

HAND SANITIZER BLEND 1- alcohol liquid

Dimachem 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.

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

946 ml NDC: 78158-001-01



Drug Facts	Purpose
Active ingredient(s) 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	

Manufactured by Dimachem Inc., Windsor, ON, Canada, 519-969-5570, dimacheminc.com

Lot# / Date:



3.78 L NDC: 78158-001-02

DIMACHEM

Hand Sanitizer Blend #1

Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer Non-sterile Solution

3.78 L (1 gallon)

NDC: 78158-001-02

Drug Facts	
Active ingredient(s) Alcohol 80% v/v	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	
<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 15-30°C (59-86°F) Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

Manufactured by Dimachem Inc., Windsor, ON, Canada, 519-969-5570, dimacheminc.com

Lot# / Date:



20 L NDC: 78158-001-03

DIMACHEM

HAND SANITIZER BLEND #1

DIMACHEM INC.
3258 MARENTETTE AVE., WINDSOR ON N8X 4G4
(519) 969-5570



UN1987

ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)
CLASS: 3
PG: III
PLACARD: FLAMMABLE



IN CASE OF EMERGENCY CALL
EN CAS D'URGENCE APPELER
CANUTEC (613) 996-6666

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

20 L (20000 mL)
NDC: 78158-001-03

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 10-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerine, hydrogen peroxide, purified water USP

Dimachem Inc., 3258 Marentette Ave., Windsor, ON, Canada N8X4G4 1-877-969-5570, www.dimacheminc.com
Produit manufacturé en un Canada certifié et approuvé ISO 9001:14001 & 18001 Registered facility
Emballage en 60 litres et conteneur recouvert en plastique.
Produit avec des faits par une entreprise canadienne certifiée de conformer avec normes ISO 9001:14001 et 18001 et le code du PST/SP 18001.
L'emballage contient des matières recyclées et est entièrement recyclable.

Active ingredient(s)Alcohol 80% v/v
PurposeAntiseptic

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.



205 L NDC: 78158-001-04

DIMACHEM

DIMACHEM INC.
3258 MARENTETTE AVE., WINDSOR ON N8X 4G4
(519) 969-5570

HAND SANITIZER BLEND #1



UN1987

ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)
CLASS: 3
PG: III
PLACARD: FLAMMABLE



IN CASE OF EMERGENCY CALL
EN CAS D'URGENCE APPELER
CANUTEC (613) 996-6666

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

205 L (205000 mL)
NDC: 78158-001-04

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 10-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerine, hydrogen peroxide, purified water USP

Dimachem Inc., 3258 Marentette Ave., Windsor, ON, Canada N8X4G4 1-519-969-5570, www.dimachem.com
Regularly manufactured in a Canadian owned and operated ISO 9001:14001 & 18001 Registered facility.
Produit fabriqué et distribué régulièrement en usine canadienne aux normes ISO 9001:14001 et à celui du PSTSP 18001.
L'emballage contient des matières recyclées et est entièrement recyclable.

Active ingredient(s)Alcohol 80% v/v
PurposeAntiseptic

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.



1025 L NDC: 78158-001-05

DIMACHEM

DIMACHEM INC.
3258 MARENTETTE AVE., WINDSOR ON N8X 4G4
(519) 969-5570

HAND SANITIZER BLEND #1



UN1987

ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)
CLASS: 3
PG: III
PLACARD: FLAMMABLE



IN CASE OF EMERGENCY CALL
EN CAS D'URGENCE APPELER
CANUTEC (613) 996-6666

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer
Non-sterile Solution

1025 L (1025000 mL)
NDC: 78158-001-05

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 10-30°C (59-86°F)
- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

glycerine, hydrogen peroxide, purified water USP

Dimachem Inc., 3258 Marentette Ave., Windsor, ON, Canada N8X4G4 1-519-969-5570, www.dimachem.com
Regularly manufactured in a Canadian owned and operated ISO 9001:14001 & 18001 Registered facility.
Produit fabriqué et distribué régulièrement en usine canadienne aux normes ISO 9001:14001 et à celui du PSTSP 18001.
L'emballage contient des matières recyclées et est entièrement recyclable.

Active ingredient(s)Alcohol 80% v/v
PurposeAntiseptic

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.



HAND SANITIZER BLEND 1

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78158-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78158-001-01	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	
2	NDC:78158-001-02	3780 mL in 1 JUG; Type 0: Not a Combination Product	05/19/2020	
3	NDC:78158-001-03	20000 mL in 1 PAIL; Type 0: Not a Combination Product	05/19/2020	
4	NDC:78158-001-04	205000 mL in 1 DRUM; Type 0: Not a Combination Product	05/19/2020	
5	NDC:78158-001-05	1025000 mL in 1 PACKAGE; Type 0: Not a Combination Product	05/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/19/2020	

Labeler - Dimachem Inc (249772141)**Establishment**

Name	Address	ID/FEI	Business Operations
Dimachem Inc		249772141	manufacture(78158-001)