

XTREME PERSONAL CARE HAND SANITIZER- alcohol gel
Taizhou Yadai Daily-Use Co., Ltd.

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.

52989-004

Active Ingredient(s)

Ethyl Alcohol 70% v/v

Purpose

Antimicrobial

Use

Hand sanitizer to help decrease bacteria on the skin

Warnings

For external use only. Flammable. Keep away from heat or flame

When using this product, keep out of eyes, ears or mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs, these may be signs of serious condition.

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

Directions

- Apply onto hands/skin, rub until dry

Inactive ingredients

Water, Triethanolamine, Carbomer, Aloe Barbadensis Leaf Juice, Glycerin, Fragrance, Propylene Glycol, Tocopheryl Acetate

072 C 7688 C 185 C



XTREME™
PERSONAL CARE

**HAND
SANITIZER
GEL**

**ANTIBACTERIAL
KILLS 99.9% GERMS**

2 fl oz
(60 mL)

EXP DATE:

Drug Facts

Active ingredient(s)	Purpose
Alcohol 70%.....	Antimicrobial

Use hand sanitizer to help reduce bacteria on the skin

Warnings
For external use only. Flammable. Keep away from heat or flame.

When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse 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 immediate medical help or contact a poison control center right away.

Directions Apply onto hands/skin, rub until dry.

Inactive ingredients Water, Triethanolamine, Carbomer, Aloe Barbadensis Leaf Juice, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate

Distributed by
Xtreme Personal Care
Edison, NJ 08817
877-536-8766
Product of China
Lot #

#CXS1-9100-BLU

8 05106 84271 0

XTREME PERSONAL CARE HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52989-004
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)	
CARBOMER 934 (UNII: Z135WT9208)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52989-004-01	20 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2020	
2	NDC:52989-004-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2020	
3	NDC:52989-004-03	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/19/2020	

Labeler - Taizhou Yadai Daily-Use Co., Ltd. (529899639)

Establishment

Name	Address	ID/FEI	Business Operations
Taizhou Yadai Daily-Use Co., Ltd.		529899639	manufacture(52989-004)

Revised: 6/2020

Taizhou Yadai Daily-Use Co., Ltd.