

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION- alcohol liquid

Cytec Industries 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.

Hand Sanitizer 80

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

Package Label - Principal Display Panel

165 kg NDC: 60378-080-01

<p>Alcohol Antiseptic 80% Topical Solution</p> <p>Hand Sanitizer Non-sterile Solution</p> <p>165 kgs (364 lbs)</p> <p>Expiry Date: _____</p> <p>NDC#: 60378-080-01</p> <p>Manufactured by: Cytex Industries Inc. 7910 Mt. Joy Rd Mt. Pleasant, TN 38474 Ph.: 1-800-438-5615</p> <p>Lot Number: _____</p> <p>Container Number: _____</p> <p>Made in the USA</p>	<p>Drug Facts</p>				
	<table border="1"> <thead> <tr> <th>Active ingredient[s]</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Alcohol 80% v/v.....</td> <td>Antiseptic</td> </tr> </tbody> </table>	Active ingredient[s]	Purpose	Alcohol 80% v/v.....	Antiseptic
	Active ingredient[s]	Purpose			
	Alcohol 80% v/v.....	Antiseptic			
	<p>Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</p>				
	<p>Warnings For external use only. Flammable. Keep away from heat or flame.</p>				
	<p>Do not use</p> <ul style="list-style-type: none"> • in children less than 2 months of age • on open skin wounds 				
	<p>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</p>				
	<p>Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</p>				
	<p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>				
<p>Directions</p> <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. 					
<p>Other information</p> <ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 					
<p>Inactive ingredients glycerin, hydrogen peroxide, purified water USP</p>					

Manufactured as per US FDA’s guidance on ‘Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)’ March 2020, Updated April 15, 2020.

830kg NDC: 60378-080-02

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution 830 kgs (1,830 lbs) Expiry Date: _____ NDC#: 60378-080-02 Manufactured by: Cytec Industries Inc. 7910 Mt. Joy Rd Mt. Pleasant, TN 38474 Ph.: 1-800-438-5615 Lot Number: _____ Container Number: _____ Made in the USA	Drug Facts				
	<table border="0"> <tr> <td>Active ingredient[s]</td> <td style="text-align: right;">Purpose</td> </tr> <tr> <td>Alcohol 80% v/v.....</td> <td style="text-align: right;">Antiseptic</td> </tr> </table>	Active ingredient[s]	Purpose	Alcohol 80% v/v.....	Antiseptic
	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 <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. 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 <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 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 					
Inactive ingredients glycerin, hydrogen peroxide, purified water USP					

Manufactured as per US FDA's guidance on 'Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)' March 2020, Updated April 15, 2020.

20 kg NDC: 60378-080-03

Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution 20 kgs (44 lbs) Expiry Date: _____ NDC#: 60378-080-03 Manufactured by: Cytec Industries Inc. 7910 Mt. Joy Rd Mt. Pleasant, TN 38474 Ph.: 1-800-438-5615 Lot Number: _____ Container Number: _____ Made in the USA	Drug Facts				
	<table border="0"> <tr> <td>Active ingredient[s]</td> <td style="text-align: right;">Purpose</td> </tr> <tr> <td>Alcohol 80% v/v</td> <td style="text-align: right;">Antiseptic</td> </tr> </table>	Active ingredient[s]	Purpose	Alcohol 80% v/v	Antiseptic
	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 <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. 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 <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 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 					
Inactive ingredients glycerin, hydrogen peroxide, purified water USP					

Manufactured as per US FDA's guidance on 'Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)' dated March 27, 2020.

ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60378-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 kg in 100 kg

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 kg in 100 kg
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 kg in 100 kg
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60378-080-01	165 kg in 1 DRUM; Type 0: Not a Combination Product	05/04/2020	
2	NDC:60378-080-02	830 kg in 1 TANK; Type 0: Not a Combination Product	05/04/2020	
3	NDC:60378-080-03	20 kg in 1 JUG; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - Cytec Industries Inc. (809749948)**Registrant** - Cytec Industries Inc. (004038550)**Establishment**

Name	Address	ID/FEI	Business Operations
Cytec Industries Inc.		004038550	manufacture(60378-080)

Revised: 4/2020

Cytec Industries Inc.