# DYNAMIC HAND SANITIZER- alcohol liquid Dynamic Packaging Solutions 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.

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#### **Hand Sanitizer**

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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** 





ART #: 03234 DESIGNER: AT PLEASE NOTE: CLIENT: DYNAMIC PACKAGING DESCRIPTION: Dynamic 22oz Hand Sanitizer Liquid DATE: JUNE 30, 2020 PROOF#: 1 COLOURS: THE CLIENT IS RESPONSIBLE APPROVED AS IS: LABEL SIZE: MATERIAL: FOR APPROVING; 4.25" X 3.3125" WHITE BOPP PMS 123 CYAN 1. ALL COPY DIE# **S696** 2. LABEL DIMENSIONS PMS 485 APPROVED WITH CHANGES INDICATED: 3. COLOURS USED COPY DIRECTION: COATING: PMS 300 4. REWIND COPY DIRECTION LOCAL, PROVINCIAL OR NATIONAL **GLOSS** Eg A Eg BLACK RE-PROOF O DATE: REGULATIONS ASSOCIATED WITH LAMINATE 3 FRONT 4 BACK DIELINE (does not print)

THIS IS NOT A COLOUR ACCURATE PROOF. Please refer to process and pantone colour charts for accurate colour representation.

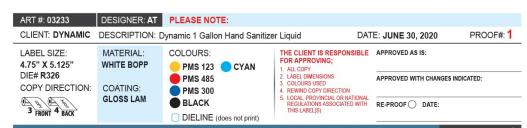
Every effort has been made to ensure the accuracy of this proof, however, the client is responsible for ensuring that albel size, copy, graphics and colour separations are accurate, and to notify Perfle
Label Inc. of any discrepancies prior to film, plate or label production. The client indemnifies Perflex Label Inc. against any liability related to costs incurred due to errors on a customer signed proof.



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#### ART #: 03232 DESIGNER: AT PLEASE NOTE: CLIENT: DYNAMIC PROOF#: 1 DESCRIPTION: Dynamic Hand Sanitizer 16oz GEL DATE: JUNE 30, 2020 THE CLIENT IS RESPONSIBLE APPROVED AS IS: COLOURS: LABEL SIZE: MATERIAL: FOR APPROVING; 5.875" X 3" WHITE BOPP PMS 123 CYAN 1. ALL COPY **DIE# S1143** 2. LABEL DIMENSIONS PMS 485 APPROVED WITH CHANGES INDICATED: 3. COLOURS USED COPY DIRECTION: COATING: PMS 300 4. REWIND COPY DIRECTION 5. LOCAL, PROVINCIAL OR NATIONAL **GLOSS LAM** 8 A E BLACK REGULATIONS ASSOCIATED WITH RE-PROOF O DATE: THIS LABEL(S) DIELINE (does not print)

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Every effor has been made to ensure the accuracy of this proof. However, the client is responsible for ensuring that label size, copy, graphics and colour separations are accurate, and to notify Perflex
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000 mL NDC: 00000-000-00

#### DYNAMIC HAND SANITIZER

alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78636-8609	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
ALCOHOL (UN	III: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78636-8609-	4000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	2	4000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78636-8609-	4000000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	



ART #: 02661 DESIGNER: AT PLEASE NOTE: CLIENT: DYNAMIC PACKAGING DESCRIPTION: Hand Sanitizer 7.5oz DATE: MARCH 20, 2020 PROOF#: 3 LABEL SIZE: MATERIAL: COLOURS: THE CLIENT IS RESPONSIBLE APPROVED AS IS: FOR APPROVING; 6" X 6" WHITE BOPP CYAN PMS 485 ALL COPY
 LABEL DIMENSIONS DIE# R999 APPROVED WITH CHANGES INDICATED: PMS 294 BLACK COLOURS USED COPY DIRECTION: COATING: REWIND COPY DIRECTION
 LOCAL, PROVINCIAL OR NATIONAL **GLOSS** RE-PROOF O DATE: REGULATIONS ASSOCIATED WITH LAMINATE THIS LABEL(S) DIELINE (does not print)

THIS IS NOT A COLOUR ACCURATE PROOF. Please refer to process and pantone colour charts for accurate colour representation. Every effort has been made to ensure the accuracy of this proof. However, the client is responsible for ensuring that label size, copy, graphics and colour separations are accurate, and to notify Perlie Label Inc. of any discrepancies prior to film, plate or label production. The client indemnifies Perliex Label Inc. against any liability related to costs incurred due to errors on a customer signed proof.



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OTC monograph not final	part333A	03/02/2020	

## Labeler - Dynamic Packaging Solutions Inc (015504356)

### Registrant - Dynamic Packaging Solutions Inc (015504356)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dynamic Packaging Solutions Inc		0 1550 4356	manufacture(78636-8609)	

Revised: 6/2020 Dynamic Packaging Solutions Inc