

SDA 40B- alcohol solution
Mann Lake Ltd

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.

Active Ingredient(s)

Alcohol 70% v/v. Purpose Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand sanitizer to help reduce bacteria that can potentially 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 the 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, triethanolamine, carbomer, purified water USP

80194-0101-1

Sanieffect Label Gel



**Topical Gel
(70%) v/v**

HAND SANITIZER / NON-STERILE SOLUTION



1 Gal. (3.78 L)

Drug Facts	
Active Ingredient(s) Alcohol 70% 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 15-30C (59-86F)• Avoid freezing and excessive heat above 40C (104F)	
Inactive ingredients purified water, glycerin, carbomer, triethanolamine	

Manufactured by:
Mann Lake Ltd.
501 1st Street S.
Hackensack, MN 56452

HS-111 | MLL 10-177 Rev 05/12/20



Lot/Batch Code:

80194-0101-2



SANI-EFFECT

GEL HAND SANITIZER

Topical Gel (70%) v/v

HAND SANITIZER / NON-STERILE SOLUTION



8 FL OZ (236 mL)

Manufactured by:
Mann Lake Ltd.
501 1st Street S.
Hackensack, MN 56452

HS-110 | MLL 10-176 Rev 05/04/20



Drug Facts	
Active Ingredient(s)	Purpose
Alcohol 70% 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	
purified water, glycerin, carbomer, triethanolamine	

SDA 40B

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80194-0101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	30 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80194-0101-1	3.78 L in 1 PACKAGE; Type 0: Not a Combination Product	05/13/2020	
2	NDC:80194-0101-2	0.236 L in 1 PACKAGE; Type 0: Not a Combination Product	05/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/13/2020	

Labeler - Mann Lake Ltd (121181846)**Registrant** - Mann Lake LTD (121181846)**Establishment**

Name	Address	ID/FEI	Business Operations
Mann Lake Ltd		121181846	manufacture(80194-0101)

Revised: 8/2022

Mann Lake Ltd