

ANTISEPTIC HAND SANITIZER- alcohol liquid
NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI

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.

BiORAD DERM ANTISEPTIC HAND SANITIZER

Drug Facts

Active ingredient

Alcohol 70%

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

1,3-butandiol, glycerin, isopropyl alcohol, lanolin, fragrance, water

Import Company: Purple Dice LLC

+1-971-235-1506

Monday-Friday 9:00 AM - 5:00 PM

Manufactured by: NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED
SIRKETI, AYTOP GIDA SITE I BLOK, NO:14-1 B GAZI MAHALLESİ SARK CADDESİ
GULGONCASI SOKAK,
SULTANBEYLI, Istanbul (Anatolia), Turkey 34920

COUNTRY OF ORIGIN: TURKEY

Packaging



ANTISEPTIC HAND SANITIZER

70% ALCOHOL

33.81 fl oz (1 qt 1.81 fl oz) (1000 mL)



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COUNTRY OF ORIGIN: TURKEY

Lot No:

Expiry:



GHS 07



GHS 02

RM 3204



8 1699856 175204 5

ANTISEPTIC HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79455-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LANOLIN (UNII: 7EV65EAW6H)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79455-001-01	0.03 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
2	NDC:79455-001-02	0.05 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
3	NDC:79455-001-03	0.1 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
4	NDC:79455-001-04	0.25 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
5	NDC:79455-001-05	0.5 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
6	NDC:79455-001-06	0.7 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
7	NDC:79455-001-07	1 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
8	NDC:79455-001-08	2 L in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2020	
9	NDC:79455-001-09	5 L in 1 CAN; Type 0: Not a Combination Product	07/13/2020	
10	NDC:79455-001-10	10 L in 1 CAN; Type 0: Not a Combination Product	07/13/2020	
11	NDC:79455-001-11	20 L in 1 DRUM; Type 0: Not a Combination Product	07/13/2020	
12	NDC:79455-001-12	30 L in 1 DRUM; Type 0: Not a Combination Product	07/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/13/2020	

Labeler - NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI
(355742649)

Establishment

Name	Address	ID/FEI	Business Operations
NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI		355742649	manufacture(79455-001)

Revised: 7/2020

NECM KIMYA AKARYAKIT URUNLERI MEDIKAL MALZEMELER SANAYI VE TICARET LIMITED SIRKETI