

DICTIONARY HAND AND SKIN DISINFECTANT- alcohol liquid

BEB Kozmetik Urunleri Imalat Sanayi Ticaret AS

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.

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 (0.3% v/v).
- c. 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 80% 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



Dictum
DICTUM HAND AND SKIN DISINFECTANT

GENERAL PUBLIC
BEFORE USING, READ THE LABEL AND THE PROCEDURE

DICTUM HAND AND SKIN DISINFECTANT (v / v)
20L, 10L, 5L, 1L, 500ml, 250ml, 100ml, 50ml PE plastic bottle
Formulation Form: Solution
Active Ingredient Ethyl Alcohol 70%
(Ethanol; CAS Number: 64-17-5, EC Number 200-578-6)
Excipients: 0.3% softener, 29.70% solvent
The opened package protects its content for 3 months provided that it is closed again.
Shelf life is 24 months from the production date.
KEEP AWAY FROM CHILDREN, FOOD AND FEEDS
DO NOT EAT, DRINK, OR USE ANYTHING DURING THE APPLICATION AND PREPARATION.
FOLLOW USE INSTRUCTIONS TO PREVENT RISKS ON HUMAN AND ENVIRONMENTAL HEALTH.
Empty packaging method of destruction: DISPOSE IN ACCORDANCE WITH EMPTY PACKAGING PROCEDURE

How to use
Hygienic Hand and Skin Cleaner:
1.1 Wash and dry hands and skin free of rough dirt
1.2 3ml solution is taken into the palm and rubbed.
Product Type 1: Biocidal Product Related to Human Hygiene
Symptoms of poisoning
LD50 Ethyl Alcohol: 10470 mg / kg Oral rat
First Aid Measures
Inhalation: Remove the patient from the source of exposure and bring it to fresh air. If prolonged contact, get medical attention immediately and show this label.
Skin Contact: Immediately remove the clothing contaminated by the product and wash the parts of the product with plenty of water and soap.
If the garment sticks to the leather, do not remove the garment. Get medical advice.
Eye contact: Remove any lenses. Wash the eyes with plenty of water for at least 15 minutes with the eyelids open. Ingestion: Rinse the patient's mouth with clean water, then drink plenty of water or milk and seek medical attention immediately.
Antidote and necessary information: It has no antidote.
CALL NO 114 TO THE NATIONAL POISON CONSULTING CENTER (UZEM).
MATTERS TO BE CONSIDERED WHEN USING AND STORING THE PRODUCT
At room temperature below 25 °C. Away from light, out of the sight and reach of children
Keep.
-Toxic to bees.
HAZARDOUS EXPRESSION AND EXPLANATION
H319 causes serious eye irritation. H225 Easily flammable: liquid and vapor.
PRECAUTIONARY STATEMENT AND EXPLANATION
P102 - Keep out of the reach of children. P305 + P351 + P338
IF IN EYES: Rinse carefully with water for several minutes.
IF SWALLOWED: Call phone number 114 or doctor / physician of the National Poison Counseling Center. P101 If medical advice is needed, keep the packaging or label.

RUHSAT SAHİBİ: BEB KOZMETİK
ÜRÜNLERİ İMALAT SAN TİC AŞ
KAVACIK MAH ÖZGÜR CAD NO3
BEYKOZ İSTANBUL
FABRIKA : TOSB 3. Cadde No:7
Tepeören / TUZLA
info@beb.com.tr
+90 216 317 24 24
**attention is used externally
undrinkable**

UN NO : 1987
REF :04. 333. 3
LOT: 2002020
BATCH: 0112020
ÜRETİM TARİHİ: 06.2020
SON KULLANMA TARİHİ: 06.2022

MADE IN TURKEY
Turkey

Bakanlık Onayı
Sağlık Bakanlığı Ruhsat Tarihi : 12.06.2020
Sağlık Bakanlığı Ruhsat No : 2020/G208



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DICTUM HAND AND SKIN DISINFECTANT

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79780-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)			ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79780-104-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79780-104-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79780-104-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79780-104-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79780-104-05	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79780-104-06	5000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
7	NDC:79780-104-07	10000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
8	NDC:79780-104-09	20000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/20/2020	

Labeler - BEB Kozmetik Urunleri Imalat Sanayi Ticaret AS (502991071)

Establishment			
Name	Address	ID/FEI	Business Operations
BEB Kozmetik Urunleri Imalat Sanayi Ticaret AS		502991071	manufacture(79780-104)