

SANITIZER WIPES- sanitizing wipes liquid
Organic Filling Solutions, LLC

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 an alcohol wipe manufactured in the USA

- 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. Glycerol (3.2% v/v)
- c. 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 75% v/v. Purpose: Antiseptic

Purpose

Multi-purpose

Use

Single use wipes for hands. Close properly after dispensing to maintain purity, as alcohol by nature evaporates quickly. Dispose properly. Apply thoroughly to hands to cover all surfaces. Rub hands together until dry.

Warnings

For external use only, hands, general cleaning. Does not replace wipes for medical procedures. Flammable; keep away from fire or flame. Do not ingest.

Do not use

- Stop use and ask a doctor if irritation and redness develop, condition persists for more than 72 hours
- Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

When using this product, keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if irritation or redness develop. Condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply thoroughly to hands to cover all surfaces. Rub hands together until dry.

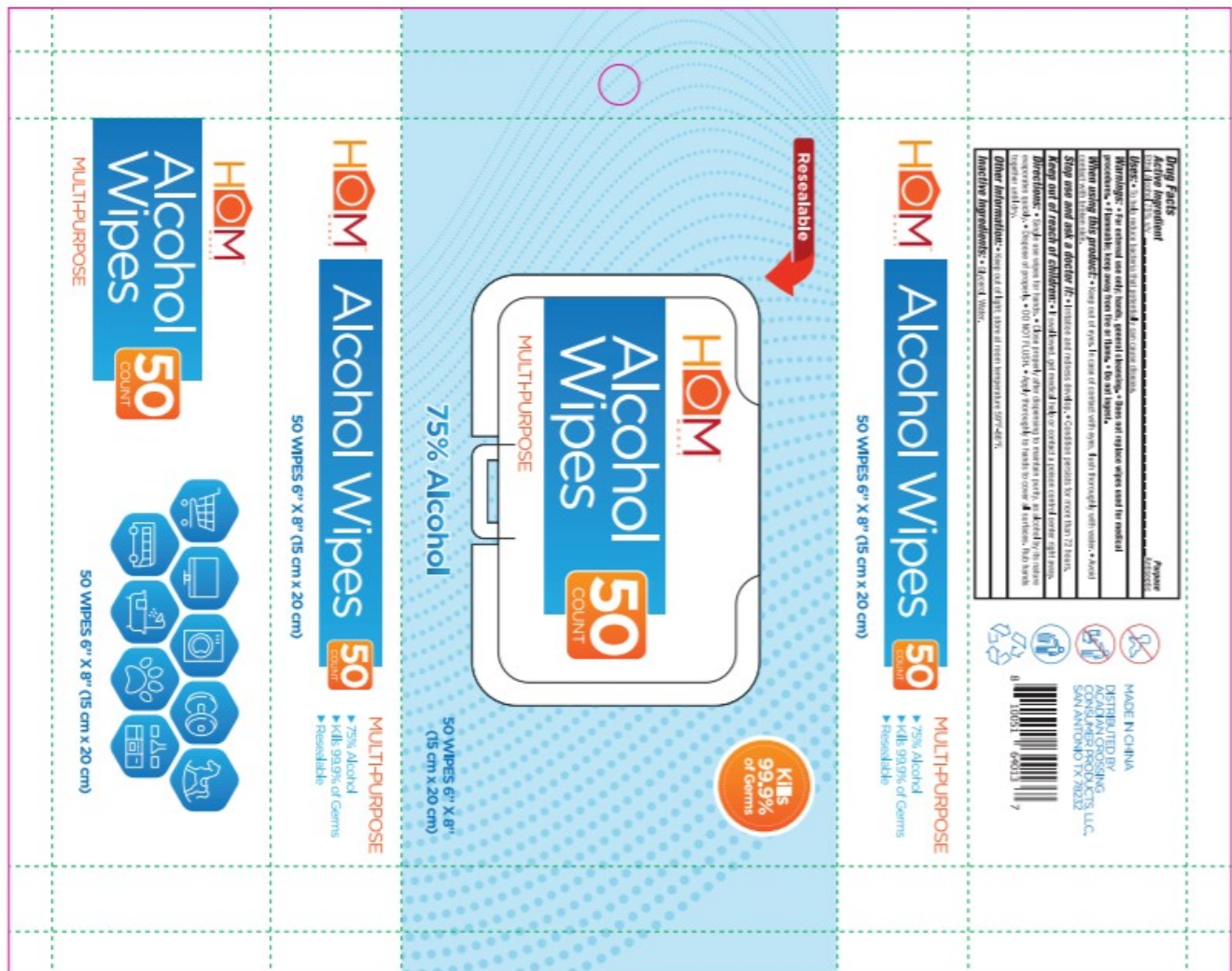
Other information

- Keep out of light, store at room temperature 59 - 86 degrees Fahrenheit

Inactive ingredients

glycerin, purified water USP

Package Label - Principal Display Panel



230 mL NDC: 76830-501-07

SANITIZER WIPES

sanitizing wipes liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76830-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	172.5 mL in 230 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	7.5 mL in 230 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:76830-501-07	230 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Organic Filling Solutions, LLC (080759841)

Establishment

Name	Address	ID/FEI	Business Operations
Organic Filling Solutions, LLC		080759841	manufacture(76830-501)