

CHIMBORAZO HAND SANITIZER- ethyl alcohol gel
Chimborazo LLC

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.

This is a hand sanitizer manufactured according to the FDA OTC Hand Sanitizer Monograph. The hand sanitizer is manufactured using only the following ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) and Center for Disease Control (CDC) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerin (1.00% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile water or boiled cold water.
- e. Carbomer 940 (<0.5% v/v)
- f. Tea Tree Oil (0.17% v/v)
- g. Lavender Oil (0.17% v/v)
- h. Triethylamine (<0.2% v/v)
- i. Trace amounts of activated charcoal from filtration of the ethanol

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

For external use only. Flammable. Keep away from heat or flame. Allergy Alert: Contains Tea Tree Oil.

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

Control Center right away.

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.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 10 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

glycerin, hydrogen peroxide, water, activated charcoal, carbomer 940, denatonium benzoate, tea tree oil

Package Label - Principal Display Panel

General Label:

Tea Tree Label

“Fragrance” in the ingredients rather than “tea tree oil”:



HAND SANITIZER
With Activated Charcoal and Tea Tree Oil

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Uses	
Hand rub to help reduce bacteria on the skin.	
Warnings	
For external use only. Flammable. Keep away from heat or flame. Allergy Alert: Contains Tea Tree Oil	
Do not use:	
<ul style="list-style-type: none"> • 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. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 10 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Activated Charcoal, Carbomer 940*, Denatonium Benzoate, Glycerin, Hydrogen Peroxide, Tea Tree Oil, Water	
*Gelled using triethylamine	
Questions? Chimborazo LLC 970-417-1603	

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Uses	
Hand rub to help reduce bacteria on the skin.	
Warnings	
For external use only. Flammable. Keep away from heat or flame. Allergy Alert: Essential Oils	
Do not use:	
<ul style="list-style-type: none"> • 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. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 10 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Activated Charcoal, Carbomer 940*, Denatonium Benzoate, Fragrance, Glycerin, Hydrogen Peroxide, Water	
*Gelled using triethylamine	
Questions? Chimborazo LLC 970-417-1603	

60 mL OR 2 oz. NDC: 80052-001-01:



HAND SANITIZER

With Activated Charcoal and Tea Tree Oil

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Uses	
Hand rub to help reduce bacteria on the skin.	
Warnings	
For external use only. Flammable. Keep away from heat or flame. Allergy Alert: Contains Tea Tree Oil	
Do not use:	
<ul style="list-style-type: none"> • 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.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 10 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Activated Charcoal, Carbomer 940*, Denatonium Benzoate, Glycerin, Hydrogen Peroxide, Tea Tree Oil, Water	
*Gelled using triethylamine	
Questions? Chimborazo LLC 970-417-1603	

2 oz.

240 mL OR 8 oz. NDC: 80052-001-02



HAND SANITIZER

With Activated Charcoal and Tea Tree Oil

Drug Facts	
Active ingredient[s]	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial
Uses	
Hand rub to help reduce bacteria on the skin.	
Warnings	
For external use only. Flammable. Keep away from heat or flame. Allergy Alert: Contains Tea Tree Oil	
Do not use:	
<ul style="list-style-type: none"> • 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.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 10 years of age when using this product to avoid swallowing. 	
Other information	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Activated Charcoal, Carbomer 940*, Denatonium Benzoate, Glycerin, Hydrogen Peroxide, Tea Tree Oil, Water	
*Gelled using triethylamine	
Questions? Chimborazo LLC 970-417-1603	

8 oz.

3785 mL OR 128 oz. NDC: 80052-001-03



HAND SANITIZER

With Activated Charcoal and Tea Tree Oil

Drug Facts	
Active ingredient[s] Ethyl Alcohol 70% v/v.....	Purpose Antimicrobial
Uses Hand rub to help reduce bacteria on the skin.	
Warnings For external use only. Flammable. Keep away from heat or flame. Allergy Alert: Contains Tea Tree Oil Do not use: <ul style="list-style-type: none"> • 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. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 10 years of age when using this product to avoid swallowing. 	
Other information <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients Activated Charcoal, Carbomer 940*, Denatonium Benzoate, Glycerin, Hydrogen Peroxide, Tea Tree Oil, Water *Gelled using triethylamine	
Questions? Chimborazo LLC 970-417-1603	

128 oz.

CHIMBORAZO HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80052-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL
Inactive Ingredients			
	Ingredient Name		Strength

DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.000005 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 1 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.004 mL in 1 mL
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.0017 mL in 1 mL
TEA TREE OIL (UNII: VIF565UC2G)	0.0017 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.2742 mL in 1 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.005 mL in 1 mL
TRIETHYLAMINE (UNII: VOU728O6AY)	0.002 mL in 1 mL
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	0.0001 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80052-001-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/20/2020	
2	NDC:80052-001-02	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/20/2020	
3	NDC:80052-001-03	3786 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/11/2020	

Labeler - Chimborazo LLC (130532330)

Registrant - Chimborazo LLC (130532330)

Establishment

Name	Address	ID/FEI	Business Operations
Chimborazo LLC		130532330	manufacture(80052-001) , label(80052-001)

Revised: 12/2020

Chimborazo LLC