

HAND SANITIZER- alcohol solution/ drops

LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN

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) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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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away.

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

CAUTION:
Flammable: Keep away from sources of ignition. Avoid contact with eyes and broken / irritated skin

Storage:
Cool and dry place, away from direct sunshine

Made in Turkey

Manufacturer: Laber Kimya Ar-Ge Sanayi Ticaret
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Email: info@laberkimya.com
Web: www.laberkimya.com

Expiry Date:

Packaging: HDPE, PET (Do not reuse)

HAZARDOUS SIGN
DANGER GHS02

NOT TESTED ON ANIMALS

CE

e100ml

CREAMOL

**HAND & SKIN
SANITIZER**

Liquid

• %80 Alcohol •

• With tea tree extract •

• Added moisturiser •

Active Ingredient (w/w): %80 Alcohol Denat (Ethanol) (64-17-5)
Other ingredients (w-w): %1 Glycerine, %0,5 Melaleuca Alternifolia Leaf Extract, %0,5 Hypericum Perforatum Extract, %17,9 Aqua (Deionized Water), %0,1 Perfume

Ready to use formula / Directions: Apply evenly to dry hands
For hygiene reasons please use it in original packaging

FOR EXTERNAL USE ONLY

Stop use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children and pets. In case of swallowing: Drink plenty of water. Poisoning Symptoms: Dizziness, loss of consciousness, slurred speech. Not known antidote. Seek help from your local health authority

Government Approval Date and No: 13.04.2020 – G30

Application and Usage	Amount	App. Frequency
Used for hands and skin. Apply evenly and rub until dries.	3-5ml	According to need

Once opened use within 3 months. 2 years shelf life.

LD50 Doses: Human: 2000mg/kg. Information indicates LC50>15800mg/l

For environmental and health risks, read the label.

Risks identification and explanation: H225 Highly flammable liquid and vapour.
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking P233 Keep container tightly closed. P240 Ground/bond container and receiving equipment. P241 Use explosion-proof electrical/ventilating/lighting/.../equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P370+P378 In case of fire: Evacuate area. P403+P235 Store in a well-ventilated place. Keep cool P501 Dispose of contents/container to the regulations.

Routine Consumer Use: Keep away from food items, beverages and animal fodder. Avoid direct contact with eyes. Just use it as indicated. Do not use on damaged skin. If it comes to spill or irritation, discontinue use.

Not Tested on Animals

100 mL NDC: 77892-0001-1

HAND SANITIZER

alcohol solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77892-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name		Strength		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77892-0001-1	100 mL in 1 BOTTLE, PLASTIC; 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	03/30/2020	

Labeler - LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN (502952094)

Establishment

Name	Address	ID/FEI	Business Operations
LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN		502952094	manufacture(77892-0001)

Revised: 5/2020

LABER KIMYA AR-GE SANAYI TICARET - LEVENT KAHRIMAN