EMELY HAND SANITIZER- alcohol gel
Laboratorios E&M SRL

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.

Emely Hand Sanitizer (Gel)

Active Ingredient(s)

Alcohol 80% v/v Purpose: Antiseptic

Purpose

Aseptic, Hand Sanitizer

Uses

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.

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)

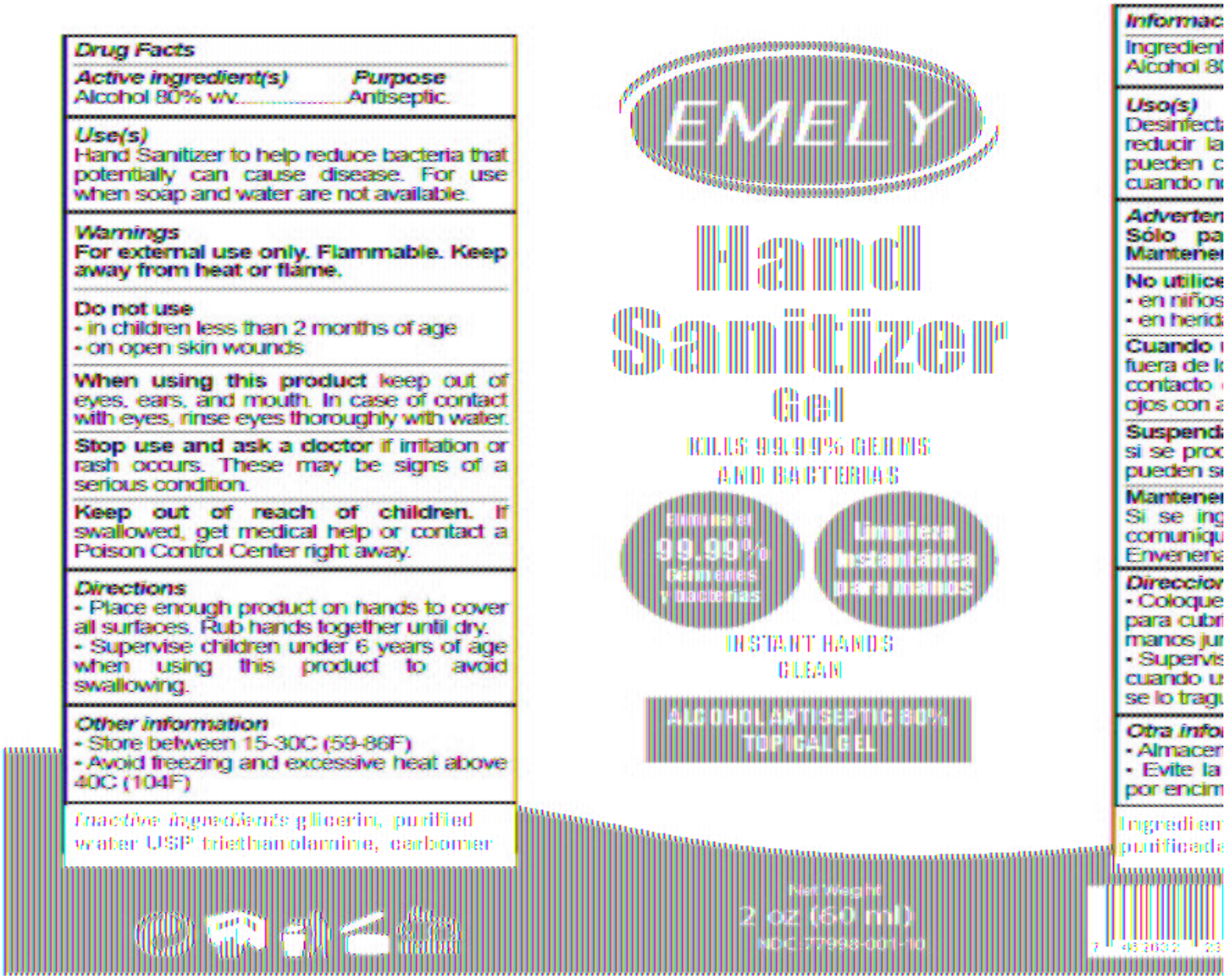
Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients

Glicerin, Purified Water USP, Triethanolamine, Carbomer

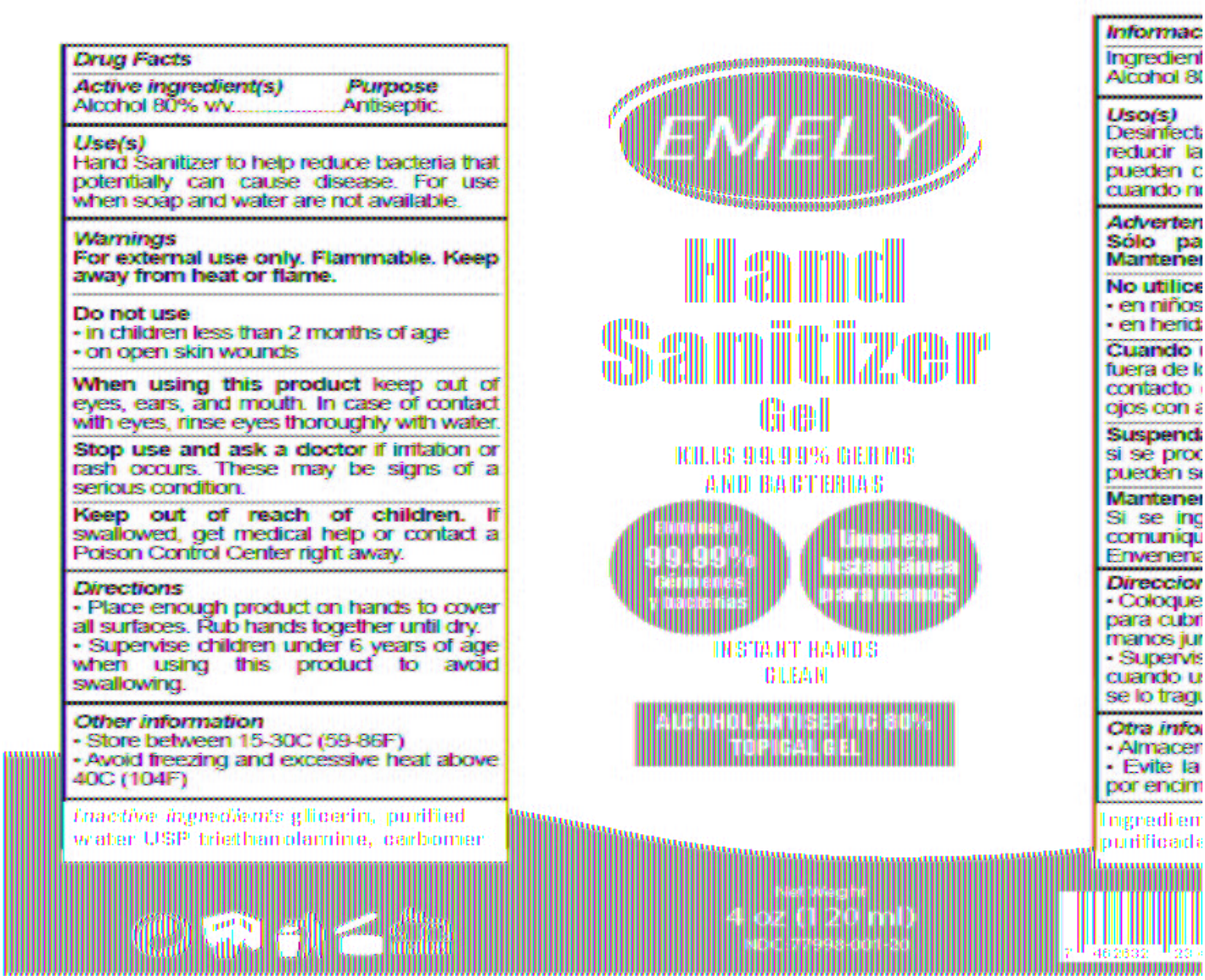
Package Label - Principal Display Panel

60 mL NDC: 77998-001-10



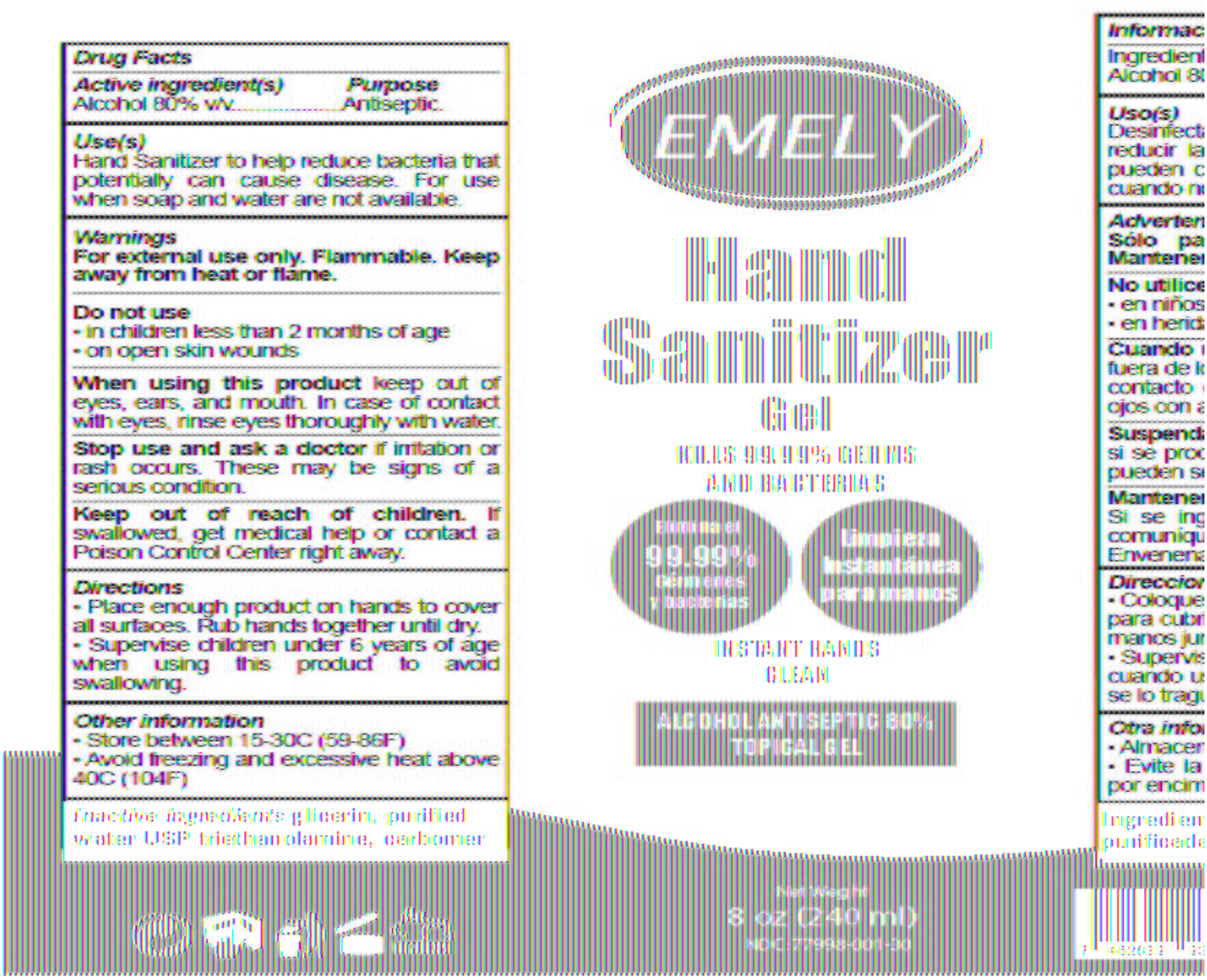
Package Label - Principal Display Panel

120 mL NDC: 77998-001-20



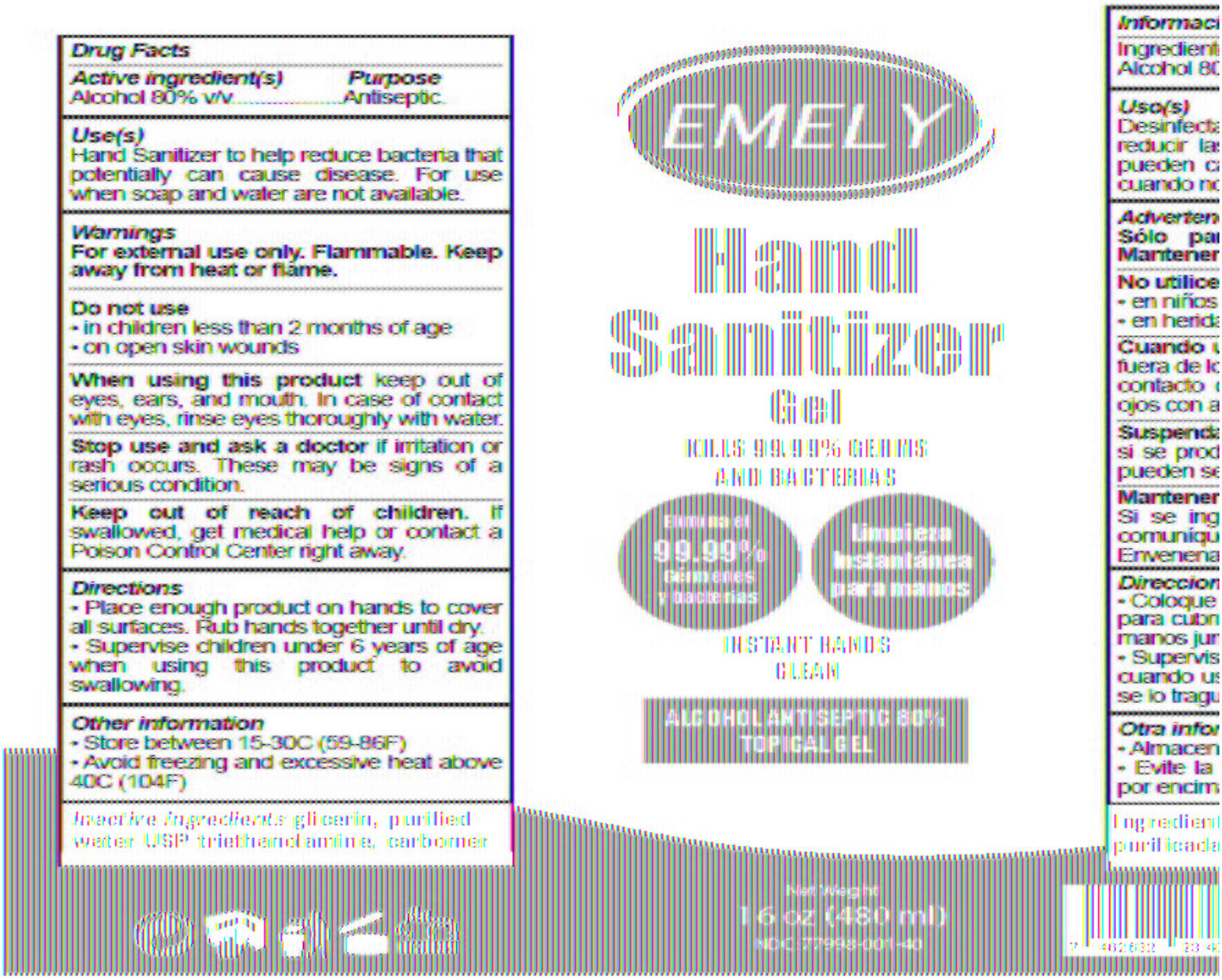
Package Label - Principal Display Panel

240 mL NDC: 77998-001-30



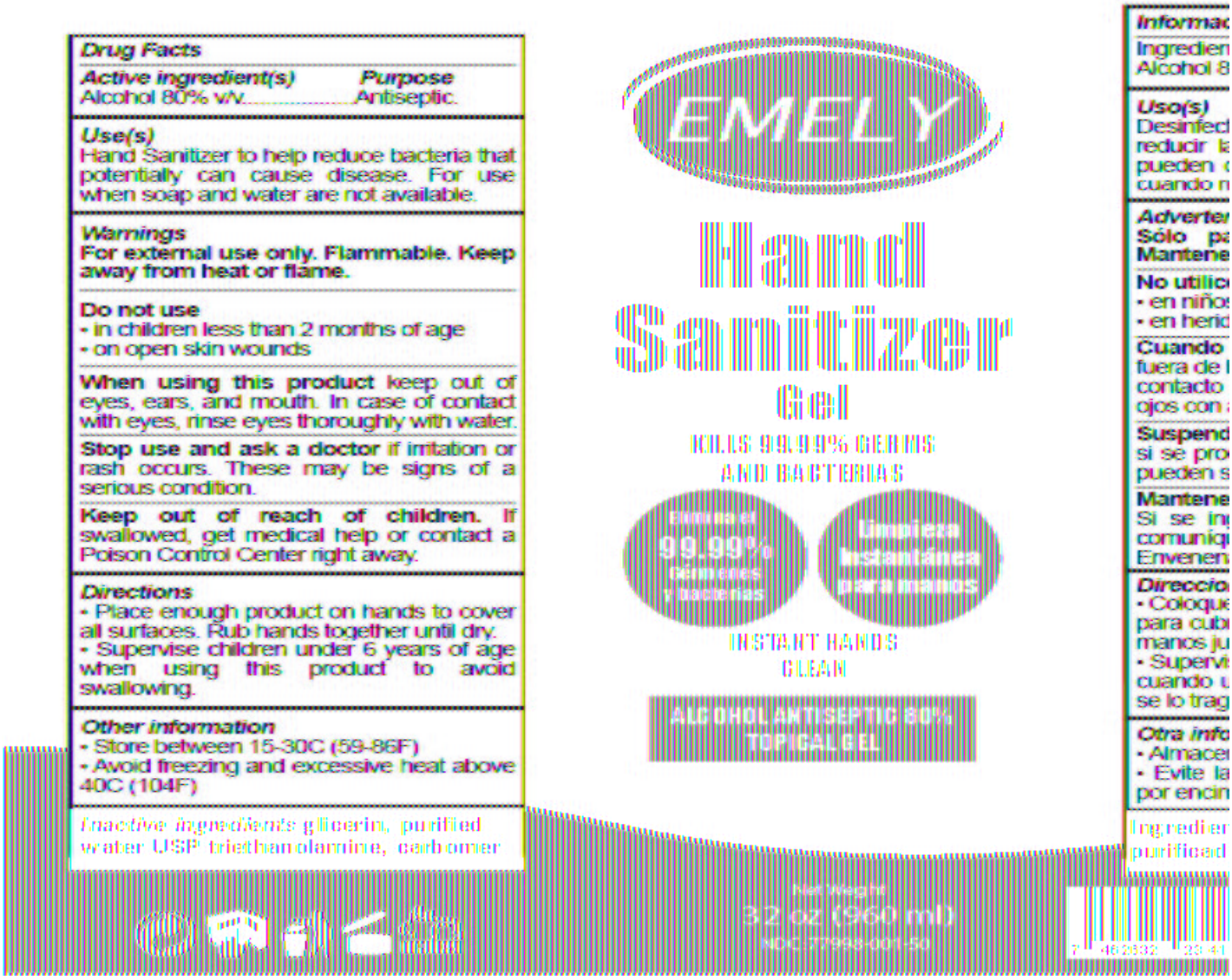
Package Label - Principal Display Panel

480 mL NDC: 77998-001-40



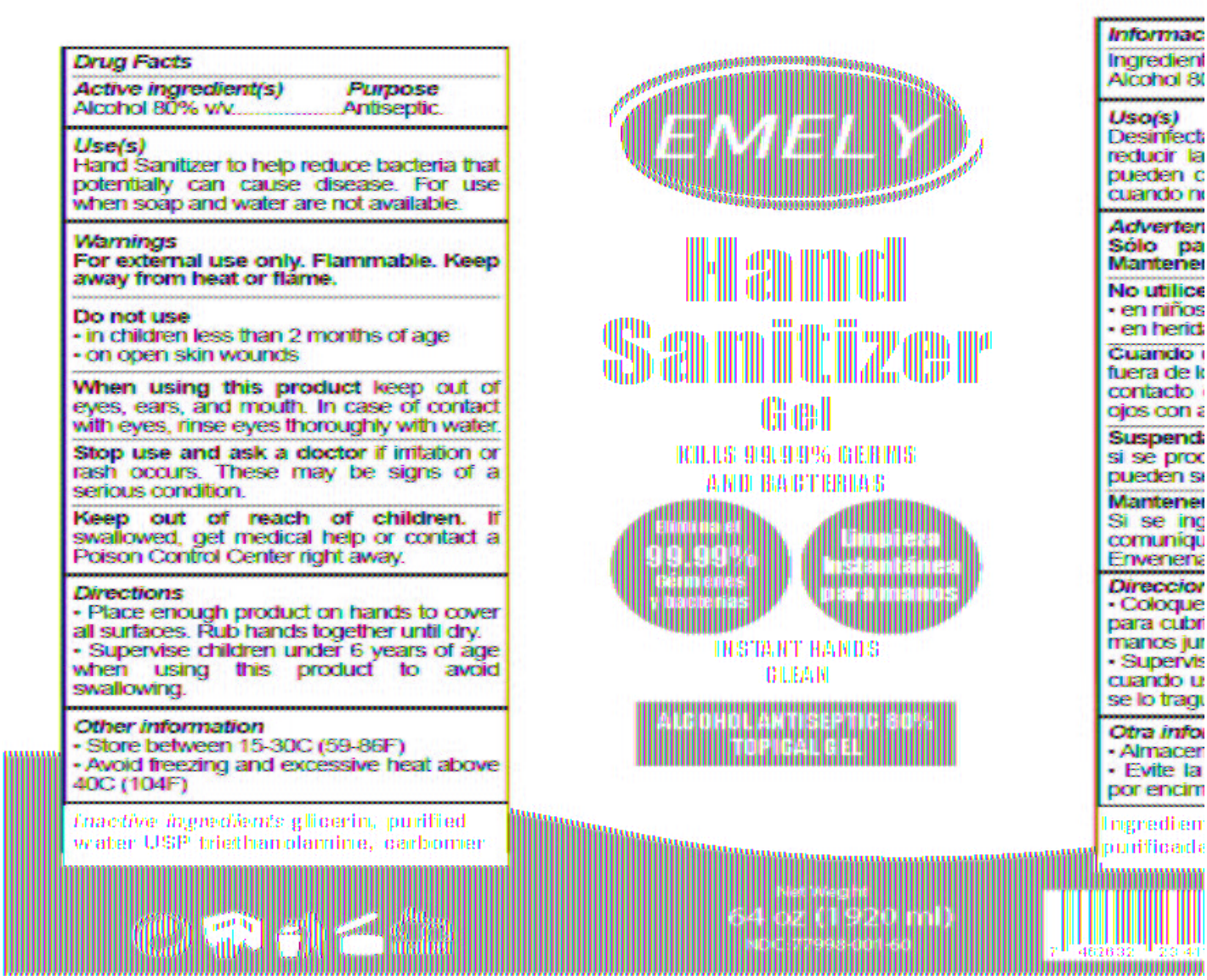
Package Label - Principal Display Panel

960 mL NDC: 77998-001-50



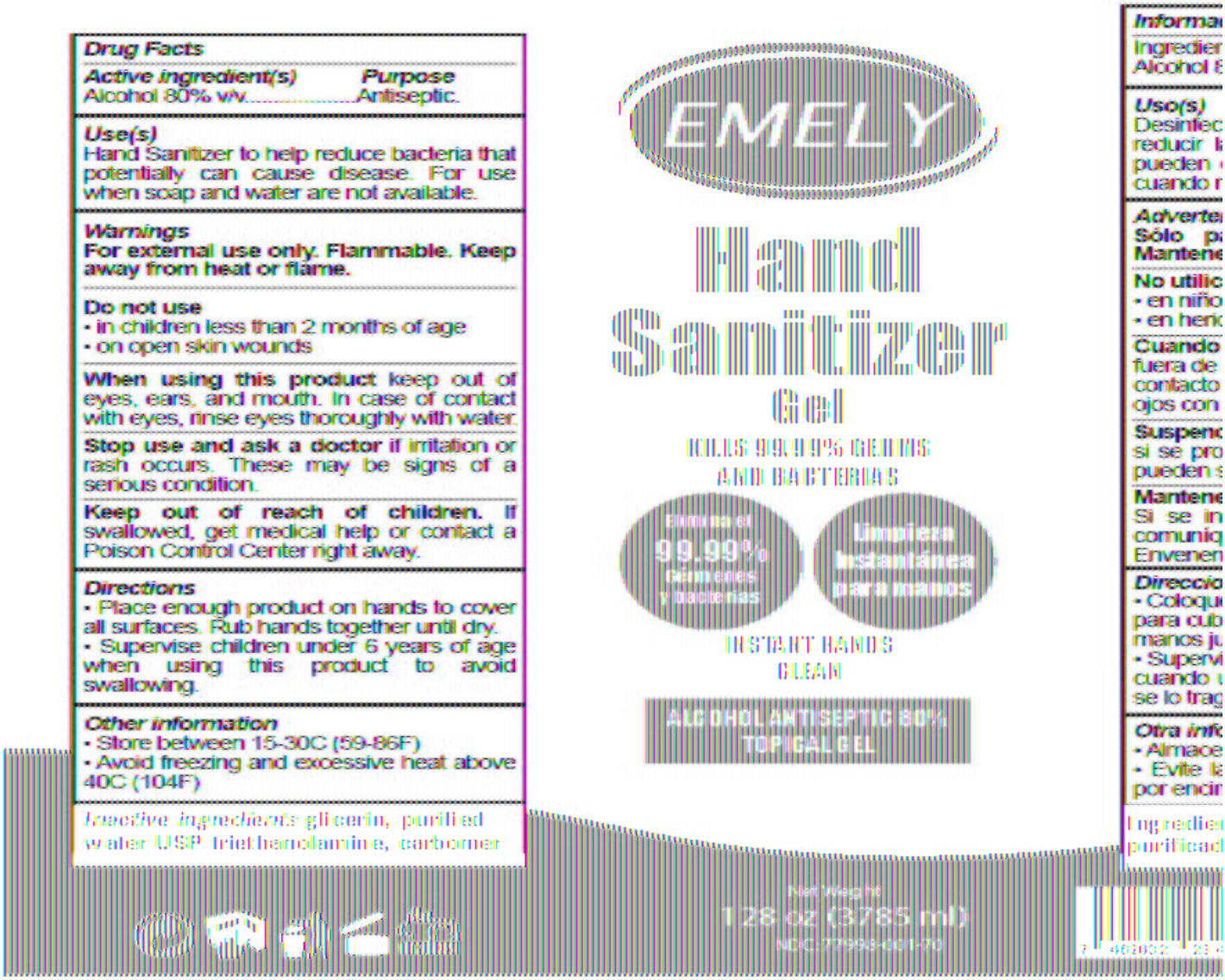
Package Label - Principal Display Panel

1920 mL NDC: 77998-001-60



Package Label - Principal Display Panel

3785 mL NDC: 77998-001-70



EMELY HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77998-001
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77998-001-10	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77998-001-20	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77998-001-30	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
4	NDC:77998-001-40	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
5	NDC:77998-001-50	960 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
6	NDC:77998-001-60	1920 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
7	NDC:77998-001-70	3785 mL in 1 BOTTLE, PLASTIC; 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 - Laboratorios E&M SRL (817468959)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios E&M SRL		817468959	manufacture(77998-001) , analysis(77998-001) , pack(77998-001) , label(77998-001)

Revised: 12/2021 Laboratorios E&M SRL