

**ISM BE-YOU-TIFUL SELF CARE STUDIO- ethyl alcohol gel**  
**HORIZON GROUP 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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**ISM BE-YOU-TIFUL SELF CARE STUDIO**

**Active Ingredients**

Ethyl Alcohol

**Purpose**

Antiseptic

**Warnings**

- **For external use only. Flammable. Keep away from heat or flame.**
- Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.
- **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.

**Uses**

- Hand Sanitizer to help reduce bacteria that potentially can cause disease.
- For use when soap and water are not available.

**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.

**Keep out of reach of children.**

If swallowed, get medical help or contact Poison Control Center right away.

**Other Information**

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

**Inactive Ingredient**

Water/Aqua/Eau,Glycerin,Carbomer,Triethanolamine,parfum,Denatonium benzoate,Red 27 (CI 45410).

**Product Label**



SPOT 928C

4cp Hand Sanitizer white adhesive label  
24.87W X 47.5H mm

FRONT



1c BACK LABEL



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## ISM BE-YOU-TIFUL SELF CARE STUDIO

ethyl alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80797-001
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HO MO POL YMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
DENATONIUM BENZO ATE (UNII: 4YK5Z54AT2)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80797-001-01	28 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/07/2020	

Revised: 10/2020

HORIZON GROUP USA, INC.