KTM POWER HAND- ethyl alcohol gel Regenera y Transforma, S.A. de C.V.

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.

KTM POWER HAND HAND SANITIZER

Drug facts

Active ingredients Ethyl alcohol 70% v/v

purpose

antiseptic

Use[s]

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.

When using this product

Do not use on open skin wounds.

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

Do not use in children less than 2 months of age.

If swallowed, get medical help or contact a Poison Center right away.

Directions

Place enough product on hands to cover all surfaces thoroughly. 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)

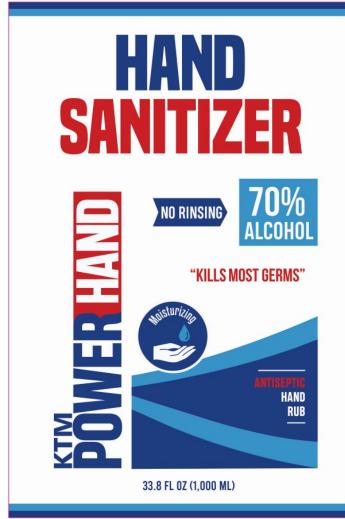
Inactive Ingredients

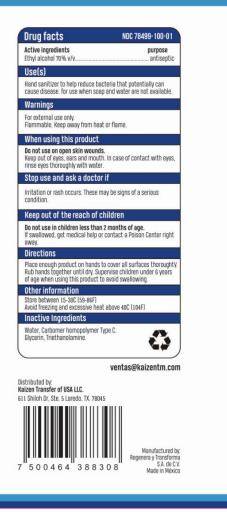
Water, Carbomer homopolymer Type C, Glycerin, Triethanolamine.

NO RINSING 70% ALCOHOL "KILLS THE MOST GERMS" Moisturizing ANTISEPTIC HAND RUB ventas@kaizentm.com Distributed by: Kaizen Transfer of USA LLC. 611 Shiloh Dr, Ste. 5 Laredo, TX. 78045 Manufactured by: Regenera y Transforma S.A.de C.V.

Packaging









K'I'	M POWER	HAND							
ethy	l alcohol gel								
Pro	oduct Informa	tion							
Product Type		HUMAN OTC DRUG Item Code (Source)		NDC:78499-100					
Rou	te of Administra	ition	TOPICAL						
Active Ingredient/Active Moiety									
		Ingred	lient Name		Basis of Strength		h Strength		
ALC	OHOL (UNII: 3K9	958V90M) (ALC	COHOL - UNII:3K9958V90M)		ALCOHOL	70 mL in	100 mL		
Inactive Ingredients									
Ingredient Name									
WAT	FER (UNII: 059QF0)KO0R)							
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)									
GLYCERIN (UNII: PDC6A3C0OX)									
TRO	LAMINE (UNII: 9	O3K93S3TK)							
Packaging									
#	Item Code		Package Description	I	Marketing Start Date	Marketing	g End Date		

1	NDC:78499-100-01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Produc	t 06/15/2020	
2	NDC:78499-100- 04	4000 mL in 1 BOTTLE; Type 0: Not a Combination Produc	t 06/15/2020	
3	NDC:78499-100- 05	3780 mL in 1 BOTTLE; Type 0: Not a Combination Produc	t 06/23/2020	
N	Iarketing Inf	ormation		
	farketing Inf		Marketing Start Date	Marketing End Date
	0	ry Application Number or Monograph Citation	Marketing Start Date 06/15/2020	Marketing End Date

Labeler - Regenera y Transforma, S.A. de C.V. (951577608)

Establishment

Name	Address	ID/FEI	Business Operations
Regenera y Transforma, S.A. de C.V.		951577608	manufacture(78499-100)

Revised: 6/2020

Regenera y Transforma, S.A. de C.V.