

HAND SANITIZER- alcohol gel
Zhongshan Biaoqi Houseware Co., 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.

Walter's 1893 Hand Sanitizer Alcohol Antiseptic 75% Topical Solution

This is a hand sanitizer manufactured using the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation):

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, 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. Propylene glycol (2.5% v/v).
- c. Polyacrylic acid (0.3% v/v).
- d. Triethanolamine (0.3% v/v).
- e. Sterile distilled water (21.9% v/v).

The firm does not add other active or inactive ingredients.

USA
HAND SANITIZER
500ml

PROOF APPROVAL FORM BRAND: WALTER'S PRODUCT: HAND SANITIZER ITEM#: Size:		Colour: <input checked="" type="checkbox"/> Green <input type="checkbox"/> Pink	Product Code: 1893
Please note: It is the client's responsibility to ensure all goods have been checked for conformity. Please read the label and have it checked before it is supplied.			
GENERAL COMMENTS <input type="checkbox"/> Brand Name <input type="checkbox"/> Quantity requested <input type="checkbox"/> Category Details	PRODUCT CODE <input type="checkbox"/> Product Description <input type="checkbox"/> Specifications <input type="checkbox"/> Variations <input type="checkbox"/> Colour	APPROVAL COMMENTS <input type="checkbox"/> MFI <input type="checkbox"/> Brand <input type="checkbox"/> Stocked by	<input type="checkbox"/> Quantity of Order <input type="checkbox"/> Special Order & settings
WITH SIGNATURES			
APPROVAL: client/wholesaler Name: _____ Signature: _____ Date: _____		APPROVAL: Walter's Name: _____ Signature: _____ Date: _____	
Name: _____ Signature: _____ Date: _____		Name: _____ Signature: _____ Date: _____	

22cm wide x 11cm high.
500 ml Pump

<table border="1" style="width: 100%; font-size: 8px;"> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <td>Active ingredient(s)</td> <td style="text-align: right;">Purpose</td> </tr> <tr> <td>Alcohol 75% v/v</td> <td style="text-align: right;">Antiseptic</td> </tr> <tr> <td colspan="2">Usage</td> </tr> <tr> <td colspan="2">Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use:</td> </tr> <tr> <td colspan="2">• In children less than 2 months of age</td> </tr> <tr> <td colspan="2">• On open skin wounds</td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td> </tr> <tr> <td colspan="2">Stop use and see a doctor if irritation or rash occurs. These may be signs of a serious condition.</td> </tr> <tr> <td colspan="2">If redness or rash of eyelids (if swallowed), get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2">• Place enough product on hands to cover all surfaces. Rubs hands together until dry.</td> </tr> <tr> <td colspan="2">• Supervise children under 6 years of age when using this product to avoid swallowing.</td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2">• Store between 15°C (59-66°F)</td> </tr> <tr> <td colspan="2">• Avoid freezing and excessive heat above 40°C (104°F)</td> </tr> <tr> <td colspan="2">Inactive ingredients: propylene glycol, polyacrylic acid, triethanolamine, water</td> </tr> </table>	Drug Facts		Active ingredient(s)	Purpose	Alcohol 75% v/v	Antiseptic	Usage		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 see a doctor if irritation or rash occurs. These may be signs of a serious condition.		If redness or rash of eyelids (if swallowed), get medical help or contact a Poison Control Center right away.		Directions		• Place enough product on hands to cover all surfaces. Rubs hands together until dry.		• Supervise children under 6 years of age when using this product to avoid swallowing.		Other information		• Store between 15°C (59-66°F)		• Avoid freezing and excessive heat above 40°C (104°F)		Inactive ingredients: propylene glycol, polyacrylic acid, triethanolamine, water		<p>Walter's 1893</p> <p>HAND SANITIZER</p> <p>Alcohol Antiseptic 75% Topical Solution</p>
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<p>VISIT US ONLINE: WALTERSSHOCARE.COM</p> <p>Distributed by WALTER'S SHOE CARE INC. 4508 HWY 7 WOODBRIDGE, ON L4L 1S8 Questions? 1-800-762-4462</p>	<p>0 67730 20177 0</p> <p>NDC 81093-002-01 500 mL (16.91 fl.oz.)</p>																																								

Walter's 500ml- Hand Sanitizer Gel
 Item# 440004519
 UPC 0-67730-20177-0
 Inner 24/PK, case dimensions 7*19.2
 Master carton dimensions 28*21.5*40

Purpose
 Antiseptic

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

propylene glycol , polyacrylic acid, triethanolamine, purified water USP

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Package Label - Principal Display Panel






500 mL NDC: 81093-002-01

998mL NDCL 81093-002-02

**USA
HAND SANITIZER
500ml**

FORM APPROVAL CODE BRAND: WALTER'S PRODUCT: HAND SANITIZER ITEM#: Please note: It is the client's responsibility to ensure all goods have been checked for completeness. Please confirm each item in the checklist below if applicable.		Final Order Date: 2/2/2021 COLOR: <input checked="" type="checkbox"/> White <input type="checkbox"/> Clear		PRODUCT CODE: 0000101010 Container: HDPE BOTTLE Packaging: FULL PRINT LABEL Print Type: PMS Initials:
STANDARD INFORMATION <input type="checkbox"/> Brand Name <input type="checkbox"/> Product Name <input type="checkbox"/> Quantity/Package <input type="checkbox"/> Other Details	REGULATORY CODE <input type="checkbox"/> Product Description <input type="checkbox"/> Manufacturer <input type="checkbox"/> Supplier <input type="checkbox"/> Country <input type="checkbox"/> Country of Origin	HSN/HSN CODES <input type="checkbox"/> HSN <input type="checkbox"/> HSN Code <input type="checkbox"/> HSN Code <input type="checkbox"/> HSN Code	<input type="checkbox"/> Country of Origin <input type="checkbox"/> Brand Name & Logo <input type="checkbox"/> Other	
APPROVAL CHECKLIST Name: _____ Signature: _____ Date: _____ Name: _____ Signature: _____ Date: _____ Name: _____ Signature: _____ Date: _____				

22cm wide x 11cm high.
500 ml Pump

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Active ingredient(s)	Purpose				
Alcohol 75% v/v	Antiseptic				

Walter's 500ml- Hand Sanitizer Gel
Item# 440004519
UPC 0-67730-20177-0
Inner 24/PK, case dimensions 7*19.2
Master carton dimensions 28*21.5*40

**USA
HAND SANITIZER
998ml**

Walter's		Walter's	
Product Information PRODUCT NAME: HAND SANITIZER NDC: 81093-002-02 Please note: It is the client's responsibility to ensure all products have been checked for accuracy. Please verify each item to the checklist below if applicable.		Product Description Container: 998ml BOTTLE Packaging: FULL PRINT LABEL Print Type: PMS Initials: _____	
CLASSIC ELEMENTS <input type="checkbox"/> Brand Name <input type="checkbox"/> Product Name <input type="checkbox"/> Quantity/Measurement <input type="checkbox"/> Container/Volume	PRODUCT COPY <input type="checkbox"/> Product Description <input type="checkbox"/> Trade Name <input type="checkbox"/> Registration <input type="checkbox"/> Expiration	ISSUED ELEMENTS <input type="checkbox"/> NPI <input type="checkbox"/> Accuracy <input type="checkbox"/> Quantity of Units <input type="checkbox"/> Special Sign-off/Storage	<input type="checkbox"/> Signature <input type="checkbox"/> Date
APPROVE CONTAINER		APPROVE LABEL	
Name: _____	Signature: _____	Date: _____	Signature: _____
Name: _____	Signature: _____	Date: _____	Signature: _____
Name: _____	Signature: _____	Date: _____	Signature: _____

27cm

Drug Facts

Active ingredient(s) alcohol 75% v/v	Purpose Antiseptic
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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.	
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Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
Active ingredients propylene glycol, polyethylene alcohol, triethanolamine, water	

VISIT US ONLINE:
WALTERSSHOECARE.COM

Our packaging is 100% recyclable.

Distributed by WALTER'S SHOE CARE INC.
4908 HWY 7 WOODBRIDGE, ON L4L 1S9
Questions? 1-800-782-4492
Designed in Toronto. Responsibly made in China.



NDC 81093-002-02

Walter's
1893
**HAND
SANITIZER**
Alcohol Antiseptic 75%
Topical Solution

14cm

998mL (33.7 fl oz.)

Walter' 998ml- Hand Sanitizer Gel
Item# 440004520
UPC 0-67730-20180-0
Inner 24/PK, case dimensions 13*6.5*26
Master carton dimensions 40*27*26.5


item# 440004520, barcode 0-67730-20180-0

Label panel image

USA HAND SANITIZER 500ml

NDC# APPROVAL FORM		Product: HAND SANITIZER	FORM#	REV#	Color: <input checked="" type="checkbox"/> White <input type="checkbox"/> Clear	Label: <input checked="" type="checkbox"/> Full Print Label <input type="checkbox"/> None
Please note: It's the client's responsibility to ensure all assets have been checked for accuracy. Please confirm each item is the specified label if applicable.						
QUANTITY ELEMENTS <input type="checkbox"/> Brand/Type <input type="checkbox"/> Product Name <input type="checkbox"/> Quantity/Measurement <input type="checkbox"/> Category/Synonyms		PRODUCT COPY <input type="checkbox"/> Exact Description <input type="checkbox"/> Abbreviation <input type="checkbox"/> Synonyms <input type="checkbox"/> Abbreviation <input type="checkbox"/> Abbreviation		WEIGHT ELEMENTS <input type="checkbox"/> N/A <input type="checkbox"/> Net Weight <input type="checkbox"/> Net Volume <input type="checkbox"/> Net Content		OTHER ELEMENTS <input type="checkbox"/> Country of Origin <input type="checkbox"/> Storage Age & Storage <input type="checkbox"/> Other
WAL-01-00000001						
APPROVAL COMMENTS		Signature	Date	Initials		
Name		Signature	Date			
Name		Signature	Date			

22cm wide x 11cm high.
500 ml Pump


Drug Facts <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 60%;">Active ingredient(s)</th> <th style="width: 40%;">Purpose</th> </tr> <tr> <td>Alcohol 75% v/v</td> <td>Antiseptic</td> </tr> </table> <p>Uses 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. 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.</p> <p>Directions • Rub 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> <p>Other information • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive ingredients propylene glycol, polyacrylic acid, triethanolamine, water</p> <p>VISIT US ONLINE: WALTERSSHOECARE.COM</p> <p>Our packaging is 100% recyclable.</p> <p>Distributed by WALTER'S SHOE CARE INC. 4908 HWY 7 WOODBRIDGE, ON L4L 1S8 Questions? 1-800-782-4492</p> <p>Designed in Toronto. Responsibly made in China.</p>	Active ingredient(s)	Purpose	Alcohol 75% v/v	Antiseptic	 <h2 style="margin: 0;">Walter's</h2> <p style="margin: 0;">1893</p> <h1 style="margin: 0;">HAND SANITIZER</h1> <p style="margin: 0;">Alcohol Antiseptic 75% Topical Solution</p> <p style="margin: 0;">500 mL (16.91 fl. oz.)</p>
Active ingredient(s)	Purpose				
Alcohol 75% v/v	Antiseptic				

Walter's 500ml- Hand Sanitizer Gel
Item# 440004519
UPC 0-67730-20177-0
Inner 24/PK, case dimensions 7*19.2
Master carton dimensions 28*21.5*40

USA HAND SANITIZER 998ml

NDC# APPROVAL FORM		Product: HAND SANITIZER	FORM#	REV#	Color: <input checked="" type="checkbox"/> White <input type="checkbox"/> Clear	Label: <input checked="" type="checkbox"/> Full Print Label <input type="checkbox"/> None
Please note: It's the client's responsibility to ensure all assets have been checked for accuracy. Please confirm each item is the specified label if applicable.						
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WAL-01-00000001						
APPROVAL COMMENTS		Signature	Date	Initials		
Name		Signature	Date			
Name		Signature	Date			

27cm

Drug Facts <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 60%;">Active ingredient(s)</th> <th style="width: 40%;">Purpose</th> </tr> <tr> <td>Alcohol 75% v/v</td> <td>Antiseptic</td> </tr> </table> <p>Uses 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. Do not use: • in children less than 2 months of age • on open skin wounds When using the 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.</p> <p>Directions • Rub 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> <p>Other information • Store between 15-30°C (59-86°F) • Avoid freezing and excessive heat above 40°C (104°F)</p> <p>Inactive ingredients propylene glycol, polyacrylic acid, triethanolamine, water</p> <p>VISIT US ONLINE: WALTERSSHOECARE.COM</p> <p>Our packaging is 100% recyclable.</p> <p>Distributed by WALTER'S SHOE CARE INC. 4908 HWY 7 WOODBRIDGE, ON L4L 1S8 Questions? 1-800-782-4492</p> <p>Designed in Toronto. Responsibly made in China.</p>	Active ingredient(s)	Purpose	Alcohol 75% v/v	Antiseptic	 <h2 style="margin: 0;">Walter's</h2> <p style="margin: 0;">1893</p> <h1 style="margin: 0;">HAND SANITIZER</h1> <p style="margin: 0;">Alcohol Antiseptic 75% Topical Solution</p> <p style="margin: 0;">998mL (33.7 fl. oz.)</p>
Active ingredient(s)	Purpose				
Alcohol 75% v/v	Antiseptic				

14cm

Walter' 998ml- Hand Sanitizer Gel
Item# 440004520
UPC 0-67730-20180-0
Inner 24/PK, case dimensions 13*6.5*26
Master carton dimensions 40*27*26.5

item# 440004520, barcode 0-67730-20180-0

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81093-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	0.3 mL in 100 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	2.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	21.9 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81093-002-01	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/01/2021	
2	NDC:81093-002-02	998 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/30/2021	

Labeler - Zhongshan Biaoqi Houseware Co., LTD (420546599)

Revised: 2/2021

Zhongshan Biaoqi Houseware Co., LTD