

DICOLOR- alcohol gel
SODI PINTURAS, S.A. DE C.V.

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.

dicolor Hand Sanitizer Gel

DIRECTIONS DOSAGE AND ADMINISTRATION

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.

INACTIVE INGREDIENTS

Inactive ingredients Water (Aqua), Glycerin, Carbomer, Triethanolamine

INDICATIONS AND USAGE

Use[s]

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

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

PURPOSE

Purpose Antmicrobial

WARNINGS AND PRECAUTIONS

Store below 110°F (43°C)

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

Supervise children under 6 years of age when using this product to avoid swallowing.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

WARNINGS

Warnings

For external use only. Flammable. Keep away from heat or flame

ACTIVE INGREDIENT

Active ingredient Ethyl Alcohol 70% v/v

ASK A DOCTOR

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

STOP USE

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

PACKAGE LABELS

1000 ML LABEL



114 X 141 mm.



114 X 141 mm.

DICOLOR

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79050-0040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.248 mL in 1 mL
AMMONIA (UNII: 5138Q19F1X)	0.007 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.02 mL in 1 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.025 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79050-0040-6	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/17/2020	

Labeler - SODI PINTURAS, S.A. DE C.V. (951579471)

Registrant - SODI PINTURAS, S.A. DE C.V. (951579471)

Establishment

Name	Address	ID/FEI	Business Operations
SODI PINTURAS, S.A. DE C.V.		951579471	manufacture(79050-0040)

Revised: 11/2020

SODI PINTURAS, S.A. DE C.V.