure touch

Wet wipes
 ANTI-BACTERIAL

%70 ALCOHOL

TRUSTED PROTECTION ANTISEPTIC

%70 ALCOHOL

NEUTREVO

72 PCS

Wet wipes

TRUSTED PROTECTION ANTISEPTIC

Pure touch

BACTERIA
 Pseudomonas Aeruginosa ✓
 Staphylococcus Aureus ✓
 Enterococcus Hirae ✓

Hygienic Protection For Skin

Saf Dokunus
 Pure touch

Wet wipes
 ANTI-BACTERIAL

Made in Turkey
 EN 14476:2013+A1

SCK Zeta

Name and address of the manufacturer
 SCK ZETA KIMYA TEMIZLIK VE KOZMETIK URUNLERI SAN. TIC. LTD. STI.
 BEYSAN SANAYI SITESI DEREBOYU CAD. NO:28 HARAMIDERE-BEYLKÖZÜ/İSTANBUL

Name and address of the license holder:
 SCK ZETA DIŞ TIC. PAZ. LTD. STI. Mecidiyeköy Mah. Büyükdere Cad. Kuğu İş Merkezi
 NO: 81 K. Kapı No: 4 Şişli İstanbul (Mülga ibare: RG-21/12/2011-28149)

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NEUTREVO ALCOHOL WET WIPES

alcohol, hydrogen peroxide cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:86818-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	0.125 mL in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86818-005-02	120 in 1 PACKAGE	03/30/2020	
1	NDC:86818-005-01	3.04 mL in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:86818-005-04	100 in 1 PACKAGE	03/30/2020	
2	NDC:86818-005-03	3.04 mL in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:86818-005-06	80 in 1 PACKAGE	03/30/2020	
3	NDC:86818-005-05	3.04 mL in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - SCK ZETA DIS TICARET (356290986)

Registrant - SCK ZETA DIS TICARET (356290986)

Establishment

Name	Address	ID/FEI	Business Operations
SCK ZETA DIS TICARET		356290986	manufacture(86818-005)

