

**SALON SAFETY SAFE TOOLS- disinfectant concentrate**  
**FGBG USA 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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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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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)

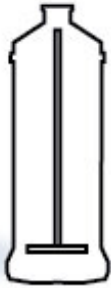
**Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

**Package Label - Principal Display Panel**



**Disinfectant Concentrate 1.5.30**  
**Kills 99.99 % of Viruses**



**Instructions: Mix 1.5 oz of concentrate into the Glass Jar add 30 oz of cold water, submerge your tools for 10 minutes for a complete disinfection, dry your tools with a paper towel, repeat this prior to each client.**

**Active Ingredients: Alkyl (50% C<sub>14</sub>, 40% C<sub>12</sub>, 10% C<sub>16</sub>) (1-3%)  
 dimethyl benzyl ammonium chloride  
 Di-N-Alkyl (50% C<sub>10</sub>, 50% C<sub>8</sub>) (1-3%)  
 Dimethyl ammonium chloride  
 Nonyphenol -10 (1-6%)  
 Sodium Nitrite (1-2%)  
 Inactive ingredients: Distilled Water (86-100%)**

**\*Not for medical use**

**Manufactured by: Promotora Ambiental S.A. de C.V, Monterrey NL  
 For SalonProf S.A. de C.V. Tijuana B.C.  
 Imported by: FGBG USA INC, Celina TX.**

**16.9 oz / 500 ml Net. Contents - Made in México - FOR SALON USE ONL  
 keep Out of Reach of Children - Danger - First Aid**

000 mL NDC:

00000-000-00

**SALON SAFETY SAFE TOOLS**

disinfectant concentrate

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80131-200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	3 g in 100 mL
<b>N-ALKYL ETHYLBENZYL DIMETHYL AMMONIUM CHLORIDE (C12-C14)</b> (UNII: ...)	N-ALKYL ETHYLBENZYL	...

G258TFN61X) (N-ALKYL ETHYLBENZYL DIMETHYL AMMONIUM (C12-C14) -  
UNII:85440928RV)

DIMETHYL AMMONIUM  
CHLORIDE (C12-C14)

5 g  
in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	86 mL in 100 mL
<b>N-NO NYLPHENOL (MIXED ISOMERS)</b> (UNII: 79F6A2ILP5)	6 mL in 100 mL
<b>SODIUM NITRATE</b> (UNII: 8M4L3H2ZVZ)	2 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80131-200-20	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/30/2020	

**Labeler** - FGBG USA INC (040805191)

### Establishment

Name	Address	ID/FEI	Business Operations
FGBG USA INC		040805191	manufacture(80131-200)

Revised: 6/2020

FGBG USA INC