HAND SANITIZER- alcohol liquid DBT Holdings, 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 Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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.

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 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

glycerin, hydrogen peroxide, purified water USP

Active ingredient[s]	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	
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 eye	s, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious co	ndition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Contro	ol Center right away.
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) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

7570.8 mL NDC: 74333-0001-2



Sanitizer Non-sterile Solution

7.57 L (7570.8 mL)

NDC: 74333-0001-2

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	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	
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.	
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) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

3785.4 mL NDC: 74333-0001-3



Sanitizer Non-sterile Solution

3.79 L (3785.4 mL)

NDC: 74333-0001-3



Alcohol Antiseptic 80%

Non-sterile Solution Topical Solution DBT Holdings, LLC 74333-0001-3

1 gal (128 fl.oz)



Alcohol Antiseptic 80% Topical Solution

Non-Sterile Solution

NDC 74333-0001-3

1gal (128 fl.oz)

ug Facts	
t <i>ive ingredient [s]</i> ohol 80% v/v.	Purpose Antiseptic
e [s] nd Sanitizer to help reduce bacteria that j ease. For use when soap and water are r	
arnings r external use only. Flammable. Keep a me.	away from heat or
n ot use n children less than 2 months of age in open skin wounds	
en using this product keep out of eyes, e of contact with eyes, rinse eyes thorough	
p use and ask a doctor if irritation or ra y be signs of a serious conditions.	sh occurs. These
ep out of reach of children. if swallowed tact a poison control center right away.	d, get medical help o
rections Place enough product on hands to cover a ands together until dry. Supervise children under 6 years of age w roduct to avoid swallowing.	
rections Store between 15-30C (59-86F) Woid freezing and excessive heat above	40C (104F)
active ingredients glycerin, hydroge rified water USP	en peroxide,

Dir • S • A Ina pur



Drug Facts	믛
Active Ingredient(s) Purpose	2
Alcohol 70% v/v Antiseptic	g
Use(s) Hand nub to decrease bacteria on the skin that sould cause decase. For use when ecap and water are not available.	buted by Taylor
Warnings For external use only. Flammable. Keep away from heat or flame	or Comm
Do not use • On children less than 2 months of age • On open skin wounds	ercial Fo
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse yes thoroughly with water.	oodae
Step use and ask a deeter if instation or rash occurs. These may be signs of a serius condition.	Nice
Keep out of reach of children. It swalkwed, get medical help or contact Poison Control Center right away.	10
Directions - Place enough poduct on hends is cover all sariace. Richtends lagehor will day. - Spanvise differe under it years of age when using this product is weld availabeing.	Rockton, IL (8
Other Information - Store between 15-00C (59-06F) - Avoid freezing and excessive heat above 40C (104F)	IL (815) 624-8333
Inactive Ingredients Fragrance (parlum), Glycerin, PEG-6 (and) AMP-Acrylales-Vinyl Isodecancate Crosspolymer, Purtled Water USP.	8333



Hand Sanitizer Non-sterile Solution

208.12 L (208197.65 mL)

NDC: 74333-0001-4

208197.65 mL NDC: 74333-0001-4

Drug Facts
ctive ingredient[s] Purpose
lcohol 80% v/vAntiseptic
lse[s]
and Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
Varnings
or external use only. Flammable. Keep away from heat or flame
o not use
in children less than 2 months of age
on open skin wounds
/hen using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
top use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
eep 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 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)
nactive ingredients glycerin, hydrogen peroxide, purified water USP



Alcohol Antiseptic 80%

Non-sterile Solution Topical Solution DBT Holdings, LLC 74333-0001-4

55 gal (7040 fl. oz)

Active ingredient [s] Alcohol 80% v/v	Purpose Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria that disease. For use when soap and water are	
Warnings For external use only. Flammable. Keep flame.	away from heat or
Do not use In children less than 2 months of age on open skin wounds 	
When using this product keep out of eyes case of contact with eyes, rinse eyes thorout	
Stop use and ask a doctor if irritation or ra may be signs of a serious conditions.	ash occurs. These
Keep out of reach of children. if swallowe contact a poison control center right away.	ed, get medical help o
Directions Place enough product on hands to cover hands together until dry. Supervise children under 6 years of age product to avoid swallowing.	
Directions Store between 15-30C (59-86F) Avoid freezing and excessive heat above	40C (104F)



Hand Sanitizer Non-sterile Solution

1040.99 L (1040988.24 mL)

NDC: 74333-0001-5

1040988.24 mL NDC: 74333-0001-5

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s]	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and wate	er 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 the	horoughly 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.
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) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



Alcohol Antiseptic 80%

Non-sterile Solution Topical Solution DBT Holdings, LLC 74333-0001-5

275 gal (35200 fl. oz)

18927.1 mL NDC: 74333-0001-1

Active ingredient [s]	Purpose
Alcohol 80% v/v	Antiseptic
Use[s] Hand Sanitizer to help reduce bacteria tha disease. For use when soap and water are	
Warnings For external use only. Flammable. Keep flame.	away from heat or
 Do not use In children less than 2 months of age on open skin wounds 	
When using this product keep out of eye case of contact with eyes, rinse eyes thoro	
Stop use and ask a doctor if irritation or r may be signs of a serious conditions.	ash occurs. These
Keep out of reach of children. if swallow contact a poison control center right away.	ed, get medical help o
Directions	
 Place enough product on hands to cover hands together until dry. 	all surfaces. Hub
 Supervise children under 6 years of age product to avoid swallowing. 	when using this
Directions	
 Store between 15-30C (59-86F) Avoid freezing and excessive heat above 	e 40C (104F)
Inactive ingredients glycerin, hydrod	en peroxide



Hand Sanitizer Non-sterile Solution

18.93 L (18927.1 mL)

NDC: 74333-0001-1

Alcohol 80% v/vAntiseptic 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 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. 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)	Drug Facts	
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 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. 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)	Active ingredient[s]	Purpose
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. 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)	Alcohol 80% v/v	Antiseptic
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. 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)	Use[s]	
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. 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)	Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap	and water are not available.
 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. 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) 	Warnings	
 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. 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) 	For external use only. Flammable. Keep away from heat or flame	
 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. 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) 	Do not use	
 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. 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) 	 in children less than 2 months of age 	
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 6 years of age when using this product to avoid swallowing. Other information • Store between 15-30C (59-86F)	on open skin wounds	
 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 6 years of age when using this product to avoid swallowing. Other information Store between 15-30C (59-86F) 	When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rin:	se eyes thoroughly with water.
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)	Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition	on.
 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) 	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Cer	nter right away.
 Supervise children under 6 years of age when using this product to avoid swallowing. Other information Store between 15-30C (59-86F) 	Directions	
Other information • Store between 15-30C (59-86F)	 Place enough product on hands to cover all surfaces. Rub hands together until dry. 	
Store between 15-30C (59-86F)	 Supervise children under 6 years of age when using this product to avoid swallowing. 	
	Other information	
 Avoid freezing and excessive heat above 40C (104F) 	• Store between 15-30C (59-86F)	
	 Avoid freezing and excessive heat above 40C (104F) 	
	Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



Alcohol Antiseptic 80%

Non-sterile Solution Topical Solution DBT Holdings, LLC 74333-0001-1



 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, mise eyes thoroughly with water.

 Stop use and ask a doctor if irritation or rash occurs. These may be signs of a sericus conditions.

 Keep out of reach of children. if swallowed, get medical help or contract a poison control center right away.

 Directions

 • Store between 15-30C (59-88F)

 • Avoid freezing and excessive heat above 40C (104F)

 Inactive ingredients glycerin, hydrogen peroxide, putfield water USP

Use[s] Hand Sanitizer to help reduce bacteria that potentially can caus disease. For use when soap and water are not available.

Purpose Antiseptic

Drug Facts Active ingredient [s] Alcohol 80% v/v



HAND SANITIZER alcohol liquid

Product Infor	mation	1					
Product T ype			HUMAN OTC DRUG	Item Code	(Source)	ND	DC:74333-0001
Route of Admini	stration	1	TOPICAL				
Active Ingred	ient/A	ctive Moi	ety				
		Ingred	ient Name		Basis of St	rength	Strength
ALCOHOL (UNII:	3K9958	V90M) (ALC	OHOL - UNII:3K9958V90M))	ALCOHOL		80 mL in 100 mL
Inactive Ingre	dients						
		Ing	gredient Name			S	trength
GLYCERIN (UNII:					1.45 n	nL in 100 i	mL
HYDRO GEN PER	O XIDE (UNII: BBX06	0 AN9 V)		0.125	mL in 100) mL
	QF0KO	0 R)					
Packaging	QF0KO	0 R)			Marketin	a Start	Marketing End
Packaging	OQF0KO	0 R)	Package Description		Marketin Dat	•	Marketing End Date
Packaging # Item Code		7.1 mL in 1 C	Package Description DNTAINER; Type 0: Not a Co	o mbina tio n		•	-
Backaging Item Code NDC:74333- 0001-1 NDC:74333- 0001-2	18927 Pro du	7.1 mL in 1 CC ct			Dat 03/30/2020	•	-
Packaging Item Code NDC:74333- 0001-1 NDC:74333- 0001-2 NDC:74333- 0001-2 NDC:74333- 0001-3	18927 Produ 7570. 3785.	7.1 mL in 1 CC ct 8 mL in 1 CO 4 mL in 1 CO	ONTAINER; Type 0: Not a Co NTAINER; Type 0: Not a Co NTAINER; Type 0: Not a Cor	mbination Produc	Dat 03/30/2020 t 03/30/2020	•	-
Packaging Item Code DC:74333- DC:74333- <td>18927 Produ 7570. 3785. 20819 Produ</td> <td>7.1 mL in 1 CC ct 8 mL in 1 CO 4 mL in 1 CO 07.65 mL in 1 ct</td> <td>ONTAINER; Type 0: Not a Co ONTAINER; Type 0: Not a Con NTAINER; Type 0: Not a Con CONTAINER; Type 0: Not a</td> <td>mbination Produc mbination Produc Combination</td> <td>Dat 03/30/2020 t 03/30/2020</td> <td>•</td> <td>-</td>	18927 Produ 7570. 3785. 20819 Produ	7.1 mL in 1 CC ct 8 mL in 1 CO 4 mL in 1 CO 07.65 mL in 1 ct	ONTAINER; Type 0: Not a Co ONTAINER; Type 0: Not a Con NTAINER; Type 0: Not a Con CONTAINER; Type 0: Not a	mbination Produc mbination Produc Combination	Dat 03/30/2020 t 03/30/2020	•	-
Packaging # Item Code 1 NDC:74333- 0001-1 2 NDC:74333- 0001-2 3 NDC:74333- 0001-3 4 NDC:74333-	18927 Produ 7570. 3785. 20819 Produ	7.1 mL in 1 CC ct 8 mL in 1 CC 4 mL in 1 CO 07.65 mL in 1 ct 988.24 mL in	ONTAINER; Type 0: Not a Co NTAINER; Type 0: Not a Co NTAINER; Type 0: Not a Cor	mbination Produc mbination Produc Combination	 Dat 03/30/2020 03/30/2020 03/30/2020 	•	-
NDC:74333- 0001-1 NDC:74333- 0001-2 NDC:74333- 0001-3 NDC:74333- 0001-4 NDC:74333- 0001-5	18927 Produ 7570. 3785. 20819 Produ 10409 Produ	7.1 mL in 1 CO ct 8 mL in 1 CO 4 mL in 1 CO 97.65 mL in 1 ct 988.24 mL in ct	ONTAINER; Type 0: Not a Co ONTAINER; Type 0: Not a Con NTAINER; Type 0: Not a Con CONTAINER; Type 0: Not a	mbination Produc mbination Produc Combination	Dat 03/30/2020 t 03/30/2020 t 03/30/2020 t 03/30/2020	•	-
P-ckaging # Item Code 1 NDC:74333- 0001-1 2 NDC:74333- 0001-2 3 NDC:74333- 0001-3 4 NDC:74333- 0001-4 5 NDC:74333-	 18927 Produ 7570. 3785. 20819 Produ 10409 Produ 	7.1 mL in 1 CC ct 8 mL in 1 CC 4 mL in 1 CO 07.65 mL in 1 ct 088.24 mL in ct	ONTAINER; Type 0: Not a Co ONTAINER; Type 0: Not a Con NTAINER; Type 0: Not a Con CONTAINER; Type 0: Not a	mbination Produc mbination Produc Combination a Combination	Dat 03/30/2020 t 03/30/2020 t 03/30/2020 t 03/30/2020	e	-

Labeler - DBT Holdings, LLC (858460095)

Establishment

Name	Address	ID/FEI	Business Operations
DBT Holdings, LLC		858460095	manufacture(74333-0001)