

HAND SANITIZER EARTHZEN- hand saniziter earthzen gel
PROBEMEX S.A. DE CV

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.

HAND SANITIZER EARTHZEN

ACTIVE INGRIDIENT

ETHYL ALCOHOL 70%

PURPOSE

ANTISEPTIC

STOP USE

STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH APPEARS AND LAST. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY

WARNING

WARNINGS: FLAMMABLE KEEP AWAY FROM HEAT OR FLAME. FOR EXTERNAL USE ONLY. WHEN USING THIS PRODUCT DO NOT USE IN OR NEAR THE YES. IN CASE OF CONTACT RINSE EYE THROUGHLY WITH WATER

DO NOT USE ON CHILDREN LESS THAN 2 MONTHS OF AGE. OPEN SKIN WOUNDS AVOID CONTACT WIITH BROKER SKIN

DIRECTIONS

PLACE ENOUGH PRODUCTO NO HANDS TO COVER ALL SUFACES. 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. AVOID FREEZING AND EXCESSIVE HEAT ABOCE 40C

MAY DISCOLOR CERTAIN FABRIC OR SUFACES

INACTIVE

WATER, CARBOMER PROPANEDIOL AMINOMETHYL PROPANOL PEG 40 HYDROGENATED CASTOR OIL GLYCERIN

WARNING

WARNING FLAMMABLE KEEP AWAY FROM HEAT

DOSAGE

PLACE ENOUGH PRODUCT ON HANDS TO COVER ALL SURFACE

KEEP OUT OF REACH

KEEP OUT OF REACH OF CHILDREN

PACKAGE



42955-011-01

42955-011-02

42955-011-03

HAND SANITIZER EARTHZEN

hand saniziter earthzen gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42955-011
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
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	0.22 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.9 mL in 100 mL
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	0.14 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.001 mL in 100 mL
PROPANEDIOL (UNII: 5965N8W85T)	0.51 mL in 100 mL
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	0.33 mL in 100 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42955-011-01	52 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2020	
2	NDC:42955-011-03	1.5 mL in 1 DOSE PACK; Type 0: Not a Combination Product	08/12/2020	
3	NDC:42955-011-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/12/2020	



EARTHZEN
Hand Sanitizer Gel
Kills 99.99% of germs*

Formulated with
70%
of alcohol

With Moisturizers
1.7 OZ (50 gr)

NDC 42955-001-XX
UG0005

DRUG FACTS				
<table border="1"> <thead> <tr> <th>ACTIVE INGREDIENT</th> <th>PURPOSE</th> </tr> </thead> <tbody> <tr> <td>Ethyl Alcohol 70% v/v</td> <td>Antiseptic</td> </tr> </tbody> </table>	ACTIVE INGREDIENT	PURPOSE	Ethyl Alcohol 70% v/v	Antiseptic
ACTIVE INGREDIENT	PURPOSE			
Ethyl Alcohol 70% v/v	Antiseptic			
<p>Uses: Hand sanitizer to help reduce germs on the skin. Recommended for repeated use.</p> <p>Warnings: FLAMMABLE. Keep away from heat or flame. For external use only. When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Do not use: On children less than 2 months of age. On open skin wounds. Avoid contact with broken skin, do not inhale or ingest.</p> <p>Step use and ask a doctor if irritation or rash appears and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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 (59-86 F). Avoid freezing and excessive heat above 40C (104 F). May discolor certain fabrics or surfaces.</p> <p>Inactive ingredients: Water (Aqua), Carbomer, Propenediol, Aminomethyl Propanol, PEG-40 Hydrogenated Castor Oil, Glycerin, Fragrance.</p> <p>* Effective at eliminating more than 99.99% of many common harmful germs and bacteria.</p>				
 <p>8 50019 50400 2</p>				
<p>Made in Mexico for: Probemex S.A. de C.V. Residencia 17 Col. Jardines del Sur, Ixtachilco, Ciudad de Mexico, Mexico. C.P. 06500 Dist. in the U.S.A. by: Terra Beauty, LLC 1396 Banyan Way Weston FL 33327</p>				

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/12/2020	

Labeler - PROBEMEX S.A. DE CV (813566395)

Registrant - PROBEMEX S.A. DE CV (813566395)

Establishment

Name	Address	ID/FEI	Business Operations
PROBEMEX S.A. DE CV		813566395	manufacture(42955-011)

