

HAND SANITIZER- hand sanitizer liquid
Yiwu Shining Cosmetics Co., Ltd.

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

Active Ingredient(s)

Ethyl alcohol 80%

Purpose

Antiseptic

Use

For personal hand hygiene to help prevent the spread of bacteria

Warnings

For external use only. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Stop use and ask/ consult a doctor/physician I health care practitioner I health care provider I health care professional if irritation develops. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Do not use on open skin wounds.

Do not use

Do not use on children/infants less than 2 years of age (unless directed by a doctor I physician I health care practitioner I health care provider I health care professional).

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Do not use on open skin wounds.

Stop use and ask/ consult a doctor/physician I health care practitioner I health care provider I health care professional if irritation develops.

Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.

Directions

Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product Use as part of your daily cleansing routine. For occasional and personal domestic use.

Other information

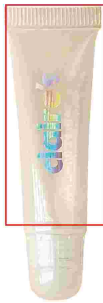
Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 40°C (104°F). May discolour certain fabrics or surfaces.

Inactive ingredients

Water (aqua). Glycerin, Hydrogen Peroxide, Denatonium Benzoate

Package Label - Principal Display Panel

7 ml Tube



Front



20 mm

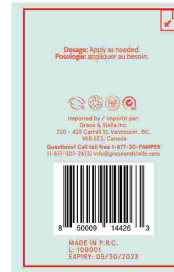
44 mm



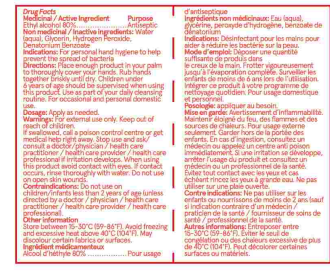
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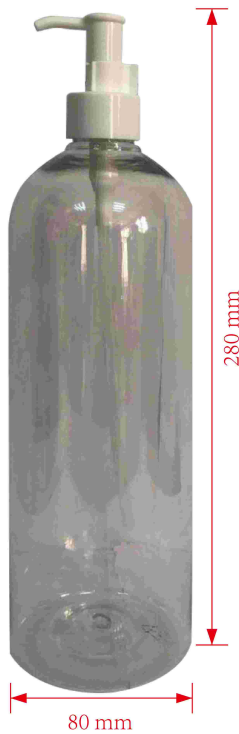
Front



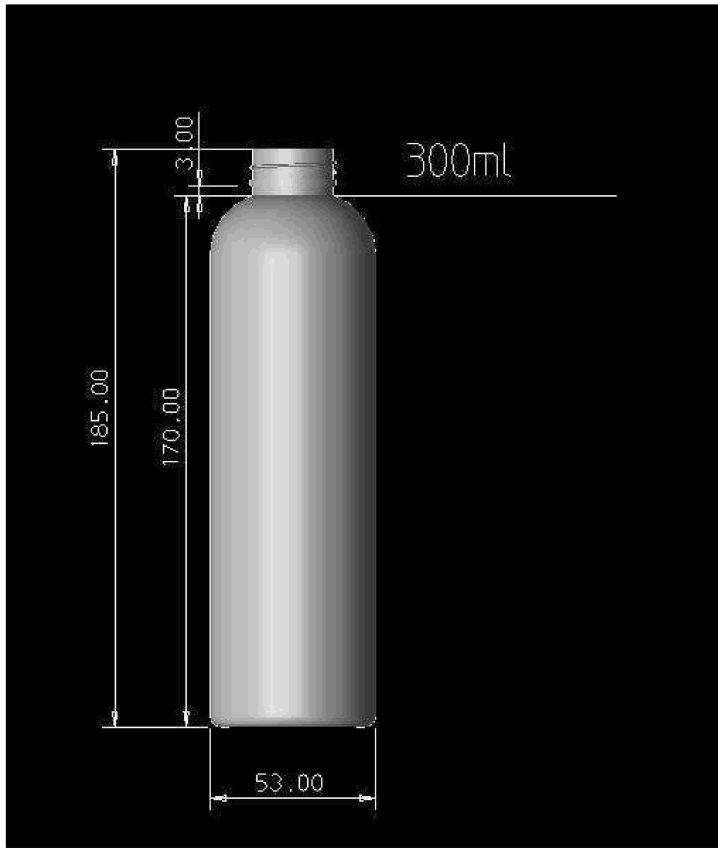
Top Page



Inside Page



235 mm



5*150m



250mm x 55mm

60 ml cylindrical bottle



grace & stella

80% Ethyl Alcohol
Alcool d'éthyle 80%

**HAND
SANITIZER**

Topical & Non-Sterile Solution
Solution topique et non stérile

NPN 12345678 | NDC 12345678

Net Wt. 60 mL / 2.03 fl.oz.

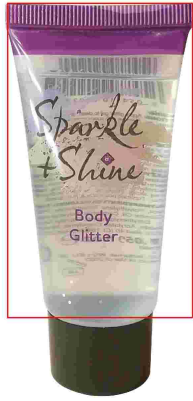
Drug Facts
Medicinal / Active ingredient
Purpose
 80% Ethyl Alcohol
Non medicinal / inactive ingredients:
 Water, Glycerin, Hydrogen Peroxide, Benzalkonium Chloride
Indications: For personal hand hygiene to help prevent the spread of bacteria.
Directions: Place enough product in your palm to thoroughly cover your hands. Rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product. Use as part of your daily cleaning routine. For occasional and general domestic use.
Dosage: Apply as needed.
Warnings: For external use only. Keep out of reach of children.
 If swallowed, call a poison control centre or your medical health care provider. Stop use and ask your doctor/physician / health care practitioner / health care provider / health care professional if irritation develops. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Do not use on open skin wounds.
Contraindications: Do not use on children under 6 years of age unless directed by a doctor / physician / health care practitioner / health care professional.
Other information: Store between 15-30°C (59-86°F). Avoid freezing and excessive heat above 42°C (104°F). May discolor certain fabrics or surfaces.

Ingredient médicamenteux
 Alcool d'éthyle 80%
Ingredients non médicamenteux: Eau, alcool, glycérine, peroxyde d'hydrogène, benzalkonium chlorure.
Indications: Désinfectant pour les mains pour aider à réduire les bactéries sur la peau.
Méthode d'emploi: Déposer une quantité suffisante de produit dans le creux de la main. Frotter vigoureusement jusqu'à l'évaporation complète. Surveiller les enfants de moins de 6 ans lors de l'utilisation. Éviter le contact à votre programme de nettoyage quotidien. Pour usage domestique et personnel.
Posologie: Appliquer au besoin.
Mise en garde: À l'extérieur seulement. À l'usage externe seulement. Garder hors de la portée des enfants. En cas d'ingestion, consultez un médecin ou appelez un centre anti-poison immédiatement. Si une irritation se développe, arrêter l'usage du produit et consulter un médecin ou un professionnel de la santé. Évitez tout contact avec les yeux et cas échéant rincer les yeux à grande eau. Ne pas utiliser sur une plaie ouverte.
Contre-indications: Ne pas utiliser sur les enfants ou nourissons de moins de 6 ans, sauf si indication contraire d'un médecin / praticien de la santé / fournisseur de soins de santé / professionnel de la santé.
Autres informations: Entreposer entre 15-30°C (59-86°F). Éviter le gel ou la congélation ou des chaleurs excessives de plus de 42°C (104°F). Peut colorier certaines surfaces ou matériaux.

90x70 mm

30 ml tube

gradient 7464U to transparency



Front



Back

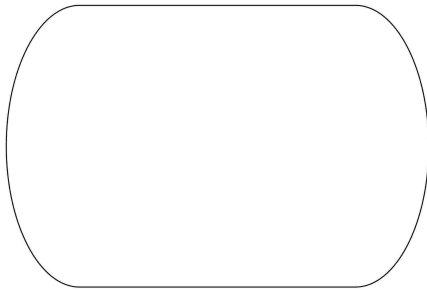


Drug Facts
Indication / Active Ingredient Purpose
For external use only. Contains 80% ethyl alcohol.
Alcohol (Ethanol) / Hydrogen Peroxide.
Indication: For external use only. Contains 80% ethyl alcohol.
Directions: For external use only. Contains 80% ethyl alcohol.
Warnings: For external use only. Contains 80% ethyl alcohol.
Precautions: For external use only. Contains 80% ethyl alcohol.
Directions: For external use only. Contains 80% ethyl alcohol.
Warnings: For external use only. Contains 80% ethyl alcohol.
Precautions: For external use only. Contains 80% ethyl alcohol.



180mm

290mm



120mm

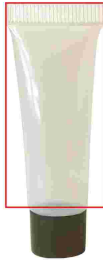


Front



Back

5 ml tube



Front



20 mm



42 mm



Back



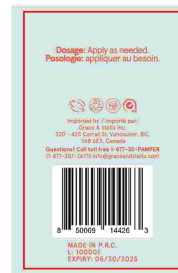
90mm
70mm
28mm

45.5mm

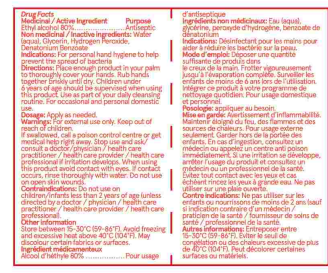


33mm

Front



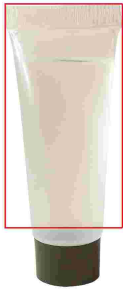
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Inside Page

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10 ml tube



Front

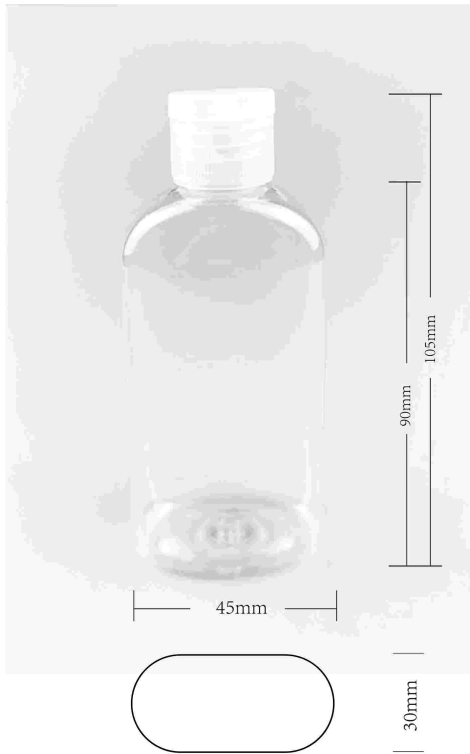


22 mm

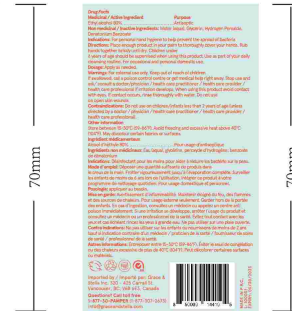
45 mm



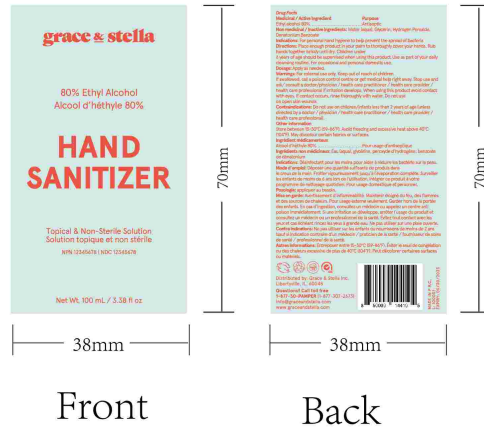
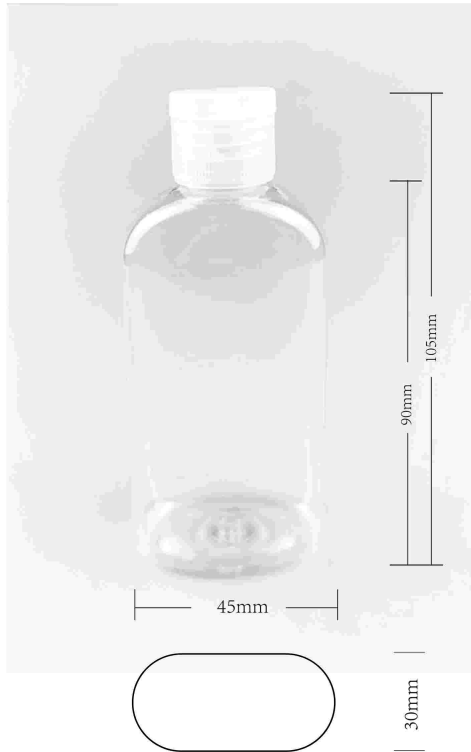
Back



Front



Back



100 ml cylindrical bottle





110x75 mm

HAND SANITIZER

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74862-002
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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
GLYCERIN (UNII: PDC6A3C0OX)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
WATER (UNII: 059QF0KO0R)	

Packaging

Marketing Status

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74862-002-04	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
2	NDC:74862-002-01	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
3	NDC:74862-002-02	7 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
4	NDC:74862-002-03	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/08/2020	
5	NDC:74862-002-05	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
6	NDC:74862-002-06	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
7	NDC:74862-002-07	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
8	NDC:74862-002-08	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
9	NDC:74862-002-09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
10	NDC:74862-002-10	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	

Marketing Information

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

Labeler - Yiwu Shining Cosmetics Co., Ltd. (543002719)

Registrant - Yiwu Shining Cosmetics Co., Ltd. (543002719)

Establishment

Name	Address	ID/FEI	Business Operations
Yiwu Shining Cosmetics Co., Ltd.		543002719	manufacture(74862-002)

Revised: 6/2020

Yiwu Shining Cosmetics Co., Ltd.