

HAND SANITIZER- ethyl alcohol 80% liquid
Southwest Specialty Food, 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.

Hand Sanitizer

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.

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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.

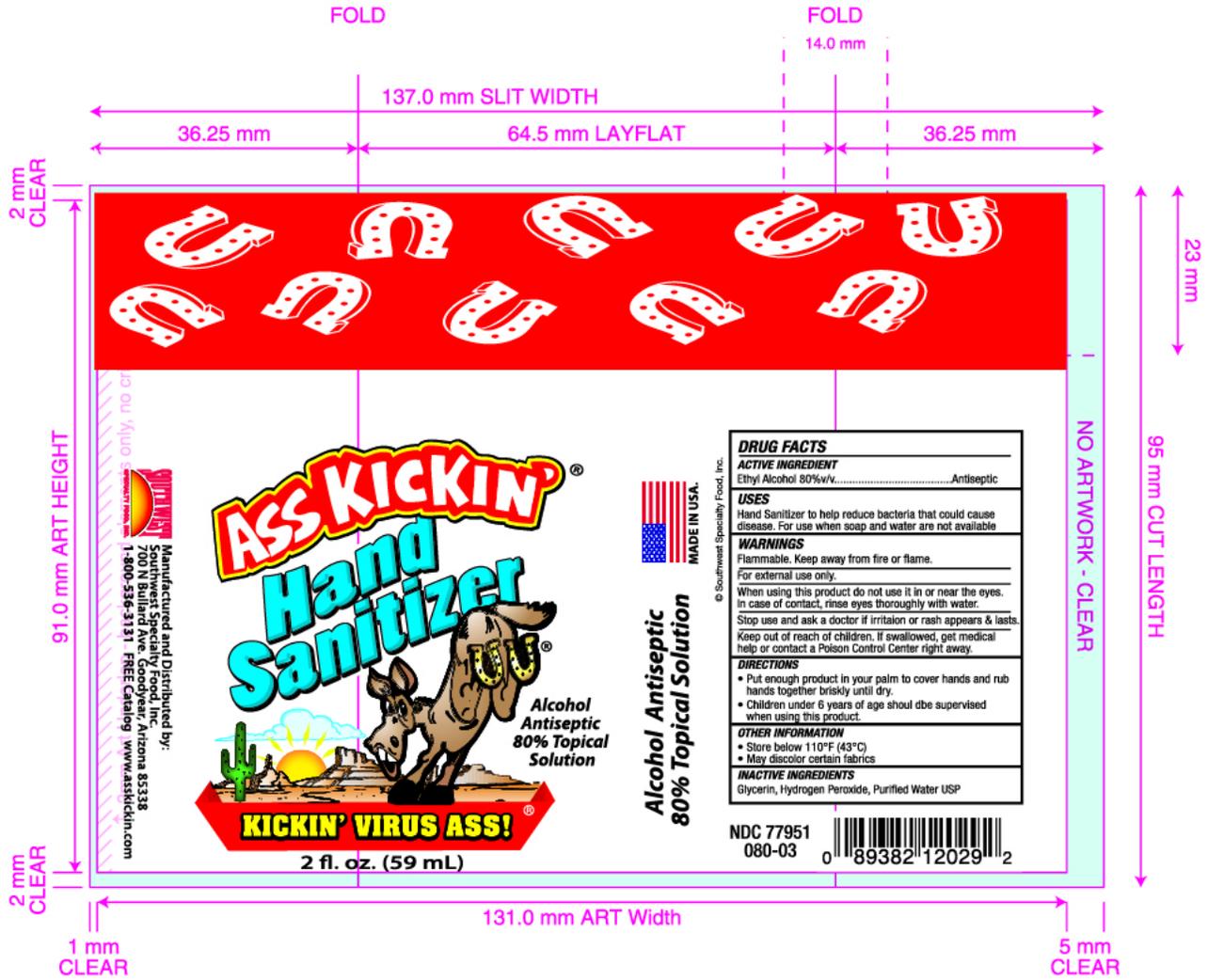
Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

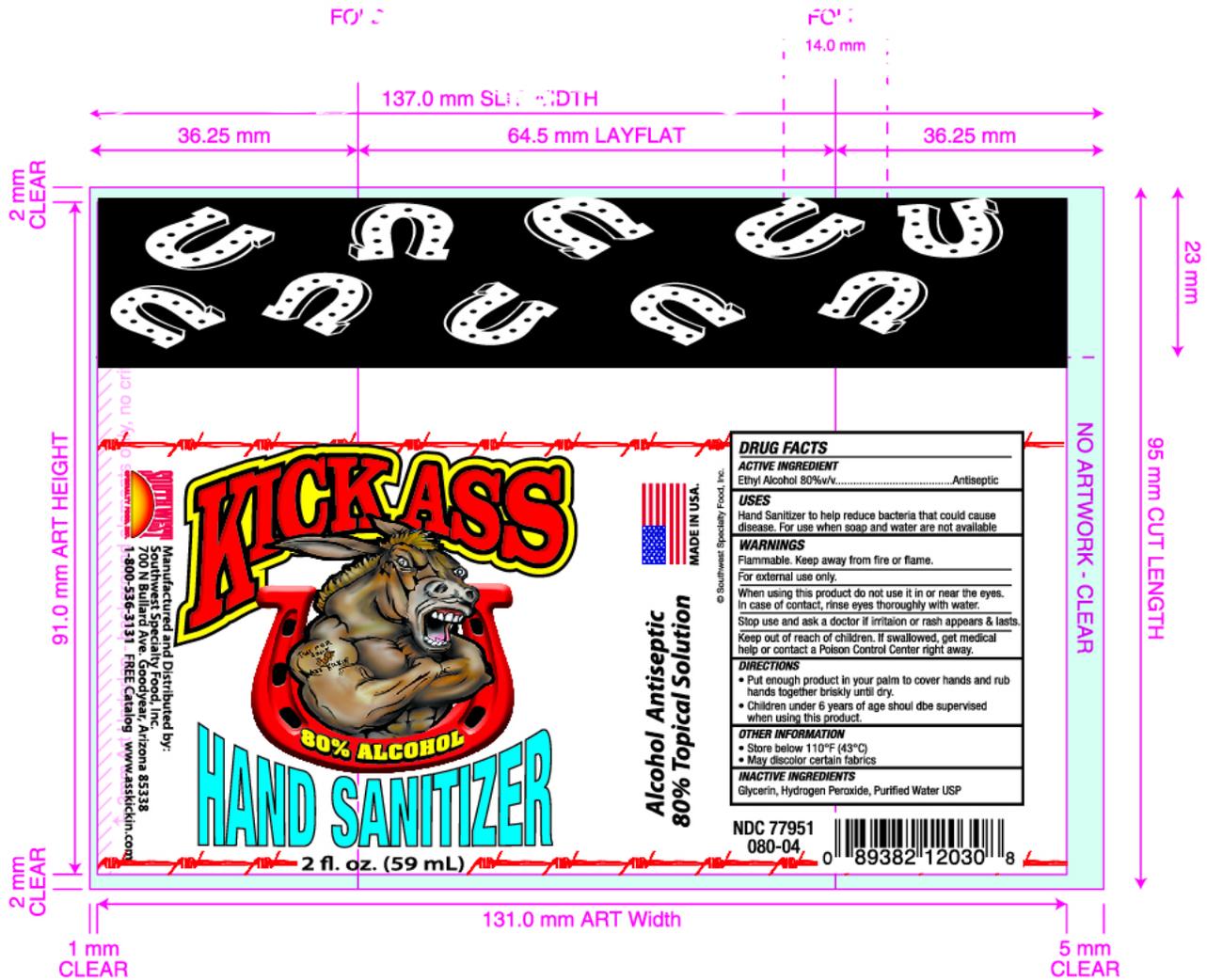
glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



Overall Size: 137mm x 95mm
 Art Area: 131mm x 91mm
 Layflat: 64.5mm
 Slit Width: 137mm
 Cut Length: 95mm

- Outline all fonts
- Embed all images
- Barcodes should be in vertical/ladder position. We recommend the barcode be black with white behind it to provide the best scan.
- 2mm art underlap on left, *no critical copy* should extend into the underlap. Background elements should run into the underlap.



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60 mL NDC 7795108003

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HAND SANITIZER

ethyl alcohol 80% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77951-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 80 mL	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 80 mL		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 80 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77951-080-03	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77951-080-04	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	06/01/2020		

Labeler - Southwest Specialty Food, Inc (196995641)

Establishment

Name	Address	ID/FEI	Business Operations
Southwest Specialty Food, Inc		196995641	manufacture(77951-080) , pack(77951-080) , label(77951-080)

Revised: 5/2020

Southwest Specialty Food, Inc