

HAND SANITIZER- alcohol gel
Audy Global Enterprises Inc.

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.

Active Ingredient(s)

Ethyl Alcohol 70%

Purpose

Antimicrobial

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.

Keep the lid of this container tightly closed.

Inactive ingredients

Carpobol 90, T.E.A Triethanolamine, Glycerin

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)

Package Label - Principal Display Panel

60 mL NDC:75778-005-60

DRUG FACTS	
Active Ingredient Ethyl Alcohol 70% v/v	Purpose Antimicrobial
Use • Place the product in a dispenser if desired. • 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 • On 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.	
Inactive Ingredients: Carbopol 90, T.E.A Triethanolamine, Glycerin.	
Keep the lid of this container tightly closed.	
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 15-30oC (59-86oF) • Avoid freezing and excessive heat above 40oC (104oF)	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	




ADVANCED HAND SANITIZER

70% ALCOHOL
FAST ACTING FORMULA
KILLS 99.9% OF GERMS

4oz (118 ML)

NET CONTENT	118 ML
BATCH NO.	EXPIRATION DATE

HOW TO USE HAND SANITIZER



PREVENTION OF CROSS INFECTION TAKE CARE OF YOUR LOVED ONES

Distributed by:
AUDYGLOBAL
ENTERPRISES
1457 VFW Pkwy, West Roxbury, MA 02132,
United States. www.audyglobal.com
For Any Concerns Contact Us at: (617) 379-0023
customerservice@audyglobal.com



KEEP OUT OF REACH OF CHILDREN.
If swallowed, get medical help or contact a Poison Control Center right away.



MADE IN MEXICO

118 mL NDC:75778-005-11

DRUG FACTS	
Active Ingredient Ethyl Alcohol 70% v/v	Purpose Antimicrobial
Use • Place the product in a dispenser if desired. • 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 • On 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.	
Inactive Ingredients: Carbopol 90, T.E.A Triethanolamine, Glycerin.	
Keep the lid of this container tightly closed.	
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 15-30oC (59-86oF) • Avoid freezing and excessive heat above 40oC (104oF)	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	




ADVANCED HAND SANITIZER

70% ALCOHOL
FAST ACTING FORMULA
KILLS 99.9% OF GERMS

8oz (236 ML)

NET CONTENT	236 ML
BATCH NO.	EXPIRATION DATE

HOW TO USE HAND SANITIZER



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KEEP OUT OF REACH OF CHILDREN.
If swallowed, get medical help or contact a Poison Control Center right away.



MADE IN MEXICO

236 mL NDC:75778-005-23

DRUG FACTS	
Active Ingredient Ethyl Alcohol 70% v/v	Purpose Antimicrobial
Use <ul style="list-style-type: none"> Place the product in a dispenser if desired. 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 <ul style="list-style-type: none"> On 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.	
Inactive Ingredients: Carbopol 90, T.E.A Triethanolamine, Glycerin.	
Keep the lid of this container tightly closed.	
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30oC (59-86oF) Avoid freezing and excessive heat above 40oC (104oF) 	
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.

MADE IN MEXICO

NET CONTENT	473ML
BATCH NO.	EXPIRATION DATE

HOW TO USE HAND SANITIZER

PREVENTION OF CROSS INFECTION

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473 mL NDC:75778-005-47

DRUG FACTS	
Active Ingredient Ethyl Alcohol 70% v/v	Purpose Antimicrobial
Use <ul style="list-style-type: none"> Place the product in a dispenser if desired. 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 <ul style="list-style-type: none"> On 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.	
Inactive Ingredients: Carbopol 90, T.E.A Triethanolamine, Glycerin.	
Keep the lid of this container tightly closed.	
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30oC (59-86oF) Avoid freezing and excessive heat above 40oC (104oF) 	
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.

MADE IN MEXICO

NET CONTENT	60 ML
BATCH NO.	EXPIRATION DATE

HOW TO USE HAND SANITIZER

PREVENTION OF CROSS INFECTION

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HAND SANITIZER
alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75778-005
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)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYACRYLIC ACID (800000 MW) (UNII: D0I6NSZ87U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75778-005-60	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/19/2020	
2	NDC:75778-005-11	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/19/2020	
3	NDC:75778-005-23	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	06/19/2020	
4	NDC:75778-005-47	473 mL in 1 BOTTLE, DISPENSING; 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 - Audy Global Enterprises Inc. (079171473)**Establishment**

Name	Address	ID/FEI	Business Operations
GRUPO DE ZAVALA S.A. DE C.V.		951577304	manufacture(75778-005)

Revised: 6/2020

Audy Global Enterprises Inc.